Formalizing Electrocardiogram (ECG) Signal Behavior in Event-B

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Abstract-Recording the electrical activity of the heart over a period of time as detected using electrical sensors is referred to as Electrocardiography (ECG). ECG is recorded as a collection of signal waves that has repetitive patterns. These patterns are usually used in the complex diagnosis process through which ECG may indicate certain problems related to the heart or other parts of the body. Despite the extensive studies conducted on the analysis of ECG signals and their thorough analysis, there is a lack of a formal model that validate their specifications, which results in several inconsistencies and problems in their interpretations and usage. This, on the other hand, may lead to ambiguities and incompleteness in the methods that are developed utilizing ECG specifications and their features. Therefore, in this paper we propose a method to formalize and validate the specifications of ECG signals in Event-B. We formally define the waves of ECG and their relation, and then formalize and validate several properties about their behavior.

Index Terms—Electrocardiography, Formalizing ECG, Event-B, Formal Methods

I. INTRODUCTION AND MOTIVATION

The continued growth in world population and the extension of life expectancy, particularly in developed countries, have placed increasing demands on the provision of ICT healthcare services. However, there are several issues that arise with the enormous development of ICT based health systems. For instance, the lack of an appropriate verification support reduces the robustness of any health systems. In addition, ambiguities and incompleteness of the specification of any health related system may lead into several technical errors in the design and usage of these systems. Electrocardiography (ECG) [1] is a standard representation of the heart's electrical activity recorded from bio-sensor on the body surface. It is used thoroughly in the diagnosis process of patients in order to identify and predict several health problems.

Several guidelines related to the interpretation of ECG signals have been developed. Medical protocols follow these guidelines in the understanding and diagnosis procedures that are based on ECG. These guidelines, however, may suffer from several ambiguities and inconsistencies in their specifications, due to the complexity of ECG and their informal presentation. In fact, García *et al.* [2] reported that the correct interpretation of ECG recordings requires the use of acquisition procedures according to approved standards. Most existing methods on standard ECG devote little attention to inadequate ECG recordings. The authors reported several sources of errors resulted from frequent ECG patterns misunderstanding.

There are several accidents where healthcare devices were too complex to be validated and verified properly before being used. Errors in this case may lead to loss of life, such as the Therac-25 accident [3]. This indicates that inadequate understanding of the specifications of the medical system and the lack of validation and verification methods may lead into severe situations in such complex and safety-critical systems. Formal methods [4], on the other hand, involve a systematic analysis that is based on mathematical reasoning to verify that design specifications comprehends certain design requirements. They have been successfully used for the precise analysis of various complex systems [5]. Therefore, they can be efficiently used to enhance trust in several medical healthcare systems, which handle huge amount and types of data and involve complex operations such as data acquisition, processing, analysis, transformation and transmission.

In this paper, we formalize the specifications of the ECG signal using Event-B [6] method. Event-B is a formal language for modeling, specifying and verifying reactive and distributed or concurrent systems using proof. The Event-B model is composed of two constructs: machine and context. The machine defines the dynamic behavior of the model, contains the system variables, events, and invariants; and the context defines the static behavior of the model, contains carrier sets, constants, axioms, and theorems. The key features of Event-B are the use of rigorous description of abstract system, and then introduce solutions or details in refinement steps to obtain more concrete specification and finally verify that proposed refinements are valid based on pre-defined invariants. The generated system model is a mathematical model that mainly made of the system description (constants, properties, variables and invariant) and several event descriptions. it describes an asynchronous system behavior and also a non-deterministic evolution of a system through guarded conditions.

We first present the informal specifications of ECG based on medical references and guidelines, then formalize the basic building elements of the ECG signal and define the details of its behavior. We also define several properties about ECG signal behavior established from their specifications in order to validate the correctness and consistency of the ECG model. The properties were also formalized using Event-B invariants, and then verified using the underlying verification framework.

There has been only recent trials to model and verify ECG related properties in the literature by Méry *et al.* [7], [8], who

presented a method for modeling the behavioral of heart nodes and verifying the functionality of a pacemaker controller using Event-B. This work is mainly concerned with the modeling of ECG interpretations, the meaning of values and their ranges, and finally the relations between these and diagnosis using ECG. The authors presented a formal model for the protocol used in interpreting the ECG. On the other hand, there is still an ambiguity and lack of formal specifications for the ECG behavior itself. In fact, there are several complex issues about ECG that still require formalization, For instance, the following are among several complex issues related to the ECG signal, first the anatomy of the ECG wave and how it is composed of several waves, second, how ECG waves are generated by the sinoatrial node the atrioventricular node, and finally how these nodes affect the normal and abnormal shape of the ECG signal.

Formal methods have been used to verify some aspects in healthcare systems. Raoul et al. [9] used model checking to verify the reliability of medical device software that is used in an infusion pump. Recently, Masci et al. [10] formalized and verified safety requirements in a commercial PCA infusion pump using the PVS higher-order logic framework. Kang et al. [11] used a combination of formal methods and simulation for building a robust WBSN model. Ayara and Najjar in [12] provides a formal model to measure the survivability of a ubiquitous healthcare system. Finally, Al-Hamadi et al. [13], [14] presented an Event-B based method for modeling and verification of WBSN. Compared to the above, we believe that we have addressed an important aspect of healthcare systems, which is related to the formal specifications of ECG, which is an issue that has not been addressed despite the sensitivity and complexity of the issue.

The rest of this paper is organized as follows: Section II presents the description of Electrocardiogram and their specifications. Section III presents the formalization of ECG in Event-B. Section IV presents properties about ECG specifications and their validation in Event-B. Section V concludes the paper with future work hints.

II. ELECTROCARDIOGRAM (ECG) SPECIFICATIONS

Electrocardiography (ECG) [1] represents the recording of the electrical activity of the heart over a period of time as detected by electrical sensors that are attached to the body of a patient. This recording, produced by this noninvasive procedure, is usually represented as repetitive signal with certain patterns. These patterns are usually used in the complex diagnosis process through which ECG may indicate certain problems related to the heart or other parts of the body. The standard 12-lead ECG is a representation of the heart's electrical activity recorded from bio-sensor on the body surface. This section describes the specifications of the basic components of the ECG signal and how are they generated based on [15].

Even though the heart system can show unpredictable behaviors; it is normally working in a stable rhythm and generates ideal ECG. Figure 1 describes how the heart system outputs the ECG components as a form of waves. There

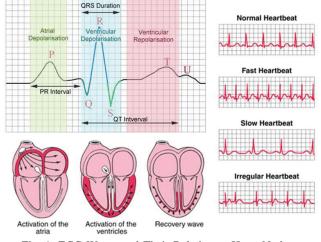


Fig. 1: ECG Waves and Their Relation to Heart Nodes

are three phases through which the heart produces the ECG, the first is the activation of the atria, during which a wave called P wave is generated by the sinoatrial node (SA). The second is the activation of the ventricles, during which a wave called QRS is generated by the atrioventricular node (AV). Finally, the recovery phase during which a wave called T wave is generated throughout the heart muscles recovery phase. In addition, there are flat signals that represents no activity between these two waves for certain periods of time. These inactive periods are represented as flat segments between the above waves. The frequency of occurrence of these waves, their duration, and their existence reflects several facts about the heart behavior such as normal, fast, slow, or abnormal status.

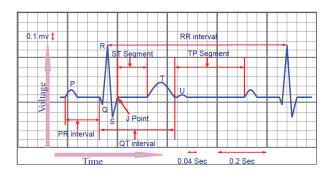


Fig. 2: ECG Signal Specifications

The activities of heart's nodes reflect the sequence of the ECG components. In order to derive the specifications of the ECG signal, we divide it into two abstract parts: active waves and idle segments. The active waves, on the other hand, are divided into three parts: P, QRS and T waves that exhibits different behaviors and different durations. The segment part includes three idle periods: PQ-segment, ST-segment and TP-segment, that exhibits similar behavior but with different durations. The Figure 2 illustrates the anatomy of the ECG

signal and its different components.

In order to distinguish different ECG signals that represent heart activity, we define each activity, as a segment or a wave, and relate it in sequence with other actives as illustrated in Figure 3 below, where all the possible ECG sequences are generated by the heart system via number of activities labeled with numbers. Assuming the heart starts its activity from the idle segment that is label with number 1, the functionality of the heart's nodes can produce four different cases:

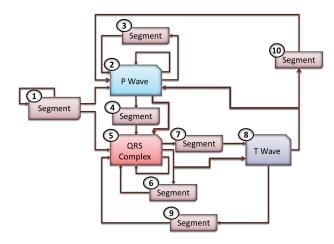


Fig. 3: ECG Waves Behaviors

Case 1 illustrates the situation where neither SA nor AV nodes are working. This is the case where we get no pulse from the heart. This is modeled by the repeated occurrence of idle segment (Block 1 in Figure 3). Once any of the heart's nodes starts working, the system goes into another state.

Case 2 illustrates the situation when only the *SA* node is functional, where the heart system generates only *P* wave signals and possibly idle segments. This represents an abnormal behavior of the heart system, where it can only generate a sequence of *P* waves, or an alternation between *P* waves and idle segments. This is depicted by repeating block 2 or alternating between blocks 2 and 3 in Figure 3. Any interruption by *AV* node would transfer the ECG to another state, while stopping the *SA* node will return the system to case 1 above.

Case 3 illustrates the situation when only the AV node functional node, where the heart system generates a QRS wave signal, possibly followed by a T wave or an idle segments or both. Hence, there are three situations that can occur to the ECG signal when the AV node is functional alone. The first one occurs for fatigued ventricles activation, where QRS is continuously repeated as illustrated by repeating Block 5. The second situation occurs for a less fatigued ventricles activation, where there is a segment between each successive QRS waves as illustrated by repeating blocks 5 and 6 in Figure 3. The third situation occurs when the heart system has the opportunity to recover from the ventricles activation, where the QRS wave and the T wave are generated with idle segments in between.

This is illustrated by the repetition of combination sequence of blocks 5, 7, 8, and 9 in the Figure 3. The heart system can be transferred between different situations as long as the AV node is functional and the SA node is not working. **Case 4** is considered the normal behavior of the heart system, where both the SA and AV node are functional and therefore, the P, QRS and T waves occur in sequence with the possibility of idle segments in between. This is illustrated by the repetition of the sequence of blocks 2, 4, 5, 7, 8, and 10. If either of SA or AV node stop working or impairment of the ventricles activation recovery, then, the status of the ECG is transferred to another case. In fact, there are several situations under this case, where the system goes from atrial depolarization to ventricles depolarization without a delay.

III. FORMALIZING ECG IN EVENT-B

Event-B [6] is a formal analysis method based on refinement and set-theory. Event-B has been used for the formal analysis of several industrial designs in different domains, such as automotive, transportation, space, and medical devices. It provides means to model complex systems and define properties about their behavior using invariants, therefore, reduces the amount of time needed for testing and verification of these systems. Event-B is supported by a tool called Rodin platform [16] which is an Eclipse IDE that provides a friendly user interface to develops Event-B models, describe properties as invariants, and provide several levels of refinements for the model.

The Event-B model consists of several parts such as context, machine, events, axioms, and invariants. The *context* is used to model the static part of the system using axioms. The *machine* covers the dynamic part using a number of events. In addition, the desired properties of the system are modeled using *invariants*, and design constraints and constants are represent using *axioms*. Events have guards, and can only be executed when guards are true, the choice of the event with valid guards to be executed at any time is non-deterministic.

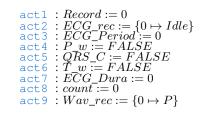
In this section, we describe the formalization of the ECG waves as specified in the previous section. First, we use an Event-B context define the basic parameters of the ECG signal using sets and constants. In addition, we use a number of axioms to represent the known facts about the ECG signal in the heart system. We define two sets ECG_State and Wav_Type. The ECG_State set contains four different states and is defined as: CG_State={Idle, P_wav, QRS_wav, T_wav} using axiom axm1 in C_ECG context below. The Wav_Type set is used to define different types of waves in ECG and is defines as: $Wav_Type = \{P, QRS, T\}$ using axiom axm2 in C ECG context below. In addition, we define several constant related to the period of the ECG cycle, including the P duration (P_Dura), the QRS duration (QRS_Dura), and the T duration (T_Dura) . These constants are defined as natural number by axioms axm3, axm4, and axm5 in C ECG context below. Other features about wave durations is defined using axioms, for instance, QRS has the least duration among all waves, is defined in axiom axm5 below. The formalization of the ECG context in Event-B is given below:

$$\begin{array}{c} \begin{array}{c} \text{CONTEXT C_ECG} \\ \text{SETS} \\ \hline \\ ECG_State \\ \text{CONSTANTS} \\ \hline \\ Idle \\ P_Dura \\ P_QRS \\ P_Dura \\ P \\ QRS \\ T \\ \hline \\ \text{AXIOMS} \\ \hline \\ \begin{array}{c} \text{axm1 : } partition(ECG_State, \{Idle\}, \{P_wav\}, \\ \{QRS_wav\}, \{T_wav\}) \\ axm2 : partition(Wav_Type, \{P\}, \{QRS\}, \{T\}) \\ axm3 : P_Dura \in \mathbb{N} \land QRS_Dura \in \mathbb{N} \\ axm4 : T_Dura \in \mathbb{N} \\ axm5 : QRS_Dura < P_Dura \land \\ QRS_Dura < T_Dura \\ \end{array}$$

END

The dynamic part of the system is made of a number of events with non-deterministic behavior, these events can take place only if their guard is valid. In order to define the behavior of ECG waves using events, we define each wave into two parts: activate and deactivate. On the other hand, idle segments need not to be activated or deactivated as it exhibits no wave behavior. In our Event-B model, we defined two record variable: ECG_rec and Wav_rec. The ECG_rec is responsible for recording the history of ECG that includes the idle segments, P waves, QRS waves, and T waves. This variable indicates the type of the ECG signal at any point of rime, therefore, it is defined as a function from natural numbers to ECG State. The Wav rec, on the other hand, is responsible for recording the history of the ECG waves only. It indicates the type of the ECG signal wave and defined as a function from natural numbers to Wav_Type. The two variables are used since there are cases in ECG specifications that are related to the occurrence of active waves only, while some are related to the occurrence of active waves and/or idle segments. We also use a counter in order to track the ECG period (ECG_Period and ECG duration ECG_Dura) by calculating the value of the past durations for waves and segments. The value of the ECG_Dura start from zero and it is incremented during the execution of the model. Another variable, Record is used to represent a time counter. Furthermore, we define a number of Boolean variables (e.g. P_w , QRS_w and T_w) to model the process of activating and deactivating the ECG waves, these variable are initially set to false to indicate no wave activity. The model below shows the formalization of the ECG signal as an Event-B machine.

MACHINE M_ECG SEES CECG VARIABLES ECG_rec Wav_rec ECG_Dura Record ECG_Period QRS_C INVARIANTS P w T_w count $\texttt{inv1} : Record \in \mathbb{N} \land ECG_Period \in \mathbb{N}$ $ECG_rec \in 0 .. Record \rightarrow ECG_State$ inv2 : $\begin{array}{l} \operatorname{inv3}: P_w \in BOOL \wedge T_w \in BOOL \wedge count \in \mathbb{N} \\ \operatorname{inv4}: ECG_Dura \in \mathbb{N} \wedge QRS_C \in BOOL \\ \operatorname{inv5}: Wav_rec \in 0 \dots count \rightarrow Wav_Type \end{array}$ **EVENTS** Initialisation begin





Next, we model the behavior of different ECG signal waves using events. First, we model the idle segment event, where, it can occur only when none of the P wave, QRS wave, and T wave is active. This is modeled using an Event-B guard, grd1, in the event Segment below. When this event is executed, ECG_Dura and Record are incremented, and the ECG_rec is set to Idle. The model below shows the component of this event. The guard grd1 in the event Segment below represents the fact that no other wave is active, while the statement act1 handles recording the ECG signal states at the current point of time, act2 on the other hand is used to increment the ECG_Dura , and finally, act3 is used to increment the counter Record.

Event Segment $\widehat{=}$ when grd1 : $P_w = FALSE \land$: $QRS_C = FALSE \land$: $T_w = FALSE$

then

 $\begin{array}{l} \texttt{act1} & : ECG_rec(Record+1) := Idle\\ \texttt{act2} & : ECG_Dura := ECG_Dura+1\\ \texttt{act3} & : Record := Record+1 \end{array}$

end

The next two events are related to the activation and deactivation of the P wave. The guard condition of activating the P wave is similar to the segment event above, where no wave should be active, this is formalized using the guard grd2 of the P P_Active event below. Moreover, the P wave cannot be generated after depolarization of the AV-node. In another words, to activate the P wave the previous wave cannot be the QRS wave. This is formalized in the guard grd2 of the P wave activation event P_Active below. When the P_Active event is executed, the *P_wav* value is assigned to the *ECG_rec* variable (act1), in addition, the ECG duration is incremented by the P wave duration by adding the value of P Dura to ECG_Dura (act2). Then, the Wav_rec variable is assigned the value P wave at the current time (act5), and Record and count variables are incremented, as illustrated in act3 and act6, respectively.

The ECG state is then changed into active P wave, this is achieved by updating the value of the P_w to *TRUE* (act4). On the other hand, deactivating the P wave occurs only after the P wave is active for sometime. This is modeled using the event $P_Deactive$. The only action required in this event is to update the P_w value to *FALSE* (act1). The description of P_Active and $P_Deactive$ events is given below:

```
Event P\_Active \cong
when grd1 : P\_w =
```

$$\begin{array}{l} \text{rd1} : P_w = FALSE \land QRS_C = FALSE \\ : \land P_w = FALSE \land T_w = FALSE \end{array}$$

end

The QRS wave is also modeled using two events, active and deactivate. The guard for the QRS activate event is formalized using *grd1* in *QRS_Active* event below which implies that no wave is currently activate. The *QRS_Active* event first changes the ECG state to active *QRS* wave by updating the value of the *QRS_w* to *TRUE* using *act1*. This event also defines the ECG signal type at this point of time to be *QRS* by assigning the *QRS_wav* value to the *ECG_rec* variable at the current point of time using *act2*. In addition, the value of the *QRS_bura* to the variable *ECG_Dura* using *act4*. The wave type is also recorded to be *QRS* type at this point of time by assigning *QRS* to *Wav_rec* at the current point of time using *act5*. Finally, the counter variables *Record* and *count* are incremented using *act6*.

On the other hand, the QRS deactivate event occurs if only after QRS wave is active. This is shown in the *QRS_Deactive* event guard (*grd2*). This event only updates the *QRS_w* value to *FALSE* (*act7*). The description of *QRS_Active* and *QRS_Deactive* events is given below:

```
Event
       QRS\_Active \cong
when
        grd1 : QRS_C = FALSE \land
                 P_w = FALSE \land T_w = FALSE
then
               : QRS\_C := TRUE
        act1
               : ECG\_rec(Record + 1) := QRS\_wav
: Record := Record + 1
        act2
        act3
        act4 : ECG_Dura := ECG_Dura + QRS_Dura
        act5 : Wav\_rec(count + 1) := QRS
act6 : count := count + 1
end
       QRS Deactive \widehat{=}
Event
when
        grd2 : QRS\_C = TRUE
then
        act7 : QRS_C := FALSE
```

end

The last two events are related to the activation and deactivation of the T wave. Activating the T wave should occur only when none of the waves is active, and after a QRS active wave, which illustrates recovering the position of the ventricles in the depolarization of the AV-node. This is modeled using an event guard which states that all waves are inactive, and wave record indicates that previous wave was QRS, which is formalized using grd1 in T_Active event below. The T wave active event, T_Active , exhibits similar behavior to previous waves active events. It updates the ECG record type to T_wav using act2, wave type to T using act5, and increments the counters using act3 and act6, and finally incrementing the ECG duration by T_Dura (act4). The deactivate event of Twave is formalized similar to the other waves. The formalization of T_Active is given below, while $T_Deactive$ event is identical to QRS_Deactive.

Event
$$T_Active \cong$$
 when

 $\begin{array}{l} \texttt{grd1} : QRS_C = FALSE \ \land T_w = FALSE \land \\ P_w = FALSE \land Wav_rec(count) = QRS \end{array}$

then

```
\begin{array}{l} \texttt{act1} : T\_w := TRUE\\ \texttt{act2} : ECG\_rec(Record+1) := T\_wav\\ \texttt{act3} : Record := Record+1\\ \texttt{act4} : ECG\_Dura := ECG\_Dura + T\_Dura\\ \texttt{act5} : Wav\_rec(count+1) := T\\ \texttt{act6} : count := count+1 \end{array}
```

end

IV. VALIDATING ECG SPECIFICATIONS EVENT-B

In order to validate the ECG signal, we derived several properties from its specifications. These properties reflect several aspects and features related to the occurrence of ECG waves. We then model these properties using Event-B invariants and use the Rodin platform to verify them.

Property 1. The first property states that the ECG signal is a sequential combination of different waves and segments, therefore the sinoatrial node and the atrioventricular node should not be active together. This property is modeled using an invariant which states that at any point of time only one of the variables $P_w=TRUE$, QRS_C , and T_w can be true as illustrated in *inv1* below:

$$\begin{array}{l} \texttt{inv1} : \neg(P_w = TRUE \land QRS_C = TRUE) \lor \\ \neg(P_w = TRUE \land T_w = TRUE) \lor \\ \neg(QRS \ C = TRUE \land T \ w = TRUE) \end{aligned}$$

Property 2. The second property states that the recovery phase should only occur after the ventricles activation that is caused by the atrioventricular node. This property is related to occurrence of the T wave after the QRS wave. The property is modeled using invariant *inv2* as shown below:

inv2: $\exists y \cdot y > 0 \land Wav_rec(y+1) = T \Rightarrow Wav_rec(y) = QRS$ **Property 3.** The model of the ECG should have the state at any point of time, this is modeled using *inv3* as shown below:

inv3 :
$$\forall x \cdot \exists y \cdot x \in dom(ECG_rec) \land y \in ECG_State \Rightarrow ECG_rec(x) = y$$

Property 4. states that all segments and waves must have a non zero duration. For instance each segment has at least 1 ms. This property is modeled using the current level of abstraction by stating that the ECG signal duration is incremented by at least one step when any wave or segment is active. This property is modeled using invariant *inv4* as follows:

 $\begin{array}{l} {\rm inv4:} \ \forall x,y \cdot x \in dom(ECG_rec) \land y \in dom(ECG_rec) \land \\ x < y \Rightarrow (ECG_Dura(x) < ECG_Dura(y)) \end{array}$

Property 5. states that the activation of the atria cannot be followed immediately by the activation of the ventricles, this means that a *QRS* wave cannot be followed immediately by a *P* wave. This property is modeled using invariant *inv5* as follows:

$$\begin{array}{l} \texttt{inv5} \ : \forall x,y \cdot x \in dom(Wav_rec) \land y \in dom(Wav_rec) \land \\ x = y + 1 \land Wav_rec(x) = P \Rightarrow Wav_rec(y) \neq QRS \end{array}$$

The Rodin Platform generated a total of 42 proof obligations related to each invariant with respect to the events in the ECG model described above. All of these obligations were successfully discharged by the Rodin proof assistant. Most of these obligations were discharged automatically by the tool, while the rest of these proof obligations had to be proven interactively throughout rewriting rules. There are several advantages for embedding ECG signal behavior in Event-B. First, We were able to verify several properties related to the specifications of ECG signals, second, existing methods target the diagnosis aspects of ECG signal, while ignoring their validation of their specifications, this may lead into several inconsistentness, in particular, in the case of incomplete or wrong interpretation of the ECG behavior. Third, This model can be further extended by adding several refinements to it. This will enable verifying more detailed properties about ECG. For instance a property such as heart rate should be within normal ranges if it ranges between 50 and 90 bpm, can be easily converted into ECG duration in terms of P wave and ORS durations, and then it can be verified while having a second level of refinement that considers wave durations as time steps. In fact, the ability to distinguish different levels of abstraction for the model is a key point in Event-B modeling and verification. It helps eliminating unnecessary details (wave length durations, for instance) at certain level of abstraction, and it provides the required means to consider it and a refined level, while maintaining the validity of properties at each level.

V. CONCLUSIONS AND FUTURE WORK

Testing and verification is essential in healthcare system that are designed and implemented based on ICT. However, verifying the correctness of a healthcare system is not straightforward, due to the complexity of these systems, and wide range of technologies used in their design. This paper proposed a formal method for the modeling and verification of ECG signal using Event-B method. We presented an abstract model for ECG behavior, then provided an embedding for it in Event-B. We have also defined several properties about ECG signal behavior established from their specifications to validate the correctness and consistency of the ECG model. Then, these properties were modeled as Event-B invariants, and verified using the underlying verification framework.

As a future work, the formalization of the ECG model can be expanded further in several directions, first, introducing a refined model of ECG, where more detailed about wave behavior can be considered, such as timing. This will enable the validating the ECG specifications at lower level of abstraction that include issues such wave durations and their relation to medical issues such as the hearth rate. Second, the formal model of the ECG can be used to build a model of medical sensors which are part of the WBSN, where further complex features and protocols can be modeled and validated in healthcare system. For instance, verifying that the WBSN will transmit the vital readings once a critical value is detected or once a periodic cycle is completed regardless of the category of the vital readings, is a property that is difficult to cover using conventional methods such as simulation.

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