Patient Monitoring for Cardiovascular Diseases

Domain Analysis

Abstract

The goal of this project was to design a patient monitoring system for cardiovascular diseases. In this document, we describe the domain analysis based on the domain description given before. We first give a glossary that clearly defines the terminology used in this analysis. Then, we provide a domain model, specify functional requirements for the system using use cases and finally specify non-functional requirements using quality attribute scenarios.

Contents

1 Glossary

In this section, we provide a glossary of the most important terminology used in this analysis.

- **Buddy**: A specific trustee that visits the patient on a regular basis and is able to estimate the current situation of the patient correctly. They can receive emergency notifications and can also input their estimations of the patient's status in the system.
- **Cardiologist**: A physician specialized in cardiology. The patient's cardiologist is the main responsible for tracking the patient's status.
- **Client**: A client is used by actors to use the system. For example, a physician can use it to check a patient's status, read a notification, update a risk level etc. Note that the term "client" focuses on the functionality, not the physical device. The device which the client runs on can also be used for other functionality, for example as a patient gateway.
- **Clinical model**: Clinical models are used in the back-end system to check and model clinical information. The DSS uses multiple heavy-weight clinical models, depending on the configuration for the patient. The patient gateway also uses clinical models for checking for emergencies called *emergency clinical models.* Every clinical model in the system can be configured.
- **Cardiovascular diseases (CVDs)**: Heart diseases or cardiovascular diseases (CVDs) are the class of diseases (or *pathologies*) that involve the heart or blood vessels (arteries and veins). While the term technically refers to any disease that affects the cardiovascular system, it is usually used to refer to those related to atherosclerosis (arterial disease). This is a condition in which an artery wall thickens as the result of a build-up of fatty materials such as cholesterol. Arterial disease can lead to heart attacks and strokes. Other pathologies are hypertension, congestive heart failure, heart transplantation, etc.
- **Data package**: The wearable unit and patient gateway transmit measurements in the form of bundled data packages. These can contain multiple data types and even multiple measurements of the same type (depending on the transmission configuration).
- **Decision support system (DSS)**: "The DSS" is used as a term for the functionality in the PMS back-end that uses clinical models to check data, estimate risk levels and determine whether notifications should be sent.
- **Electronic Health Record (EHR)**: A common enabler in e-health. The EHR makes a patient's medical record available electronically to allow healthcare professionals from different medical institutions to communicate patient data in a fast, efficient and reliable way. The data collected by the patient monitoring system should be integrated in the patient's EHR. Since the hospital already integrates with the EHR and the patient monitoring system already integrates with the HIS, the patient monitoring system is assumed to integrate with the EHR through the HIS.
- **Emergency clinical model:** A clinical model used on the patient gateway. These models are a lot less calculation-intensive than the clinical models used by the DSS and use a smaller data set. Every clinical model in the system can be configured.
- **Emergency notification:** An emergency notification is sent out by the gateweay when it measures abnormal data. The DSS will check the emergency notification and send out medical notifications if correct.
- **Health professional**: A general term to refer to all professionals involved in providing health care. Examples are GPs, specialists, nurses and telemedicine operators.
- **General Practitioner (GP)**: The physician involved with the general treatment of patients. Each patient has one specific preferred GP, but can visit others too (e.g. the GP on duty in the weekend).
- **Hospital information system (HIS)**: The HIS is the IT system the hospital is using, even before the monitoring system is deployed. It serves multiple purposes to our system, such as data integration, a clinical workstation, a user database etc.
- **Medical notifications**: Medical notifications are sent out when the DSS estimates that the patient's risk level should be changed. In this case, a notification is sent to the medical supervisors who can approve the estimation. Medical notifications are labeled red, yellow or green.

- **Medical supervisor**: A medical supervisor is in charge of supervising the treatment of the patient. The medical supervisor checks the patient's status, receives notifications, assesses the patient's status and confirms or declines risk estimations. In this document, the medical supervisor is always the patient's cardiologist.
- **Monitoring history**: The whole collection of sensor data of a patient collected by the patient monitoring system.
- **Non-electronic sensor data**: Sensor data acquired using non-electronic sensors, such as patient questionnaires.
- **Notification**: A notification is sent out by the system on several events. The precise information of the notification depends on the event. The most important notifications in the system are *medical notifications*, others are system notifications, regular updates etc.
- **Patient**: A patient already diagnosed with CVD.
- **Patient gateway (PG)**: The patient gateway receives data from the WU and sends this to the PMS back-end in data packages. It can also check the received data for emergencies with an emergency clinical model. Note that the term "gateway" focuses on functionality, not a physical device. The device the gateway runs on can also be used for other functionality, for example a client.
- **Patient record**: Synonym for a patient's electronic health record.
- **Pathology**: A pathology is a diagnosed disease. A patient suffering from CVD can have several pathologies, such as atherosclerosis (arterial disease), hypertension, congestive heart failure, heart transplantation, etc.
- **Patient monitoring system (PMS)**: "PMS" is used to refer to the system as a whole. This term is used as a synonym for "System".
- **PMS back-end**: The part of the system apart from the clients, the patient gateway and the wearable unit. This acts as a server to the rest of the system.
- **Questionnaire**: A questionnaire can be used by an actor (e.g., patient, buddy) to input structured data in the system. For example, a patient can fill in a daily questionnaire about how he feels (pain, diarrhea etc).
- **Risk level**: The most important outcome of the clinical models are a risk level for each patient. A risk level gives an impression of the risk of the patient to have a malignant event in the near future. Generally, the risk level can be represented by a number, for example a percentage. This value is of importance to the physicians. The risk level can also have an impact on the system configuration. For this purpose, the exact number is evaluated as being "high" risk, "low" risk or "medium" risk. The thresholds for each of these risk levels can be set by a physician (cardiologist).
- **Sensor data**: Electronic data concerning the patient's status sent by electronic sensors.
- **Specialist**: A physician specialized in a certain field of medicine. Examples are cardiologists, thoracic surgeons, vascular surgeons and neurologists.
- **System**: "The system" is used to refer to the whole. It includes the PMS back-end, the patient gateway, the WU etc. This term is used as a synonym for "Patient Monitoring System".
- **Technical nurse:** An employee at the hospital handling the technicalities of PMS at that location, e.g. doing the initial setup of the WU for a patient. The technical nurse has both the needed technical and medical knowledge needed for these tasks. The technical nurse can be an employee of the hospital or a telemedicine operator of the PMS company.
- **Technical Supervisor:** A technical supervisor is in charge of the technical part of the PMS system. It can either be the technical nurse, or the telemedicine callcenter.
- **Telemedicine callcenter**: The telemedicine callcenter is a group of telemedicine operators responsible for monitoring the system, handling user questions and fixing technical problems.
- **Telemedicine operator**: A member of the telemedicine callcenter responsible for monitoring the system, handling user questions and fixing technical problems.
- **Trustee**: A person allowed by the patient to use the system. A trustee can be anyone, ranging from a patient's family and friends to his neighbors who want to help. Amongst others, trustees can keep up-to-date of the patient's status by checking his status using the system or by being subscribed to notifications. Moreover, each patient can assign one of their trustees to be their *buddy*.

- **Wearable Unit (WU)**: The wearable unit is the device worn by the patient which measures multiple clinical parameters (heart rate, blood pressure etc) and sends these to the patient gateway.

2 Domain models

This section shows the domain model of the patient monitoring system and lists constraints that apply to it. Because of the size of the domain model, we split it into multiple views. For readability reasons, only multiplicities differing from *0..** are shown.

2.1 General

The general domain model is shown in Fig. 1.

2.2 Basic data flow

The basic data flow domain model is shown in Fig. 2.

2.3 Risk level and notifications

The risk level and notifications domain model is shown in Fig. 3.

2.4 Constraints

- A patient has to be diagnosed with CVD before being signed up for the PMS.
- A risk level estimation can only be approved into a risk level by a medical supervisor.
- A medical supervisor can only approve a risk level estimation after receiving a medical notification.
- Medical Supervisors only receive notification about the patients they supervise.
- For estimating the risk level of a patient, clinical risk models only take into account sensor data of that patient.
- Each patient has one entry in the Electronic Health Record (EHR) and each entry corresponds to a single patient.

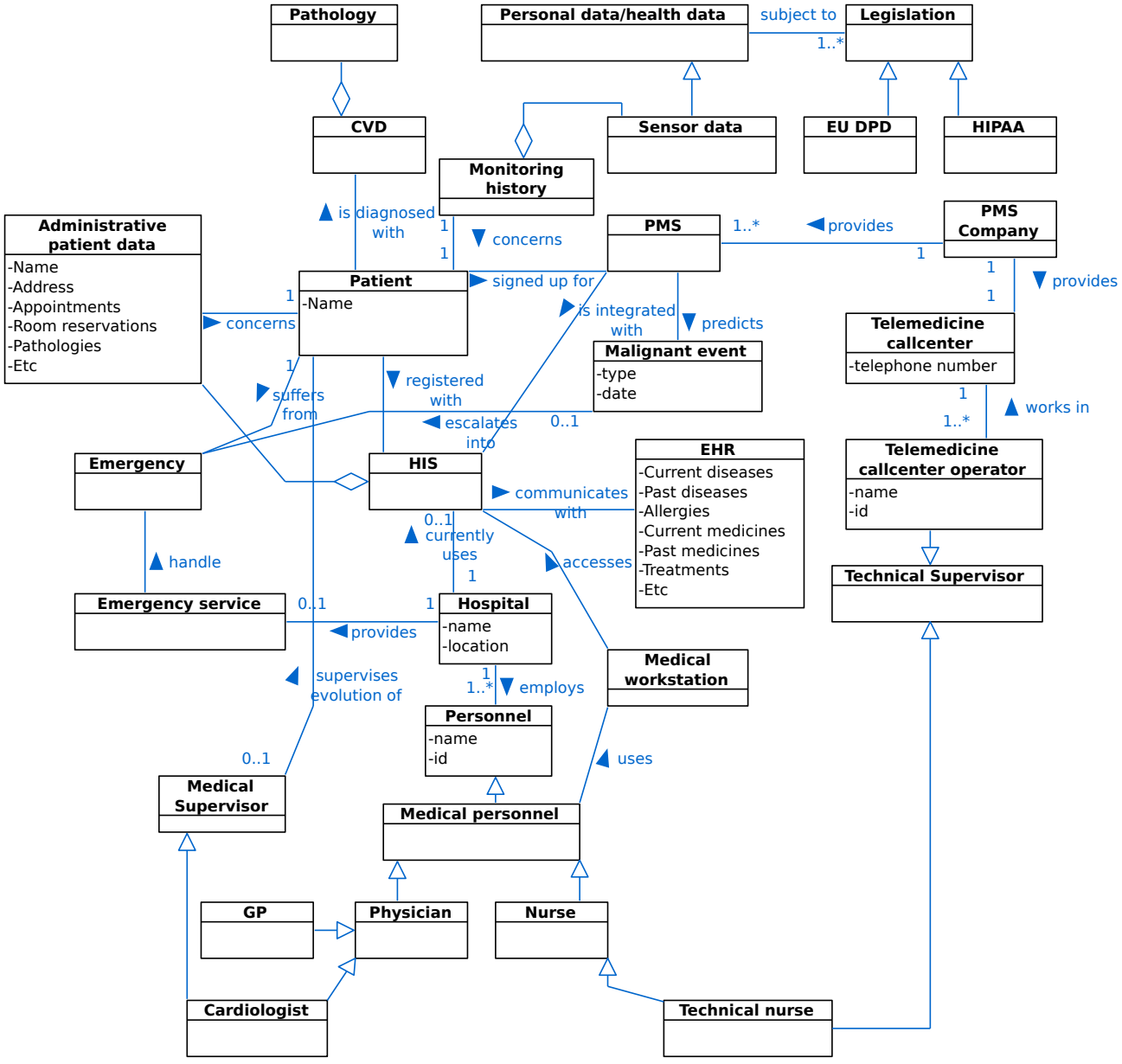

Figure 1: Domain model: General.
For readability reasons, only multiplicities differing from *0..** are shown.

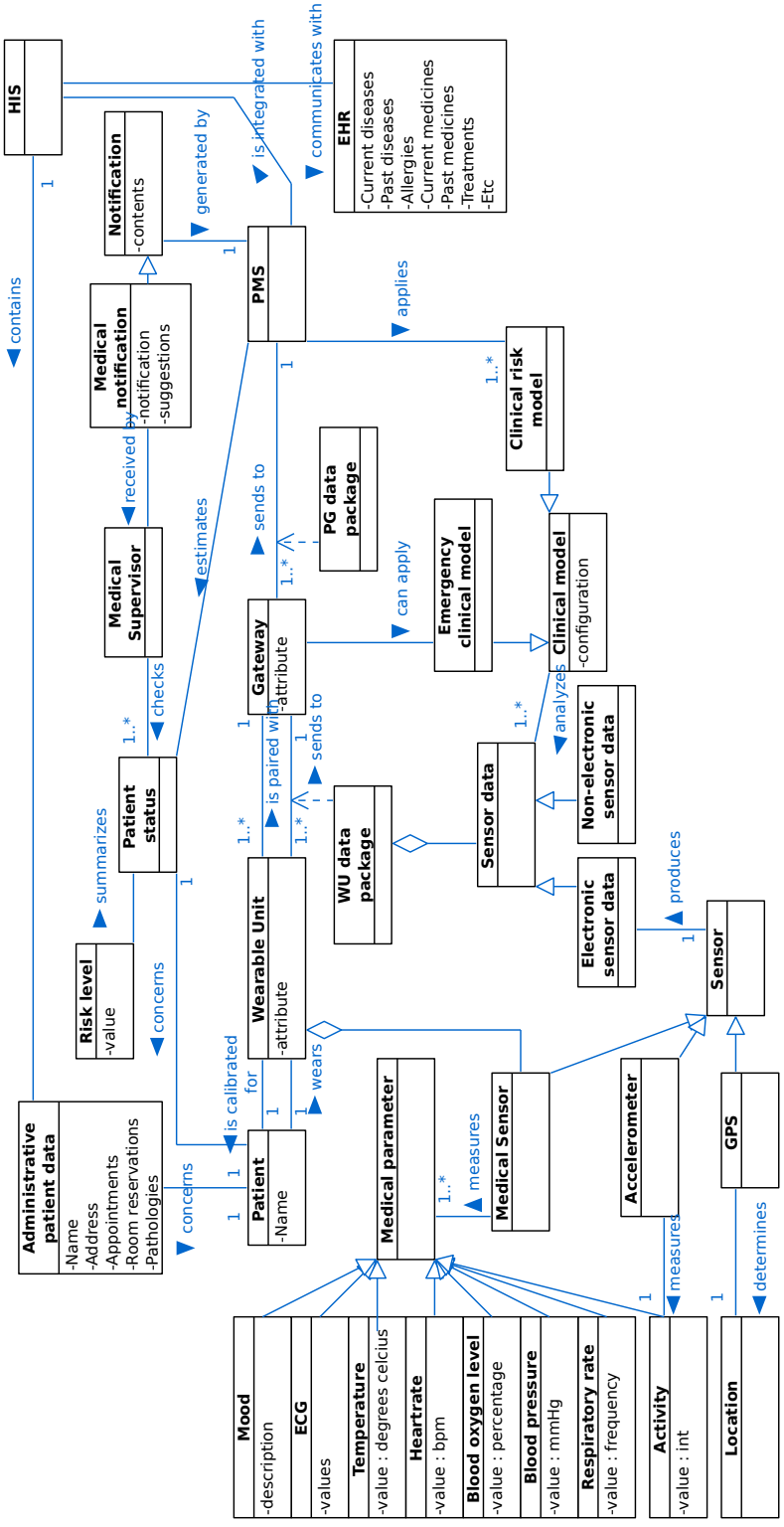

Figure 2: Domain model: Basic data flow.
For readability reasons, only multiplicities differing from *0..** are shown.

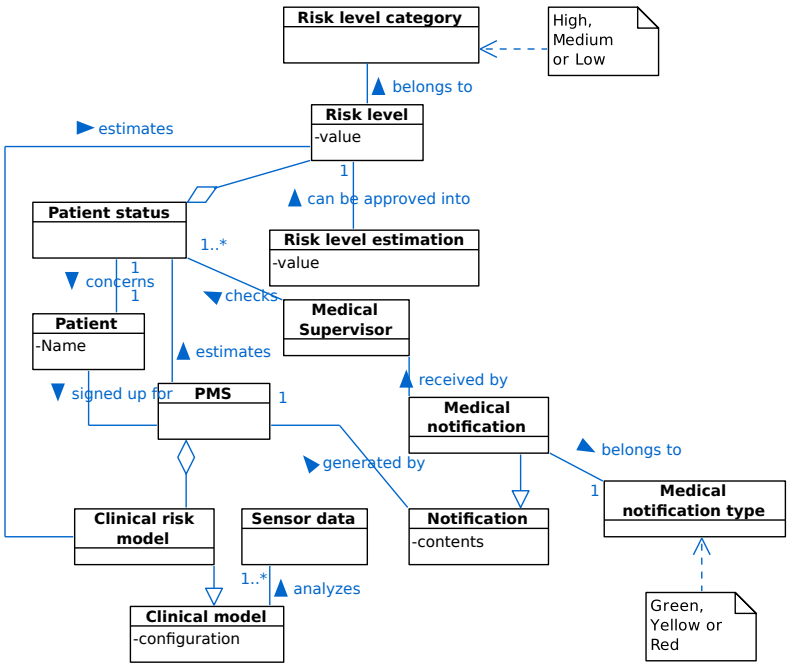

Figure 3: Domain model: Risk level and notifications.
For readability reasons, only multiplicities differing from *0..** are shown.

3 Functional requirements

Use case model

In this section, we model the required functionality of the patient monitoring system in the form of *use cases*. Figure 4 shows an overview of the actors involved in these use cases. Figure 5 shows the relations between all use cases.

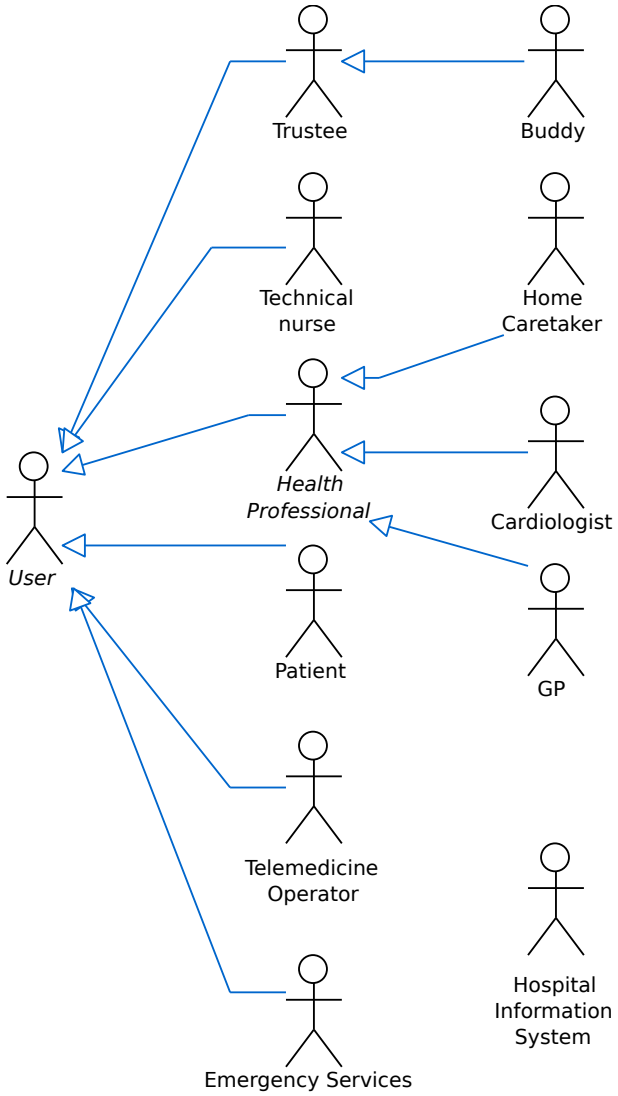

Figure 4: Actor hierarchy of the use cases

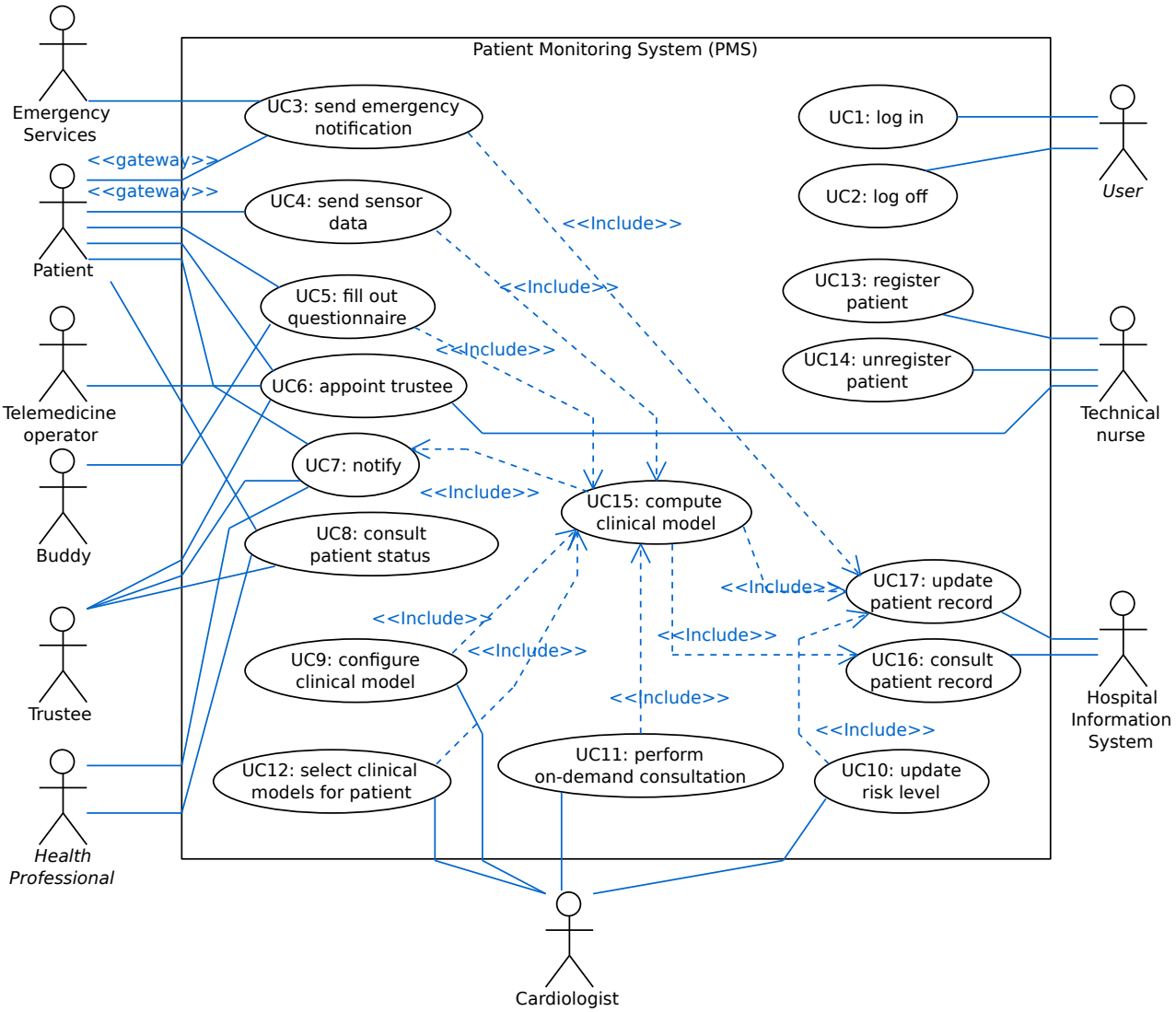

Figure 5: Use case diagram

3.1 *UC1*: log in

- **Name:** log in
- **Primary actor:** the User
- **Interested parties:**
  - *PMS:* wants to authenticate its users.
- **Preconditions:** The User is registered into the system and has credentials to prove his identity.
- **Postconditions:** The User has authenticated himself in the PMS.
- **Main scenario:**
  1. The User indicates he wants to authenticate into the PMS.
  2. The PMS asks him to provide his credentials (e.g. username and password).
  3. The User provides his credentials.
  4. The PMS verifies the provided credentials and authenticates the User.
- **Alternative scenarios:**

  4b. The provided credentials were incorrect, resume at step 2.

3.2 *UC2*: log off

- **Name:** log off
- **Primary actor:** the User
- **Interested parties:**
  - *PMS:* wants to authenticate its users.
- **Preconditions:** The User has authenticated himself in the PMS (cf. *log in (UC1)*).
- **Postconditions:** The User has logged off.
- **Main scenario:**
  1. The User indicates he wants to log off from the PMS.
  2. The PMS logs him off.
- **Alternative scenarios:**

3.3 *UC3*: send emergency notification

- **Name:** send emergency notification
- **Primary actor:** the Patient (via his patient gateway)
- **Secondary actor:** the Emergency Services
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled him in the PMS.
  - *Health Professional*: is involved in the Patient's treatment.
  - *Buddy or Trustee:* keeps an eye on the Patient and is interested in his status.
  - *Emergency Services:* responsible for dealing with emergency situations (e.g. sending an ambulance to the patient).
  - *Patient:* wants to be treated in a time when an emergency situation arises.
- **Preconditions:**
- **Postconditions:** The patient monitoring system has received the emergency notification, verified it, and informed the Emergency Services (by means of an emergency notification).

- **Main scenario:**
  1. The patient gateway receives the sensor data from the wearable unit, identifies a potential emergency situation, prepares it (packages the sensor data as an *emergency notification*). There is no need to authenticate explicitly: the patient gateway itself provides a proof of the Patient's identity to the PMS. The patient gateway sends the prepared package to the PMS, together with proof of the Patient's identity.
  2. The PMS receives the emergency notification and applies a dedicated (yet fast) clinical model for confirming the emergency.
  3. The PMS confirms the emergency, stores it in the patient record (**include:** *update patient record (UC17)*) and sends an emergency notification with all relevant data to the Emergency Services.
- **Alternative scenarios:**

  3b. After verifying the emergency notification, the PMS decides there is no need to issue an emergency notification, but marks this event in the patient record (**include:** *update patient record (UC17)*).

3.4 *UC4*: send sensor data

- **Name:** send sensor data
- **Primary actor:** the Patient (via his patient gateway)
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled him in the PMS.
  - *Health Professional*: is involved in the Patient's treatment.
  - *Buddy or Trustee:* keeps an eye on the Patient and is interested in his status.
  - *Patient:* has been registered in the PMS and wants the system to keep an eye on his status.
- **Preconditions:**
- **Postconditions:** The patient monitoring system has registered the sensor data (readings), and processes it.
- **Main scenario:**
  1. The patient gateway has received the sensor data from the wearable unit, prepared them (packaging). There is no need to authenticate explicitly: the patient gateway itself provides a proof of the Patient's identity to the PMS. The patient gateway sends the packaged sensor data to the PMS (according to the configured transmission rate), together with proof of the Patient's identify.
  2. The PMS receives the sensor data, stores it and schedules it for processing (**include**: *compute clinical model (UC15)*).
- **Alternative scenarios:**

3.5 *UC5*: fill out questionnaire

- **Name:** fill out questionnaire
- **Primary actor:** the Patient or a Buddy
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled him in the PMS.
  - *Health Professional*: is involved in the Patient's treatment.
  - *Buddy:* keeps an eye on the Patient and keeps the PMS up-to-date on his status.
- **Preconditions:** The primary actor is authenticated into the system (cf. *log in (UC1)*).
- **Postconditions:**
  - The patient monitoring system processed the questionnaire.

  - The PMS has logged this event.

- **Main scenario:**

  1. The main actor indicates he wants to fill out a questionnaire to inform the PMS about the Patient's status.
  2. The PMS presents the main actor with a list of questionnaires available to him.
  3. The main actor selects a questionnaire.
  4. The PMS presents the main actor the list of questions enclosed within the questionnaire.
  5. The main actor answers the questions and submits the information to the PMS.
  6. The PMS receives the information, stores it, logs this event and schedules it for processing (**include**: *compute clinical model (UC15)*).

- **Alternative scenarios:**

  2b. The PMS does not have a questionnaire for the main actor to fill out and informs him of this.

3.6 *UC6*: appoint trustee

- **Name:** appoint trustee
- **Primary actor:** the Patient, a Telemedicine callcenter, or a Technical Nurse
- **Secondary actor:** the Trustee
- **Interested parties:**
  - *Patient:* wants to appoint someone in his vicinity (e.g. neighbour, family member) as his trustee.
  - *Health Professional*: is involved in the Patient's treatment
  - *Trustee:* keeps an eye on the Patient
    - *Buddy*: Trustee that also keeps the PMS up-to-date on the Patient's status.
- **Preconditions:** The main actor is authenticated into the system (cf. *log in (UC1)*).
- **Postconditions:**
  - The Patient Monitoring System will keep the Trustee up-to-date about the patient's status and notifications.
  - If the Trustee is also a Buddy, he will be given the means to fill in questionnaires and as such keep the PMS up-to-date about the Patient's progress.
  - The PMS has logged this event.
- **Main scenario:**

  1. The main actor indicates he wants to appoint a Trustee that will be kept up-to-date about the Patient's status and notifications.
  2. The PMS presents the main actor with the means to provide contact information about the Trustee (e.g. e-mail address),
  3. The main actor provides the required contact information about the Trustee.
  4. The PMS contacts the Trustee with detailed information how to create an account in the PMS (credentials, etc) and to communicate with the PMS (e.g. smartphone application).
  5. The PMS logs this event.
  6. The Trustee confirms this and creates an account.
  7. The PMS registers the Trustee in the system.
  8. The PMS logs this event.
  9. The PMS sends a confirmation message to the main actor and the Trustee.

- **Alternative scenarios:**

3b. The main actor fills in the required contact information about the Trustee and also indicates that the Trustee should be a Buddy, who can enter information about the Patient into the system.

3c. The Trustee is already registered in the PMS, skip to step 7.

5b. The Trustee declines the request to act as the Patient's trustee and the main actor is notified of this.

3.7 *UC7*: notify

- **Name:** notify
- **Primary actor:** the Patient Monitoring System
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled him in the PMS.
  - *Health Professional*: is involved in the Patient's treatment
  - *Trustee:* keeps an eye on the Patient
  - *Patient:* wants to be up-to-date about his status
- **Preconditions:** The PMS has previously received sensor data (*UC4*), processed it (*UC15*), and determined that notifications should be sent.
- **Postconditions:** The registered parties will have received a notification about the Patient's status.
- **Main scenario:**
  1. The PMS determines and looks up the registered parties interested in notifications (Health Professionals, Cardiologist, Trustee, and the Patient himself).
  2. The PMS prepares a notification specifically for the registered party (e.g. the cardiologist receives a detailed medical notification, while the Patient only gets a summary), and sends out these notifications.
  3. The registered party receives the notification.
- **Alternative scenarios:**

3.8 *UC8*: consult patient status

- **Name:** consult patient status
- **Primary actor:** the Trustee, the Health Professional, the Patient
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled him in the PMS.
  - *Health Professional*: is involved in the Patient's treatment and wants to be up-to-date
  - *Trustee:* keeps an eye on the Patient
  - *Patient:* wants to be up-to-date about his status
- **Preconditions:**
  - The main actor is authenticated (cf. *log in (UC1)*).
- **Postconditions:**
  - The main actor has consulted the Patient's status.
  - The PMS has logged this event.
- **Main scenario:**
  1. The main actor indicates he wants to consult the current status of the Patient.
  2. The PMS looks up the information, and presents it to the main actor, tailored specifically to the expertise level of the main actor (e.g. the cardiologist receives a detailed medical information, while the Patient only gets a summary).
  3. The PMS logs this event.
- **Alternative scenarios:**

3.9 *UC9*: configure a clinical model

- **Name:** configure a clinical model
- **Primary actor:** the Cardiologist
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled him in the PMS.
  - *Patient:* is monitored by the PMS and his data is processed by a clinical model
- **Preconditions:**
  - The Cardiologist is authenticated (cf. *log in (UC1)*).
  - The Cardiologist is watching a patient's status (cf. *consult patient status (UC8)*).
- **Postconditions:**
  - The PMS has registered the configuration and will process the sensor data from the Patient accordingly.
  - The PMS has logged this event.
- **Main scenario:**
  1. The Cardiologist indicates he wants to configure a clinical model specifically for the Patient.
  2. The PMS presents the Cardiologist with the list of clinical models that have previously been selected for the patient.
  3. The Cardiologist indicates which clinical model he wants to (re)configure.
  4. The PMS presents the Cardiologist with a number of configuration options (e.g. thresholds), related to the clinical model.
  5. The Cardiologist changes one or more configuration options and confirms the (re)configuration.
  6. The PMS stores the new configuration, and logs this event.
  7. The PMS schedules a recalculation of the Patient's status with the newly-configured clinical model (**Include:** *compute clinical model (UC15)*).
- **Alternative scenarios:**

3.10 *UC10*: update risk level

- **Name:** update risk level
- **Primary actor:** the Cardiologist
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled him in the PMS.
  - *Patient:* is monitored by the PMS and his data is processed by a clinical model
- **Preconditions:**
  - The Cardiologist is authenticated (cf. *log in (UC1)*).
  - The Cardiologist has received a notification from the PMS providing risk estimates (cf. *notify (UC7)*, *optional*).
  - The Cardiologist is watching a patient's status (cf. *consult patient status (UC8)*).
- **Postconditions:**
  - The PMS has adapted the risk level of the patient.
  - The PMS has logged this event.
- **Main scenario:**
  1. The Cardiologist indicates he wants to change the risk level of the Patient.
  2. The PMS presents the Cardiologist with the option to change risk level to green, yellow or red.

3. The Cardiologist indicates which risk level he wants the Patient's risk level to change to.
4. The PMS changes the risk level of the Patient and updates the patient record (**Include:** *update patient record (UC17)*).

- **Alternative scenarios:**

1b. The Cardiologist indicates he wants to accept the risk level estimation given by the PMS in a notification. Forward to step 4.

3.11 *UC11:* perform on-demand consultation

- **Name:** perform on-demand consultation
- **Primary actor:** the Cardiologist
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled him in the PMS.
  - *Patient:* is monitored by the PMS and his data is processed by a clinical model
- **Preconditions:**
  - The Cardiologist is authenticated (cf. *log in (UC1)*).
  - The Cardiologist is watching a patient's status (cf. *consult patient status (UC8)*).
- **Postconditions:** The Cardiologist has performed an on-demand consultation.
- **Main scenario:**
  1. The Cardiologist indicates he wants to receive current data for the patient from the PMS.
  2. The PMS issues a request to the Patient's gateway for current sensor data.
  3. The Patient gateway responds by sending the current sensor data for the patient.
  4. The PMS schedules the processing of the sensor data (**Include:** *compute clinical model (UC15)*) and presents the results of the on-demand consultation to the Cardiologist.
- **Alternative scenarios:**

3.12 *UC12*: select clinical models for patient

- **Name:** select clinical models for patient
- **Primary actor:** the Cardiologist
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled him in the PMS.
  - *Patient:* is monitored by the PMS and his data is processed by a clinical model
- **Preconditions:**
  - The Cardiologist is authenticated (cf. *log in (UC1)*).
  - The Cardiologist is watching a patient's status (cf. *consult patient status (UC8)*).
- **Postconditions:**
  - The PMS has registered the selected clinical models, and will use them to process the Patients sensor data.
- **Main scenario:**
  1. The Cardiologist indicates he wants to select the clinical models for the Patient.
  2. The PMS presents the Cardiologist with the list of clinical models that are available in the PMS.
  3. The Cardiologist indicates which clinical model(s) he wants to apply to the Patient.
  4. The PMS stores the choices of the Cardiologists, and logs this event.

1. The PMS schedules a recalculation of the Patient's status with the newly-selected clinical models (**Include:** *compute clinical model (UC15)*) and presents the results to the Cardiologist.

- **Alternative scenarios:**

3.13 *UC13*: register patient

- **Name:** register patient
- **Primary actor:** the Technical Nurse
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, and want him to register in the PMS.
  - *Patient:* is suffering CVD and wants to be monitored by the PMS
  - *Technical Nurse:* executes the registration process
- **Preconditions:**
  - The Cardiologist has approved the Patient's registration.
  - The Technical Nurse is authenticated (cf. *log in (UC1)*).
- **Postconditions:**
  - The Patient is registered in the PMS.
  - The PMS has logged this event.
- **Main scenario:**
  1. The Technical Nurse indicates she wants to start the registration process for a Patient (e.g. by selecting the appropriate patient record).
  2. The PMS asks her to select two devices and asks her to pair them.
  3. The Technical Nurse selects a wearable unit and a patient gateway for the Patient, pairs both devices. She also links the patient gateway to the identity of the Patient (e.g. serial number of the gateway, or unique identifier) for authentication purposes.
  4. The PMS initializes the system, performs diagnostic tests, requests first sensor data from the gateway, and shows these to the Technical Nurse.
  5. The Technical Nurse double-checks the sensor data and, if necessary, calibrates the sensors.
  6. The PMS allows the nurse to set authentication credentials (e.g. password) for the Patient.
  7. The Technical Nurse enters the authentication credentials.
  8. The PMS registers the Patient.
- **Alternative scenarios:**

3.14 *UC14*: unregister patient

- **Name:** unregister patient
- **Primary actor:** the Technical Nurse
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, and wants him to stop using the PMS.
  - *Patient:* has improved a lot and can be unregistered from the PMS.
  - *Technical Nurse:* executes the unregistration process.
- **Preconditions:**
  - The Patient is registered in the PMS (cf. *register patient (UC13)*).
  - The Technical Nurse is authenticated (cf. *log in (UC1)*).
  - The Cardiologist has approved the Patient's unregistration.

- **Postconditions:**
  - The Patient is unregistered from the PMS.
  - The PMS has logged this event.
- **Main scenario:**
  1. The Technical Nurse indicates she wants to start the unregistration process for a Patient by indicating so in his patient record.
  2. The PMS unregisters the wearable unit and patient gateway, unregisters the patient (stops the monitoring), and logs this event.
- **Alternative scenarios:**

3.15 *UC15*: compute clinical model

- **Name:** compute clinical model
- **Primary actor:** the Patient Monitoring system
- **Interested parties:**
  - *Cardiologist:* wants to keep track of a patient's status, and if necessary, adjust treatment,
  - *Health Professional*: wants to keep track of a patient's status,
  - *Trustee*: wants to keep track of a patient's status,
  - *Patient:* is suffering CVD and wants to be monitored by the PMS.
- **Preconditions:**
  - The PMS has received new information (sensor data cf. *send sensor data (UC4)* or questionnaire cf. *fill out questionnaire (UC5)*) about the Patient.
  - The Cardiologist has selected at least one clinical model for the Patient (cf. *select clinical models for patient (UC12)*).
- **Postconditions:** The PMS updates the patient's status, and if necessary, issues a notification to the interested parties
- **Main scenario:**
  1. The PMS looks up the patient's monitoring history, current status, and patient record (medication,etc) (**include:** *consult patient record (UC16)*)
  2. The PMS applies the clinical model(s) to the newly-arrived information (sensor data, questionnaire) and the already-known data.
  3. The PMS determines whether or not the results of risk estimation indicate a potential change in risk level, and if so
     (a) The PMS determines the interested parties (Cardiologist, Trustee, Health Professionals, Patient)
     (b) the PMS issues a notification (**Include:** *notify (UC7)*)
  4. The PMS determines whether the newly-arrived sensor data and the results of risk estimation should propagate to the patient record
     (a) If so, **include:** *update patient record (UC17)*
- **Alternative scenarios:**

3.16 *UC16*: consult patient record

- **Name:** consult patient record
- **Primary actor:** the Patient Monitoring System (PMS)
- **Secondary actor:** the Hospital Information System (HIS)

- **Interested parties:**
  - *PMS:* wants to keep track of a patient's status, also the information external to the PMS itself (e.g. from the EHR via the hospital, or from other hospital departments),
  - *HIS*: provides access to the patient record.
  - *Health Professional:* wants to have access to up-to-date information about the patient.
- **Preconditions:**
- **Postconditions:** The PMS has received the patient record from the HIS
- **Main scenario:**
  1. The PMS requests a look-up of the patient record from the HIS.
  2. The HIS performs the look-up and provides the patient record to the PMS.
- **Alternative scenarios:**

3.17 *UC17*: update patient record

- **Name:** update patient record
- **Primary actor:** the Patient Monitoring System (PMS)
- **Secondary actor:** the Hospital Information System (HIS)
- **Interested parties:**
  - *PMS:* wants to update the patient record at the hospital with relevant information about the patient's health (e.g. certain events, summarized data, etc)
  - *HIS*: provides access to the patient record.
  - *Health Professional:* wants to keep the patient (medical) record up-to-date.
- **Preconditions:**
  - The PMS is monitoring a patient of the hospital (HIS).
- **Postconditions:**
  - The PMS has added data to the patient record.
  - The HIS might (or might not) update the EHR with this information.
- **Main scenario:**
  1. The PMS sends an update to the patient record in the HIS.
  2. The HIS stores the data accepted from the PMS.
- **Alternative scenarios:**

4 Non-functional requirements

In this section, we model the non-functional requirements for the patient monitoring system in the form of *quality attribute scenarios*. We provide three requirements for Availability (Section 4.1), three requirements for Performance (Section 4.2), and three requirements for Modifiability (Section 4.3).

4.1 Availability

4.1.1 *Av1*: Communication channel between the patient gateway and the PMS

Because of a failure in the intermediate telecom infrastructure, or a failure (crash) in the patient gateway, or an internal communication component, key functionalities of the PMS are compromised: sensor data readings can not be sent from the patient gateway to the PMS.

- **Source:** external or internal
- **Stimulus:**
  - the external communication channel(s) between the patient gateway and the PMS responsible for delivery of sensor data readings is failing, or the patient gateway itself (responsible for aggregating and sending sensor data readings) is failing (e.g. if the patient gateway is a mobile device, its battery may have run empty),
  - or, an internal communication (sub-)system(s) of the PMS fail(s).
- **Artifact:** external device(s), external communication channel(s), internal communication (sub-)system(s)
- **Environment:** normal execution
- **Response:**
  - Prevention:
    - the Telemedicine company has negotiated a Service-Level Agreement (SLA) with the intermediate telecom operator that stipulates:
      - if the patient gateway is a mobile device: at least 80% coverage in the broad region in which the PMS will operate and average bandwidth of at least 64Kb/s (e.g. EDGE or 3G);
      - if the patient gateway is a fixed device: at least 95% availability of the communication channel, and average bandwidth of at least 256Kb/s.
    - if the patient gateway is a mobile device, and the patient moves out of range (or the device battery is almost empty), it must warn the patient in a timely fashion.
  - Detection:
    - The PMS must be able to detect this independently; i.e. by observing a lack of updates that are expected according to the transmission rates configured on the gateway (cf. Table 1 of the Domain Description).
    - The PMS must be able to differentiate between both possible causes, by querying the state of the internal communication (sub-)system responsible for accepting sensor data readings.
    - The PMS keeps track of how long there has been a lack of communication.
  - Resolution:
    - In both cases, the PMS System Administrator is notified
      - in case of a failing communication sub-system, the system administrator must redeploy the failing component, or revert it to a previously working state.
      - in case of a failing communication channel, the system administrator must contact the telecom operator to resolve this.
- **Response measure:**
  - Detection time depends on the transmission rate configured on the gateway (and indirectly on the risk level), but does not exceed this with more than 5 minutes. So, if an expected update does not arrive at expected time T, detection must have taken place before T+5 minutes.

        * Once detected, in 90% of the cases, the notifications sent to the system administrator arrive within 2 minutes if the patient has a red risk level, within 5 minutes if the patient has a yellow risk level, and within 10 minutes in case of a green risk level.
    - Resolution:
        * Redeployment or roll-back of the communication subsystem does not take longer than 5 minutes.
        * The SLA with the telecom operator stipulates availability of technical support within 10 minutes and resolution within the hour.

4.1.2 *Av2*: Availability of the patient record database in the Hospital Information System (HIS)

The PMS can temporarily not access the patient record database in the Hospital Information System (HIS), either due to a failure within the HIS, or a disruption in the communication channels between the PMS and the HIS. As a consequence, the PMS can neither consult patient data, nor update patient data in the HIS.

- **Source:** external
- **Stimulus:**
    - there is a failure (e.g. crash) in the HIS patient record database, or
    - a disruption in the communication channel between the PMS and the HIS subsystem.
- **Artifact:** external communication channels, external system
- **Environment:** normal execution.
- **Response:**
    - Detection: the problem is detected by the PMS, and the PMS System Administrator is notified.
    - The system goes into degraded modus:
        * There is no disruption of PMS functionality,
            · When needed, the PMS provides an older copy of the patient record, and indicates clearly that this might be outdated information to its users.
            · Updates (*writes*) to the HIS Patient record database are not omitted, only postponed.
        * The PMS keeps track of how long there has been a lack of communication.
    - Resolution: the PMS System Administrator notifies the HIS System Administrator which solves the issue.
- **Response measure:**
    - Detection happens within 30 seconds of the failure.
        * The PMS System Administrator contacts the HIS System Administrator at the latest within 10 minutes after detection.
        * The system goes in degraded modus immediately after detection.
    - Resolution is done at the latest 1 hour after detection (deadline).

4.1.3 *Av3*: Internal PMS database failure

The internal subsystem database responsible for storing the (raw) sensor data readings fails/crashes.

- **Source:** internal
- **Stimulus:** the database responsible for storing the sensor data readings fails.
- **Artifact:** internal subsystem
- **Environment:** normal execution.
- **Response:**
    - This does not affect the availability of other types of persistent data, such as (i) the registered parties that should receive notification, (ii) the pairing of wearable unit, gateway and patient, (iii) the authentication credential data, (iv) the processed results (after applying clinical models), etc.

  - Detection: the PMS is able to detect this problem and goes into degraded modus.
    * The PMS System administrator is notified of this problem.
  - Resolution:
    * For patients with red or yellow risk status, there is a back-up server available
    * The PMS System Administrator restarts the database server, or if necessary, reverts to a previous state

- **Response measure:**
  - Detection happens within 5 seconds.
  - In case of yellow or red patient risk status,
    * there is a seamless transition to the backup database (no disruption)
    * no data updates are omitted, regardless of the size or frequency of the updates (patient data readings typically represent detailed high-volume data)
  - In case of a green risk level, at the most two regular updates are omitted
  - Resolution:
    * the database is restarted within a minute,
    * roll-back to a previous or back-up state happens within 5 minutes

4.2 Performance

4.2.1 *P1*: Storage of sensor data readings

The internal subsystem database responsible for storage of (raw) sensor data readings receives a large amount of parallel updates; i.e. from many patients at the same time.

- **Source:** patient gateway
- **Stimulus:** multiple patient gateways send sensor data readings to the PMS in parallel
- **Artifact:** system
- **Environment:** normal modus
- **Response:**
  - if the system fails to comply to the specific deadlines listed below, it goes into "overload" modus,
    * in overload modus, sensor data readings are processed according to the priority of the update; i.e. sensor data readings for patients in a red risk level are stored before sensor data readings patients for patients with green or yellow risk levels.
    * If previous sensor data readings for patients with a green risk level have already been processed by the system, and the risk level estimation did not indicate a potential increase in risk level for this patient, sensor data readings can be omitted.

- **Response measure:**
  - updates of sensor data readings for patients with
    * red risk level happen before a 750 msec deadline.
    * yellow risk level happen before a 1500 msec deadline.
    * green risk level happen before a 3000 msec deadline.
      · Omission of sensor data readings for patients with a green risk level does not happen more than twice consecutively.

4.2.2 *P2*: Risk estimation by clinical models

As clinical models are typically highly complex and computationally intensive, it might occur that new information (sensor data readings) arrive at the PMS in a faster rate than they can be processed by the risk estimation algorithms/clinical models.

The throughput of the (sub-)system responsible for performing risk estimation (a process that is triggered by sensor data reading updates) and issuing notifications for a specific patient is crucial. Especially when the PMS is scaled to a larger patient base, it is realistic that multiple risk estimation calculations are started in parallel, which increases the pressure on this (sub-)system.

- **Source:** new information (update of sensor data readings, or questionnaires), by patient, caretaker, GP, or trustee
- **Stimulus:** patient risk estimation by applying clinical models
- **Artifact:** the (sub-)system responsible for performing risk estimation and issuing notifications
- **Environment:** normal modus
- **Response:**
  - In normal modus, the subsystem processes the incoming information updates in a first-in, first-out order
  - In overload modus,
    - the subsystem changes the processing order by prioritization according to the patients risk level: risk level estimations for patients with a red risk level are performed before risk level estimation for patients with a yellow and green risk level
    - Additionally, load is balanced over multiple instances of this sub-system
- **Response measure:**
  - In normal modus, the system goes into "overload modus" when the throughput $>$ 20 risk estimations/minute,
  - In overload modus, there is no starvation of risk estimation jobs for patients with a green risk level: any risk level estimation job must be initiated before a hard 10 minute deadline after arrival into the queue.

4.2.3 *P3*: Emergency notifications

The patient gateway issues an emergency notification, and the PMS must verify whether or not this is an actual emergency situation, and if so, issue an emergency notification to the Emergency Services.

- **Source:** Patient gateway
- **Stimulus:** sends an emergency notification.
- **Artifact:** the (sub-)system responsible for verifying emergency notifications and and sending emergency notifications to the Emergency Services.
- **Environment:** normal modus
- **Response:**
  - The clinical models used to verify emergencies
    - are light-weight and fast and,
    - do not rely on the patient's monitoring history, health record, earlier sensor data, or treatment (stateless).
- **Response measure:**
  - Emergency verification does not take longer than 5 ms (*deadline*)
  - Throughput of this subsystem should be at least 4 emergency notifications per second.

4.3 Modifiability

4.3.1 *M1*: Integration of the PMS into a different Hospital Information System

The PMS is currently being integrated into one specific Hospital Information System (HIS), as part of the pilot project (as mentioned in Section 1). Nonetheless, it would be beneficial for our company if we could provide our telemedicine services to other hospitals as well. For this, we need to integrate with different HISs.

- **Source:** a new customer (a hospital)

- **Stimulus:** wants to optimize the efficacy of CVD treatment, while minimizing the costs. Therefore, they want to monitor (a subset) of their CVD patients remotely, using our telemedicine services.
- **Artifact:** this modification affects mostly front-end components (components interacting with the HIS), not the core business components of the PMS.
- **Environment:** at design time
- **Response:**
  - The design must be adapted, and an implementation must be provided of the affected components. The new (versions of the adapted components) must be tested before deployment.
  - The PMS must integrate client software (e.g. on the cardiologist workstation) for the PMS into the HIS.
  - Effects:
    * This modification affects interactions with the HIS
      · in terms of patient record access,
      · notification delivery,
      · emergency notification delivery
    * does not affect the core functionalities related to risk estimation, sensor data reading delivery and processing, notifications to actors not affiliated with the hospital.
- **Response measure:**
  - The development costs for this modification must not exceed 100 man months of development time.
  - Interfaces with components that are not affected should remain unmodified

4.3.2 *M2*: New type of sensor in the wearable unit.

Research has shown that CVD treatment is 15% more effective if we also monitor the bioimpedance of a patient (the response of a living organism to an externally applied electric current). For this, the wearable unit manufacturer has released a new version of their device (the wearable unit – *version 2.0*), which has a new sensor for measuring this entity. Of course, the PMS must be able to process this new type of data.

- **Source:** CVD research
- **Stimulus:** indicates that it is valuable to measure bioimpedance of a patient as well.
- **Artifact:** this modification affects the inner workings of the PMS: the gateway, the interfaces, the clinical models that perform risk estimation, etc
- **Environment:** at design time
- **Response:**
  - The client software on the gateway and the Technical Nurse's work station must be updated so that the new sensor can be read, calibrated and configured
  - The PMS interfaces must be adapted so that it can accept this new type of information (fluid index readings),
  - Clinical models must be added/updated so that they take this new type of information into account (Cf. M3)
  - This modification does not affect the notification system, nor the interaction between the PMS with the HIS
- **Response measure**
  - This modification must be done with a maximal cost of 20 man months of development time.

4.3.3 *M3*: New clinical model/optimized clinical model

Research (result of performing data mining activities on the fine-grained operational data kept by the PMS) has shown that one of the clinical models currently in use for risk estimation can be improved. This model is updated to a version that is more efficient (computational-wise) and leads to more correct risk estimations.

- **Source:** us, the PMS
- **Stimulus:** want to optimize risk estimation, and by extension the efficacy of our system
- **Artifact:** the subsystem responsible for risk estimation
- **Environment:** at run time
- **Response:**
  - The new or updated clinical risk model is deployed at run time (in the running PMS).
  - This update does not affect currently ongoing risk calculation, even if an existing clinical model is replaced with a new implementation.
  - The modification only affects the subsystem responsible for risk estimation
    - but does not lead to down time of this subsystem, other subsystems, or the entire PMS
- **Response measure:**
  - Deployment or installation of the new clinical model does not take longer than 30 minutes. The updated or new clinical model can be used immediately.