Chapter 10
Formalisation of Electrocardiogram (ECG)

Abstract Today, an evidence-based medicine has given number of medical practice clinical guidelines and protocols. Clinical guidelines systematically assist practitioners with providing appropriate health care for specific clinical circumstances. However, a significant number of guidelines and protocols are lacking in quality. Indeed, ambiguity and incompleteness are more likely anomalies in medical practices. From last few years, many researchers have tried to address the problem of protocol improvement in clinical guidelines, but results are not sufficient since they believe on informal processes and notations. Our objective is to find anomalies and to improve the quality of medical protocols using well known formal techniques, such as Event-B. In this chapter; we use a modelling language to capture the guidelines for their validation. We have established a classification of the possible properties to be verified in a guideline. Our approach is illustrated with a guideline which published by the National Guideline Clearing House (NGC) and AHA/ACC Society. Our main contribution is to evaluate the real-life medical protocols using refinement based formal methods for improving quality of the protocols. Refinement based formalisation is very easy to handle any complex medical protocols. For this evaluation, we have selected a real-life reference protocol (ECG Interpretation), which covers a wide variety of protocol characteristics related to the several heart diseases. We formalise the given reference protocol, verify a set of interesting properties of the protocol and finally determine anomalies. Our main results are: to formalise an ECG interpretation protocol for diagnosing the ECG signal in an optimal way; to discover a hierarchical structure for the ECG interpretation efficiently using incremental refinement approach; a set of properties which should be satisfied by the medical protocol; verification proofs for the protocol and properties according to the medical experts; and perspectives of the potentials of this approach. Finally, we have shown the feasibility of our approach for analysing the medical protocols.

10.1 Introduction

A promising and challenging application area for the application of formal methods is a clinical decision making, as it is vital that the clinical decisions are sound. In fact, ensuring safety is the primary preoccupation of medical regulatory agencies. Medical guidelines are "systematically developed statements to assist

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practitioners and patient decisions about appropriate health care for specific circumstances" [11, 36]. Based on updated empirical evidence; the medical protocols to provide clinicians with health-care testimonial and facilitate the spreading of high-standard practices. In fact, this way represents that adherence to protocol may reduce the costs of care up to 25 % [36]. In order to reach their potential benefits, protocols must fulfil strong quality requirements. Medical bodies worldwide have made efforts in this direction, e.g. elaborating appraisal documents that take into account a variety of aspects, of both protocols and their development process. However, these initiatives are not sufficient since they rely on informal methods and notations. The informal methods and notations have not any mathematical foundation.

We are concerned with a different approach, namely the quality improvement of medical protocols through formal methods. In this chapter, we report on our experiences in the formalisation and verification of a medical protocol for diagnosis of the Electrocardiogram (ECG) [21, 22]. The ECG signals are too complex for diagnosis. All kinds of diseases related to the heart are predictable using 12-lead ECG signals. A high number of medical guidelines for the ECG interpretation has been published in the literature and on the Internet, making them more accessible. Currently, protocols are described using a combination of different formats, e.g. text, flow diagrams and tables. These approaches are used in form of informal processes and notations for analysing the medical protocols, which are not sufficient for medical practices. As a result, the ECG interpretation guidelines and protocols[1] still contain ambiguous, incomplete or even inconsistent elements.

The idea of our work is translating the informal descriptions of the ECG interpretation into a more formal language, with the aim of analysing a set of properties of the ECG protocol. In addition to the advantages of such a kind of formal verification, making these descriptions more formal can serve to expose problematic parts in the protocols.

Formal methods have well structured representation language with clear and well-defined semantics, which can be used for taxonomy verification of clinical the guidelines and medical protocols. The representation language represents guidelines and protocols explicitly and in a non-ambiguous way. The process of verification using formal semantic representation of guidelines and protocols to allow the determination of consistency and correctness.

Formal modelling and verification of medical protocol to have been carried out as a case study to assess the feasibility of this approach. Throughout our case study, we have shown formal specification and verification of medical protocols. The ECG interpretation protocol is very complex, ambiguous, incomplete and inconsistent.

The contribution of this chapter is to give a complete idea of formal development of the ECG interpretation protocol, and we have discovered a hierarchical structure for the ECG interpretation efficiently using incremental refinement approach [21, 22]. Same approach can be also applied for developing a formal model of the protocol of any other disease. Our approach is based on the Event-B [1, 7]

[1] Guideline and protocol are different terms. The term protocol is used to represent a specialised version of a guideline. In this chapter, we use them indistinctively.

modelling language which is supported by the Rodin platform integrating tools for proving models and refinements of the models. Here, we present an incremental proof-based development to model and verify such interdisciplinary requirements in the Event-B [1, 7]. The ECG interpretation models must be validated to ensure that they meet requirements of the ECG protocols. Hence, validation must be carried out by both formal modelling and medical domain experts.

We have used a general formal modelling tool like Event-B [1] for modelling a complex medical protocol related to diagnoses of the ECG signal. To apply a refinement based technique to model a medical protocol is our main objective. The Event-B supports refinement technique. The refinement supported by the Rodin [29] platform guarantees the preservation of safety properties. The safety properties are detection of an actual disease under the certain conditions. The behaviour of the final system is preserved by an abstract model as well as in the correctly refined models. This technique is used to model a medical protocol more rigorously based on formal mathematics, which helps to find the anomalies and provide the consistency and correctness of the medical protocol. The current work intends to explore those problems related to the modelling of the ECG protocols. The formalisation of the ECG protocol is based on the original protocol, and all the safety properties and related assumptions are verified with the medical experts. Moreover, an incremental development of the ECG interpretation protocol model helps to discover the ambiguous, incomplete or even inconsistent elements in current the ECG interpretation protocol.

10.1.1 Structure of This Chapter

The outline of the remaining chapter is as follows. Section 10.2 contains related work. Section 10.3 presents selection of medical protocol for formalisation. We give a brief outline of the ECG in Sect. 10.4. In Sect. 10.5, we explore the incremental proof-based formal development of the ECG interpretation protocol. The verification results are discussed in Sect. 10.6. Finally, Sect. 10.7 summarises the chapter.

10.2 Related Work

Section 10.2 currently presents ongoing research work related to computer-based medical guidelines and protocols for clinical purposes. From past few years many languages have been developed for representing medical guidelines and protocols using various levels of formality based on expert's requirements. Although we have used the Event-B modelling language for guidelines and protocol representation in our case study. Various kinds of protocol representation languages like Asbru [33, 36], EON [26], PROforma [12] and others [27, 38] are used to represent a formal semantics of guidelines and medical protocols.

Clinical guidelines are useful tools to provide some standardisation and helps for improving the protocols. A survey paper [15] presents benefits and comparison through an analysis of different kinds of systems, which are used by clinical guidelines. This paper covers a wide scope of clinical guidelines related literatures and tools, which are collected from the medical informatics area.

An approach for improving guidelines and protocols is by evaluating the physician. Evaluation process involves the scenario and evidence based testing, which compares the actions. The actions are performed by physicians to handle particular patient case using testimonials that are prescribed by the guidelines [24]. When results of the actions deviate, evaluation process can be either focused on the explanation alternatively provide some valuable feedback for improving the guidelines and protocols [20]. An intention based evaluation process are deduced by the physicians from both the patient data and the performed actions. These are then verified against the intentions reported in the guidelines.

Automated quality assessment of clinical actions and patient outcomes is another area of related work, which is used to derive structured quality indicators from formal specifications of guidelines. This technique is used in decision support [2]. Such kinds of indicators is used as formal properties in our work that guideline must comply with.

Decision-table based techniques for the verification and simplification of guidelines are presented by Shiffman et al. [34, 35]. The basic idea behind this approach is to describe guidelines as condition/action statements: *If the antecedent circumstances exist, then one should perform the recommended actions* [34]. Completeness and consistency are two main properties for verification, when guidelines and protocols are expressed in terms of decision-table. Again, these properties are internal coherence properties, whereas we are focused on domain-specific properties.

Formal development of the guidelines and protocols using clinical logic may be incomplete or inconsistent. This problem is tackled by Miller et al. [25]. *If "if-then" rules are used as representation language for guidelines, incompleteness means that there are combinations of clinically meaningful conditions to which the system (guideline) is not able to respond* [25]. The verification of rule-based clinical guidelines using semantic constraints is supported by the commander tool. This tool is able to identify clinical conditions where the rules are incomplete. Miller et al. [25] were able to find a number of missing rules in various case studies of the guidelines and protocols.

Guidelines enhancement is represented through adoption of an advanced Artificial Intelligence techniques [6]. This paper has proposed an approach for verification of the guidelines, which is based on the integration of a computerised guidelines management system with a model-checker. They have used SPIN model checker [8, 14] for executing and verifying medical protocols or guidelines. A framework for authoring and verification of clinical guidelines is provided by Beatriz et al. [28]. The verification process of guidelines is based on combined approach of Model Driven Development (MDD) and Model Checking [8] to verify guidelines against semantic errors and inconsistencies. UML [30, 39] tool is used for modelling the guidelines, and a generated formal model is used as the input model for a model checker.

Jonathan et al. [31] have proposed a way to apply formal methods, namely interactive verification to improve the quality of medical protocols or guidelines. They have applied this technique for the management of jaundice in newborns based on guidelines of American Academy of Pediatrics. This paper includes formalisation of the jaundice protocol and verifies some interesting properties. Simon et al. [5] have used the same protocol for improvement purpose using a modelling language Asbru, temporal logic for expressing the quality requirements, and model checking for proof and error detection.

Applying a formal approach for improving medical protocol is one major area of research, which helps to the medical practitioners for improve the quality of patient care. A project Protocure [37] is a European project, which is carried out by five different institutions. The main objective of this project is for improving medical protocol through integration of formal methods. The main motivation of this project is to identify anomalies like ambiguity and incompleteness in the medical guidelines and protocols. Presently, all medical protocols and guidelines are in text, flow diagrams and tables formats, which are easily understandable by the medical practitioners. But these are incomplete and ambiguous due to lack of formal semantics. The idea of using formal methods is to uncover these ambiguous, incomplete or even inconsistent parts of the protocols, by defining all the different descriptions more precisely using a formal language and to enable verification. Mainly, the researchers have used Asbru [36] language for protocol description and KIV for interactive verification system [3].

Asbru [36] is a main modelling language for describing medical protocol and formal proof of the medical protocol is possible through KIV interactive theorem prover [3]. Guideline Markup Tool (GMT) [17] is an editor who helps to translate guidelines into Asbru. An additional functionality of the tool is to define relations between the original protocol and its Asbru translation with a link macro [17]. Asbru language is used for protocol description and Asbru formalisations are translated into KIV. Asbru is considered as a semi-formal language to support the tasks necessary for protocol-based care. It is called a semi-formal language because of its semantics, although more precise than in other protocol representation languages, are not defined in a formal way. This semi-formal quality makes Asbru suitable for an initial analysis but not for systematic verification of protocols [23].

According to our literatures survey, existing medical protocol tools are based on semi-formal techniques. Existing techniques [6, 25, 36] based on formal techniques are failed to scale the complexity of the protocol. They have not given any proper idea to model the medical protocols only using formal techniques due to complex nature of the medical protocol. To tackle the complexity of the protocol in formal methods is only a solution to use the refinement approach to model the whole protocol from abstract level to a final concrete model. In this chapter, we have provided sufficient detailed information about modelling a complex protocol using any formal method technique. In this study, we have tried to model a medical protocol, completely based on formal semantics and to check various anomalies. To overcome from the existing problems [23, 32] in the area of development of medical protocols, we have used the general formal modelling tool like Event-B [1]

for specifying a complex medical protocol related to the diagnoses of ECG signal. The main objective to use Event-B modelling language is to model medical protocols using the refinement approach. The medical protocols are very complex and to model a complex protocol, a refinement approach is very helpful, which introduces peculiarity of the protocols in an incremental way. This technique is used to model a medical protocol more rigorously based on formal mathematics, which helps to find the anomalies and provide the consistency and correctness of the medical protocol.

10.3 Selection of Medical Protocol

Concerning the protocols that is the object of our study, we have selected the ECG interpretation that covers a wide range of protocol characteristics related to the heart diseases. All kinds of medical guidelines and protocols to differ from each others along several dimensions, which can be referred to the contents of the protocols or to its form. General practitioners (GPs), nurses and a large group of people related to this domain[2] are the *most important target users* of the guidelines and protocols, and the main aspects of clinical practice are to cover *diagnosis* as well as help in treatments. The medical guidelines and protocols, which are used by general practitioners and nurses, are also characterised by time dimensions; short time-span protocols; long-time span protocols. The form of guidelines and protocols are related to the textual descriptions. Sometimes it is also represented in the textual form as well as the combination with *tables* and *flowcharts*.

The ECG interpretation protocol [4, 16] aims at cardiologist as well as GPs and covers both diagnosis and treatment over a long period of time. The ECG interpretation protocol can be considered more precisely: one is in daily use by cardiologist, and the other is included in the repository of the National Guideline Clearinghouse (NGC), American College of Cardiology/American Heart Association (ACC/AHA). The basic standard for inclusion in the NGC and ACC/AHA are that the guidelines and protocols to contain well structured meaningful informations and systematically developed statements. The contents are produced under the supervision of medical specialty associations. It should be also based on literatures, reviewed and revised within the last 5 years. Furthermore, the ECG interpretation protocol has been published in a peer-reviewed scientific journal. In summary, the chosen protocol covers different aspects while fulfilling high-quality standards, which are the good criteria for selection of our case study.

In the following sections, we will use the ECG interpretation protocol as the main example in our explanations, and we therefore give a brief description of this protocol. The Electrocardiogram (ECG or EKG) interpretation is a common technique to trace abnormalities in the heart system and various levels of tracing help to find severe diseases. The guideline is more than 100 pages document, which contains knowledge in various notations: the main text; a list of factors to be considered

[2] http://www.guideline.gov/.

when assessing an abnormality in the ECG signal and a flowchart describing the steps in the ECG interpretation protocol. The protocol consists of an evaluation (or diagnosis) part and a treatment part, to be performed in the successive way. During the application of guidelines and protocols, as soon as the possibility of a more serious disease is uncovered, the recommendation is to leave the protocol without any further actions.

10.4 Basic Overview of Electrocardiogram (ECG)

The electrocardiogram (ECG or EKG) [13, 16] is a diagnostic tool that measures and records the electrical activity of the heart precisely in the form of signals. Clinicians can evaluate the conditions of a patient's heart from the ECG and perform further diagnosis. Analysis of these signals can be used for interpreting diagnosis of a wide range of the heart conditions and to predict the related diseases. The ECG records are obtained by sampling the bioelectric currents sensed by several electrodes, known as leads. A typical one-cycle ECG tracing is shown in Fig. 10.1. Electrocardiogram term is introduced by Willem Einthoven in 1893 at the meeting of Dutch Medical Society. In 1924, Einthoven received the Nobel Prize for his life's work in developing the ECG [4, 9, 10, 13, 16, 18, 19].

The normal electrocardiogram (ECG or EKG) is depicted in Fig. 10.1. All kinds of segments and intervals are represented in this ECG diagram. The depolarisation and repolarisation of the ventricular and atrial chambers are presented by deflection of the ECG signal. All these deflections are denoted by alphabetic order (P-QRS-T). Letter P indicates the atrial depolarisation, and the ventricular depolarisation is represented by QRS complex. The ventricular repolarisation is represented by T-wave. The atrial repolarisation appears during the QRS complex and generates a very low amplitude signal which cannot be uncovered from a normal ECG signal.

10.4.1 Differentiating the P-, QRS- and T-waves

Sequential activation, depolarisation, and repolarisation are deflected distinctly in the ECG due to anatomical difference of the atria and ventricles. Even all sequences are easily distinguishable when they are not in a correct sequence: P-QRS-T. The QRS-complex is easily identifiable between P- and T-waves because it has characteristic waveform and dominating amplitude. This amplitude is about 1000 μm in a normal heart and can be much greater in the ventricular hypertrophy. Normal duration of the QRS-complex is 80–90 ms. In case of non-existence of the atrial hypertrophy; an amplitude and duration of the P-wave are about 100 μm and 100 ms, respectively. The T-wave has about twice of the amplitude and duration of the P-wave. The T-wave can be differentiated from the P-wave by observing that the T-wave follows the QRS-complex after about 200 ms. In the ECG signal several parameters are used to evaluate the conditions of a patient's heart from the ECG. The

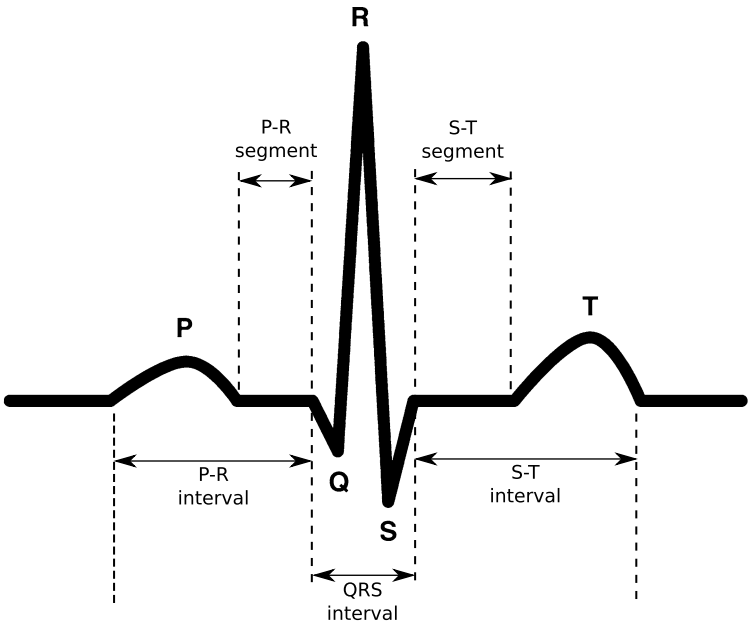

Fig. 10.1 A typical one-cycle ECG tracing

parameters are: PR-interval, P-wave, QRS duration, Q-wave, R-wave, ST-segment, T-wave, Axis, QT-interval. All these parameters have several characteristics that are used for diagnosis.

10.5 Formal Development of the ECG Interpretation

10.5.1 Abstract Model: Assessing Rhythm and Rate

We begin by defining the Event-B context. The context uses sets and constants to define axioms and theorems. Axioms and theorems represent the logical theory of a system. The logical theory is the static properties and properties of the target system. In the context, we define constants *LEADS*, *HState* and *YesNoState* that are related to an enumerated set of the ECG leads, normal and abnormal states of the heart and yes-no states, respectively. These constants are extracted from the ECG interpretation protocol [9, 10, 13, 16]. The standard 12-lead electrocardiogram is a representation of the heart's electrical activity recorded from electrodes on the body surface. A set of leads is represented as $LEADS = \{I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6\}$. Normal and abnormal states of the heart are represented by $HState = \{OK, KO\}$ and yes-no states are represented by $YesNoState = \{Yes, No\}$. Figure 10.2 depicts an incremental formal development

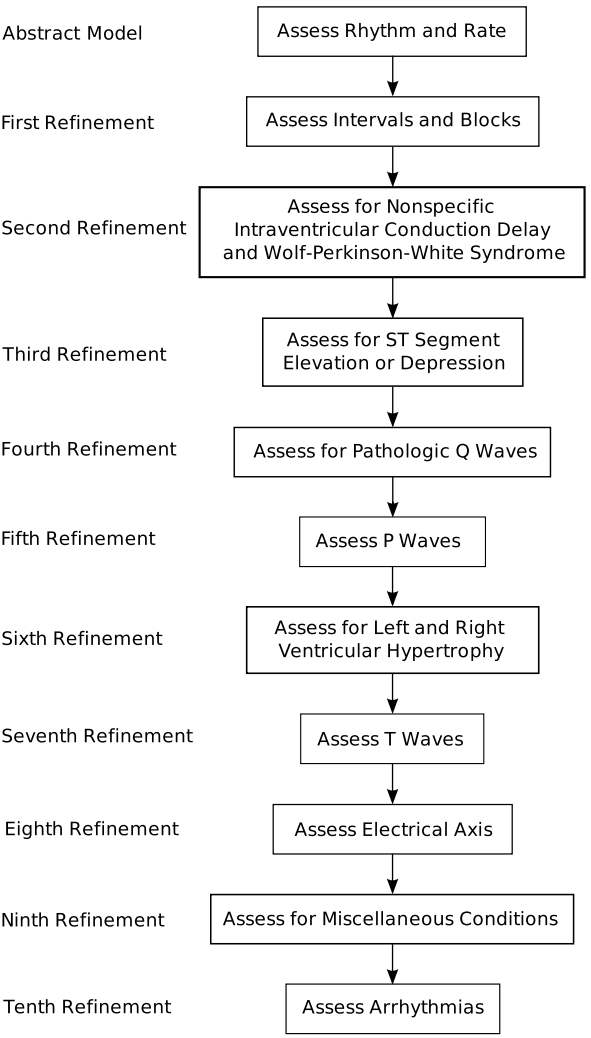

Fig. 10.2 ECG interpretation protocols refinements

of the ECG interpretation protocol. In our development process, some refinements are decomposed into several refinements for the simplicity. Every refinement level introduces a *diagnosis* criteria for different components of the ECG signal, and each new criteria helps to analyse a particular set of diseases. A particular set of diseases is introduced in the multiple context related to each refinement.

Figure 10.3 shows an abstract representation of a *diagnostic-based* system development, where a root node (top circle in Fig. 10.3) represents a set of conditions for testing any particular disease abstractly. The possible abstract outcomes of a diagnosis criterion are in form of *OK* and *KO*, which are represented by two branches. The *KO* represents that the diagnosis criteria have found some conditions for further testing, while the *OK* represents the absence of any disease. The dash line of

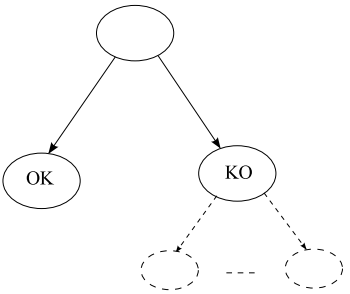

Fig. 10.3 Abstract representation

circles and arrows represent the next level of refinement for further analysing of any particular diseases according to the guidelines and protocol.

Our abstract Event-B model of the ECG interpretation protocol assesses the *rhythm* and *heart rate* to distinguish between normal and abnormal heart. Figure 10.4 presents a basic diagram of the ECG analysis at an abstract level according to the standard procedure of the ECG protocol analysis. The specification consists of just three-state variables (*inv*1–*int*3) *Sinus*, *Heart_Rate* and *Heart_State*. The *Sinus* variable is represented by *YesNoState* as enumerated sets. The last two variables *Heart_Rate* and *Heart_State* are introduced as to show the heart rate limit and heart states. One possible approach is to introduce a set of variables (*RR_Int_equidistant*, *PP_Int_equidistant*, *P_Positive*, *PP_Interval* and *RR_Interval*) representing total functions mapping leads (LEADS) to a standard data type (*BOOL*, $\mathbb{N}$) in invariants (*inv*4–*inv*8). The RR and PP equidistant intervals in the ECG signal are represented by variables *RR_Int_equidistant* and *PP_Int_equidistant* as the total functions from *LEADS* to *BOOL*. The *RR_Int_equidistant* and *PP_Int_equidistant* are functions, which represent RR and PP equidistant interval's states in a boolean form. A variable *P_Positive* represents a positive wave of the signal also as a total function from *LEADS* to *BOOL*. The *P_Positive* function is used to show the positive visualisation of the P-waves. The next variables PP and RR intervals in the ECG signal are represented by the variables *PP_Interval* and *RR_Interval* as the total functions from

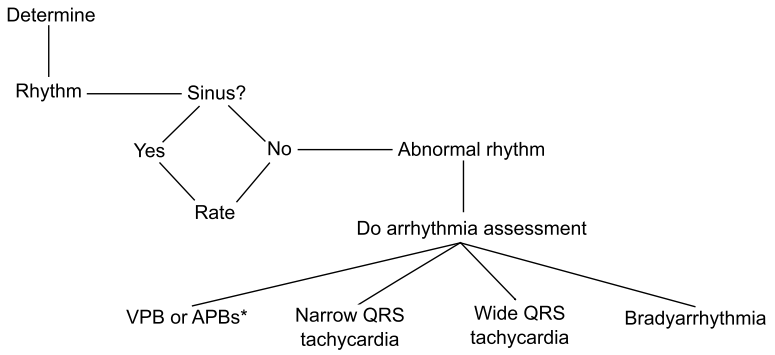

Fig. 10.4 Basic diagram of assessing rhythm and rate (adapted from [16])

LEADS to $\mathbb{N}$. The *PP_Interval* and *RR_Interval* functions are used to calculate the PP and RR-intervals.

$$
\begin{array}{l}
inv1 : Sinus \in YesNoState \\
inv2 : Heart\_Rate \in 1 \mathinner{..} 300 \\
inv3 : Heart\_State \in HState \\
inv4 : RR\_Int\_equidistant \in LEADS \rightarrow BOOL \\
inv5 : PP\_Int\_equidistant \in LEADS \rightarrow BOOL \\
inv6 : P\_Positive \in LEADS \rightarrow BOOL \\
inv7 : PP\_Interval \in LEADS \rightarrow \mathbb{N} \\
inv8 : RR\_Interval \in LEADS \rightarrow \mathbb{N} \\
inv9 : P\_Positive(II) = FALSE \Rightarrow Sinus = No \\
inv10 : ((\forall l \cdot l \in \{II, V1, V2\} \\
\qquad \Rightarrow \\
\qquad PP\_Int\_equidistant(l) = FALSE \vee \\
\qquad RR\_Int\_equidistant(l) = FALSE \vee \\
\qquad RR\_Interval(l) \neq PP\_Interval(l)) \\
\qquad \vee \\
\qquad P\_Positive(II) = FALSE) \Rightarrow Sinus = No \\
inv11 : Sinus = Yes \Rightarrow ((\exists l \cdot l \in \{II, V1, V2\} \wedge \\
\qquad PP\_Int\_equidistant(l) = TRUE \wedge \\
\qquad RR\_Int\_equidistant(l) = TRUE \wedge \\
\qquad RR\_Interval(l) = PP\_Interval(l)) \\
\qquad \wedge \\
\qquad P\_Positive(II) = TRUE) \\
inv12 : Heart\_Rate \in 60 \mathinner{..} 100 \wedge Sinus = Yes \\
\qquad \Rightarrow \\
\qquad Heart\_State = OK \\
inv13 : Heart\_Rate \in 1 \mathinner{..} 300 \setminus 60 \mathinner{..} 100 \wedge Sinus = Yes \\
\qquad \Rightarrow \\
\qquad Heart\_State = KO \\
inv14 : Heart\_Rate \in 60 \mathinner{..} 100 \wedge Sinus = No \\
\qquad \Rightarrow \\
\qquad Heart\_State = KO
\end{array}
$$

A set of invariants (*inv*9–*inv*14) represents the safety properties, and these are used to verify the required conditions for the ECG interpretation protocol using all possible behaviour of the heart system and analysis of the signal features, which are collected from the ECG signals. All these safety properties are designed under the supervision of cardiologist experts to verify the correctness of the formal model. These invariants in form of safety properties are extracted from the original protocol.

The invariant (*inv*9) states that if positive visualisation of the P-wave is *FALSE*, then there is no sinus rhythm. According to the clinical document, lead II is best for visualisation of the P-waves to determine the presence of sinus rhythm. The next invariant (*inv*10) is stronger invariant to identify the non-existence of the sinus rhythm. This invariant states that if the PP intervals (*PP_Int_equidistant*) or

RR intervals (*RR_Int_equidistant*) is not equidistant (*FALSE*), or the RR intervals (*RR_Interval*) and PP intervals (*PP_Interval*) are not equivalent, in all leads (II, V1, V2), or positive visualisation of the P-wave in lead II is *FALSE*, then there is no sinus rhythm. Similarly, next invariant (*inv*11) confirms, if the rhythm is sinus, then the PP intervals (*PP_Int_equidistant*) and RR intervals (*RR_Int_equidistant*) are equidistant, and the RR intervals (*RR_Interval*) and PP intervals (*PP_Interval*) are equal, exist in any leads (II, V1, V2), and the P-wave is positive in lead II. The invariant (*inv*12) represents that if the heart rate (*Heart_Rate*) is belonging between 60–100 bpm and the sinus rhythm is *Yes*, then the *Heart_State* is *OK*. The next two invariants (*inv*13–*inv*14) represent *KO* state of the Heart, mean the heart has any disease. The invariant (*inv*13) states that if the heart rate (*Heart_Rate*) is belonging between less than 60 bpm and greater than 100 bpm but less than 300 bpm, and the sinus rhythm is *Yes*, then the heart state (*Heart_State*) is *KO*. Similarly, the last invariant (*inv*14) represents that if the heart rate (*Heart_Rate*) is in between 60–100 bpm and the sinus rhythm is *No*, then the *Heart_State* is *KO*, means heart has any disease.

Three significant events *Rhythm_test_TRUE*, *Rhythm_test_FALSE* and *Rhythm_test_TRUE_abRate* are introduced in the abstract model. The *Rhythm_test_TRUE* represents successful ECG testing and found the sinus rhythm *Yes* and the heart state is *OK*. The next event *Rhythm_test_FALSE* represents successful ECG testing and found the sinus rhythm is *No* and the heart state is *KO*. Third event *Rhythm_test_TRUE_abRate* represents successful ECG testing and found the sinus rhythm is *Yes* and the heart state is *KO* due to abnormal heart rate. These events are the abstract events, which are equivalent to the first step of diagnosis of the ECG signal of the original protocol. We have taken some assumptions for modelling the medical protocol. These assumptions are extracted from the original protocol. In our formal model, all invariants and assumptions are verified with the medical experts. Our developed formal models are always complied with existing original protocols.

Mostly, events are used to test the criteria of possible disease using the ECG features. The criteria for testing the sinus rhythm is to focus on leads V1, V2, and II. The leads V1 and II are best for visualisation of the P-waves to determine the presence of the sinus rhythm or an arrhythmia, and the V1 and V2 are best to observe for the bundle branch block. If the P-waves are not clearly visible in V1, assess them in lead II, which usually shows well-formed P-waves [16]. Identification of the P-wave and then the RR intervals allow the interpreter to discover immediately whether the rhythm is sinus or other and to take the following steps:

- Confirm, if the rhythm is sinus, that the RR intervals are equidistant, that the P-wave is positive in lead II, and that the PP intervals are equidistant and equal to the RR interval.
- Do an arrhythmia assessment if the rhythm is abnormal.
- Determine the heart rate.

EVENT Rhythm_test_TRUE
ANY *rate*
WHERE
grd1 : $(\exists l \cdot l \in \{II, V1, V2\} \land PP\_Int\_equidistant(l) = TRUE \land$
$RR\_Int\_equidistant(l) = TRUE \land$
$RR\_Interval(l) = PP\_Interval(l)) \land$
$P\_Positive(II) = TRUE$
grd2 : $rate \in 60 \,..\, 100$
THEN
act1 : $Sinus := Yes$
act2 : $Heart\_Rate := rate$
act3 : $Heart\_State := OK$
END

EVENT Rhythm_test_FALSE
ANY *rate*
WHERE
grd1 : $(\forall l \cdot l \in \{II, V1, V2\} \Rightarrow PP\_Int\_equidistant(l) = FALSE$
$\lor RR\_Int\_equidistant(l) = FALSE \lor$
$RR\_Interval(l) \neq PP\_Interval(l)) \lor$
$P\_Positive(II) = FALSE$
grd2 : $rate \in 1 \,..\, 300$
THEN
act1 : $Sinus := No$
act2 : $Heart\_Rate := rate$
act3 : $Heart\_State := KO$
END

EVENT Rhythm_test_TRUE_abRate
ANY *rate*
WHERE
grd1 : $(\exists l \cdot l \in \{II, V1, V2\} \land PP\_Int\_equidistant(l) = TRUE \land$
$RR\_Int\_equidistant(l) = TRUE \land$
$RR\_Interval(l) = PP\_Interval(l)) \land$
$P\_Positive(II) = TRUE$
grd2 : $rate \in 1 \,..\, 300 \setminus 60 \,..\, 100$
THEN
act1 : $Sinus := Yes$
act2 : $Heart\_Rate := rate$
act3 : $Heart\_State := KO$
END

In the abstract model, we have seen that the sinus rhythm and heart rate are introduced for the ECG interpretation in a single atomic step. This provides for a clear and simple specification of the essence of the basic ECG interpretation protocol and predicts the heart state (*OK* or *KO*). However, in the real protocol, the ECG interpretation and heart state prediction is not atomic. Instead, the ECG interpretation and

prediction are also encountered lots of diagnosis to find the various kinds of heart diseases.

This section describes the abstract model of the ECG interpretation protocol. Every level of refinement introduces new context file for adding static properties of the system and list of heart diseases after introducing certain protocol of the ECG interpretation. Every refinement level is used to introduce a new set of diagnosis criteria to test the ECG signals. The following sections presents a sufficient detail information of the remaining refinement stages helping a reader to understand the rational of each refinement stage for formalising the ECG interpretation protocol.

10.5.2 First Refinement: Assess Intervals and Blocks

In an abnormal ECG signal, all the ECG features are varying according to the symptoms of heart diseases. We formalise the ECG interpretation protocol using an incremental approach, where we determine all features of the ECG signal. This level of refinement determines the PR- and QRS-intervals for the ECG interpretation. These intervals classify different kinds of the heart diseases.

Invariants (*inv*1–*inv*3) represent a set of new introduced variables in the refinement for expressing formalisation of the ECG interpretation protocol. These variables are *PR_Int*, *Disease_step2*, *QRS_Int*. Other variables (*M_Shape_Complex*, *Slurred_S*, *Notched_R*, *Small_R_QS* and *Slurred_S_duration*) are introduced as total functions in invariants (*inv*4–*inv*8) where total functions are mapping from leads (LEADS) to *BOOL* and $\mathbb{N}_1$, respectively. The function *M_Shape_Complex* returns existence of M-shape complex from the ECG signals in form of *TRUE* or *FALSE*. The function *Slurred_S* represents Slurred S-wave, the function *Notched_R* represents notched R-wave and the function *Small_R_QS* represents small R- or QS-waves, in boolean type. The function *Slurred_S_duration* is used to calculate Slurred-S duration.

A set of invariants (*inv*9–*inv*14) presents safety properties to validate formal representation of the ECG interpretation protocol. All these properties are derived from the original protocol to verify the correctness and consistency of the system. These properties are formulated through logic experts as well as cardiologist experts according to the original protocol. The main advantage of this technique is that if any property does not hold by the model, then it helps to find anomalies or to find missing parts of the model such as required conditions and parameters.

Invariants (*inv*9–*inv*13) represent an abnormal state of the heart (*KO*) to identify any disease and unsatisfying condition for features of the ECG signal, in the formal diagnosis process. While the last invariant (*inv*14) presents all the required properties for a normal heart. It states that if the heart rate is in between 60 to 100 bpm, the sinus rhythm is *Yes*, the PR interval is less than or equal to 200 ms and the QRS interval is less than 120 ms, then the heart state is *OK*.

$$
\begin{aligned}
&inv1 : PR\_Int \in 120 \mathinner{..} 250 \\
&inv2 : Disease\_step2 \in Disease\_Codes\_Step2 \\
&inv3 : QRS\_Int \in 50 \mathinner{..} 150 \\
&inv4 : M\_Shape\_Complex \in LEADS \rightarrow BOOL \\
&inv5 : Slurred\_S \in LEADS \rightarrow BOOL \\
&inv6 : Notched\_R \in LEADS \rightarrow BOOL \\
&inv7 : Small\_R\_QS \in LEADS \rightarrow BOOL \\
&inv8 : Slurred\_S\_duration \in LEADS \rightarrow \mathbb{N}_1 \\
&inv9 : Sinus = Yes \wedge PR\_Int > 200 \wedge Disease\_step2 = First\_degree\_AV\_Block \\
&\qquad \Rightarrow \\
&\qquad Heart\_State = KO \\
&inv10 : Sinus = Yes \wedge QRS\_Int \geq 120 \wedge Disease\_step2 \in \{LBBB, RBBB\} \\
&\qquad \Rightarrow \\
&\qquad Heart\_State = KO \\
&inv11 : Sinus = Yes \wedge Disease\_step2 = First\_degree\_AV\_Block \\
&\qquad \Rightarrow \\
&\qquad Heart\_State = KO \\
&inv12 : Sinus = Yes \wedge Disease\_step2 = LBBB \\
&\qquad \Rightarrow \\
&\qquad Heart\_State = KO \\
&inv13 : Sinus = Yes \wedge Disease\_step2 = RBBB \\
&\qquad \Rightarrow \\
&\qquad Heart\_State = KO \\
&inv14 : Heart\_Rate \in 60 \mathinner{..} 100 \wedge Sinus = Yes \wedge PR\_Int \leq 200 \wedge QRS\_Int < 120 \\
&\qquad \Rightarrow \\
&\qquad Heart\_State = OK
\end{aligned}
$$

To express formal logic for a new set of diagnoses for the ECG signal, we introduce three events *PR_Test*, *QRS_Test_LBBB* and *QRS_Test_RBBB*. The *PR_Test* interval represents, if the PR intervals are abnormal ($>$200 ms), then consider the first-degree atrioventricular (AV) block. The next two events *QRS_Test_LBBB* and *QRS_Test_RBBB* are used to assess the QRS duration for the bundle branch block and states that, if the QRS interval is $\geq$120 ms, the bundle branch block is present. Understanding the genesis of the QRS complex is an essential step and clarifies the ECG manifestations of bundle branch blocks [16]. We formalise the basic criteria to distinguish between RBBB and LBBB in the diagnosis process.

Left Bundle Branch Block (LBBB)

- QRS duration $\geq$120 ms.
- A small R- or QS-wave in V1 and V2.
- A notched R-wave in leads I, V5, and V6.

Right Bundle Branch Block (RBBB)

- QRS duration $\geq$120 ms.
- M-shaped complex in V1 and V2.
- Slurred S-wave in leads 1, V5, V6; and an S-wave that is of greater amplitude (length) than the preceding R-wave.

Right Bundle Branch Block (RBBB)

- QRS duration $\geq$120 ms.
- M-shaped complex in V1 and V2.
- Slurred S-wave in leads I, V5, V6; and an S-wave that is of greater amplitude (length) than the preceding R-wave.

The event PR_Test is used to capture the PR interval in the ECG signal, and to assess the first degree AV block. A set of guards of this event states that the current PR interval is within the range of 120 ms to 220 ms, and it is greater than 200 ms, sinus rhythm is *Yes*, and the heart is in abnormal state.

EVENT PR_Test
  ANY *pr*
  WHERE
    grd1 : $pr \in 120 \,..\, 220$
    grd2 : $pr > 200$
    grd3 : $Sinus = Yes$
    grd4 : $Heart\_State = KO$
  THEN
    act1 : $PR\_Int := pr$
    act2 : $Disease\_step2 := First\_degree\_AV\_Block$
END

The event QRS_Test_LBBB is used to diagnose left bundle branch block through testing of QRS-wave. This event refines QRS_Test. The guards of this event state that the current QRS interval is within the range of 50 ms to 150 ms, and it is greater than or equal to 120 ms, sinus rhythm is *Yes*, the heart is in abnormal state, notched R-wave is TRUE in leads (I, V5, and V6), and small R- or QS-wave is TRUE in leads V1 and V2.

EVENT QRS_Test_LBBB Refines QRS_Test
  ANY *qrs*
  WHERE
    grd1 : $qrs \in 50 \,..\, 150$
    grd2 : $qrs \geq 120$
    grd3 : $Sinus = Yes$
    grd4 : $Heart\_State = KO$
    grd5 : $Notched\_R(I) = TRUE \wedge Notched\_R(V5) = TRUE \wedge$
      $Notched\_R(V6) = TRUE$
    grd6 : $Small\_R\_QS(V1) = TRUE \wedge Small\_R\_QS(V2) = TRUE$
  THEN
    act1 : $QRS\_Int := qrs$
    act2 : $Disease\_step2 := LBBB$
END

The event QRS_Test_RBBB refines QRS_Test that is used to diagnose right bundle branch block through the testing of QRS-wave. The guards of this event state that the current QRS interval is within the range of 50 ms to 150 ms, and it is greater than or equal to 120 ms, sinus rhythm is *Yes*, the heart is in abnormal state, M-shaped complex is TRUE in leads (V1 and V2), slurred S-wave is TRUE in leads I, V5 and V6, and slurred S-wave duration is greater than 40 ms in leads I, V5, and V6.

EVENT QRS_Test_RBBB Refines QRS_Test
ANY qrs
WHERE
grd1 : $qrs \in 50 \,..\, 150$
grd2 : $qrs \geq 120$
grd3 : $Sinus = Yes$
grd4 : $Heart\_State = KO$
grd5 : $M\_Shape\_Complex(V1) = TRUE \wedge$
$M\_Shape\_Complex(V2) = TRUE$
grd6 : $Slurred\_S(I) = TRUE \wedge Slurred\_S(V5) = TRUE \wedge$
$Slurred\_S(V6) = TRUE \wedge$
grd7 : $Slurred\_S\_duration(I) > 40 \wedge Slurred\_S\_duration(V5) > 40 \wedge$
$Slurred\_S\_duration(V6) > 40$
THEN
act1 : $QRS\_Int := qrs$
act2 : $Disvease\_step2 := RBBB$
END

10.5.3 Second Refinement: Assess for Nonspecific Intraventricular Conduction Delay and Wolff-Parkinson-White Syndrome

This level of refinement of the ECG interpretation assesses for nonspecific intraventricular conduction delay (IVCD) and Wolff-Parkinson-White (WPW) syndrome. The WPW syndrome may mimic an inferior MI (see in further refinements). If the WPW syndrome, RBBB, or LBBB is not present, interpret as nonspecific intraventricular conduction delay (IVCD) and assess for the presence of electronic pacing [16]. Some new variables (*Delta_Wave* and *Disease_step3*) are introduced in this refinement to assess atypical right bundle branch block using ECG signal. Two invariants (*inv*3–*inv*4) are used to declare new variables in form of the total functions mapping leads (LEADS) to *BOOL*. These functions are used to calculate the ST-segment elevation and epsilon wave, respectively. Invariants (*inv*5–*inv*8) represent an abnormal state of the heart (*KO*) when the sinus rhythm is *Yes* and any new particular disease is found in this refinement. All these properties are derived from the original protocol to verify the correctness and consistency of the system according to the cardiologist.

$inv1 : Delta\_Wave \in \mathbb{N}$
$inv2 : Disease\_step3 \in Disease\_Codes\_Step3$
$inv3 : ST\_elevation \in LEADS \rightarrow BOOL$
$inv4 : Epsilon\_Wave \in LEADS \rightarrow BOOL$
$inv5 : Sinus = Yes \wedge Disease\_step3 = WPW\_Syndrome$
$\Rightarrow$
$Heart\_State = KO$
$inv6 : Sinus = Yes \wedge Disease\_step3 = Brugada\_Syndrome$
$\Rightarrow$
$Heart\_State = KO$
$inv7 : Sinus = Yes \wedge Disease\_step3 = RV\_Dysplasia$
$\Rightarrow$
$Heart\_State = KO$
$inv8 : Sinus = Yes \wedge Disease\_step3 = IVCD$
$\Rightarrow$
$Heart\_State = KO$

We have introduced four events *QRS_Test_Atypical_RLBBB_WPW_Syndrome*, *QRS_Test_Atypical_RBBB_Brugada_Syndrome*, *QRS_Test_Atypical_RBBB_RV_Dysplasia* and *QRS_Test_Atypical_RBBB_IVCD* to interpret atypical right bundle branch block using QRS interval. The basic rules for assessing the ECG signal in this refinement are given as follows:

- If the QRS duration is prolonged $\geq$110 ms and bundle branch block appears to be present but is atypical, consider WPW syndrome, particularly if there is a tall R-wave in leads V1 and V2.
- Assess for a short PR interval $\leq$120 ms and for a delta wave.

The event *QRS_Test_Atypical_RLBBB_WPW_Syndrome* is used to identify a disease WPM Syndrome, where a set of required conditions for diagnosis purpose is given in form of guard predicates. The guards of this event state that the QRS interval is greater than or equal to 110 ms, already symptoms of RBBB or LBBB is identified, summation of delta wave and PR interval is less than or equal to 120 ms, and the heart is in abnormal state (*KO*).

EVENT QRS_Test_Atypical_RLBBB_WPW_Syndrome
ANY $sympt, d\_wave$
WHERE
grd1 : $QRS\_Int \geq 110$
grd2 : $sympt = A\_RBBB \vee sympt = A\_LBBB$
grd3 : $d\_wave \in \mathbb{N}$
grd4 : $d\_wave + PR\_Int) \leq 120$
grd5 : $Heart\_State = KO$
THEN
act1 : $Delta\_Wave := d\_wave$
act2 : $Disease\_step3 := WPW\_Syndrome$
END

The next event *QRS_Test_Atypical_RBBB_Brugada_Syndrome* is used to trace the symptoms of Brugada Syndrome. The guards of this event presents that the heart is in state of Atypical RBBB, QRS interval is greater than or equal to 110 ms, slurred S-wave is FALSE in leads V5 and V6, the heart has not the symptoms of WPW syndrome and the possibility of any other diseases, ST elevation is TRUE in leads V1 and V2, and the sinus rhythm is *Yes*.

EVENT QRS_Test_Atypical_RBBB_Brugada_Syndrome
  ANY $sympt, dis$
  WHERE
    grd1 : $sympt = A\_RBBB$
    grd2 : $QRS\_Int \geq 110$
    grd3 : $Slurred\_S(V5) = FALSE \wedge Slurred\_S(V6) = FALSE$
    grd4 : $dis \in Disease\_Codes\_Step3 \setminus \{WPW\_Syndrome, NDS3\}$
    grd5 : $ST\_elevation(V1) = TRUE \wedge ST\_elevation(V2) = TRUE$
    grd6 : $Sinus = Yes$
  THEN
    act1 : $Disease\_step3 := Brugada\_Syndrome$
END

The event *QRS_Test_Atypical_RBBB_RV_Dysplasia* captures the diagnosis process for Right Ventricular Dysplasia (RV Dysplasia), where a set of guards explores the required symptoms using predicates. These predicates express that the heart is in state of Atypical RBBB, QRS interval is greater than or equal to 110 ms, the heart has not the symptoms of WPW syndrome, Brugada Syndrome and the possibility of any other diseases, and epsilon wave is TRUE in leads V1 and V3.

EVENT QRS_Test_Atypical_RBBB_RV_Dysplasia
  ANY $sympt, dis$
  WHERE
    grd1 : $sympt = A\_RBBB$
    grd2 : $QRS\_Int \geq 110$
    grd3 : $dis \in Disease\_Codes\_Step3 \setminus \{WPW\_Syndrome,$
      $Brugada\_Syndrome, NDS3\}$
    grd4 : $Epsilon\_Wave(V1) = TRUE \wedge Epsilon\_Wave(V3) = TRUE$
  THEN
    act1 : $Disease\_step3 := RV\_Dysplasia$
END

The event *QRS_Test_Atypical_RBBB_IVCD* captures the essential conditions to determine the IVCD. A set of guards of this event describes that QRS interval is

greater than or equal to 110 ms, the heart has not the symptoms of WPW syndrome, Brugada Syndrome, RV Dysplasia, and the possibility of any other disease.

EVENT QRS_Test_Atypical_RBBB_IVCD
  ANY *dis*
  WHERE
    grd1 : $QRS\_Int \geq 110$
    grd2 : $dis \in Disease\_Codes\_Step3 \setminus \{WPW\_Syndrome, Brugada\_Syndrome, RV\_Dysplasia, NDS3\}$
  THEN
    act1 : $Disease\_step3 := IVCD$
END

10.5.4 Third Refinement: Assess for ST-segment Elevation or Depression

This refinement provides a criterion for the ST-segments assessment by introducing some new variables (*ST_seg_ele* and *ST_depression*) in form of total functions mapping leads (LEADS) to $\mathbb{N}$ in invariants (*inv*2–*inv*3). The ST-segment for elevation and ST depression features are calculated by the *ST_seg_ele* and *ST_depression* functions. Invariants (*inv*4–*inv*8) are introduced for representing the safety properties to confirm an abnormal state of the heart (*KO*) when sinus rhythm is *Yes* and a new disease is found in this refinement.

$inv1 : Disease\_step4 \in Disease\_Codes\_Step4$
$inv2 : ST\_seg\_ele \in LEADS \rightarrow \mathbb{N}$
$inv3 : ST\_depression \in LEADS \rightarrow \mathbb{N}$
$inv4 : Sinus = Yes \wedge Disease\_step4 \in \{Acute\_inferior\_MI, Acute\_anterior\_MI \Rightarrow Heart\_State = KO$
$inv5 : Sinus = Yes \wedge Disease\_step4 = STEMI \Rightarrow Heart\_State = KO$
$inv6 : Sinus = Yes \wedge Disease\_step4 \in \{Troponin, CK\_MB\} \Rightarrow Heart\_State = KO$
$inv7 : Sinus = Yes \wedge Disease\_step4 = Non\_STEMI \Rightarrow Heart\_State = KO$
$inv8 : Sinus = Yes \wedge Disease\_step4 = Ischemia \Rightarrow Heart\_State = KO$

Four new events *ST_seg_elevation_YES*, *ST_seg_elevation_NOTCKMB_Yes*, *ST_seg_elevation_NO_TCKMB_No* and *Acute_IA_MI* are defined to cover *diagnosis* related to the ECG signals. All these events are used to interpret about the

ECG signal using ST-segment elevation or depression features [16]. To assess the ST-segments elevation or depression; we have formalised the following the textual criteria:

- Focus on the ST-segment for elevation or depression. ST-elevation $\geq$1000 µm (0.1 mV) in two or more contiguous ECG leads in a patient with chest pain indicates ST elevation MI (STEMI). The diagnosis is strengthened if there is reciprocal depression.
- ST-elevation in leads II, III, and aVF, with marked reciprocal depression in leads I and aVL, diagnostic of acute inferior MI.
- ST-segment elevation in V1 through V5, caused by extensive acute anterior MI.
- The ECG of a patient with a subtotal occlusion of the left main coronary artery. Note the ST elevation in aVR is greater than the ST elevation in V1, a recently identified marker of left main coronary disease.
- Features of non-ST-elevation MI (non-Q-wave MI).
- Elevation of the ST-segment may occur as a normal variant and ST-segment abnormalities and MI.

These textual sentences are formulated in the incremental development of our ECG protocol. This refinement advises scrutiny of the ST-segment before assessment of the T-waves, electrical axis, QT interval, and hypertrophy because the diagnosis of acute MI or ischemia is vital and depends on careful assessment of the ST-segment. Above given criteria are more complex and too ambiguous to represent. Therefore, we have formalised this part through careful cross reading of many reliable sources such as literature and encounter suggestions of the medical experts.

The event *ST_seg_elevation_YES* presents a diagnoses process for the ST Elevation Myocardial Infarction (STMEI). A set of guard predicates characterised the heart state and shows that the sinus rhythm is *Yes*, the ST elevation is TRUE and the length of ST segment elevation is greater than or equal to 1000 µm in two or more leads (II, III, aVF), or the ST elevation is TRUE and the length of ST segment elevation is greater than or equal to 1000 µm in two or more contiguous precordial leads V1 to V6, and disease must be Acute anterior MI or Acute inferior MI.

EVENT ST_seg_elevation_YES
WHEN
grd1 : $Sinus = Yes$
grd2 : $(\exists l, k \cdot l \in \{II, III, aVF\} \wedge k \in \{II, III, aVF\} \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$(ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\wedge l \neq k)$

$\vee$
$((\exists l1, k1 \cdot l1 \in \{V1, V2, V3, V4, V5, V6\} \wedge k1 \in \{V1, V2, V3, V4, V5, V6\} \wedge$
$(ST\_elevation(l1) = TRUE \wedge ST\_elevation(k1) = TRUE)$
$\wedge$
$(ST\_seg\_ele(l1) \geq 1000 \wedge ST\_seg\_ele(k1) \geq 1000)$
$\wedge l1 \neq k1$
$\wedge$
$($
$(l1 = V1 \wedge k1 = V2) \vee$
$(l1 = V2 \wedge k1 = V3) \vee$
$(l1 = V3 \wedge k1 = V4) \vee$
$(l1 = V4 \wedge k1 = V5) \vee$
$(l1 = V5 \wedge k1 = V6)$
$)$
$))$

grd3 : $Disease\_step4 \in \{Acute\_inferior\_MI, Acute\_anterior\_MI\}$

THEN

act1 : $Disease\_step4 := STEMI$

END

The event *ST_seg_elevation_NOTCKMB_Yes* is used to trace the symptoms of the Non-ST Elevation Myocardial Infarction (Non-STMEI). A set of guard predicates characterised the heart state and shows that the sinus rhythm is *Yes*, ST elevation is TRUE and the length of ST segment elevation is greater than or equal to 1000 μm in anyone lead (II, III, aVF), or the ST elevation is FALSE and the length of ST segment elevation is less than 1000 μm in all leads (II, III, aVF), the ST depression is greater than or equal to 1000 μm in two or more leads (LEADS), and disease must be Troponin, CK-MB.

EVENT ST_seg_elevation_NOTCKMB_Yes Refines ST_seg_elevation_NO

WHEN

grd1 : $Sinus = Yes$

grd2 : $(\exists l, k \cdot l \in \{II, III, aVF\} \wedge k \in \{II, III, aVF\} \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$(ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\wedge l = k)$
$\vee$
$(\forall l1 \cdot l1 \in \{II, III, aVF\} \Rightarrow$
$(ST\_elevation(l1) = FALSE \wedge ST\_seg\_ele(l1) < 1000))$

grd3 : $\exists l, k \cdot l \in LEADS \wedge k \in LEADS \wedge$
$(ST\_depression(l) \geq 1000 \wedge ST\_depression(k) \geq 1000)$
$\wedge l \neq k$

grd4 : $Disease\_step4 \in \{Troponin, CK\_MB\}$

THEN

act1 : $Disease\_step4 := Non\_STEMI$

END

The event *ST_seg_elevation_NO_TCKMB_No* captures the essential conditions to determine the ischemia. A set of guards of this event describes that the sinus

rhythm is *Yes*, the ST elevation is TRUE and the length of ST segment elevation is greater than or equal to 1000 μm in anyone lead (II, III, aVF), or the ST elevation is FALSE and the length of ST segment elevation is less than 1000 μm in all leads (II, III, aVF), ST depression is greater than or equal to 1000 μm in two or more leads (LEADS), and disease must be Troponin, CK-MB.

EVENT ST_seg_elevation_NO_TCKMB_No Refines ST_seg_elevation_NO
WHEN
grd1 : $Sinus = Yes$
grd2 : $(\exists l, k \cdot l \in \{II, III, aVF\} \wedge k \in \{II, III, aVF\} \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$(ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\wedge l = k)$
$\vee$
$(\forall l1 \cdot l1 \in \{II, III, aVF\} \Rightarrow$
$(ST\_elevation(l1) = FALSE \wedge ST\_seg\_ele(l1) < 1000))$
grd3 : $\exists l, k \cdot l \in LEADS \wedge k \in LEADS \wedge$
$(ST\_depression(l) \geq 1000 \wedge ST\_depression(k) \geq 1000)$
$\wedge l \neq k$
grd4 : $Disease\_step4 \notin \{Troponin, CK\_MB\}$
THEN
act1 : $Disease\_step4 := Ischemia$
END

The event *Acute_IA_MI* presents a diagnoses process for the Acute inferior MI and Acute anterior MI. A set of guard predicates characterised the heart state and shows that the sinus rhythm is *Yes*, the ST elevation is TRUE and the length of ST segment elevation is greater than or equal to 1000 μm in two or more leads (II, III, aVF), or the ST elevation is TRUE and the length of ST segment elevation is greater than or equal to 1000 μm in two or more contiguous pre-cordial leads V1 to V6.

EVENT Acute_IA_MI
WHEN
grd1 : $Sinus = Yes$
grd2 : $(\exists l, k \cdot l \in \{II, III, aVF\} \wedge k \in \{II, III, aVF\} \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$(ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\wedge l \neq k)$
$\vee$
$((\exists l1, k1 \cdot l1 \in \{V1, V2, V3, V4, V5, V6\} \wedge k1 \in \{V1, V2, V3, V4, V5, V6\} \wedge$
$(ST\_elevation(l1) = TRUE \wedge ST\_elevation(k1) = TRUE)$
$\wedge$
$(ST\_seg\_ele(l1) \geq 1000 \wedge ST\_seg\_ele(k1) \geq 1000)$
$\wedge l1 \neq k1$
$\wedge$

(
$(l1 = V1 \land k1 = V2) \lor$
$(l1 = V2 \land k1 = V3) \lor$
$(l1 = V3 \land k1 = V4) \lor$
$(l1 = V4 \land k1 = V5) \lor$
$(l1 = V5 \land k1 = V6)$
)
))

THEN

act1 : $Disease\_step4 :\in \{Acute\_inferior\_MI, Acute\_anterior\_MI\}$

END

10.5.5 Fourth Refinement: Assess for Pathologic Q-wave

This refinement only introduces new guidelines to interpret Q-wave feature of the ECG signal and assessment-related diseases to the Q-wave and R-wave [16]. Some new variables are represented by a set of invariants (*inv*1–*inv*2) to handle the required features of the Q-wave and R-wave to diagnose the ECG signal. The functions *Q_Normal_Status* and *R_Normal_Status* represent the normal state of the Q and R-waves in a boolean type. The next three invariants (*inv*3–*inv*5) are used to declare new variables in form of total functions mapping leads (LEADS) to $\mathbb{N}$, and an invariant (*inv*6) is also total function mapping leads (LEAD) to *BOOL*. The functions *Q_Width*, *Q_Depth* and *R_Depth* calculate the Q-wave width, Q-wave depth and R-wave depth, respectively. The last function *Q_Wave_State* represents the boolean state of the Q-wave for all leads. Two other new variables *Age_of_Inf* and *Mice_State* represent infarction age and miscellaneous states. An enumerated set of infarction age and miscellaneous states define as $Age\_of\_Infarct = \{recent, indeterminate, old\}$ and $Mice\_State5 = \{Exclude\_Mimics\_MI, late\_transition, normal\_variant, borderline\_Qs, NMS\}$, respectively in the context. The variable *Disease_step5* represents a group of diseases of this refinement level as analysis of the Q-wave from the ECG signals. Some invariants (*inv*10–*inv*13) are introduced as representing the safety properties to confirm an abnormal state of the heart (*KO*). All invariants have similar form for checking the heart state under the various disease conditions. These invariants state that if the sinus rhythm is *Yes* and a new disease is found, then the heart must be in the abnormal (*KO*) state.

*inv*1 : $Q\_Normal\_Status \in BOOL$
*inv*2 : $R\_Normal\_Status \in BOOL$
*inv*3 : $Q\_Width \in LEADS \rightarrow \mathbb{N}$
*inv*4 : $Q\_Depth \in LEADS \rightarrow \mathbb{N}$
*inv*5 : $R\_Depth \in LEADS \rightarrow \mathbb{N}$
*inv*6 : $Q\_Wave\_State \in LEADS \rightarrow BOOL$
*inv*7 : $Age\_of\_Inf \in Age\_of\_Infarct$
*inv*8 : $Mice\_State \in Mice\_State5$
*inv*9 : $Disease\_step5 \in Disease\_Codes\_Step5$

$$
\begin{aligned}
&inv10 : Sinus = Yes \wedge Disease\_step4 = Acute\_anterior\_MI \\
&\qquad \Rightarrow \\
&\qquad Heart\_State = KO \\
&inv11 : Sinus = Yes \wedge Disease\_step4 = Acute\_inferior\_MI \\
&\qquad \Rightarrow \\
&\qquad Heart\_State = KO \\
&inv12 : Sinus = Yes \wedge Disease\_step5 = Hypertrophic\_cardiomyopathy \\
&\qquad \Rightarrow \\
&\qquad Heart\_State = KO \\
&inv13 : Sinus = Yes \wedge Disease\_step5 \in \\
&\qquad \{anterior\_MI, LVH, emphysema, lateral\_MI\} \\
&\qquad \Rightarrow \\
&\qquad Heart\_State = KO
\end{aligned}
$$

In this level of refinement, we have introduced nine events (*Q_Assessment_Normal*, *Q_Assessment_Abnormal_AMI*, *Q_Assessment_Abnormal_IMI*, *Determine_Age_of_Infarct*, *Exclude_Mimics*, *R_Assessment_Normal*, *R_Assessment_Abnormal*, *R_Q_Assessment_R_Abnormal_V1234* and *R_Q_Assessment_R_Abnormal_V56*) for assessing the Q-wave and R-wave in all leads of the ECG signals. We have represented the formal notation of following guidelines, which are used to assess the Q-wave and the R-wave:

- Assess for the loss of R-waves-pathologic Q-waves in leads I, II, III, aVL, and aVF.
- Assess for R-wave progression in V2 through V4. The variation in the normal QRS configuration that occurs with rotation. The R-wave amplitude should measure from 1000 μm to at least 20000 μm in V3 and V4. Loss of R-waves in V1 through V4 with ST-segment elevation indicates acute anterior MI.
- Loss of R-wave in leads V1 through V3 with the ST-segment isoelectric and the T-wave inverted may be interpreted as anteroseptal MI age indeterminate (i.e., infarction in the recent or distant past). Features are given of old anterior MI and lateral infarction in this refinement.

Sometimes, R-wave progression in leads V2 through V4 are very poor, may be caused by the following reasons: improper lead placement, late transition, anteroseptal or anteroapical MI, LVH Severe chronic obstructive pulmonary disease, particularly emphysema may cause QS complexes in leads V1 through V4, which may mimic MI; a repeat ECG with recording electrodes placed one intercostal space below the routine locations should cause R-waves to be observed in leads V2 through V4, Hypertrophic cardiomyopathy, LBBB [16].

The event *Q_Assessment_Normal* presents a diagnoses process to test the normal state of the Q-wave. A set of guard predicates of this event shows that the width of Q-wave is less than 40 ms and the depth of Q-wave is less than or equal to 3000 μm in leads II and aVF, the width of Q-wave is less than 40 ms in lead aVL, the width of Q-wave is less than 40 ms and the depth of Q-wave is less than or equal to 7000 μm in lead III and the width of Q-wave is less than or equal to 7000 μm in lead aVL, and the depth of Q-wave is less than 40 ms and less than or equal to 1500 μm in lead I.

EVENT Q_Assessment_Normal
WHEN
grd1 : $Q\_Width(II) < 40 \wedge Q\_Depth(II) \leq 3000 \wedge$
$Q\_Width(aVF) < 40 \wedge Q\_Depth(aVF) \leq 3000 \wedge$
$Q\_Width(aVL) < 40$
grd2 : $Q\_Width(III) \leq 40 \wedge Q\_Depth(III) \leq 7000 \wedge Q\_Depth(aVL) \leq 7000$
grd3 : $Q\_Depth(I) < 40 \wedge Q\_Depth(I) \leq 1500$
THEN
act1 : $Q\_Normal\_Status := TRUE$
END

The event *Q_Assessment_Abnormal_AMI* is used to identify the Acute_anterior_ MI symptoms of the heart using ECG signal. A list of guards are defined to cover the conditions of the diagnosis process. These guards express that the sinus rhythm is *Yes*, ST elevation is TRUE and the length of ST segment elevation is greater than or equal to 1000 µm in two or more leads (II, III, aVF), or the ST elevation is TRUE and the length of ST segment elevation is greater than or equal to 1000 µm in two or more contiguous pre-cordial leads V1 to V6, the width of Q-wave is greater than or equal to 40 ms and the depth of Q-wave is greater than or equal to 3000 µm in leads V5 and V6, the width of Q-wave is greater than or equal to 40 ms and depth of Q-wave is greater to 7000 µm in lead aVL, the width of Q-wave is greater than or equal to 40 ms and the depth of Q-wave is greater to 1500 µm in lead I, and the normal state of the Q-wave is FALSE.

EVENT Q_Assessment_Abnormal_AMI
WHEN
grd1 : $Sinus = Yes$
grd2 : $(\exists l, k \cdot l \in \{II, III, aVF\} \wedge k \in \{II, III, aVF\} \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$(ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\wedge l \neq k)$
$\vee$
$((\exists l1, k1 \cdot l1 \in \{V1, V2, V3, V4, V5, V6\} \wedge k1 \in \{V1, V2, V3, V4, V5, V6\} \wedge$
$(ST\_elevation(l1) = TRUE \wedge ST\_elevation(k1) = TRUE)$
$\wedge$
$(ST\_seg\_ele(l1) \geq 1000 \wedge ST\_seg\_ele(k1) \geq 1000)$
$\wedge l1 \neq k1$
$\wedge$
$($
$(l1 = V1 \wedge k1 = V2) \vee$
$(l1 = V2 \wedge k1 = V3) \vee$
$(l1 = V3 \wedge k1 = V4) \vee$
$(l1 = V4 \wedge k1 = V5) \vee$
$(l1 = V5 \wedge k1 = V6)$
$)$
$))$

grd3 : $Q\_Width(V5) \geq 40 \wedge Q\_Depth(V5) > 3000 \wedge$
$Q\_Width(V6) \geq 40 \wedge Q\_Depth(V6) > 3000$
grd4 : $Q\_Width(aVL) \geq 40 \wedge Q\_Depth(aVL) > 7000$
grd5 : $Q\_Width(I) \geq 40 \wedge Q\_Depth(I) > 1500$
grd6 : $Q\_Normal\_Status = FALSE$
THEN
act1 : $Disease\_step4 := Acute\_anterior\_MI$
END

The event *Q_Assessment_Abnormal_IMI* is used to characterised the symptoms of Acute_inferior_MI symptoms. A set of guards are used to satisfy the required condition for the symptoms of Acute_inferior_MI. A list of guards state that the sinus rhythm is *Yes*, the ST elevation is TRUE and the length of ST segment elevation is greater than or equal to 1000 μm in two or more leads (II, III, aVF), or the ST elevation is TRUE and the length of ST segment elevation is greater than or equal to 1000 μm in two or more contiguous pre-cordial leads V1 to V6, the width of Q-wave is greater than or equal to 40 ms and the depth of Q-wave is greater than or equal to 3000 μm in lead II, the width of Q-wave is greater than 40 ms and the depth of Q-wave is greater than or equal to 7000 μm in lead III, the width of Q-wave is greater than or equal to 40 ms and the depth of Q-wave is greater to 3000 μm in lead aVL, and the normal state of the Q-wave is FALSE.

EVENT Q_Assessment_Abnormal_IMI
WHEN
grd1 : $Sinus = Yes$
grd2 : $(\exists l, k \cdot l \in \{II, III, aVF\} \wedge k \in \{II, III, aVF\} \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$(ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\wedge l \neq k)$
$\vee$
$((\exists l1, k1 \cdot l1 \in \{V1, V2, V3, V4, V5, V6\} \wedge k1 \in \{V1, V2, V3, V4, V5, V6\} \wedge$
$(ST\_elevation(l1) = TRUE \wedge ST\_elevation(k1) = TRUE)$
$\wedge$
$(ST\_seg\_ele(l1) \geq 1000 \wedge ST\_seg\_ele(k1) \geq 1000)$
$\wedge l1 \neq k1$
$\wedge$
(
$(l1 = V1 \wedge k1 = V2) \vee$
$(l1 = V2 \wedge k1 = V3) \vee$
$(l1 = V3 \wedge k1 = V4) \vee$
$(l1 = V4 \wedge k1 = V5) \vee$
$(l1 = V5 \wedge k1 = V6)$
)
))
grd3 : $Q\_Width(II) \geq 40 \wedge Q\_Depth(II) > 3000 \wedge$
$Q\_Width(III) > 40 \wedge Q\_Depth(III) > 7000 \wedge$

$Q\_Width(aVF) \geq 40 \wedge Q\_Depth(aVF) > 3000$
grd4 : $Q\_Normal\_Status = FALSE$
THEN
act1 : $Disease\_step4 := Acute\_inferior\_MI$
END

The event *Determine_Age_of_Infarct* is used to determine the age of Infarct during diagnosis process. The age of Infarct can be in different states as *recent*, *old*, and *indeterminate*. These states can be determined if the heart disease can be classified using anyone disease that is given in the guards of the event.

EVENT Determine_Age_of_Infarct
WHEN
grd1 : $Disease\_step4 = Acute\_inferior\_MI$
$\vee$
$Disease\_step5 \in \{anterior\_MI, LVH, emphysema\}$
$\vee$
$Mice\_State = Exclude\_Mimics\_MI$
$\vee$
$Disease\_step2 = LBBB$
THEN
act1 : $Age\_of\_Inf :\in \{recent, old, indeterminate\}$
END

The event *Exclude_Mimics* is used to identify the Hypertrophic cardiomyopathy. The guards of this event state that the heart has the condition of Acute inferior MI, and the miscellaneous state of the heart confirms the Exclude Mimics MI.

EVENT Exclude_Mimics
ANY *exmi*
WHERE
grd1 : $Disease\_step4 = Acute\_inferior\_MI$
grd2 : $exmi \in Mice\_State5 \wedge exmi = Exclude\_Mimics\_MI$
THEN
act1 : $Disease\_step5 := Hypertrophic\_cardiomyopathy$
act2 : $Mice\_State := borderline\_Qs$
END

The event *R_Assessment_Normal* presents a diagnoses process to test the normal state of the R-wave. A set of guard predicates of this event shows that the depth of R-wave is greater than or equal to 0 μm and less than or equal to 6000 μm in lead V1 and age is greater than 30 years, the depth of R-wave is greater than 200 μm and less than or equal to 12000 μm in lead V2 and age is less than 30, and the depth of R-wave is greater than or equal to 1000 μm and less than or equal to 24000 μm in lead V3 and age is greater than 30. Here, the age is relevant to the diagnosis of myocardial infarction.

EVENT R_Assessment_Normal
ANY *age*
WHERE
grd1 : $R\_Depth(V1) \geq 0 \wedge R\_Depth(V1) \leq 6000 \wedge age > 30$
grd2 : $R\_Depth(V2) > 200 \wedge R\_Depth(V2) \leq 12000 \wedge age < 30$
grd3 : $R\_Depth(V3) \geq 1000 \wedge R\_Depth(V3) \leq 24000 \wedge age > 30$
THEN
act1 : $R\_Normal\_Status := TRUE$
END

The event *R_Assessment_Abnormal* is used to identify the miscellaneous states of the heart, when the R-wave of the ECG signal is abnormal.

EVENT R_Assessment_Abnormal
WHEN
grd1 : $R\_Normal\_Status = FALSE$
THEN
act1 : $Mice\_State :\in \{late\_transition, normal\_variant\}$
END

The event *R_Q_Assessment_R_Abnormal_V1234* is used to determine the anterior MI, LVH and emphysema with miscellaneous state Exclude Mimics MI. A set guards shows that the normal state of the R-wave is FALSE, the state of Q-wave is TRUE in leads V1 to V4.

EVENT R_Q_Assessment_R_Abnormal_V1234
WHEN
grd1 : $R\_Normal\_Status = FALSE$
grd2 : $Q\_Wave\_State(V1) = TRUE \wedge$
$Q\_Wave\_State(V2) = TRUE \wedge$
$Q\_Wave\_State(V3) = TRUE \wedge$
$Q\_Wave\_State(V4) = TRUE$
THEN
act1 : $Disease\_step5 :\in \{anterior\_MI, LVH, emphysema\}$
act1 : $Mice\_State := Exclude\_Mimics\_MI$
END

The event *R_Q_Assessment_R_Abnormal_V56* diagnose the lateral MI and Hypertrophic cardiomyopathy. The guards of this event state that the state of Q-wave is TRUE in leads V5 and V6, and the heart state is in abnormal state (*KO*).

EVENT R_Q_Assessment_R_Abnormal_V56
WHEN
grd1 : $Q\_Wave\_State(V5) = TRUE \wedge$
$Q\_Wave\_State(V6) = TRUE$
grd3 : $Heart\_State = KO$
THEN
act1 : $Disease\_step5 :\in \{lateral\_MI, Hypertrophic\_cardiomyopathy\}$
END

10.5.6 Fifth Refinement: P-wave

This refinement level introduces a criterion to assess the P-wave for abnormalities, including the atrial hypertrophy in the ECG signal [16]. A new variable *Disease_step6* is introduced in this refinement to introduce a set of diseases related to the P-wave. Some new variables are also introduced to assess the P-wave from 12-leads ECG signals, which are represented by *inv*2–*inv*4. The first two invariants introduce new variables in form of total functions mapping from leads (LEADS) to $\mathbb{N}$. These functions return height and broadness of the P-waves. The next invariant (*inv*4) represents total function mapping leads (LEADS) to *BOOL*. It returns diphasic state in a boolean type. A set of invariants (*inv*5–*inv*7) are representing the confirmation of an abnormal state of the heart (*KO*). These invariants state that if the sinus rhythm is *Yes* and a new disease is found, then the heart will be in an abnormal state. The invariant (*inv*5) is checking for existence of multiple diseases during the P-wave diagnosis. Five new events *P_Wave_assessment_Peaked_Broad_No*, *P_Wave_assessment_Peaked_Yes*, *P_Wave_assessment_Peaked_Yes_Check_RAE*, *P_Wave_assessment_Broad_Yes* and *P_Wave_assessment_Broad_Yes_Check_LAE* are introduced to assess the P-wave.

$inv1 : Disease\_step6 \in Disease\_Codes\_Step6$
$inv2 : P\_Wave\_Peak \in LEADS \rightarrow \mathbb{N}$
$inv3 : P\_Wave\_Broad \in LEADS \rightarrow \mathbb{N}$
$inv4 : Diphasic \in LEADS \rightarrow BOOL$
$inv5 : Sinus = Yes \wedge Disease\_step6 \in$
$\{RVH, RV\_strain, pulmonary\_embolism,$
$RAE, mitral\_stenosis, mitral\_regurgitation, LV\_failure,$
$LAE, dilated\_cardiomyopathy, LVH\_cause\}$
$\Rightarrow$
$Heart\_State = KO$
$inv6 : Sinus = Yes \wedge Disease\_step6 = LAE \Rightarrow Heart\_State = KO$
$inv7 : Sinus = Yes \wedge Disease\_step6 = RAE \Rightarrow Heart\_State = KO$

The textual representation of formal notation of the P-wave assessment is given in [16]. We have formalised all the textual guidelines.

The event *P_Wave_assessment_Peaked_Broad_No* shows that there is not any particular condition related to the heart disease under the specified guards. The guard of this event state that the peak of P-wave is less than 3000 μm in leads II

and VI, or the broad of P-wave is less than 110 ms in leads II and VI, or the diphasic is FALSE in lead (II or VI).

EVENT P_Wave_assessment_Peaked_Broad_No
WHEN
grd1 : $(P\_Wave\_Peak(II) < 3000 \wedge$
$P\_Wave\_Peak(V1) < 3000)$
$\vee$
$(P\_Wave\_Broad(II) < 110 \wedge P\_Wave\_Broad(V1) < 110) \vee$
$Diphasic(II) = FALSE \vee$
$Diphasic(V1) = FALSE$
THEN
act1 : $Disease\_step6 := NDS6$
END

The event *P_Wave_assessment_Peaked_Yes* is used to assess the heart condition using ECG signal. The guards of this events state that the peak of P-wave is greater than or equal to 3000 μm in lead II and VI and the heart is in abnormal state.

EVENT P_Wave_assessment_Peaked_Yes
WHEN
grd1 : $P\_Wave\_Peak(II) \geq 3000$
grd2 : $P\_Wave\_Peak(V1) \geq 3000$
grd3 : $Heart\_State = KO$
THEN
act1 : $Disease\_step6 := RAE$
END

The event *P_Wave_assessment_Peaked_Yes_Check_RAE* is used to identify several diseases related to the RVH, RV strain, and pulmonary. The guards of this event are very simple that formalise basic assessment process to discover the disease from the ECG signal. The guards of this event state that the peak of P-wave is greater than or equal to 3000 μm in lead II and VI, the heart is in abnormal state and the heart condition must be equivalent by RAE.

EVENT P_Wave_assessment_Peaked_Yes_Check_RAE
Refines P_Wave_assessment_Peaked_Yes
WHEN
grd1 : $P\_Wave\_Peak(II) \geq 3000$
grd2 : $P\_Wave\_Peak(V1) \geq 3000$
grd3 : $Heart\_State = KO$
grd4 : $Disease\_step6 = RAE$
THEN
act1 : $Disease\_step6 :\in \{RVH, RV\_strain, pulmonary\_embolism\}$
END

The event *P_Wave_assessment_Broad_Yes* is used to trace the heart condition for the left atrial enlargement (LAE). The guards of this event formalise to assess the disease from the ECG signal. The guards of this event state that the broad of P-wave is greater than or equal to 110 ms in leads II and VI, or the diphasic is TRUE in lead (II or VI), and the heart state is in abnormal state.

EVENT P_Wave_assessment_Broad_Yes
WHEN
grd1 : $(P\_Wave\_Broad(II) \geq 110 \wedge P\_Wave\_Broad(V1) \geq 110) \vee$
$Diphasic(II) = TRUE \vee$
$Diphasic(V1) = TRUE$
grd2 : $Heart\_State = KO$
THEN
act1 : $Disease\_step6 := LAE$
END

The event *P_Wave_assessment_Broad_Yes_Check_LAE* is refinement of *P_Wave_assessment_Broad_Yes* and it is used to identify the several diseases (mitral stenosis, mitral regurgitation, LV failure, dilated cardiomyopathy, LVH cause). The guards of this event state that the broad of P-wave is greater than or equal to 110 ms in leads II and VI, or the diphasic is TRUE in lead (II or VI), the heart state is in abnormal state, and the traced disease be equivalent to LAE.

EVENT P_Wave_assessment_Broad_Yes_Check_LAE
Refines P_Wave_assessment_Broad_Yes
WHEN
grd1 : $(P\_Wave\_Broad(II) \geq 110 \wedge P\_Wave\_Broad(V1) \geq 110) \vee$
$Diphasic(II) = TRUE \vee$
$Diphasic(V1) = TRUE$
grd2 : $Heart\_State = KO$
grd3 : $Disease\_step6 = LAE$
THEN
act1 : $Disease\_step6 :\in \{mitral\_stenosis, mitral\_regurgitation, LV\_failure, dilated\_cardiomyopathy, LVH\_cause\}$
END

10.5.7 Sixth Refinement: Assess for Left and Right Ventricular Hypertrophy

The Left Ventricular Hypertrophy (LVH) and Right Ventricular Hypertrophy (RVH) are assessed by this refinement. The criteria for LVH and RVH are not applicable if the bundle branch block is present [16]. Thus, it is essential to exclude the

LBBB and RBBB early in the interpretive sequences as delineated previously in refinement 2 and refinement 3. This refinement introduces two new variables *S_Depth* and *R_S_Ratio* in form of total functions mapping leads (LEADS) to $\mathbb{N}$. These functions are used to calculate the S-wave depth and ratio of R-wave and S-wave from the 12-leads ECG signal.

Invariants (*inv*3–*inv*4) are used to verify an abnormal state (*KO*) of the heart in case of detecting any disease. Two new events (*LVH_Assessment* and *RVH_Assessment*) are introduced to assess the LVH and RVH from the 12-leads ECG. Detailed textual representation of assessment of the LVH and RVH is given in [16].

$$
\begin{array}{l}
inv1 : S\_Depth \in LEADS \rightarrow \mathbb{N} \\
inv2 : R\_S\_Ratio \in LEADS \rightarrow \mathbb{N} \\
inv3 : Sinus = Yes \wedge Disease\_step6 = RVH \Rightarrow Heart\_State = KO \\
inv4 : Sinus = Yes \wedge Disease\_step6 = LVH\_cause \Rightarrow Heart\_State = KO
\end{array}
$$

The event *LVH_Assessment* refines *P_Wave_assessment_Broad_Yes_Check_LAE*. This event is used to assess the Left Ventricular Hypertrophy (LVH) causes. A set of guards is used to satisfy the required condition for the symptoms of LVH. The guards of this event state that the broad of P-wave is greater than or equal to 110 ms in leads II and V1, or the diphasic is TRUE in lead II or V1, through the previous assessment of the disease indicates that the symptoms of LAE, sex is 0 or 1, where 0 denotes for man and 1 denotes for woman, an addition of the depth of S-wave in lead V1 and R-wave in lead V5 is greater than 35000 µm or an addition of depth of S-wave in lead V1 and R-wave in lead V6 is greater than 35000 µm, an addition of the depth of S-wave in lead aVL and R-wave in lead V1 is greater than or equal to 24000 µm for a man or 18000 µm for woman, LVH specificity is equal to 90 and sensitivity is less than 40, if the previous assessment of the disease indicates the symptoms of LAE then LVH specificity should be less than 98, and heart state is in abnormal state.

EVENT LVH_Assessment Refines P_Wave_assessment_Broad_Yes_Check_LAE
ANY *LVH_specificity*, *sensitivity*, *sex*
WHERE

$$
\begin{array}{ll}
\text{grd1} : & (P\_Wave\_Broad(II) \geq 110 \wedge P\_Wave\_Broad(V1) \geq 110) \vee \\
& Diphasic(II) = TRUE \vee \\
& Diphasic(V1) = TRUE \\
\text{grd2} : & Disease\_step6 = LAE \\
\text{grd5} : & sex \in \{0, 1\} \\
\text{grd3} : & ((S\_Depth(V1) + R\_Depth(V5)) > 35000 \\
& \vee \\
& (S\_Depth(V1) + R\_Depth(V6)) > 35000) \\
\text{grd4} : & ((R\_Depth(aVL) + S\_Depth(V1) \geq 24000) \wedge sex = 0) \\
& \vee \\
& ((R\_Depth(aVL) + S\_Depth(V1) \geq 18000) \wedge sex = 1)
\end{array}
$$

grd6 : $LVH\_specificity = 90$
$\wedge$
$sensitivity < 40$
grd7 : $Disease\_step6 = LAE \Rightarrow LVH\_specificity < 98$
grd8 : $Heart\_State = KO$
THEN
act1 : $Disease\_step6 := LVH\_cause$
END

The event *RVH_Assessment* refines *P_Wave_assessment_Broad_Yes_Check_RAE*. This event is used to identify the Right Ventricular Hypertrophy RVH. A list of guards presents the required conditions for the symptoms of RVH. The guards of this event state that the peak of P-wave is greater than or equal to 3000 μm in leads II and V1, using previous assessment of the disease indicates the symptoms of RAE, the depth of R-wave is greater than or equal to 7000 μm and age is greater than 30 years, the depth of S-wave is greater than or equal to 7000 μm in leads V5 or V6, the ratio of R- and S-wave is greater than or equal to 1 in lead V1, the ratio of R-wave and S-wave is less than or equal to 1 in lead V5 or V6, angular axis is greater than or equal to 110 degree, the previous assessment of the disease does not indicate the symptoms of LBBB or RBBB, QRS interval is less than 120 ms, and heart state is in abnormal state.

EVENT RVH_Assessment Refines P_Wave_assessment_Peaked_Yes_Check_RAE
ANY $age, aixs$
WHERE
grd1 : $P\_Wave\_Peak(II) \geq 3000$
grd2 : $P\_Wave\_Peak(V1) \geq 3000$
grd3 : $Disease\_step6 = RAE$
grd4 : $R\_Depth(V1) \geq 7000 \wedge age > 30$
grd5 : $S\_Depth(V5) \geq 7000 \vee$
$S\_Depth(V6) \geq 7000$
grd6 : $R\_S\_Ratio(V1) \geq 1$
grd7 : $R\_S\_Ratio(V5) \leq 1$
$\vee$
$R\_S\_Ratio(V6) \leq 1$
grd8 : $aixs \in 0 \,..\, 360 \wedge aixs \geq 110$
grd9 : $Disease\_step2 \notin \{LBBB, RBBB\}$
grd10 : $QRS\_Int < 120$
grd11 : $Heart\_State = KO$
THEN
act1 : $Disease\_step6 := RVH$
END

10.5.8 Seventh Refinement: Assess T-wave

This refinement is used to assess the pattern of T-wave changes in the 12-leads ECG signals. The T-wave changes are usually nonspecific [16]. The T-wave inversion associated with the ST-segment depression or elevation indicates myocardial ischemia. A new variable *T_Normal_Status* represents as a boolean state like *TRUE* is for normal state, and *FALSE* is for abnormal state. A variable *Disease_step8* is introduced in this refinement to assess a set of diseases related to T-wave from the ECG signals. Invariants (*inv*3–*inv*8) represent variables in form of total functions mapping leads (LEADS) to possible other attributes (*T_State*, *T_State_B*, *BOOL*, $\mathbb{N}$ and *T_State_l_d*).

The function *T_Wave_State* represents the T-wave states like peaked or flat, or inverted. Similarly, the function *T_Wave_State_B* also represents the T-wave states like upright or inverted, or variable using second method of diagnosis of the T-wave. The function *Abnormal_Shaped_ST* and *Asy_T_Inversion_strain* returns boolean state of the abnormal ST-shape and asymmetric T-wave inversion strain pattern, respectively. The Function *T_inversion* calculates deep the T-wave inversion and the last function *T_inversion_l_d* represents the localised and diffuse T-inversion.

From *inv*9 to *inv*15 represent an abnormal state of the heart due to finding some diseases. All these invariants are similar to the previous level of refinements. This refinement is very complex, and we have formalised two alternate diagnosis for the ECG signal. We have introduced many events to assess the T-wave from the ECG signals and to predict the various diseases related to the T-wave. Events are *T_Wave_Assessment_Peaked_V123456*, *T_Wave_Assessment_Peaked_V12*, *T_Wave_Assessment_Peaked_V12_MI*, *T_Wave_Assessment_Flat*, *T_Wave_Assessment_Inverted_Yes*, *T_Wave_Assessment_Inverted_No*, *T_Wave_Assessment_Inverted_Yes_PM*, *T_Wave_Assessment_B*, *T_Wave_Assessment_B_DI*, *T_Inversion_Likely_Ischemia*, *T_Inversion_Diffuse_B*. All these events estimate a different kinds of properties from the T-wave signal for obtaining the correct heart disease. A long textual representation for analysing the T-wave is given in [16].

$$
\begin{aligned}
&inv1 : T\_Normal\_Status \in BOOL \\
&inv2 : Disease\_step8 \in Disease\_Codes\_Step8 \\
&inv3 : T\_Wave\_State \in LEADS \rightarrow T\_State \\
&inv4 : T\_Wave\_State\_B \in LEADS \rightarrow T\_State\_B \\
&inv5 : Abnormal\_Shaped\_ST \in LEADS \rightarrow BOOL \\
&inv6 : Asy\_T\_Inversion\_strain \in LEADS \rightarrow BOOL \\
&inv7 : T\_inversion \in LEADS \rightarrow \mathbb{N} \\
&inv8 : T\_inversion\_l\_d \in LEADS \rightarrow T\_State\_l\_d \\
&inv9 : Sinus = Yes \wedge Disease\_step8 = Nonspecific \Rightarrow Heart\_State = KO \\
&inv10 : Sinus = Yes \wedge Disease\_step8 = Nonspecific\_ST\_T\_changes \\
&\qquad\qquad \Rightarrow \\
&\qquad\qquad Heart\_State = KO
\end{aligned}
$$

$inv11 : Sinus = Yes \wedge Disease\_step8 = posterior\_MI \Rightarrow Heart\_State = KO$
$inv12 : Sinus = Yes \wedge Disease\_step8 \in \{Definite\_ischemia,$
$Probable\_ischemia, Digitalis\_effect\}$
$\Rightarrow$
$Heart\_State = KO$
$inv13 : Sinus = Yes \wedge Disease\_step8 = Definite\_ischemia \Rightarrow Heart\_State = KO$
$inv14 : Sinus = Yes \wedge Disease\_step8 = Probable\_ischemia \Rightarrow Heart\_State = KO$
$inv15 : Sinus = Yes \wedge Disease\_step8\_B \in \{Cardiomyopathy, other\_nonspecific\}$
$\Rightarrow$
$Heart\_State = KO$

The event *T_Wave_Assessment_Peaked_V123456* presents basic symptoms for assessing the hyperkalaemia. The guards of this event state that the heart is in abnormal state, and the state of T-wave is peaked in leads from V1 to V6.

EVENT T_Wave_Assessment_Peaked_V123456
WHEN
grd1 : $Heart\_State = KO$
grd2 : $\forall l \cdot l \in \{V1, V2, V3, V4, V5, V6\} \Rightarrow T\_Wave\_State(l) = Peaked$
THEN
act1 : $Disease\_step8 := Hyperkalemia$
END

The event *T_Wave_Assessment_Peaked_V12* is used to assess normal variant in the ECG signal. A list of conditions for assessing the normal variant is given in the guards. The guards of this event state that the normal status of the R-wave is FALSE, the state of T-wave is peaked in leads V1 and V2, the ST elevation is TRUE and the ST segment elevation is greater than or equal to 1000 μm, or the abnormal shape of ST segment is TRUE in anyone lead, or the ST elevation is FALSE or the ST segment elevation is less than 1000 μm, and the abnormal shape of ST segment is FALSE in any two leads, inversion in T-wave is less than 5000 μm in all leads, and the status of T-wave is FALSE.

EVENT T_Wave_Assessment_Peaked_V12
WHEN
grd1 : $R\_Normal\_Status = FALSE$
grd2 : $T\_Wave\_State(V1) = Peaked \wedge$
$T\_Wave\_State(V2) = Peaked$
grd3 : $((\exists l, k \cdot l \in LEADS \wedge k \in LEADS \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$((ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\vee$
$(Abnormal\_Shaped\_ST(l) = TRUE \wedge Abnormal\_Shaped\_ST(k) = TRUE))$
$\wedge l = k)$
$\vee$

$(\forall l1, k1 \cdot l1 \in LEADS \wedge k1 \in LEADS \wedge$
$((ST\_elevation(l1) = FALSE \vee ST\_elevation(k1) = FALSE)$
$\vee$
$((ST\_seg\_ele(l1) < 1000 \vee ST\_seg\_ele(k1) < 1000)$
$\wedge$
$(Abnormal\_Shaped\_ST(l1) = FALSE \vee$
$Abnormal\_Shaped\_ST(k1) = FALSE)))$
$\Rightarrow l1 \neq k1))$

grd4 : $\forall l \cdot l \in LEADS \Rightarrow T\_inversion(l) < 5000$
grd5 : $T\_Normal\_Status = FALSE$

THEN

act1 : $Mice\_State := normal\_variant$

END

The event *T_Wave_Assessment_Peaked_V12_MI* is used to discover the posterior MI from the ECG signal. A list of guards has characterised the conditions for assessing the posterior MI. These guards state that the state of T-wave is peaked in V1 and V2, the ST elevation is TRUE and the ST segment elevation is greater than or equal to 1000 μm, or the abnormal shape of ST segment is TRUE in anyone lead, or the ST elevation is FALSE or the ST segment elevation is less than 1000 μm, and the abnormal shape of ST segment is FALSE in any two leads, inversion in T-wave is greater than 5000 μm in all leads, and the deep inversion in T-wave is localised in leads from V2 to V5 and II, III, aVF.

EVENT T_Wave_Assessment_Peaked_V12_MI

WHEN

grd1 : $T\_Wave\_State(V1) = Peaked \wedge$
$T\_Wave\_State(V2) = Peaked$
grd2 : $((\exists l, k \cdot l \in LEADS \wedge k \in LEADS \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$((ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\vee$
$(Abnormal\_Shaped\_ST(l) = TRUE \wedge Abnormal\_Shaped\_ST(k) = TRUE))$
$\wedge l = k)$
$\vee$
$(\forall l1, k1 \cdot l1 \in LEADS \wedge k1 \in LEADS \wedge$
$((ST\_elevation(l1) = FALSE \vee ST\_elevation(k1) = FALSE)$
$\vee$
$((ST\_seg\_ele(l1) < 1000 \vee ST\_seg\_ele(k1) < 1000)$
$\wedge$
$(Abnormal\_Shaped\_ST(l1) = FALSE \vee$
$Abnormal\_Shaped\_ST(k1) = FALSE)))$
$\Rightarrow l1 \neq k1))$
grd3 : $\forall l \cdot l \in LEADS \Rightarrow T\_inversion(l) > 5000$
grd4 : $T\_inversion\_l\_d(V2) = Localized \wedge$
$T\_inversion\_l\_d(V3) = Localized \wedge$
$T\_inversion\_l\_d(V4) = Localized \wedge$

$T\_inversion\_l\_d(V5) = Localized$
grd5 : $T\_inversion\_l\_d(II) = Localized \wedge$
$T\_inversion\_l\_d(III) = Localized \wedge$
$T\_inversion\_l\_d(aVF) = Localized$
grd7 : $T\_Normal\_Status = FALSE$
THEN
act1 : $Disease\_step8 := posterior\_MI$
END

The event *T_Wave_Assessment_Flat* is used to trace Nonspecific ST-T changes including other several diseases. To identify these diseases, a set of guards is given that represents the required conditions. These guards state that the state of T-wave is flat in all leads, the ST elevation is TRUE and the ST segment elevation is greater than or equal to 1000 µm, or the abnormal shape of ST segment is TRUE in anyone lead, or the ST elevation is FALSE or the ST segment elevation is less than 1000 µm, and the abnormal shape of ST segment is FALSE in any two leads, inversion in T-wave is less than 5000 µm in all leads, and the normal state of T-wave is FALSE.

EVENT T_Wave_Assessment_Flat
WHEN
grd1 : $\forall l \cdot l \in LEADS \Rightarrow T\_Wave\_State(l) = Flat$
grd2 : $((\exists l, k \cdot l \in LEADS \wedge k \in LEADS \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$((ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\vee$
$(Abnormal\_Shaped\_ST(l) = TRUE \wedge Abnormal\_Shaped\_ST(k) = TRUE))$
$\wedge l = k)$
$\vee$
$(\forall l1, k1 \cdot l1 \in LEADS \wedge k1 \in LEADS \wedge$
$((ST\_elevation(l1) = FALSE \vee ST\_elevation(k1) = FALSE)$
$\vee$
$((ST\_seg\_ele(l1) < 1000 \vee ST\_seg\_ele(k1) < 1000)$
$\wedge$
$(Abnormal\_Shaped\_ST(l1) = FALSE \vee$
$Abnormal\_Shaped\_ST(k1) = FALSE)))$
$\Rightarrow l1 \neq k1))$
grd3 : $\forall l \cdot l \in LEADS \Rightarrow T\_inversion(l) < 5000$
grd5 : $T\_Normal\_Status = FALSE$
THEN
act1 : $Disease\_step8 := Nonspecific\_ST\_T\_changes$
act1 : $Disease\_step8\_B :\in \{Cardiomyopathy, Electrolyte\_depletion,$
$Alcohol, Myocarditis, Other\}$
END

The event *T_Wave_Assessment_Inverted_Yes* presents basic symptoms for assessing the definite ischemia, probable ischemia, and digitalis effect. The guards of this event state that the state of T-wave is inverted and the ST elevation is TRUE

in all leads, or the normal state of Q-wave is FALSE, and the heart is in abnormal state.

EVENT T_Wave_Assessment_Inverted_Yes
WHEN
grd1 : $\forall l \cdot l \in LEADS \Rightarrow T\_Wave\_State(l) = Inverted$
grd2 : $\forall l \cdot l \in LEADS \Rightarrow ST\_elevation(l) = TRUE$
$\vee$
$Q\_Normal\_Status = FALSE$
grd3 : $Heart\_State = KO$
THEN
act1 : $Disease\_step8 :\in \{Definite\_ischemia, Probable\_ischemia, Digitalis\_effect\}$
END

The event *T_Wave_Assessment_Inverted_No* is used to trace the condition of nonspecific of the heart using ECG signal. The guards of this event specify that the state of T-wave is inverted and the ST elevation is FALSE in all leads, or the normal state of Q-wave is TRUE, and the heart is in abnormal state.

EVENT T_Wave_Assessment_Inverted_No
WHEN
grd1 : $\forall l \cdot l \in LEADS \Rightarrow T\_Wave\_State(l) = Inverted$
grd2 : $\forall l \cdot l \in LEADS \Rightarrow ST\_elevation(l) = FALSE$
$\vee$
$Q\_Normal\_Status = TRUE$
grd3 : $Heart\_State = KO$
THEN
act1 : $Disease\_step8 := Nonspecific$
END

The event *T_Wave_Assessment_Inverted_Yes_PM* is used to find the symptoms for pulmonary embolism from the ECG signal. A set of guards is used that specifies underlined conditions for the pulmonary embolism. The guards of this event state that the peak of P-wave is greater than or equal to 3000 μm in leads II and VI, through the previous assessment RAE has been identified, the state of T-wave is inverted and the ST elevation is TRUE in all leads or the normal state of Q-wave is FALSE, the ST elevation is TRUE and the ST segment elevation is greater than or equal to 1000 μm, or the abnormal shape of ST segment is FALSE in anyone lead, or the ST elevation is FALSE and the ST segment elevation is less than 1000 μm, or the abnormal shape of ST segment is FALSE in any two leads, the Asymmetric T inversion strain is TRUE in leads V1 to V3, and the normal state of T-wave is FALSE.

EVENT T_Wave_Assessment_Inverted_Yes_PM
WHEN
grd1 : $P\_Wave\_Peak(II) \geq 3000$
grd2 : $P\_Wave\_Peak(V1) \geq 3000$
grd3 : $Disease\_step6 = RAE$
grd4 : $((\forall p \cdot p \in LEADS \Rightarrow T\_Wave\_State(p) = Inverted) \wedge$
$(\forall t \cdot t \in LEADS \Rightarrow ST\_elevation(t) = TRUE$
$\vee$
$Q\_Normal\_Status = FALSE))$
grd5 : $((\exists l, k \cdot l \in LEADS \wedge k \in LEADS \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$((ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\vee$
$(Abnormal\_Shaped\_ST(l) = FALSE \wedge$
$Abnormal\_Shaped\_ST(k) = FALSE))$
$\Rightarrow l = k)$
$\vee$
$(\forall l1, k1 \cdot l1 \in LEADS \wedge k1 \in LEADS \wedge$
$(ST\_elevation(l1) = FALSE \wedge ST\_elevation(k1) = FALSE)$
$\wedge$
$((ST\_seg\_ele(l1) < 1000 \wedge ST\_seg\_ele(k1) < 1000)$
$\vee$
$(Abnormal\_Shaped\_ST(l1) = FALSE \wedge$
$Abnormal\_Shaped\_ST(k1) = FALSE))$
$\Rightarrow l1 \neq k1))$
grd6 : $Asy\_T\_Inversion\_strain(V1) = TRUE \wedge$
$Asy\_T\_Inversion\_strain(V2) = TRUE \wedge$
$Asy\_T\_Inversion\_strain(V3) = TRUE$
grd8 : $T\_Normal\_Status = FALSE$
THEN
act1 : $Disease\_step6 := pulmonary\_embolism$
END

The event *T_Wave_Assessment_B* is used to identify the status of the T-wave. Moreover, this event assess the pattern of T-wave changes. The guards of this event state that the state of T-wave is upright in leads I, II, and V3 to V6, the state of T-wave is inverted in lead aVL, and the state of T-wave is variable in leads III, aVL, aVF, V1 and V2.

EVENT T_Wave_Assessment_B
WHEN
grd1 : $\forall l \cdot l \in \{I, II, V3, V4, V5, V6\} \Rightarrow T\_Wave\_State\_B(l) = Upright$
grd2 : $T\_Wave\_State\_B(aVL) = Inverted\_B$
grd3 : $\forall l \cdot l \in \{III, aVL, aVF, V1, V2\} \Rightarrow T\_Wave\_State\_B(l) = Variable$
THEN
act1 : $T\_Normal\_Status := TRUE$
END

The event *T_Wave_Assessment_B_DI* refines *T_Wave_Assessment_Inverted_Yes*. This event is used to discover the symptoms for definite ischemia from the ECG signal. A set of guards is used that specifies underlined conditions for definite ischemia. The guards of this event state that the ST elevation is TRUE in all leads or the normal status of Q-wave is FALSE, the normal status of T-wave is FALSE, the ST elevation is TRUE and the ST segment elevation is greater than or equal to 1000 μm, or the abnormal shape of ST segment is TRUE in any two leads.

EVENT T_Wave_Assessment_B_DI Refines T_Wave_Assessment_Inverted_Yes
WHEN
grd2 : $\forall l \cdot l \in LEADS \Rightarrow ST\_elevation(l) = TRUE$
$\vee$
$Q\_Normal\_Status = FALSE$
grd3 : $T\_Normal\_Status = FALSE$
grd4 : $\exists l, k \cdot l \in LEADS \wedge k \in LEADS \wedge$
$((ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000) \vee$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\vee$
$(Abnormal\_Shaped\_ST(l) = TRUE \wedge Abnormal\_Shaped\_ST(k) = TRUE))$
$\wedge$
$l \neq k$
THEN
act1 : $Disease\_step8 := Definite\_ischemia$
END

The event *T_Inversion_Likely_Ischemia* refines *T_Wave_Assessment_Inverted_Yes*. This event is used to trace the symptoms for probable ischemia from the ECG signal. A set of guards is used that specifies the required conditions for the probable ischemia. The guards of this event state that the state of T-wave is inverted in all leads, the ST elevation is TRUE in all leads or the normal status of Q-wave is FALSE, the inversion in T-wave is greater than 5000 μm in all leads, the ST elevation is TRUE and the ST segment elevation is greater than or equal to 1000 μm, or the abnormal shape of ST segment is TRUE in anyone lead, or the ST elevation is FALSE or the ST segment elevation is less than 1000 μm, and the abnormal shape of ST segment is FALSE in any two leads, the inversion in T-wave is localised in leads II, III, aVF, and V2 to V5, and the normal state of T-wave is FALSE.

EVENT T_Inversion_Likely_Ischemia Refines T_Wave_Assessment_Inverted_Yes
WHEN
grd1 : $\forall l \cdot l \in LEADS \Rightarrow T\_Wave\_State(l) = Inverted$
grd2 : $\forall l \cdot l \in LEADS \Rightarrow ST\_elevation(l) = TRUE$
$\vee$
$Q\_Normal\_Status = FALSE$
grd3 : $\forall l \cdot l \in LEADS \Rightarrow T\_inversion(l) > 5000$

grd4 : $((\exists l, k \cdot l \in LEADS \wedge k \in LEADS \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$((ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\vee$
$(Abnormal\_Shaped\_ST(l) = TRUE \wedge Abnormal\_Shaped\_ST(k) = TRUE))$
$\wedge l = k)$
$\vee$
$(\forall l1, k1 \cdot l1 \in LEADS \wedge k1 \in LEADS \wedge$
$((ST\_elevation(l1) = FALSE \vee ST\_elevation(k1) = FALSE)$
$\vee$
$((ST\_seg\_ele(l1) < 1000 \vee ST\_seg\_ele(k1) < 1000)$
$\wedge$
$(Abnormal\_Shaped\_ST(l1) = FALSE \vee$
$Abnormal\_Shaped\_ST(k1) = FALSE)))$
$\Rightarrow l1 \neq k1))$

grd5 : $T\_inversion\_l\_d(V2) = Localized \wedge$
$T\_inversion\_l\_d(V3) = Localized \wedge$
$T\_inversion\_l\_d(V4) = Localized \wedge$
$T\_inversion\_l\_d(V5) = Localized$

grd6 : $T\_inversion\_l\_d(II) = Localized \wedge$
$T\_inversion\_l\_d(III) = Localized \wedge$
$T\_inversion\_l\_d(aVF) = Localized$

grd7 : $T\_Normal\_Status = FALSE$

THEN

act1 : $Disease\_step8 := Probable\_ischemia$

END

The event *T_Inversion_Diffuse_B* is used to diagnose the symptoms for cardiomyopathy, other nonspecific from the ECG signal. A set of guards is used that specifies the required conditions that state that the ST elevation is TRUE and the ST segment elevation is greater than or equal to 1000 μm, or the abnormal shape of ST segment is TRUE in anyone lead, or the ST elevation is FALSE or the ST segment elevation is less than 1000 μm, and the abnormal shape of ST segment is FALSE in any two leads, the inversion in T-wave is greater than 5000 μm in all leads, the T inversion is diffuse, and the normal state of T-wave is FALSE.

T_Inversion_Diffuse_B

WHEN

grd1 : $((\exists l, k \cdot l \in LEADS \wedge k \in LEADS \wedge$
$(ST\_elevation(l) = TRUE \wedge ST\_elevation(k) = TRUE)$
$\wedge$
$((ST\_seg\_ele(l) \geq 1000 \wedge ST\_seg\_ele(k) \geq 1000)$
$\vee$
$(Abnormal\_Shaped\_ST(l) = TRUE \wedge$
$Abnormal\_Shaped\_ST(k) = TRUE))$
$\wedge l = k)$

$$
\begin{array}{l}
\quad \vee \\
\quad (\forall l1, k1 \cdot l1 \in LEADS \wedge k1 \in LEADS \wedge \\
\quad ((ST\_elevation(l1) = FALSE \vee ST\_elevation(k1) = FALSE) \\
\quad \vee \\
\quad ((ST\_seg\_ele(l1) < 1000 \vee ST\_seg\_ele(k1) < 1000) \\
\quad \wedge \\
\quad (Abnormal\_Shaped\_ST(l1) = FALSE \vee \\
\quad Abnormal\_Shaped\_ST(k1) = FALSE))) \\
\quad \Rightarrow l1 \neq k1)) \\
\text{grd2} : \forall l \cdot l \in LEADS \Rightarrow T\_inversion(l) > 5000 \\
\text{grd3} : \forall l \cdot l \in LEADS \Rightarrow T\_inversion\_l\_d(l) = Diffuse \\
\text{grd4} : T\_Normal\_Status = FALSE \\
\textbf{THEN} \\
\text{act1} : Disease\_step8\_B :\in \{Cardiomyopathy, other\_nonspecific\} \\
\textbf{END}
\end{array}
$$

10.5.9 Eighth Refinement: Assess Electrical Axis

After finding all kinds of information about abnormal ECG, it is also essential to check the electrical axis (see Table 10.1) using two simple clues:

- If leads I and aVF are upright; the axis is normal.
- The axis is perpendicular to the lead with the most equiphasic or smallest QRS deflection. Left-axis deviation and the commonly associated left anterior fascicular block are visible in ECG signal.

This refinement is very essential refinement for the ECG interpretation because of the different angle of the ECG signal gives different output and angle based prediction can be changed [16]. So, for accuracy of the ECG interpretation electrical axis must be included. New variables *minAngle*, *maxAngle*, *Axis_Devi* and *Dis-*

Table 10.1 Electrical axis

Most equiphasic lead	Lead perpendicular	Axis
		Lead I and aVF positive = normal axis
III	aVR	Normal = +30 degrees
aVL	II	Normal = +60 degrees
		Lead I positive and aVF negative = Left axis
II	aVL (QRS positive)	Left = −30 degrees
aVR	III (QRS negative)	Left = −60 degrees
I	aVF (QRS negative)	Left = −90 degrees
		Lead I negative and aVF positive = right axis
aVR	III (QRS positive)	Right = +120 degrees
II	aVL (QRS negative)	Right = +150 degrees

ease_step9 have been defined here for assessment of the electrical axis. A new variable *QRS_Axis_State* is defined as a total function mapping from leads (LEADS) to *QRS_directions*. This function represents the QRS-axis direction of the leads. Two invariants (*inv*6–*inv*7) represent the safety properties in assessment of the correct axis. These invariants are verifying an abnormal state of the heart (*KO*) using axis position.

$$
\begin{array}{l}
inv1 : minAngle \in -90 \mathinner{..} 180 \\
inv2 : maxAngle \in -90 \mathinner{..} 180 \\
inv3 : Axis\_Devi \in Axis\_deviation \\
inv4 : Disease\_step9 \in Disease\_Codes\_Step9 \\
inv5 : QRS\_Axis\_State \in LEADS \rightarrow QRS\_directions \\
inv6 : Disease\_step9 \in \{LPFB, Dextrocardia, NV\_MSEC\} \wedge \\
\qquad maxAngle = 180 \wedge minAngle = 110 \\
\qquad \Rightarrow \\
\qquad Heart\_State = KO \\
inv7 : Disease\_step9 \in \{LAFB, MSCHD, Some\_Form\_VT, ED\_OC\} \\
\qquad \wedge maxAngle = -90 \wedge minAngle = -30 \\
\qquad \Rightarrow \\
\qquad Heart\_State = KO
\end{array}
$$

In this refinement level, we introduce various events for assessing different kinds of features from 12 leads ECG signal corresponding to the angle. Following events are introduced in this refinement: *Axis_Assessment_QRS_upright_Yes_Age_less_40*, *Axis_Assessment_QRS_upright_Yes_Age_gre_40*, *Axis_Assessment_QRS_upright_No_QRS_positive*, *Axis_Assessment_QRS_upright_No_QRS_negative*, *Misc_Disease_Step9_LAD*, *Misc_Disease_Step9_RAD*, *R_Q_Assessment_R_Abnormal_V56_axis_deviation*.

The event *Axis_Assessment_QRS_upright_Yes_Age_less_40* refines *Axis_Assessment_QRS_upright_Yes*. This event is used to find the electrical axis. A set of guards is used that specifies that the QRS axis state is upright in leads I and aVF, and age is less than 40 years.

EVENT Axis_Assessment_QRS_upright_Yes_Age_less_40
Refines Axis_Assessment_QRS_upright_Yes
  ANY *age*
  WHERE
    grd1 : $QRS\_Axis\_State(I) = D\_Upright \wedge$
           $QRS\_Axis\_State(aVF) = D\_Upright$
    grd2 : $age \in \mathbb{N} \wedge age < 40$
  THEN
    act1 : $minAngle := 0$
    act2 : $maxAngle := 110$
END

The event *Axis_Assessment_QRS_upright_Yes_Age_gre_40* refines *Axis_Assessment_QRS_upright_Yes*. This event is similar to the last event that is also used to assess the electrical axis. The minimum angle is -30 and maximum angle is 90. A set of guards is used that defines that the QRS axis state is upright in leads I and aVF, and age is greater than 40 years.

EVENT Axis_Assessment_QRS_upright_Yes_Age_gre_40
Refines Axis_Assessment_QRS_upright_Yes
  ANY *age*
  WHERE
    grd1 : $QRS\_Axis\_State(I) = D\_Upright \wedge$
           $QRS\_Axis\_State(aVF) = D\_Upright$
    grd2 : $age \in \mathbb{N} \wedge age > 40$
  THEN
    act1 : $minAngle := -30$
    act2 : $maxAngle := 90$
END

The event *Axis_Assessment_QRS_upright_No_QRS_positive* refines *Axis_Assessment_QRS_upright_No*. This event is used to determine the electrical axis and left axis deviation (LAD) in leads. A set of guards is used that defines that the QRS axis state is not upright in leads I and aVF, the QRS axis state is positive in leads I and aVF, and the heart is in abnormal state.

EVENT Axis_Assessment_QRS_upright_No_QRS_positive
Refines Axis_Assessment_QRS_upright_No
  WHEN
    grd1 : $\neg(QRS\_Axis\_State(I) = D\_Upright \wedge$
           $QRS\_Axis\_State(aVF) = D\_Upright)$
    grd2 : $QRS\_Axis\_State(I) = D\_Positive \wedge$
           $QRS\_Axis\_State(aVF) = D\_Positive$
    grd3 : $Heart\_State = KO$
  THEN
    act1 : $minAngle := -30$
    act2 : $maxAngle := -90$
    act3 : $Axis\_Devi := LAD$
END

The event *Axis_Assessment_QRS_upright_No_QRS_negative* refines *Axis_Assessment_QRS_upright_No*. This event is used to identify the electrical axis and right axis deviation (RAD) in leads. A set of guards is used that defines that the QRS axis state is not upright in leads I and aVF, the QRS axis state is negative in leads I and aVF, and the heart is in abnormal state.

EVENT Axis_Assessment_QRS_upright_No_QRS_negative
Refines Axis_Assessment_QRS_upright_No
WHEN
grd1 : $\neg(QRS\_Axis\_State(I) = D\_Upright \wedge$
$QRS\_Axis\_State(aVF) = D\_Upright)$
grd2 : $QRS\_Axis\_State(I) = D\_Negative \wedge$
$QRS\_Axis\_State(aVF) = D\_Negative$
grd3 : $Heart\_State = KO$
THEN
act1 : $minAngle := 110$
act2 : $maxAngle := 180$
act3 : $Axis\_Devi := RAD$
END

The event *Misc_Disease_Step9_LAD* assess miscellaneous diseases like LAFB, MSCHD, etc. A set of guards is used that defines that the axis deviation is left axis deviation (LAD) in leads, negative minimum angle is -30, negative maximum angle is -90 and the heart is in abnormal state.

Misc_Disease_Step9_LAD
WHEN
grd1 : $Axis\_Devi = LAD \wedge$
$minAngle = -30 \wedge$
$maxAngle = -90$
grd2 : $Heart\_State = KO$
THEN
act1 : $Disease\_step9 :\in \{LAFB, MSCHD, Some\_Form\_VT, ED\_OC\}$
END

The event *Misc_Disease_Step9_LAD* assess several diseases like LPFB, Dextrocardia, NV MS-EC. A set of guards is used that defines that the axis deviation is right axis deviation (RAD) in leads, positive minimum angle is 110, positive maximum angle is 180 and the heart is in abnormal state.

Misc_Disease_Step9_RAD
WHEN
grd1 : $Axis\_Devi = RAD \wedge$
$minAngle = 110 \wedge$
$maxAngle = 180$
grd2 : $Heart\_State = KO$
THEN
act1 : $Disease\_step9 :\in \{LPFB, Dextrocardia, NV\_MSEC\}$
END

The event *R_Q_Assessment_R_Abnormal_V56_axis_deviation* refines *R_Q_Assessment_R_Abnormal_V56*. This event is used to identify the lateral MI. A set of guards is used that formalises that the state of Q-wave is TRUE in leads V5 and V6,

the axis deviation is right axis deviation (RAD) in leads, positive minimum angle is 110, positive maximum angle is 180 and the heart is in abnormal state.

EVENT R_Q_Assessment_R_Abnormal_V56_axis_deviation
Refines R_Q_Assessment_R_Abnormal_V56
WHEN
grd1 : $Q\_Wave\_State(V5) = TRUE \wedge$
$Q\_Wave\_State(V6) = TRUE$
grd2 : $Axis\_Devi = RAD \wedge$
$minAngle = 110 \wedge$
$maxAngle = 180$
grd3 : $Heart\_State = KO$
THEN
act1 : $Disease\_step5 := lateral\_MI$
END

10.5.10 Ninth Refinement: Assess for Miscellaneous Conditions

There are lots of heart diseases, and it is very difficult to predict everything. A lot of conditions make it more and more ambiguous. This refinement level keeps multiple miscellaneous conditions about the ECG interpretation [16]. Following conditions are given for miscellaneous conditions as follows:

- Artificial pacemakers: If electronic pacing is confirmed, usually no other diagnosis can be made from the ECG.
- Prolonged QT syndrome: See normal QT parameters listed in Table 10.2. No complicated formula is required for assessment of the QT intervals.

A variable *MC_Step10_Test_Needed* is declared to represent miscellaneous condition tests as a boolean type *TRUE* or *FALSE*. Variable *Disease_step10* is introduced in this refinement to assess a set of diseases of miscellaneous conditions from the ECG signal. The next two invariants (*inv*2–*inv*3) represent the abnormality of the heart state (*KO*) in case of discovery of new miscellaneous diseases. In this refinement, we introduce only two events (*Miscellaneous_Conditions_Step10* and *Misc_Disease_Step10_Dextrocardia_Test*) to discover miscellaneous conditions from the ECG signal.

Table 10.2 Clinically useful approximation of upper limit of QT interval (ms)

Heart rate (bpm)	Male	Female
45–65	<470	<480
66–100	<410	<430
>100	<360	<370

$inv1 : MC\_Step10\_Test\_Needed \in BOOL$
$inv2 : Disease\_step10 \in Misc_{Disease}\_Codes\_Step10$
$inv3 : Sinus = Yes \wedge Disease\_step10 \in \{Incomplete\_RBBB,$
$Long\_QT, Hypokalemia, Digitalis\_toxicity, Hypothermia,$
$Electronic\_pacing, Pericarditis, Hypercalcemia\}$
$Electrical\_alternans$
$\Rightarrow$
$Heart\_State = KO$
$inv4 : Sinus = Yes \wedge Disease\_step9 = Dextrocardia$
$\Rightarrow$
$Heart\_State = KO$

The event *Miscellaneous_Conditions_Step10* is used to assess miscellaneous disease. It is very difficult to identify all the possible diseases using ECG signal, therefore a set of disease is classified under the miscellaneous conditions. This event is used to find the several diseases. A set of guards is used that specifies that the further test is needed that is presented as a boolean type, and the heart is in abnormal state.

EVENT Miscellaneous_Conditions_Step10
WHEN
grd1 : $MC\_Step10\_Test\_Needed = TRUE$
grd2 : $Heart\_State = KO$
THEN
act1 : $Disease\_step10 :\in \{Incomplete\_RBBB, Pericarditis, Long\_QT, Hypokalemia,$
$Digitalis\_toxicity, Electrical\_alternans, Electronic\_pacing, Hypothermia,$
$Hypercalcemia\}$
END

The event *Misc_Disease_Step10_Dextrocardia_Test* refines *Misc_Disease_Step9_RAD* and this event is modelled to assess the Dextrocardia. A list of required conditions is formalised in form of guards. These guards present that the axis deviation is right axis deviation (RAD) in leads, minimum angle is 110, maximum angle is 180, boolean state for further testing is TRUE, and the heart is in abnormal state.

EVENT Misc_Disease_Step10_Dextrcardia_Test Refines Misc_Disease_Step9_RAD
WHEN
grd1 : $Axis\_Devi = RAD \wedge$
$minAngle = 110 \wedge$
$maxAngle = 180$
grd2 : $MC\_Step10\_Test\_Needed = TRUE$
grd3 : $Heart\_State = KO$
THEN
act1 : $Disease\_step9 := Dextrocardia$
END

10.5.11 Tenth Refinement: Assess Arrhythmias

This is the final refinement of the ECG interpretation of the system. In this refinement, we introduce different kinds of tachyarrhythmias and give the protocols for assessment as follows:

- Narrow complex tachycardia: Gives the differential diagnosis of narrow QRS complex tachycardia.
- Wide complex tachycardia: Gives the differential diagnosis of wide QRS complex tachycardia.

$$
\begin{aligned}
&inv1 : NW\_QRS\_Tachycardia\_RT\_State \in \\
&\qquad NW\_QRS\_Tachycardia\_RI \\
&inv2 : Disease\_step11 \in Misc\_Disease\_Codes\_Step11 \\
&inv3 : Sinus = Yes \wedge Disease\_step11 \in \\
&\qquad \{Ventricular\_Premature\_Beats, Nodal\_Premature\_Beats, \\
&\qquad Bradyarrhythmias, Narrow\_QRS\_Tachycardias, \\
&\qquad Wide\_QRS\_Tachycardias, Atrial\_Premature\_Beats\} \\
&\qquad \Rightarrow Heart\_State = KO \\
\\
&inv4 : Sinus = Yes \wedge Distease\_step11\_NW\_QRST \in \\
&\qquad \{Sinus\_Tachycardia, Supraventricular\_Tachycardia, \\
&\qquad WPW\_Syndrome\_Orthodromic, Torsades\_de\_pointes, \\
&\qquad Atrial\_Tachycardia, AF\_Fixed\_AV\_Conduction, AVNRT, \\
&\qquad Ventricular\_Tachycardia, WPW\_Syndrome\_Antidromic, \\
&\qquad AF\_Variable\_AV\_Conduction\_BBB\_WPW\_Synd\_Anti, \\
&\qquad AF\_BBB\_WPW\_Synd\_Antidromic\} \\
&\qquad \Rightarrow Heart\_State = KO \\
\\
&inv5 : Sinus = Yes \wedge Distease\_step11\_NW\_QRST \in \\
&\qquad \{AF\_Variable\_AV\_Conduction, AVNRT, \\
&\qquad AT\_Paroxysmal\_NParoxysmal, AT\_Variable\_AV\_Block, \\
&\qquad AF\_Fixed\_AV\_Conduction, WPW\_Syndrome\_OCMT, \\
&\qquad Sinus\_Tachycardia, Multifocal\_Atrial\_Tachycardia, \\
&\qquad Atrail\_Fibrillation\} \\
&\qquad \Rightarrow Heart\_State = KO \\
\\
&inv6 : NW\_QRS\_Tachycardia\_RT\_State = Regular \wedge \\
&\qquad Distease\_step11\_NW\_QRST \in \{Sinus\_Tachycardia, \\
&\qquad WPW\_Syndrome\_OCMT, AF\_Fixed\_AV\_Conduction, \\
&\qquad AVNRT, AT\_Paroxysmal\_NParoxysmal\} \\
&\qquad \Rightarrow Heart\_State = KO \\
\\
&inv7 : NW\_QRS\_Tachycardia\_RT\_State = Irregular \wedge \\
&\qquad Distease\_step11\_NW\_QRST \in \{Atrail\_Fibrillation, \\
&\qquad AT\_Variable\_AV\_Block, AF\_Variable\_AV\_Conduction, \\
&\qquad Multifocal\_Atrial\_Tachycardia\} \\
&\qquad \Rightarrow Heart\_State = KO
\end{aligned}
$$

$$
\begin{array}{l}
inv8 : NW\_QRS\_Tachycardia\_RT\_State = Regular \wedge \\
\quad Distease\_step11\_NW\_QRST \in \{Ventricular\_Tachycardia, \\
\quad Sinus\_Tachycardia, AF\_Fixed\_AV\_Conduction, \\
\quad Supraventricular\_Tachycardia, Atrial\_Tachycardia, \\
\quad AVNRT, WPW\_Syndrome\_Antidromic, \\
\quad WPW\_Syndrome\_Orthodromic\} \\
\quad \Rightarrow Heart\_State = KO \\
\\
inv9 : NW\_QRS\_Tachycardia\_RT\_State = Irregular \wedge \\
\quad Disteavse\_step11\_NW\_QRST \in \\
\quad \{AF\_Variable\_AV\_Conduction\_BBB\_WPW\_Synd\_Anti, \\
\quad Torsades\_de\_pointes, AF\_BBB\_WPW\_Synd\_Antidromic\} \\
\quad \Rightarrow Heart\_State = KO
\end{array}
$$

A new variable *NW_QRS_Tachycardia_RT_State* is defined to express the QRS tachycardia regular or irregular state using *inv*1. A variable *Disease_step11* is introduced in this refinement to assess arrhythmias from the ECG signals. All rest of the invariants (*inv*3–*inv*9) represents an abnormal state (*KO*) of the heart after analysing the arrhythmia and related disease. All invariants have similar kinds of properties. We introduce five new events to assess tachyarrhythmias from the 12-leads ECG signals in case of abnormal rhythm. Five events are *Rhythm_test_FALSE_Step11*, *Step11_N_QRS_Tachycardia_Regular*, *Step11_N_QRS_Tachycardia_Irregular*, *Step11_W_QRS_Tachycardia_Regular* and *Step11_W_QRS_Tachycardia_Irregular*.

The event *Rhythm_test_FALSE_Step11* is used to identify the heart state, sinus rhythm, heart rate and several diseases that are not identified through the last assessment process. The guards of this event shows that the equidistant of PP interval is FALSE or the equidistant of RR interval is FALSE, the RR interval is not equal to the PP interval in leads II, V1, V2, or the positive state of P-wave is FALSE, and the heart rate is within the range of 1 to 300 bps.

$$
\begin{array}{l}
\textbf{Rhythm\_test\_FALSE\_Step11} \\
\quad \textbf{ANY } rate \\
\quad \textbf{WHERE} \\
\quad\quad \text{grd1} : (\forall l \cdot l \in \{II, V1, V2\} \Rightarrow PP\_Int\_equidistant(l) = FALSE \vee \\
\quad\quad\quad RR\_Int\_equidistant(l) = FALSE \vee \\
\quad\quad\quad RR\_Interval(l) \neq PP\_Interval(l)) \\
\quad\quad\quad \vee \\
\quad\quad\quad P\_Positive(II) = FALSE \\
\quad\quad \text{grd2} : rate \in 1 \mathinner{..} 300 \\
\quad \textbf{THEN} \\
\quad\quad \text{act1} : Sinus := No \\
\quad\quad \text{act2} : Heart\_Rate := rate \\
\quad\quad \text{act3} : Heart\_State := KO \\
\quad\quad \text{act4} : Disease\_step11 :\in \{Atrial\_Premature\_Beats, Ventricular\_Premature\_Beats, \\
\quad\quad\quad Bradyarrhythmias, Narrow\_QRS\_Tachycardias, Wide\_QRS\_Tachycardias, \\
\quad\quad\quad Nodal\_Premature\_Beats\} \\
\textbf{END}
\end{array}
$$

The event *Step11_N_QRS_Tachycardia_Regular* refines Step11_N_QRS_Tachycardia. This event assesses the different kinds of diseases like sinus tachycardia, AVNRT, etc. A set of guards of this event is used to formalise the required conditions. These conditions present that the heart has no sinus rhythm, the heart is in abnormal state, the heart rate is within 1 to 60 or 100 to 300 range, through previous assessment the heart has the conditions of narrow QRS tachycardia, and the state of narrow QRS tachycardia is regular.

EVENT Step11_N_QRS_Tachycardia_Regular Refines Step11_N_QRS_Tachycardia
WHEN
grd1 : $Sinus = No$
grd2 : $Heart\_State = KO$
grd3 : $Heart\_Rate \in 1 \mathinner{..} 300 \setminus 60 \mathinner{..} 100$
grd4 : $Disease\_step11 = Narrow\_QRS\_Tachycardias$
grd5 : $NW\_QRS\_Tachycardia\_RT\_State = Regular$
THEN
act1 : $Distease\_step11\_NW\_QRST :\in \{Sinus\_Tachycardia, AVNRT, AF\_Fixed\_AV\_Conduction, AT\_Paroxysmal\_NParoxysmal, WPW\_Syndrome\_OCMT\}$
END

The event *Step11_N_QRS_Tachycardia_Irregular* refines Step11_N_QRS_Tachycardia. The action of this event specifies to identify several diseases using ECG signal. The guards of this event state that the heart has no sinus rhythm, heart is in abnormal state, the heart rate is within 1 to 60 or 100 to 300 range, through previous assessment the heart has the conditions of narrow QRS tachycardia, and the state of narrow QRS tachycardia is irregular.

EVENT Step11_N_QRS_Tachycardia_Irregular Refines Step11_N_QRS_Tachycardia
WHEN
grd1 : $Sinus = No$
grd2 : $Heart\_State = KO$
grd3 : $Heart\_Rate \in 1 \mathinner{..} 300 \setminus 60 \mathinner{..} 100$
grd4 : $Disease\_step11 = Narrow\_QRS\_Tachycardias$
grd5 : $NW\_QRS\_Tachycardia\_RT\_State = Irregular$
THEN
act1 : $Distease\_step11\_NW\_QRST :\in \{AF\_Variable\_AV\_Conduction, Atrail\_Fibrillation, AT\_Variable\_AV\_Block, Multifocal\_Atrial\_Tachycardia\}$
END

The event *Step11_W_QRS_Tachycardia_Regular* refines Step11_W_QRS_Tachycardia. As similar to the last event, the action of this event also specifies to identify several diseases from the ECG signal. A set of guards presents required conditions. These required conditions show that the heart has no sinus rhythm, heart is in abnormal state, the heart rate is within 1 to 60 or 100 to 300 range, through previous assessment the heart has the conditions of wide QRS tachycardia, and the state of narrow QRS tachycardia is regular.

EVENT Step11_W_QRS_Tachycardia_Regular Refines Step11_W_QRS_Tachycardia
WHEN
grd1 : $Sinus = No$
grd2 : $Heart\_State = KO$
grd3 : $Heart\_Rate \in 1 \mathinner{..} 300 \setminus 60 \mathinner{..} 100$
grd4 : $Disease\_step11 = Wide\_QRS\_Tachycardias$
grd5 : $NW\_QRS\_Tachycardia\_RT\_State = Regular$
THEN
act1 : $Distease\_step11\_NW\_QRST :\in \{Ventricular\_Tachycardia, Supraventricular\_Tachycardia, AVNRT, WPW\_Syndrome\_Orthodromic, Sinus\_Tachycardia, Atrial\_Tachycardia, AF\_Fixed\_AV\_Conduction, WPW\_Syndrome\_Antidromic\}$
END

The event *Step11_W_QRS_Tachycardia_Irregular* refines Step11_W_QRS_Tachycardia. A list of guards presents that the heart has no sinus rhythm, heart is in abnormal state, the heart rate is within 1 to 60 or 100 to 300 range, through previous assessment of the heart has the conditions of wide QRS tachycardia, and the state of narrow QRS tachycardia is irregular. The action of this event is used to identify several diseases from the ECG signal that are given in the action.

EVENT Step11_W_QRS_Tachycardia_Irregular Refines Step11_W_QRS_Tachycardia
WHEN
grd1 : $Sinus = No$
grd2 : $Heart\_State = KO$
grd3 : $Heart\_Rate \in 1 \mathinner{..} 300 \setminus 60 \mathinner{..} 100$
grd4 : $Disease\_step11 = Wide\_QRS\_Tachycardias$
grd5 : $NW\_QRS\_Tachycardia\_RT\_State = Irregular$
THEN
act1 : $Distease\_step11\_NW\_QRST :\in \{AF\_BBB\_WPW\_Synd\_Antidromic, AF\_Variable\_AV\_Conduction\_BBB\_WPW\_Synd\_Anti, Torsades\_de\_pointes\}$
END

Here, we have given required safety properties in form invariants in all refinements. All these properties are derived from the original protocol to verify the correctness and consistency of the system. These properties are formulated through logic experts as well as cardiologist experts according to the original protocol. The main advantage of this technique is that if any property is not holding by the model, then it helps to find anomalies or to find missing parts of the model such as required conditions and parameters. A technical report [21] contains the complete formal representation of the ECG interpretation protocol.

10.5.12 Proof Statistics

All the proof obligations for all ten refinements are generated and proved using the Rodin prover [29]. Table 10.3 shows statistics of the ECG interpretation protocol us-

Table 10.3 Proof statistics

Model	Total number of POs	Automatic proof	Interactive proof
Abstract model	41	33 (80 %)	8 (20 %)
First refinement	61	54 (88 %)	7 (12 %)
Second refinement	41	38 (92 %)	3 (8 %)
Third refinement	51	36 (70 %)	15 (30 %)
Fourth refinement	60	35 (58 %)	25 (42 %)
Fifth refinement	43	22 (51 %)	21 (49 %)
Sixth refinement	38	14 (36 %)	24 (64 %)
Seventh refinement	124	29 (23 %)	95 (77 %)
Eighth refinement	52	30 (57 %)	22 (43 %)
Ninth refinement	21	9 (42 %)	12 (52 %)
Tenth refinement	67	43 (64 %)	24 (36 %)
Total	599	343 (58 %)	256 (42 %)

ing refinement approach. In the table, the POs column represents the total number of proof obligations generated for each level. The interactive POs column represents the number of those proof obligations that have to be proved interactively. Those proof obligations that are not proved interactively are proved completely automatically by the prover. The complete development of the ECG interpretation protocol system results in 599 (100 %) proof obligations, in which 343 (58 %) are proved automatically by the Rodin tool. The remaining 256 (42 %) proof obligations are proved interactively using Rodin tool. In seventh refinement, numbers of POs are higher than other refinements because significantly in this level; number of variables and events are higher than another level of refinements. All the proofs are discharged completely automatic as well as interactive for all refinement levels. All these proofs are involved either by the complexity of the formal expression that proved by *do case* or finiteness constraints on a set of leads. The main interactive steps involved instantiating for total function of the different features of the ECG interpretation in every level of refinement. In order to guarantee the correctness of the system, we have established various invariants in the stepwise refinement. All these invariants are derived from the original protocol to verify the correctness and consistency of the system under the guidance of the cardiologist expert. Most of the invariants are introduced for checking the abnormality of the features of the ECG signal. Detection of an abnormal criteria, the heart shows surety of a particular disease or a set of diseases. A set of diseases are distinguished in next level of refinements.

10.6 Lesson Learnt

The task of modelling of the ECG interpretation protocol in the Event-B has required a significant effort. It is a typical knowledge engineering task, where the knowledge is the original document, is transformed into the Event-B formal notation, which provides a significant hierarchical structure for analysing the ECG interpretation protocol and to diagnose different kinds of heart diseases. As the result, the Event-B ECG interpretation protocol specification is much more lengthy than the original text: the original ECG interpretation protocol. The complete formal specification of the ECG interpretation protocol in the Event-B is more than 200 pages.

We consider that logic-based modelling approach is very difficult to model a complex medical protocol. This approach has required a good understanding of logic as well as knowledge of the medical protocol. We have spent lots of time with medical experts to understand the structure of the medical protocols for formalising purpose. For modelling the ECG protocol, we have consulted with cardiologist and medical experts. The formal model of ECG protocol is based on original protocol and checked by medical experts [21, 22].

We cannot strictly say that the formal representation of the ECG interpretation protocol in the Event-B modelling language has contributed to the improvement of the original protocol. Most important contribution is refinements-based formal development of the ECG interpretation protocol and to generate a new optimal way of the ECG interpretation protocol for diagnosing the ECG signal. The developed formal model is proved and verified according to the given protocol properties as discussed in the formal development. Furthermore, the Event-B formalisation has served to disambiguate unclarities in the original document that resulted from the modelling stage: a number of ambiguity and repetition diagnosis problems with original document are uncovered and resolved by refining the formal specification of the ECG interpretation protocol in the Event-B. The formal model can help to restructure the original document of guidelines and protocols.

The verification attempts have served to clarify any remaining problems in the original ECG interpretation protocol document. More importantly, we have shown that it is possible in practice to systematically analyse whether a protocol formalised in the Event-B complies with certain medically relevant properties. Various properties of the ECG interpretation protocol have been the object of formal verification using the Event-B system, with different type of results. Mostly, the given properties of the ECG interpretation protocol have been confirmed by the formal representation of the ECG interpretation protocol. However, in other cases, verification is not simple and lots of ambiguous informations, i.e. it is not possible to complete the proof or further development of the model due to ambiguity. We have introduced some additional assumptions with the help of cardiologist experts for describing the conditions needed to make the property true and added more conditions to remove the ambiguity. These assumptions are missing piece of information in the medical protocol, which helps to improve the medical protocol. We have applied a pragmatic approach to collect lots of information through literature survey and medical experts advises for finding the exact facts to introduce new assumptions and conditions for discharging all the generated proof obligations.

For example, pieces of informations missing from the original ECG interpretation protocol like it is not given that how many leads should hold particular property during diagnosis. As per our solution, we have applied test for particular properties in all leads. This results in a characterisation of the circumstances under which the property holds. The obtained characterisation is analysed by the medical experts under all the possible conditions, and it can be used either to redefine the property or to improve the original ECG interpretation protocol text by documenting the cases under which the property does (or does not) hold.

More importantly, numerous anomalies became apparent during the Event-B modelling of the ECG interpretation protocol. Here, we have used term anomaly to refer to any issues that are not able to represent satisfactory of the original ECG interpretation protocol. Some set of anomalies, which have found during the development of the system are described below. We have grouped all anomalies in three well known general categories: ambiguity, inconsistency and incompleteness.

10.6.1 Ambiguous

Ambiguous is a well-known anomaly in the area of formal representation, and it is very hard to interpret. For instance, a problem we encountered while modelling the ECG interpretation protocol is determining whether the terms "ST-depression" and "ST-elevation" had the same meaning or not. These are terms that are used in the ECG interpretation original protocol, but not defined elsewhere. Similarly, what is the difference between "ischemia", "definite ischemia", "probable ischemia" and "likely ischemia".

In the ECG interpretation, there are 12 leads ECG signals, which are used for interpretation, but a lot of places in the original document not clarify in which lead the particular property should hold. Such kinds of information are very ambiguous and give lots of confusions to model the system.

10.6.2 Inconsistencies

Inconsistencies are other kinds of anomalies which are always given conflicting results or different decisions on same patient data. The problems derived from inconsistent elements are very serious and as such must be avoided during development. The ECG interpretation protocol presents several inconsistencies. For instance, we found an inconsistency in form of applicable conditions in the ECG protocol. It expresses that the conditions are applicable to both "male" and "female" under some certain circumstances. However, elsewhere in the protocol an action is advised that these conditions of the protocol are not applicable to "female".

10.6.3 Incompleteness

Either missing pieces of information or insufficient information in the original document are always related to the incompleteness anomaly. In either case, incompleteness hinders a correct interpretation of the guidelines and protocols. For example, the original protocol contains "normal variant" factors to be considered when assessing the T-wave. However, what "normal variant" exactly means is missing in the protocol. As an example of insufficient information for "normal variant", we provide the class of diseases for further analysis the system.

10.7 Summary

Refinement is a key concept for developing the complex systems, since it starts with a very abstract model and incrementally adds new details to the set of requirements. We have outlined an incremental refinement-based approach for formalising medical protocols using the Rodin tool. The approach we have taken is not specific to the Event-B. We believe a similar approach could be taken using others state-based notations such as ASM, TLA$^+$, Z, etc. The Rodin proof tool is used to generate the hundreds of proof obligations and to discharge those obligations automatically and interactively. Another key role of the tool is in helping us to discover appropriate gluing invariants to prove the refinements. In summary, some key lessons are that incremental development with small refinement steps; appropriate abstractions at each level and powerful tool support are all invaluable in such a kind of formal development.

In this chapter, we have shown the formal representation of medical protocol. The formal model of medical protocol is verified, and this verified model is not only feasible but also useful for improving the existing medical protocol. We have fully formalised a real-world medical protocols (ECG interpretation) in an incremental refinement-based formalisation process, and we have used proof tools to systematically analyse whether the formalisation complies with certain medically relevant protocol properties [21, 22]. The formal verification process has discovered a number of anomalies which all are discussed in the previous section. Throughout this process, we have obtained the following concrete results:

- A formal specification language like Event-B is used for modelling a complex system, is used to model the medical practice protocols. The Event-B is a general modelling language tool. The Event-B is used to present a formal specification for a real-life medical protocols; ECG interpretation.
- The ECG interpretation protocol is formalised in the Event-B modelling language. The medical protocol ECG interpretation is used in our study has been developed in incremental way and finally transformed into a concrete formal representation. Each proved refinement level of the formal model of the protocol represents feasibility and correctness.

- In our formal verification process of the ECG interpretation, we have obtained a list of anomalies.
- Verification proofs for the ECG interpretation protocol, and properties have proved using the Rodin proof tool. Generated proof obligations and proofs show that formal verification of the ECG interpretation protocols is feasible.
- Original protocol of the ECG is also based on some hierarchy, but in that hierarchy, some diagnosis is repeating in multiple branches (see in [16]). We have also discovered an optimised hierarchical structure for the ECG interpretation efficiently using incremental refinement approach, which can help to diagnose more efficiently then old techniques, and this obtained hierarchical structure is verified through medical experts.

The ECG interpretation protocol [21, 22] is very complex, and it interprets various kinds of heart diseases. Improving quality of medical protocol using the formal verification tools like highly mathematical based modelling languages; Event-B, is the main contribution of our work. We have also discovered a hierarchical structure for the ECG interpretation efficiently that helps to discover a set of conditions that can be very helpful to diagnose particular disease an early stage of the diagnosis without using multiple diagnosis. Our hierarchical tree structure provides more concrete solutions for the ECG interpretation protocol and helps to improve the original ECG interpretation protocol. Our objective behind this work is that if any medical protocol is developed under particular circumstances to handle a set of specific properties according to the medical experts, formal verification can also meet whether the protocol actually complies with them. This has been the first attempt ever in verifying medical protocols with mathematical rigour with the generalised formal modelling tool Event-B. The main objective of this approach to test correctness and consistency of the medical protocol using refinement based incremental development. This approach is not only for diagnosis purpose, but it may be applicable to covering a large group of other categories (i.e. treatment, management, prevention, counselling, evaluation, etc.)[3] related to the medical protocols.

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