Patient Monitoring Service (PMS)

Part 1: Application case description

The project involves the development of a *patient monitoring service* (in short: PMS) for cardiovascular diseases. This document describes the project and its application domain and outlines the existing technological and business constraints. Section 1 provides some background about the domain of e-health and patient monitoring services. Section 2 describes the problem domain in further detail. Then, Section 3 lists the key stakeholders involved in the development of this system, and Section 4 describes a number of additional constraints the system should comply with. Finally, Appendix A lists the functional requirements of PMS as use cases.

1 Context

The COVID-19 pandemic has created pressures on national health services that are previously unseen. One of the consequences is that incentives are increased for health care providers to seek for more efficient ways to treat and manage patients in an *extra-muros* context: outside of the hospital premises, while keeping beds maximally reserved for more acute treatments. The recent technological development of telemedicine services, paired with the ubiquity of sensing devices and the Internet-of-Things serves as an additional accelerator to this trend [1].

Cardiovascular diseases. Heart diseases or cardiovascular diseases (CVDs) are a class of diseases 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 arteriosclerosis (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, etc.

Population-based studies in the youth show that the precursors of heart diseases start in adolescence [2]. CVDs are slow, in the sense that they develop over decades, but as they become more acute in older patients, CVD is often associated to a patients' age. Although some symptoms can be treated (for example, obstructed heart vessels can be bypassed), prevention is of utter importance (for example, change in diet). Smoking, hypertension, and other conditions can increase the risk by several times.

As the western world faces population aging, the impact of CVDs increases continually. Most countries face high and increasing rates of cardiovascular disease. In 2015, cardiovascular diseases (CVD) cost the EU economy over 210 billion, and of this total cost, €111bn (53%) was spent on health care, €45bn

(21%) in informal care costs, €32bn (15%) due to early mortality; and €23bn (11%) due to absence from work or early retirement [3]. The priority in CVD treatment is on (i) primary prevention and timely diagnosis of the disease, and to (ii) management of the disease, i.e. prediction and prevention of malignant events (e.g., heart failure) after diagnosis.

E-health and telemedicine. *Electronic health* has large potential for increasing the quality of care delivered to patients, while decreasing overall health care costs. It can therefore mainly contribute to the management of CVDs, less to the primary prevention and timely diagnosis. The term "e-health" is defined broadly, grouping all types of health care practice supported by electronic processes and communication. It ranges from medical knowledge management (medical journals, etc.) to software solutions for appointment scheduling and patient data management [4].

Another instance of e-health is the centralization of patient data in an *electronic health record* (EHR) which enables different health care professionals to communicate patient data in a fast, efficient and reliable way. *Telemedicine* is another instance of e-health, which enables the remote treatment and monitoring of patients, for example at home. As opposed to treatment and monitoring at the hospital, telemedicine has the potential to drastically cut costs in hospitalization.

A patient monitoring service or system focuses not so much on active treatment, but on monitoring of the patient and the disease. It offers extensive and up-to-date information to the physician without being overly obtrusive in the patients' day-to-day life. By continually monitoring the patient, the physician can predict and therefore prevent malignant events, for example by changing the diagnosis or adapting the treatment.

Positioning

In this assignment, we assume the point of view of a startup software company that enters the market with a novel patient monitoring service[1] (PMS) for the management of cardiovascular diseases (CVD). At this stage of the development, initial collaboration with a local hospital for pilot studies is already arranged. Although this service is being built with one specific hospital in mind, it would evidently be beneficial for our company if we can extend our offering to other hospitals as well.

The goal is to offer the PMS *as a service*: instead of developing, selling or licensing the software as-is, our company will provide and maintain a patient monitoring infrastructure which will interact with the hospital services. The system itself will be located and hosted outside of the hospital infrastructure, but it will be well-integrated in the existing hospital infrastructure or Hospital Information System (HIS), for example to access patient records, offer decision support functionalities to the cardiologist, for invoicing, etc. It will also synchronize data with Electronic Health Record (EHR) services.

Key innovations. Whereas existing systems and services are relatively rigid in how they support the different models (e.g., using static rule-based

[1] Although this assignment presents in fact a simplification of reality, the requirements and description of the problem domain are based on a number of actual systems and research prototypes in the e-health space.

decision models), our service will flexibly apply innovative ML algorithms and classifiers [5, 6] (which are shown to outperform traditional approaches [7]) to perform risk estimation on a frequent basis and monitor the evolution of CVD in specific patients.

2 Description of the problem domain

This section discusses the overall goals and requirements of the Patient Monitoring Service (PMS).

2.1 Overall System Goals

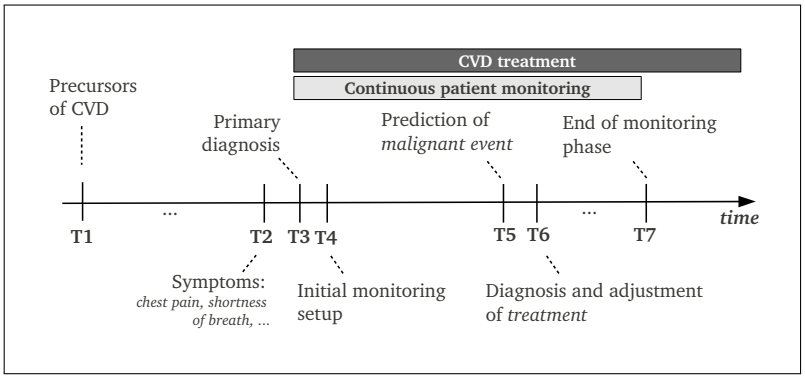

Figure 1: High-level timeline overview of the treatment of a CVD patient.

Figure 1 schematically outlines the typical evolution of CVD. The enrollment of a patient in the CVD monitoring scheme happens after primary diagnosis (T3 in Figure 1), and it ends when it is considered no longer necessary by the physician in the context of overall follow-up and CVD treatment. The main goal of the service is to offer a sound and patient-centric solution for continuous and remote monitoring, in support of timely decision making and accurate prediction of malignant events, without in turn being overly invasive in the patient's day-to-day life.

- **Continuous and remote monitoring.** Patient monitoring is a very powerful tool in treatment and management of long-term diseases such as CVD. Automated continuous patient monitoring can give physicians a detailed and up-to-date view on the evolution of the disease. Current technologies allow patients to be monitored 24/7 without the need for the patient to be confined in a hospital bed.
- **Timely decision making.** Continuous patient monitoring also aids health care professionals in their decision making, offering them an extensive and up-to-date view on the patient's status. This leads to improved diagnoses, while reducing the necessity of frequent in-person consultations.
- **Prediction of malignant events.** Furthermore, continuous monitoring of the patient's health status can predict malignant events such as heart attacks. By

automated prediction of such events, health care professionals can be notified in a timely fashion, and the occurrence of malignant events such as heart attacks can be prevented.

- **Invasiveness in the patient's day-to-day life.** To ensure acceptability of such a monitoring service, a patient should not be bound to one place for the monitoring to happen.

The remainder of this chapter zooms in on these four aspects of the patient monitoring service.

2.2 Continuous monitoring

To monitor CVD patients, many parameters are of relevance, such as the heart rate, weight, blood pressure, body temperature, etc. In the patient monitoring service, these measurements are provided by electronic sensors, but also directly by the user.

Wearable unit. The most important enabler for monitoring CVD patients is the *wearable unit*. This device bundles a number of sensors for CVD and is worn by the patient close to the heart, for example as a chest band. The wearable unit has a battery lifetime of at least 8 hours and is minimal in size in order to not hinder the patient. The wearable unit is a medical device capable of continually measuring the following medical parameters:

- the **heart rate** in beats per minute (bpm). Normal levels for a healthy person are between 60 bpm and 100 bpm. For correct interpretation, the heart rate values should be correlated with the activity level of the patient.
- a continuous **electrocardiograph** (ECG) which plots the electrical activity of the heart over time (see Figure 2). The fundamental parameters to evaluate are the **maximum ventricular rate** (maximal heart rate) in bpm, the presence of **ventricular arrhythmias** (abnormalities of the heart rate and rhythm) and the presence of ischemia signs (restriction in blood supply).
- the **respiratory rate** (based on sound). Normal levels for a healthy person are within 12 and 20 breaths per minute. This value also needs to be correlated to the activity level of the patient.
- the **blood oxygen level** in percentage. Normal levels for a healthy person are within 90% and 100%.
- the **blood pressure** (the pressure exerted by circulating blood upon the walls of blood vessels) in millimeters of mercury (mmHg). Normal levels for a healthy person are within 85 mmHg and 140 mmHg systolic.
- the **activity level** using the accelerometer. The activity level is expressed as a single number.
- the **body temperature** in degrees Celsius. Normal levels for a healthy person are within 35 degrees and 37 degrees.

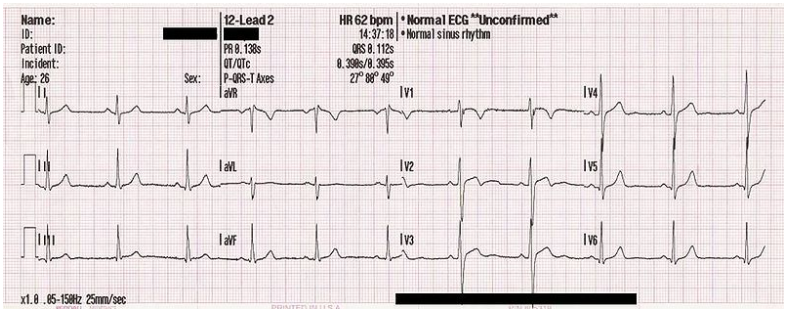

Figure 2: An ECG of a 26-year-old male.

Additional inputs. Next to the wearable unit, support for other measuring devices, sensors or services could be integrated in support of the patient monitoring service. For example, the patient's weight can be obtained (in kg.) with a smart scale. A GPS chip (e.g., in a smartphone) delivers info about the geographic location of the patient. In future implementations of the PMS, the service should also provide support for daily or weekly questionnaires to be filled in by the patient, which allows collecting different types of relevant information (e.g. on the patient's state of mind, activities, etc.). Many sensor-based lifestyle tracking applications already on the market collect relevant data which may be taken into account during the follow-up and treatment of CVD-related pathologies in a patient.

Patient gateway. Sensors will not communicate directly with the PMS back-end service, but the collected data will go through an intermediate device: the *patient gateway*. For practical reasons, the role of patient gateway will be filled in by the patient's smartphone and the gateway logic will be supported by a smartphone application specifically developed for the PMS.

Every sensor communicates directly with the gateway, which makes abstraction of specific communication technologies, protocols and channels, but is (most of the time) capable of connecting to the back-end services.

The data collected from the sensors and other inputs are aggregated by the gateway and transmitted to the patient monitoring service. The gateway never transmits raw data to the system, only processed values in packages. The exact contents of a data package and the transmission rate can be configured on the gateway. By default, the configuration is determined by the patient's risk level (see Section 2.4). For example, in case of low risk, only a single average blood pressure value for the monitoring period is required during the planned transmission. In case of high risk, it can be useful to acquire the maximum, minimum and average daily values. Table 1 gives an overview of the default configuration for high risk, which has the highest transmission rates. These default rates can be explicitly overwritten by a physician.

Next to periodically transmitting the measurements, the gateway also supports transmitting data on demand. The physician has the ability to request the measurements instantly, in which case the system pushes the request to the gateway. For example, to perform a remote consultation, the physician can pull the latest data in full detail.

Parameter	Transmission rate	Derived measure
Heart rate	48/day	Avg, max, min, variance
ECG	24/day	Full ECG of 30 sec.
Respiratory rate	48/day	Avg, max, min
Oxygen level	24/day	Avg, max, min
Blood pressure	48/day	Avg, max, min
Activity level	4/day	Single value
Temperature	6/day	Avg

Table 1: Default configuration for high risk.

Apart from synchronizing obtained data from the wearable unit to the PMS, the gateway application will provide a user interface to patients, allowing them to manage their devices (e.g., consult battery percentage), consult the obtained sensor data and risk values, follow-up on overall treatment, contact their GP or request support. It could even support a social network that allows CVD patients to share experiences.

Impact on day-to-day life. A consequence of the technological advances in low-power wearable sensors and mobile communication networks is that the patient is not bound to one place for the monitoring to happen. Monitoring is transparent and does not prohibit the patient from performing regular day-to-day activities. Obviously, in terms of invasiveness, specific attention is to be spent not only on physical interference but also on data privacy in general (cf. Section 4).

2.3 Risk estimation and notifications

The system uses the monitoring data sent by the gateway to continuously make estimates of the patient's current CVD health status and the evolution therein. The underlying goal is to predict upcoming malignant events (such as a heart attacks) and keep the appropriate parties (general practitioner, cardiologist, etc.) up-to-date by sending notifications.

To achieve this, patients are divided into *risk levels* (low, medium, and high risk). The physician determines the initial risk level of a patient depending on the primary diagnosis.

After that, the system monitors the patient and continually estimates whether or not a patient's risk level should change, using *clinical risk models*. These models combine different technologies such as data mining, machine learning, probability models (e.g., Bayesian networks) and ontologies to model the data and derive a risk estimate combining all given inputs. The inputs for the clinical risk models are: (i) the new data sent by the gateway, (ii) the old data in the system, (iii) the pathologies of the patient (as determined by the physician), and (iv) the current risk level. Optionally, artifacts related to previous classifications are also used (e.g., specifically trained classifiers for one patient).

To clarify how this works, we provide the example of a very simple clinical risk model. This model estimates a patient's risk using *thresholds* for each medical parameter, determined on a per-patient basis. These thresholds determine whether the monitored values are to be considered normal, worrisome

or dangerous. Default values for each of these thresholds depend on the risk level of the patient, but the physician is able to override each of the threshold values. Table 2 shows the default threshold values for the systolic blood pressure parameter.

Risk level	**Normal**	**Worrisome**	**Dangerous**
Low	105–120	90–105, 120–150	80–90, 150–190
Medium	95–135	90–95, 135–160	80–90, 160–190
High	90–150	85–90, 150–170	80–85, 170–190

Table 2: Default thresholds for systolic blood pressure (mmHg).
Notice the wider ranges for patients with higher risk-levels. Because of their cardiovascular conditions, their normal values will be, for example, more elevated, than the normal values of low-risk patients.

A different example is HeartScore [8] which provides an interactive tool targeted at the general population and not at known high-risk CVD patients. It is not suitable for event detection, but it can be support decision-making and is definitely useful for patients as it shows their overall progress, and so integration of HeartScore-like calculations is definitely useful.

It is generally accepted that no single clinical model is suited for all different CVD pathologies, and thus the system will need to support different clinical models. In addition, a single patient's CVD monitoring schedule is typically supported by multiple clinical models that employ different types of algorithms or are aimed at assessing different aspects. The overall outcome of a risk estimation for a single patient is then based on the combination of the outcomes of the individual clinical models selected for that patient. Certain clinical model versatile or generic (and thus be deployed and configured system-wide), but others may be specific to certain CVD pathologies, or even need to be configured on a per-patient basis. In any case, all risk calculations are executed by PMS.

The threshold-based risk model described above is obviously a highly simplistic example, and as discussed earlier, one of the innovative features of the new patient monitoring service is that it will rely on clinical risk models that incorporate more advanced Machine Learning classifiers. These are provided by a third party, an external research organization specialized in data-centric CVD monitoring and treatment. This third party will provide trained models for specific pathologies and different risk levels, which can be used in the continuous monitoring of patients. These models can be updated over time. To be able to run these models, the PMS will use a machine learning framework.

The main goal of the patient monitoring service is to aid and support medical decision making, *not* to make actual medical decisions. Only the physician is granted authority to effectively change the risk level of the patient in the system.

If the system estimates that a patient's risk level should or may change (typically based on a number of different risk estimations and risk models), the physician is notified in order to assess the estimation and approve, revise or decline it.

In general, there are three notification levels: green, yellow, and red. These levels indicate the degree of urgency or priority with which the notification

should be dealt with. A red notification is sent when the patient's status changes significantly and requires immediate and urgent attention. A yellow notification is sent when the patient's status changes non-critically but remains potentially dangerous. A green notification is sent when the patient's status reverts to a lower risk level. Of course, the exact content of the notification depends on the precise event.

2.4 Physician decision support

The medical models used for the estimation of patient risk levels are also used to aid physicians in their decision making, for example on a consultation. When a physician checks on the status of a patient, the most important and relevant information is shown in a structured and efficient way. For this, the system has to be able to evaluate the patient's status. Through the implementation of standard clinical models and by applying medical guidelines, routine clinical consultations are made more consistent and informative. For example, the system knows that the physician was recently notified of a malignant event with the patient. Now, the system shows the current risk estimate of the patient, together with all the information relevant to the event (for example, a graph of the blood pressure or an ECG). Of course, physicians are still able to request any additional information they want.

2.5 Patient support

Similarly to physicians, patients can also make use of the medical models. When patients want to check their own status, they also expect to see the most important and relevant information in a structured and efficient way. Of course, there is an important difference in the way this data is presented to these actors: in case of the patient, this data must not be too technical or clinical. The system offers patients a customized view on his data, for example a simple graph indicating the percentage improvement since last week.

2.6 Medical emergencies

As an extension to the green, yellow and red notifications, the system can also send *emergency notifications*. An emergency notification is sent to the Hospital Emergency services (cf. Section 4) in case of a life-threatening event such as a heart attack. Emergency notifications are sent in case of *ongoing* emergencies, while other notifications are sent when malignant events are *predicted* or anticipated.

Regular notifications are sent by the system after analyzing new data using medical risk models. For emergencies, this system is too slow since the fastest transmission rate is 48 times per day. Therefore, the gateway is extended with a general-purpose, lightweight, medical emergency model, which is also threshold-based (as the one presented in Section 2.3). Similar to the other risk models, default threshold values depend on the patient's risk level but can be explicitly overwritten by a physician.

The gateway uses this model to interpret the measurements itself and alerts the system of a possible emergency, along with the necessary data. The system re-checks the data for an emergency using more extensive models and sends out

an emergency notification if needed. Note however, that we are not building a live-saving device: handling emergencies is not a primary goal of the system, and the timely delivery of an emergency notification should not be guaranteed in every case.

3 Main stakeholders

Patients. The system applies to patients who have already been diagnosed with CVD and now need to be monitored for treating or controlling their disease (which does not hold for every CVD patient). They want the system to help them in the treatment and management of the disease and would like this to happen in the most comfortable way.

Physicians. The system will be used by different types of physicians. In practice, cardiovascular disease is treated by specialists such as cardiologists, thoracic surgeons, vascular surgeons, neurologists, and radiologists, depending on the organ system that is being treated. Another important stakeholder in this context is also the patient's general practitioner (GP) who keeps a holistic overview of overall patient health.

The system should support these physicians in their job, primarily by aiding their decision making. Physicians want the information they need in a structured and efficient way, for example by being notified of important updates of a patient's status or a clean graph of the patient's evolution. Also note that we are building a system for use by a hospital, but not every physician needs to be in that same location. A GP typically has their own independent practice, and often specialists also hold practice outside of hospital premises.

Nurses. Nurses are responsible for the more practical part of the patient's treatment. In general, nurses at the hospital do not take part directly in the system. However, a specialized team is responsible for the setup and configuration of the sensors after a patient has been diagnosed and recommended to use the system.

Emergency call center. The emergency call center in the hospital receives all emergency calls and responds appropriately, for example by dispatching an ambulance to the scene. They also receive emergency notifications from the monitoring service. With an emergency, they want to receive as much information as possible to correctly assess the situation and the urgency to determine the most appropriate response. Therefore, they also want to access the detailed monitoring information. Moreover, an emergency notification also needs to be entered in the system so other appropriate parties (the specialist, the GP etc.) can be notified to be kept up-to-date.

Telemedicine operators. The telemedicine operators deal with issues and provide technical and setup support, ranging from patients who notice that their wearable unit is malfunctioning, to a hospital administrator who notices that data updates are not working correctly.

The telemedicine operators also follow up the overall management of the system. They integrate risk models and deal with updates and upgrades of the

functionality, provisioning system resources, etc. They are notified by the system when a patient's sensor has not sent in data for a long time or the data seems incorrect (e.g., impossible outliers). They handle notifications where further human assessment is needed to determine further actions.

The hospital. As mentioned in Section 1, our company's first client is a specific hospital. More specifically, we –as a telemedicine company– have been contracted for a pilot project, involving only a limited number of CVD patients. If successful, the hospital will deploy and apply this monitoring service to a larger patient base in the future.

The hospital's main stake is that the patient monitoring service will aid them in raising the quality of CVD treatment, thereby increasing the efficiency and effectiveness of CVD treatment. Furthermore, by introducing CVD patient monitoring from home, CVD patients are kept out of the hospital and this frees up space and resources allocated previously for on premise patient monitoring.

Electronic health record service The Electronic Health Record (EHR) service collects patients' health records from diverse health organizations and provides different physicians with an efficient means to consult patient data while also providing patients with access to their own records. This service can be performed by an individual hospital itself or by a specialized third party, for example one service used by all hospitals and physicians in a geographic region. The data collected by the patient monitoring service will eventually be integrated into the patient's EHR and kept up to date via the HIS.

Legal departments. Both the legal department of our company as well as that of the hospital need the system to comply to health care regulations. More information about the precise health care regulations can be found in Section 4.3. It is important the system is not only compliant to these regulations by design but is provably compliant throughout its operation.

Hospital financial department. The hospital financial department is responsible for invoicing their customers, the patients. It is imperative that the systems provide clear usage and billing reports so that this is done correctly.

Telecom operators. Telecom operators provide means for the sensors and the gateways to communicate with the system. A service level agreement (SLA) between our company and the telecom operators determines the capabilities of these communication channels.

ML model provider. This stakeholder represents a clinical research institute that trains and prepares specific Machine Learning models tailored to specific pathologies under the broader CVD umbrella. This institute allows downloading these models and classifiers, which can in turn be executed using a ML framework. This third party also prepares regular updates and improvements to these models.

4 Key building blocks and constraints

Next to the general problem domain description, there are a number of specific constraints highly relevant to the patient monitoring service.

4.1 Hospital Information System (HIS)

As mentioned in Section 1, the patient monitoring service will be deployed and maintained as a standalone platform by our company. Nonetheless, it should integrate tightly with the existing Hospital Information System (HIS) currently in use at the hospital. A relevant resource in this specific respect is the HL7 FHIR (Fast Healthcare Interoperability Resources) standard [2] which is widely adopted in the e-health domain. The desired integration covers a number of dimensions:

Patient data. Evidently, the hospital has full ownership of patient records and patient data, and the patient monitoring service (PMS) will not change this. This implies that the measurements gathered by the PMS must be integrated in the patient record storage of the hospital itself. However, keep in mind that some of the measured data (cf. Section 2.2) is very fine-grained and updated frequently.

Physician workstation. As part of the existing HIS, the physician (e.g., a cardiologist) already has a means to connect to the hospital, either through their personal workstation or remotely (if they have their own practice), to consult patient records, extend notes of patient consultations, etc. As the patient monitoring service offers the physician with a number of new functionalities related to decision support, remote configuration of the sensors, daily patient follow-up and receiving notifications, these must be integrated in the physician's workstation.

Patient registration. When a patient is first introduced to the monitoring service, they receive a wearable unit containing a set of sensors. First, these must be paired or linked to the specific patient. Secondly, they must be initialized and calibrated according to the patient's context, and this setup must be tested before sending the patient home. This process of patient registration happens at the hospital (e.g., after a check-up), and is conducted by a trained nurse.

Emergency situation. When the automated decision support identifies an emergency situation (cf. Section 2.3), it must be able to trigger an emergency procedure by contacting the emergency services already offered by the hospital (e.g., 112) and possibly also the other stakeholders involved in the patient's treatment, such as his physician and GP.

Accounting. Finally, for purposes of accounting, the hospital must be kept aware on a day-to-day basis of the costs incurred during operation of the patient monitoring service. Typical costs include the maintenance of the platform (e.g.,

[2] The standard specifications can be found at `https://hl7.org/fhir/`.

repairing sensors), computational cost (e.g., to perform risk assessment), storage costs, bandwidth costs, and operation costs of the call-center.

4.2 Financial constraints

Evidently, setting up and maintaining a pilot project such as the one described in this assignment is a costly operation. For this project, our company has negotiated a million-euro contract with one specific hospital. Since the pilot project involves monitoring of actual CVD patients, a Service-Level Agreement (SLA) has been enclosed as part of this contract. This agreement stipulates certain quality requirements (in terms of performance and availability). For example, there should be an upper limit in the time it takes for an emergency notification to reach its destination.

Also, our company has to negotiate a number of service-level agreements with several of third parties: the telecom operator to ensure the desired degree of patient connectivity, the hardware manufacturer for acquisition, maintenance, upgrade and repair, etc.

4.3 Legal constraints

Because the data handled in the system is medical data, the system has to comply to several laws. In the EU, medical information is regarded as personal information and falls under the General Data Protection Regulation [9] (GDPR). Without going into too much detail, the main guiding principles are:

- Health information cannot be collected and used without explicit patient consent, and in this case only for purposes of continuous CVD treatment, unless processing is necessary to protect the vital interests of the patient (e.g., emergencies), payment or administration of the service.
- Disclosure of identity information should be minimized: if the data can be anonymized or de-identified, it should be (e.g., when opening up the data for research purposes).
- Patient should be able to locate and view all of their health information. They should also be able to delete and modify all personal administrative information (right to rectification, right to removal, etc.).
- Health data should be stored for a number of years, depending on the country (30 years in Belgium, 6 years in the US).
- Accountability: anytime the patient's data is disclosed to a third party, this event should be monitored and logged.

The system should apply to at least all rules stated above.

4.4 Security

Considering the nature of the patient monitoring service (patient health information is considered sensitive information) and the legal implications listed above, it is evident that security is key concern in the system. In this assignment we limit the scope to *user authentication* and *user action logging*.

User authentication. Authentication is the process of ensuring the identity of the different actors. It should not be possible for a user to act as another user (spoofing) and users should not be able to access the system unauthorized. It is clear that the patient monitoring service has a large variety of types of users, and it is realistic that the concrete realization of authentication will differ highly between these users: for example, physicians may use a badge to authenticate themselves, whereas patients may be authenticated implicitly, because they are using a wearable unit that is linked to his identity.

User action logging. Logging is the process of storing information about every action performed by the actors and the system itself. It enables the checking of system compliance to business or security policies, or in case of security-related incidents, trace the incident to a user. A log contains information such as the identity of the actor, the action, the object on which the action is performed, a timestamp etc. Note that user action logging depends on correct user authentication.

References

[1] M. R. Cowie and C. S. Lam, "Remote monitoring and digital health tools in cvd management," *Nature Reviews Cardiology*, vol. 18, no. 7, pp. 457–458, 2021.

[2] N. A. Proudfoot, S. King-Dowling, J. Cairney, S. R. Bray, M. J. MacDonald, and B. W. Timmons, "Physical activity and trajectories of cardiovascular health indicators during early childhood," *Pediatrics*, vol. 144, no. 1, 2019.

[3] R. L.-F. Jose Leal, Richeal Burns, "MEP Heart Group — The cost of cardiovascular disease in the European Union," February 2017. [Online]. Available: https://mepheartgroup.eu/wp-content/uploads/The_cost_of_cardiovascular_disease_in_the_European_Union_-_Jose_Leal.pdf

[4] "eHealth - Wikipedia, the free encyclopedia," Jan. 2021. [Online]. Available: http://en.wikipedia.org/wiki/EHealth

[5] R. Nakanishi, P. J. Slomka, R. Rios, J. Betancur, M. J. Blaha, K. Nasir, M. D. Miedema, J. A. Rumberger, H. Gransar, L. J. Shaw *et al.*, "Machine learning adds to clinical and cac assessments in predicting 10-year chd and cvd deaths," *Cardiovascular Imaging*, vol. 14, no. 3, pp. 615–625, 2021.

[6] A. D. Jamthikar, D. Gupta, L. E. Mantella, L. Saba, J. R. Laird, A. M. Johri, and J. S. Suri, "Multiclass machine learning vs. conventional calculators for stroke/cvd risk assessment using carotid plaque predictors with coronary angiography scores as gold standard: a 500 participants study," *The International Journal of Cardiovascular Imaging*, vol. 37, no. 4, pp. 1171–1187, 2021.

[7] I. A. Kakadiaris, M. Vrigkas, A. A. Yen, T. Kuznetsova, M. Budoff, and M. Naghavi, "Machine learning outperforms acc/aha cvd risk calculator in mesa," *Journal of the American Heart Association*, vol. 7, no. 22, p. e009476, 2018.

[8] "HeartScore: cardiovascular disease (CVD) risk assessment and management," Jan. 2021. [Online]. Available: http://www.heartscore.org/

[9] European Union, "Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC," *Official Journal of the European Union*, vol. 59, no. L 119, pp. 1–88, May 2016.

A Functional Requirements

A.1 Actors

An overview of the actors in the use cases is given in Figure 3. These actors are:

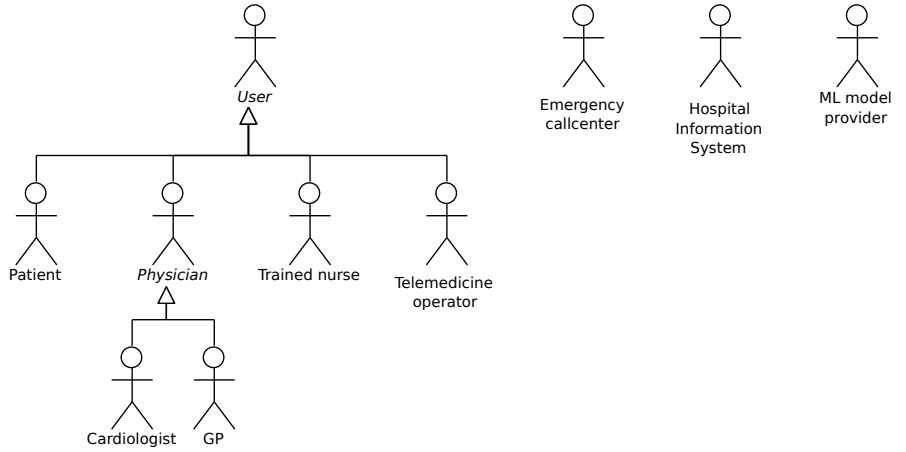

Figure 3: Overview of the actors in the use cases

A.2 Use case diagram

An overview of the use cases is given in Figure 4.

A.3 Textual use cases

In this section, we model the required functionality of the Patient Monitoring Service (PMS) in the form of *use cases*.

A.3.1 *UC1*: log in

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

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

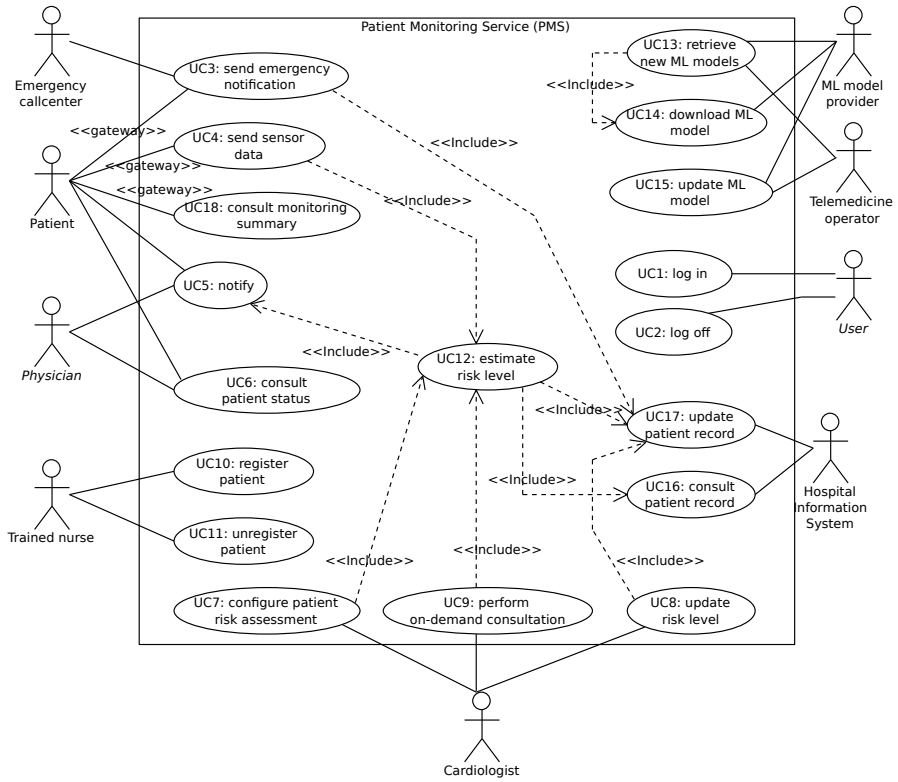

Figure 4: Overview of the use cases.

A.3.2 *UC2*: log off

- **Name:** log off
- **Primary actor:** User
- **Interested parties:**
  - PMS*:* wants to authenticate its users.
- **Preconditions:** The User is authenticated to the PMS (cf. *UC1*: log in).
- **Postconditions:** The User has logged off.
- **Main scenario:**
  1. The User indicates they want to log off from the PMS.
  2. The PMS logs them off.
- **Alternative scenarios:** None

A.3.3 *UC3*: send emergency notification

- **Name:** send emergency notification
- **Primary actor:** Patient (via patient gateway)
- **Secondary actor:** Emergency call center
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled them in the PMS.
  - *Physician:* is involved in the Patient's treatment.
  - *Emergency call center:* responsible for dealing with emergency situations (e.g., sending an ambulance to the patient).
  - *Patient:* wants to be treated in time when an emergency situation arises.
- **Preconditions:** The patient is registered with the PMS (cf. *UC10*: register patient).
- **Postconditions:** The PMS has received the emergency notification, verified it, and informed the Emergency call center by means of (an updated) 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, for example an API token that uniquely identifies the patient to the system. 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) emergency estimation model for confirming the emergency.
  3. The PMS confirms the emergency, sends an emergency notification with all relevant data to the Emergency call center, and updates the patient record with the relevant information (e.g., type of emergency, date, etc.) (**Include:** *UC17*: update patient record).
- **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:** *UC17*: update patient record).

A.3.4 *UC4*: send sensor data

- **Name:** send sensor data
- **Primary actor:** Patient (via patient gateway)
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled them in the PMS.
  - *Physician:* is involved in the Patient's treatment.
  - *Patient:* wants the system to keep an eye on the evolution of their CVD.
- **Preconditions:** The patient is registered with the PMS (cf. *UC10*: register patient).
- **Postconditions:** The PMS has registered the sensor data (readings) and processes them.
- **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**: *UC12*: estimate risk level).
- **Alternative scenarios:** None

A.3.5 *UC5*: notify

- **Name:** notify
- **Primary actor:** PMS
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled them in the PMS.
  - *Physician:* is involved in the Patient's treatment
  - *Patient:* wants to be up-to-date about their status.
- **Preconditions:** The PMS has previously received sensor data (cf. *UC4*: send sensor data), processed it (*UC12*: estimate risk level), 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 (Physicians, Cardiologist, 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:** None

A.3.6 *UC6*: consult patient status

- **Name:** consult patient status
- **Primary actor:** Physician or Patient
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled them in the PMS.
  - *Physician:* is involved in the Patient's treatment and wants to be up-to-date.
  - *Patient:* wants to be up-to-date about their status.
- **Preconditions:** The primary actor is authenticated (cf. *UC1*: log in).
- **Postconditions:**
  - The primary actor has consulted a patient's status.
  - The PMS has logged this event.
- **Main scenario:**
  1. The primary actor indicates they want to consult the current status of a patient.
  2. The PMS looks up the information, and presents it to the primary actor, tailored specifically to the expertise level of the primary 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:** None

A.3.7 *UC7*: configure patient risk assessment

- **Name:** configure patient risk assessment
- **Primary actor:** Cardiologist
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled them in the PMS.
  - *Patient:* is monitored by the PMS to estimate their risk level.
- **Preconditions:**
  - The Cardiologist is authenticated (cf. *UC1*: log in).
  - The Cardiologist is watching a patient's status (cf. *UC6*: consult patient status).
- **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 requests to configure the patient's risk assessment.
  2. The PMS presents the Cardiologist with an overview of the configurable options with their current value, if any. This includes, for example, which measurements should be monitored for the patient, e.g., heart rate and blood pressure, any relevant thresholds, e.g., typical rest heart rate, and underlying conditions that should be considered such as hypertension.
  3. The Cardiologist changes one or more configuration options and confirms the (re)configuration.

4. The PMS stores the new configuration and logs this event.
5. The PMS schedules a recalculation of the patient's risk level with the updated configuration (**Include:** *UC12*: estimate risk level).

- **Alternative scenarios:** None

A.3.8 *UC8*: update risk level

- **Name:** update risk level
- **Primary actor:** Cardiologist
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled them in the PMS.
  - *Patient:* is monitored by the PMS to estimate their risk level.
- **Preconditions:**
  - The Cardiologist is authenticated (cf. *UC1*: log in).
  - The Cardiologist may have received a notification from the PMS providing risk estimates for a patient (cf. *UC5*: notify).
  - The Cardiologist is watching a patient's status (cf. *UC6*: consult patient status).
- **Postconditions:**
  - The PMS has adapted the risk level of the patient.
  - The PMS has logged this event.
- **Main scenario:**
  1. The Cardiologist indicates the need to change the risk level of a patient.
  2. The PMS presents the Cardiologist with the option to change risk level to low, medium, or high.
  3. The Cardiologist indicates which risk level the patient's risk level should be changed to.
  4. The PMS changes the risk level of the Patient and updates the patient record (**Include:** *UC17*: update patient record).
- **Alternative scenarios:**
  - 1b. The Cardiologist indicates they wants to accept the risk level estimation given by the PMS in a notification. Forward to step 4.

A.3.9 *UC9*: perform on-demand consultation

- **Name:** perform on-demand consultation
- **Primary actor:** Cardiologist
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient, decided upon treatment, and enrolled them in the PMS.
  - *Patient:* is monitored by the PMS to estimate their risk level.
- **Preconditions:**
  - The Cardiologist is authenticated (cf. *UC1*: log in).
  - The Cardiologist is watching a patient's status (cf. *UC6*: consult patient status).
- **Postconditions:** The Cardiologist has performed an on-demand consultation.
- **Main scenario:**

1. The Cardiologist requests to receive the current data for a 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.
4. The PMS schedules the processing of the sensor data (**Include:** *UC12*: estimate risk level) and presents the results of the on-demand consultation to the Cardiologist.

- **Alternative scenarios:** None

A.3.10 *UC10*: register patient

- **Name:** register patient
- **Primary actor:** Trained nurse
- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient and want to register them in the PMS.
  - *Patient:* is suffering from CVD and wants to be monitored by the PMS.
  - *Trained nurse:* executes the registration process.
- **Preconditions:**
  - The Cardiologist has approved the patient's registration.
  - The Trained nurse is authenticated (cf. *UC1*: log in).
- **Postconditions:**
  - The patient is registered in the PMS.
  - The PMS has logged this event.
- **Main scenario:**
  1. The Trained nurse indicates to the PMS a registration process should be started for a patient (e.g., by selecting the appropriate patient record).
  2. The PMS asks to select two devices and asks her to pair them.
  3. The Trained nurse selects a wearable unit and a patient gateway for the patient, pairs both devices. The Trained Nurse 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 Trained nurse.
  5. The Trained nurse double-checks the sensor data and, if necessary, calibrates the sensors.
  6. The PMS allows the nurse to set authentication credentials (e.g., username and password) for the patient.
  7. The Trained nurse enters the authentication credentials.
  8. The PMS registers the patient.
- **Alternative scenarios:** None

A.3.11 *UC11*: deregister patient

- **Name:** deregister patient
- **Primary actor:** Trained nurse

- **Interested parties:**
  - *Cardiologist:* has diagnosed the patient and wants them to stop using the PMS.
  - *Patient:* has improved sufficiently and can be deregistered from the PMS.
  - *Trained nurse:* executes the deregistration process.
- **Preconditions:**
  - The Patient is registered in the PMS (cf. *UC10*: register patient).
  - The Trained nurse is authenticated (cf. *UC1*: log in).
  - The Cardiologist has approved the Patient's deregistration.
- **Postconditions:**
  - The Patient is deregistered from the PMS.
  - The PMS has logged this event.
- **Main scenario:**
  1. The Trained nurse indicates to the PMS a patient should be deregistered (e.g., by selecting the appropriate patient record).
  2. The PMS deregisters the wearable unit and patient gateway, deregisters the patient (stops the monitoring), and logs this event.
- **Alternative scenarios:** None

A.3.12 *UC12*: estimate risk level

- **Name:** estimate risk
- **Primary actor:** PMS
- **Interested parties:**
  - *Cardiologist:* wants to keep track of a patient's status, and if necessary, adjust treatment.
  - *Physician:* 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 sensor data (cf. *UC4*: send sensor data) for a patient.
  - The cardiologist has configured the patient's risk assessment (cf. *UC7*: configure patient risk assessment).
- **Postconditions:** The PMS updated the patient's status, and if necessary, issued 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:** *UC16*: consult patient record), and risk assessment configuration.
  2. The PMS applies all models in the risk assessment to the newly arrived information and the already-known data.
  3. The PMS determines that the patient's estimated risk level should change based on the combined result from the models in the risk assessment.
  4. The PMS determines the interested parties (e.g., Cardiologist, Physicians, and Patient) and issues the necessary notifications (**Include:** *UC5*: notify).

5. The PMS determines that the newly arrived sensor data and the results of the risk assessment should propagate to the patient record and sends an appropriate update (**Include:** *UC17*: update patient record).

- **Alternative scenarios:**

3b. The PMS determines that the patient's estimated risk level should **not** change based on the combined result from the models in the risk assessment. Skip to step 5.

5b. The PMS determines that the newly arrived sensor data and the results of risk estimation should **not** propagate to the patient record. Use case ends.

A.3.13 *UC13*: retrieve new ML models

- **Name:** retrieve new ML models
- **Primary actor:** Telemedicine operator
- **Secondary actor:** ML model provider
- **Interested parties:**
  - *Physician:* wants to ensure the most appropriate medical care is given to patients.
- **Preconditions:** The Telemedicine operator is authenticated to the system (cf. *UC1*: log in).
- **Postconditions:** The PMS has retrieved and stored newly available ML models.
- **Main scenario:**

1. The Telemedicine operator indicates to the system to check for newly available ML models.
2. The PMS queries the model provider for a list of available ML models.
3. The ML model provider replies with a list of all available ML models, including metadata including an identifier and version number.
4. The PMS determines that new ML models are available and, for each such model, the PMS provides the Telemedicine operator with an option to download the new ML model from the ML model provider (**Include:** *UC14*: download ML model)

- **Alternative scenarios:**

4b. The PMS determines no new ML models are available and informs the Telemedicine operator of this. Use case ends.

A.3.14 *UC14*: download ML model

- **Name:** download ML model
- **Primary actor:** PMS
- **Secondary actor:** ML model provider
- **Interested parties:**
  - *Physician:* wants to ensure the most appropriate medical care is given to patients.
- **Preconditions:** None
- **Postconditions:** An ML model was retrieved from the ML model provider and installed into the system.

- **Main scenario:**
  1. The PMS queries the ML model provider for a specific ML model by providing by model identifier.
  2. The ML model provider replies with the corresponding ML model.
  3. The PMS adds the received model to its repository of installed ML models.
- **Alternative scenarios:** None

A.3.15 *UC15*: update ML model

- **Name:** Update ML model
- **Primary actor:** Telemedicine operator
- **Secondary actor:** ML model provider
- **Interested parties:**
  - *Physician:* wants to ensure the most appropriate medical care is given to patients.
- **Preconditions:** The Telemedicine operator is authenticated to the system (cf. *UC1*: log in).
- **Postconditions:** The PMS has updated an available ML model.
- **Main scenario:**
  1. The Telemedicine operator requests a list of ML models available in the system.
  2. The PMS presents the Telemedicine operator with the list of available ML models.
  3. The Telemedicine operator selects a specific model to inspect in more detail.
  4. The PMS retrieves the details of the specified ML model and shows this to the Telemedicine operator.
  5. The Telemedicine operator indicates that the model should be updated.
  6. The PMS queries the ML model provider to retrieve all updates available for the specified model.
  7. The ML model provider replies with the requested updates.
  8. The system applies the received updates to the installed ML model.
  9. The PMS informs the Telemedicine operator that the ML model was updated.
- **Alternative scenarios:**

  2b. No ML models are currently installed in the system, the Telemedicine operator is informed of this. Use case ends.

  7b. The model provider replies that no updates are available for the selected ML model. The system informs the Telemedicine operator that the installed ML model is already the most recent version. Use case ends.

A.3.16 *UC16*: consult patient record

- **Name:** consult patient record
- **Primary actor:** PMS

- **Secondary actor:** Hospital Information System (HIS)
- **Interested parties:**
  - PMS*:* wants to keep track of a patient's status, also the information external to the PMS itself
  - HIS*:* provides access to the patient record.
  - *Physician:* wants to have access to up-to-date information about the patient.
- **Preconditions:** The patient is registered with the PMS (cf. *UC10*: register patient).
- **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 service performs the look-up and provides the patient record to the PMS.
- **Alternative scenarios:** None

A.3.17 *UC17*: update patient record

- **Name:** update patient record
- **Primary actor:** PMS
- **Secondary actor:** 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.
  - *Physician:* wants to keep the patient (medical) record up-to-date.
- **Preconditions:** The PMS is monitoring a patient of the hospital.
- **Postconditions:**
  - The PMS has provided information for the patient record in the HIS.
- **Main scenario:**
  1. The PMS sends an update to the patient record in the HIS.
  2. The HIS accepts the data from PMS and processes it further.
- **Alternative scenarios:** None

A.3.18 *UC18*: consult monitoring summary

- **Name:** consult monitoring summary
- **Primary actor:** Patient
- **Interested parties:** None
- **Preconditions:** The User is authenticated to the PMS (cf. *UC1*: log in).
- **Postconditions:**
  - The PMS has provided the patient with a summary of their information in the system.
- **Main scenario:**
  1. The Patient indicates, via their gateway, that they want a summary of their monitoring information.

2. The PMS retrieves the patient's information and compiles a summary suited for a layperson and sends this to the patient gateway. This summary can contain, for example, a graph showing the risk level changes over time.
3. The patient gateway shows the received summary to the patient, e.g., as tables and/or graphs.

- **Alternative scenarios:** None