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# Remote Elderly Monitoring Systems on a Human-centric Perspective

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# REMOTE ELDERLY MONITORING SYSTEMS ON A HUMAN-CENTRIC PERSPECTIVE

*Research full-length paper*

*Internet of Things (IoT) Systems Enable Smart Living and Business*

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## Abstract

*Information systems based on the Internet of Things (IoT) are driving revolutionary solutions in innumerable domains, as the sensitive domain of healthcare. Indicatively, remote monitoring of patients and real-time diagnosis are anticipated as complex systems, offering various services to the associated humans (e.g. patients and caregivers). While researchers focus on the technology necessary to implement remote healthcare systems, such as Remote Elderly Monitoring System (REMS), human concerns restricting their wider adoption are often neglected. Such concerns are transformed into criticalities, that should be considered during system design. In this work, a human-centric perspective on REMS design is explored. Following this perspective, supported tasks are decodified, human concerns associated to REMS usage are identified and revealed criticalities, that stem from human concerns, are extracted. Furthermore, existing REMS implementations are examined, based on the tasks supported and criticalities addressed, resulting in the identification of ways to further improve such systems.*

*Keywords: Internet of Things, Human-Centric, Actor, Task, Criticality, Remote Health Monitoring.*

## 1 Introduction

Information Systems (ISs) become more and more complex (Xia and Lee 2005), making difficult to develop and manage them. To accommodate IS engineering, integrated methodologies, such as for example the Zachman framework (Sowa and Zachman 1992), have been developed, allowing their conceptualization based on different perspectives. Business and system are examples of such perspectives; the first one focuses on processes and human activities, owned and performed by the system stakeholders, while the second one on provided services and system components supporting them. Note that even though this perspective is undoubtedly important for system design, it may fail to capture all the concerns raised by the stakeholders of the system on the business perspective. This results in neglecting design requirements that stem from the human entities of the system (e.g., actors). Thus, a method incorporating actor concerns, identified through the business perspective into the system perspective, consisting of integrated design views of the system, is needed (Mara Nikolaidou et al. 2009). As information systems become more complex, utilizing the advent of IoT, it is important to explore requirements and concerns critical for their operation, in terms of both business and system perspective.

Health IS, based on IoT, support healthcare activities (Babu and Jayashree 2016), such as: real-time diagnosis of medical issues, telecare and telemedicine, remote monitoring of patients. They are rapidly increasing in variety, size, complexity, and sophistication (Kalid et al. 2018). Such systems are mainly composed of hardware (e.g., sensors, smartphones) and software (e.g., specialized operating systems,

Cloud services, etc), providing different services to the users. Health system components may be characterized by different criticality (Alan Burns and Davis 2013), either safety-critical related to human safety (Knight 2002) or mission-critical related to the purpose of the organization (Ciccozzi et al. 2017). Identifying the criticalities in such systems is crucial. In (Kotronis et al. 2018), we introduce an approach to explore criticality influencing the design of health IoT systems. In that paper, focus was given to the remote monitoring and diagnosis for the sensitive demographic of elderly subjects, i.e. the REMS use case. In general, REMS deals with the real-time diagnosis of a medical incident. Medical information from the patient (elderly individual), e.g., stemming from embedded sensors, is transmitted to the healthcare provider (caregiver) in a different location (e.g., a hospital) (Bujnowska-Fedak and Grata-Borkowska 2015). The criticalities, restricting REMS functionality, imposed to REMS components were identified. However, focus was given on the system perspective, considering REMS designer concerns. What about the actor's concerns, e.g. the patient and the caregiver, using REMS? To promote REMS usage, one should also consider and generate criticalities, restricting REMS functionality, from a human-centric perspective.

The purpose of this work is to define a suitable abstraction level, oriented towards the human-centric perspective of a system, alternative to the existing views, focusing solely on translating the human concerns into the system criticalities. In order to achieve that, the following steps were taken:

- decoding the tasks performed by REMS users,
- clarify REMS users' concerns while using the system,
- identify and decode related criticalities, depicting the restrictions imposed to corresponding REMS functionality, stemming from the user's concerns,
- examine REMS implementations, in order to explore whether the aforementioned approach is accommodated by them, and
- propose ways towards further improvement of the usage of such systems.

The rest of the paper is structured as follows: In Section 2, related work is discussed. The proposed human-centric approach to study a system as well as basic concepts, related to that approach, are presented in Section 3. The detection and decoding of REMS actors, and concerns, as well as their tasks, and criticalities, are introduced in Section 4 (4.1 and 4.2). An overview of commercial and research-based REMSs is described in Section 5. Finally, we conclude in Section 6.

## 2 Related Work

A remote healthcare monitoring system for elderly individuals, falls within the Ambient Assisted Living (AAL) domain (Memon et al. 2014), and acts as a platform that enables professional health caregivers (e.g., doctors) to monitor the health status of a patient unobtrusively, remotely, and in real-time, reducing the number of times a patient has to travel for a regular check at the premises of a healthcare facility. Existing literature reviews in health monitoring systems mainly focus on architecture and communication technologies of the related components and systems. A comprehensive study of context-aware computing in healthcare for the elderly that aims to highlight the current technologies, in order to address the issues that could improve healthcare services is presented in (Mshali et al. 2018). Another study (Robbins, Keung, and Arvanitis 2018), addresses the potential effect of digital interventions in active ageing, by reviewing existing literature.

However, all these reviews aim to identify the functionality provided by remote healthcare monitoring system without exploring the way they may be utilized by the end-users, e.g patients and caregivers using them. The penetration of IoT system is strongly related to the willingness of humans to actually use IoT devices (Mantzana et al. 2007). Thus, complementary to the aforementioned studies, the tasks perform by humans in a typical remote healthcare monitoring system should be identified along with their concerns on how to perform these tasks, as for example confidentially concerns. To pursue such an effort, REMS is used as a use case.

Several research works on REMS have been proposed, which aimed at continuous patient monitoring in environments, such as home, office, ambulance, and hospital. A number of indicative REMS is presented below, including both research-based and commercially available systems, chosen based on their maturity and wide usage, in order to explore the human-centric nature of their attributes and users concerns.

At first, the proposed research-based REMS are described. A system that facilitates the use of smart devices by elderly users and behaves as a gateway for telehealth applications, is the Smartstone (Belagente et al. 2016). The Smartstone is a low-cost smart device that involves a simple and portable sensor that can conveniently be worn on the earlobe. The sensing capabilities of the device include measuring heart rate and bio-impedance signs of the user continuously, while real-time data delivery to a mobile device is available. The device can interact with the patient through a ringtone or a vibration in case of an emergency or as a reminder for pill intake. The collected data can be uploaded into a cloud-based remote repository (Google drive) and can be available for doctors at all times. The ability of the caregiver to remotely access patient health data is also available in this system, however security of the above data transmission is not assessed. A prototype developed by a collaboration of Fraunhofer Institutes is presented is the senSave system (Lorenz and Oppermann 2009). It aims to contribute to the improvement of medical treatment for cardio-vascular diseases for the elderly, through the integration of medical components and sensors, such a ECG and oxygen saturation. A user-friendly mobile device, that incorporates sensors integrated into a shirt, can be worn by the patient. The sensors can record ECG, pulse and oxygen saturation signals, at a continuous rate and transmit the data to a PDA. Another service included in this system is the ability of the user to view the health information and send them via Internet to the health centre. From the caregiver point of view, the doctor can view patient's cardiovascular readings and respond to any irregularities, or advice patients over the phone, in case of emergency. Finally, a health monitoring system that achieves a physical integration of microelectronic with textile and clothing structures is Textronic (Frydrysiak and Tesiorowski 2016). The main purpose here is to monitor residents of nursing homes with the use of sensors that are integrated in clothing. Textile sensory elements and textile signal lines are implemented in the structure of the clothing that are easily worn by the user. Furthermore, the measurement of physiological parameters is non-invasive which means that does not interfere directly in the human body and is completely safe for the user. The system enables the continuous data acquisition for a number of parameters, such as pulse, temperature, breathing frequency, positioning inside and outside room. A real time, wireless, data transmission from sensors to a mobile device is available, while the data can be also send via Internet to the health providers. The service of generating alarm signals in the form of reports such as texts for cell phones or emails for nurses or for the patient's family is also provided.

A number of commercial REMS are also presented. Medtronic (Medtronic 2018) is a healthcare company that provides medical technologies for the aging population, with a number of products with various sensing capabilities are offered here. The enrolment of the patient to the eligible services, that involve the collection of patient's biometrics and symptoms data on a daily basis is required, in order for data to be accessed by a web-based interactive platform or through telephone. The collected data is sent to the Medtronic Care Management Service (MCMS), while patients can connect with the providers through a video-based system. On the other side, the caregiver can view and edit data to meet specific requirements and an alert service is supported in case of an emergency. Another system, Biotronik (Biotronik 2018) is a commercial healthcare approach for patients with heart and blood vessel diseases. The available devices can be implanted to the patient in order to treat and manage arrhythmia-related conditions. Some of the patient-oriented services in this system, include the continuous monitoring of cardiac signs from a device, and the wireless transmission of retrieved data to the Home Monitoring Service Center (HMSC) automatically, on a daily basis. The connection with the HMSC is supported through an encrypted data transmission, in order to sustain a basic security requirement. In terms of caregiver related services, the ability to review cardiac function data is supported, while the system can alert about relevant changes in patient health and the device's status, in case of emergency.

The tasks offered to REMS users by the aforementioned systems, along with their ability to serve user concerns may be used as a criterion to examine REMS over a human-centric perspective and identify the criticalities restricting REMS design.

### 3 A Human-Centric Perspective on System Design

Common system design models typically represent structural, physical, or behavioural aspects of the system-under-study (Object Management Group - SysML 2018); focus is given on a system-centric view of them. Such a view illustrates the services offered by the system, the subsystems and components that comprise it (Friedenthal, Moore, and Steiner 2014; Bourgeois 2014). Both services and components are restricted by critical design requirements, stemming from both the concerns of the organization building the system and the humans using it. The first one are commonly capture by the system designer (M. Nikolaidou and Anagnostopoulos 2005). What about human concerns? They are usually dealt within in the business perspective, suitable for the conceptualization of activities (and their characteristics) enrolled by actors within an organization (McCormack 2001). However, this knowledge should be incorporated into system design views, serving the system perspective (Mara Nikolaidou et al. 2009).

Towards this direction, a human-centric view for system design is introduced in the following (see figure 1). The actor’s concerns, representing the desirable functionality, affect the system and its design philosophy. Therefore, the centre of attention is shifted from the system to the human. Such a transition, could help improving the communication between different design disciplines (e.g., system designer, human user of system) during system design and could ideally improve the system itself.

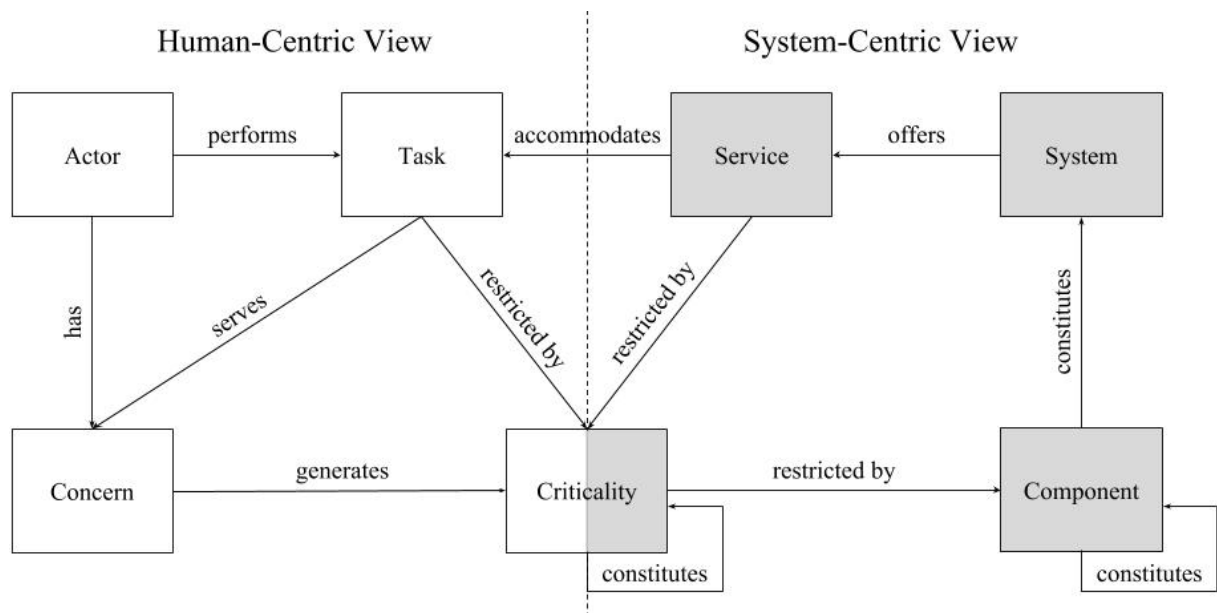


Figure 1. Separating Human- from System-Centric View.

Within the human-centric perspective, focus is given on the actor, e.g., the human user, the tasks she performs, and the generated related concerns. The actor refers to any individual or organization that interacts with the system and affects it or is affected by it (Mantzana et al. 2007). Regarding the concerns, according to the IEEE architecture group (Hilliard 2000), they represent “the interests pertaining to a system’s design, operation or any other aspects, critical to one or more actors”. In addition, the task represents a specific work, performed by an actor (Object Management Group - BPMN 2018).

Regardless of how a System has been implemented, it provides specific Services, that accommodate corresponding Tasks. These Tasks, performed by Actors, serve the Concerns that the Actors have. Concerns generate Criticalities, that may comprise other Criticalities and restrict both the Tasks and the

Components of the System. Note that a Component can be part of another Component; together, they compose the System. The dashed-line, depicted in the Figure, separates the human-centric and the system-centric view. On the one hand, the white-coloured elements, i.e. the Actor, Task, Concern, and Criticality, are related, independently of the System implementations. On the other hand, the system-centric view depicts the connection between the grey-coloured elements, i.e. System, Service, Component and Criticality. Note that the Criticality element is the common feature between the two views since they affect both the human and the system; for example, a system criticality may arise from a criticality, affecting the human.

## 4 The Human-Centric View of REMS

Concerning REMS use case, the actors and the task they perform have already been identified (see section 2). In the REMS, two main actors are involved, i.e. the patient and the caregiver. In the context of the EMBIoT project (Proj. No. NPRP 9-114-2-055), we conducted interviews in Hamad Medical Corporation (Hamad Medical Corporation 2018) of Qatar, to identify actor's concerns and extract corresponding criticalities. Caregivers were asked about the concerns the actors' must consider, generated during the remote monitoring process. Deriving specific concerns, we extracted corresponding criticalities for both the patient and the caregiver. In section 4.1, the actors and corresponding concerns are described, while in Section 4.2, the primary tasks and associated criticalities are identified.

### 4.1 REMS Actors and Concerns

Delving into the REMS's actors, the patient, stays at her own home, while her vital signs are monitored, using a variety of diagnostic tools and devices, i.e. medical sensors, and the caregiver gains access to health statistics and medical records of their patients in real-time, while communicating with the patient in case of emergency. While the actors perform specific tasks, there are multiple obstacles –concerns– to consider. These concerns must be addressed in order for the actors to get the most benefit out of this system.

The concerns of the patients can be the following. The acquisition method and cost of the medical equipment (e.g., medical devices) are necessary for the activation of the monitoring system. In addition, the properties of the medical devices, e.g. if they are portable and comfortable for the user, affect their level of usage. Specifically, these medical devices should be easy to deploy and use by the patient, in order to measure and record her vital signs. Moreover, the ownership of the measured physiological signs and other health parameters, related to the health status of the patient, is a paramount concern. Additionally, the safety and privacy of the measured signs as well as any information exchanged –orally or via digital messages– during the communication of the patient with the caregiver in case of emergency is critical from a technical, ethical and legal perspective. This also falls in the context of the patient-caregiver confidentiality, while communicating via mobile/broadband networks.

For the caregiver the need to infer the patient's medical status and provide an accurate diagnosis, based on transmitted physiological signs and updated medical history/records of the patient, is critical. In order to access this medical information about the patients, the caregiver must have an easy but reliable way to use the system. Another concern is about the level of alertness of the caregivers, when there's a cause for immediate medical attention. Moreover, the provisioning of treatment and care to the patients, in case of an emergency, should be fast, effective and efficient. Last but not least, privacy of the information and caregiver-patient confidentiality are the same concerns as those expressed from the patient's point of view.

## 4.2 REMS Tasks and Criticalities

The aforementioned actors perform specific tasks in a REMS, in view of their concerns; in turn, these concerns generate specific criticalities that restrict the tasks. The task-level outcome of this interdependency is described in detail in the following.

### 4.2.1 Tasks performed by a patient

**Acquire device.** REMS's purpose is to help improve the quality of life of an elderly patient, whilst reducing the cost of care (Lukowicz, Kirstein, and Troster 2004). Small, portable, wearable or even implantable devices can monitor the patient's conditions (e.g., vital signs), while she remains in her home environment, replacing the use of large, uncomfortable medical instruments at a healthcare facility's premises (Salditt and Bothell 2004). In order to be an active part of a REMS, the patient must acquire these devices. The associated concerns can be expressed via the following questions: how can the patient acquire a medical device, and how much is it going to cost the patient? Although the overall cost of acquiring medical devices can remain low, it is critical for an elderly to have the ability to afford the devices. The acquisition method and corresponding costs may vary for her, as she may purchase or lease a device from her caregiver, a certified healthcare equipment seller, etc.

**Wear device.** The majority of medical sensors is portable; they can be wearable (e.g., hand-worn, like smart watches or elastic bands), on-body (e.g., clothes, small patches, chest straps, etc) or in-body (e.g., implanted under the patient's skin). Before an elderly patient wears a sensor, she wants to know whether the properties of the devices are suitable for the patient's comfort; restricting the size (e.g., being smaller), weight (e.g., being lighter) and power (e.g., being more energy-efficient) of wearables or I planted devices is necessary for patient comfort and reliability. In addition, all sensors, falling within the context of healthcare devices, must comply to specific regulations to ensure that they are appropriate and safe for the patient (McGrath and Scanail 2013).

**Activate device.** Depending on the elderly's health status (e.g., mobility, chronic comatose conditions), there are two cases for using a medical device: either (i) the elderly wears it, powers it on, uses it for a small time period, and switches it off, or (ii) she powers it on once and the sensor is programmed to run consistently for a long time period. Sensors with excellent usability and flexibility are critical components of a REMS that can continuously monitor physiological signs of the patient without any apparent lack of comfort on her side.

**Measure vital signs.** While active, sensors are capable of measuring physiological signs such as heart rate (HR), body temperature (BT), respiration rate (RR), and systolic blood pressure (BP) (Pantelopoulos and Bourbakis 2010). Here, as a common example, we focus on Electrocardiogram (ECG) sensors measuring the patient's heart rate in beats per minute (BPM), able to detect heart failure and cardiovascular diseases, such as heart attacks, arrhythmias and strokes (Achten and Jeukendrup 2003).

**View vital signs.** Following the measurement of the patient's vital signs, the sensor can display the collected health sign values to the patient; some sensors are designed with a small display screen while others can interface with devices, such as smartphones, and automatically transmit the results (in the form of a small report) to the connected device (Adrian Burns et al. 2010). An important concern pertaining to the activation of the device and the measurement and recording of vital signs is how easily the patient can deploy and use a device. Note that the latter concern cuts through the activation, measurement and recording tasks. Both "measure vital signs" and "record vital signs" tasks are restricted by the real-time remote monitoring of patients, as it is the most important challenge in telemedicine. Acquiring accurate real-time medical data can help diagnose a disease quickly and resort to proper medical countermeasures. A failure to perform the measurement or to show the results to the patient or the caregiver within a given time window may result in serious harm, even loss of human life.

**Manage personal data.** An important process within a REMS is the transmission of sensor-collected data via the Internet to a remote server for further monitoring and analysis. The patient may be given the ability to upload the data to a personal Cloud account for permanent storage or directly to the



healthcare facility's database to be combined and incorporated with her pre-existing medical history and records. Patients can even keep track of their vital signs, which are added automatically to their patient records. However, once this information is available electronically, the concerns that must be addressed are who is authorized to access the patient data, as well as how is the security and privacy of the patient data ensured. Secure use of medical databases or Cloud-based solutions in REMS is critical, because of the sensitivity of the patients' data. HIPAA (Annas et al. 2003) enforces some very strict regulations about maintaining the privacy of medical data (note that HIPAA is a regulatory act effectively expressing the patients' concerns within a legal framework). This becomes even more important within the newly introduced European framework for data protection, General Data Protection Regulation (GDPR) (Botrugno 2018).

**Communicate.** The patient can communicate with her caregiver or emergency healthcare personnel via mobile/broadband networks, in order to inform the caregiver about disturbances, ask about abnormal data values, etc. The communication is subject to the constraints of doctor-patient confidentiality. A critical challenge/concern associated to this communication is how to ensure that the communication mediated between patient and caregiver, is secure/protected, confidential, and conforms to the relevant ethical principles.

**Deactivate device.** This task is the opposite of the activation, although with similar concerns, where the elderly individual can deactivate the medical devices, terminating the remote monitoring process.

#### 4.2.2 Tasks performed by a caregiver

**Monitor vital signs.** Providing the highest quality medical care requires fast action from the side of healthcare providers. Without access to real-time, clinical-grade data, a physician is unable to have complete insight into the patient's condition. Sometimes, the difference can be made in just a matter of minutes/seconds. Healthcare providers can be empowered by remote patient monitoring systems thanks to the ability to garner real-time insights about patients; if readings look askew (e.g., surpassing pre-defined thresholds), doctors can view the associated generated alerts and act quickly to address the issue. Note though, that healthcare providers may amass tons of patient medical data from different monitoring sources. By leveraging medical data analytics, raw monitoring data can be transformed to usable and actionable intelligence, enabling the caregivers to diagnose medical conditions remotely and treat their patients as fast as possible.

**Review patient records.** The caregiver needs to be able to remotely access the elderly's digital health records, review the data history, analyse it using the system's automated environment, modify or add new data to the records. In practice, the health information of a patient can be securely accessed from any web or mobile device. Caregivers and patients can be granted access to update information at any time using e.g., mobile applications. Maintaining up-to-date health records is vital to keep the caregiver's view in sync with the patient's actual health status. Note though, that the use of such technologies justifiably generates concerns related to security, data access control, confidentiality and privacy. Moreover, at the same time, access to data should be easy for the caregiver; going through slow and complicated processes may be problematic.

**Act on emergency.** In case of an emergency, actions like: communication between doctor and patient while the patient is at home, support, treatment and medical advice to the patient, e.g., increase or decrease dosage of a medicine, remote specialist and physician consultations, or even dispatching an ambulance, are taken from the caregiver's side to help the elderly at home. Effective and seamless communication in healthcare is imperative when it comes to providing appropriate patient care and thus, it is critical for both patients and caregivers. The communication and consultations can be overall faster, cheaper and more efficient than traditional healthcare appointments (Alexopoulou et al. 2010). Note though that the critical challenge/concern is the same as the one expressed from the patient's point of view, i.e. how to ensure that the communication mediated between patient and caregiver is secure/protected, confidential, and conforms to the relevant ethical principles; for example, eavesdropping from third parties while an emergency is under development is not acceptable.

Actor	Concern	Task	Criticality
Patient	<ol style="list-style-type: none"> <li>1. Acquisition method cost</li> <li>2. Device properties</li> <li>3. Ease of deploy/use</li> <li>4. Data ownership</li> <li>5. Information safety/privacy</li> <li>6. Confidentiality</li> </ol>	Acquire device	1. Affording devices
		Wear device	<ol style="list-style-type: none"> <li>1. Complying with regulations</li> <li>2. Restricting size, weight &amp; power</li> </ol>
		Activate device	1. Operating with ease/flexibility
		Measure vital signs	1. Monitoring in real-time
		View vital signs	1. Monitoring in real-time
		Manage personal data	<ol style="list-style-type: none"> <li>1. Maintaining data privacy</li> <li>2. Handling information with ease</li> </ol>
		Communicate	<ol style="list-style-type: none"> <li>1. Reassuring confidentiality</li> <li>2. Ensuring information protection</li> </ol>
		Deactivate device	1. Operating with ease/flexibility
Caregiver	<ol style="list-style-type: none"> <li>1. Keep up with patient status</li> <li>2. Ease of use</li> <li>3. Notifications/alerts</li> <li>4. Provide treatment</li> <li>5. Information safety/privacy</li> <li>6. Confidentiality</li> </ol>	Monitor vital signs	<ol style="list-style-type: none"> <li>1. Operating with ease/flexibility</li> <li>2. Monitoring in real-time</li> <li>3. Handling information with ease</li> </ol>
		Review patient records	<ol style="list-style-type: none"> <li>1. Maintaining data privacy</li> <li>2. Handling information with ease</li> <li>3. Operating with ease/flexibility</li> </ol>
		Act on emergency	<ol style="list-style-type: none"> <li>1. Reassuring confidentiality</li> <li>2. Ensuring information protection</li> </ol>

Table 1. Identified actors, concerns, tasks and criticalities.

## 5 Human-centric Perspective through REMS Implementations

In this section, the proposed human-centric perspective is validated, as it is utilized to explore whether existing REMS implementations a) are accommodating identified basic REMS tasks and b) are considering patient and caregiver concerns, supporting the extracted, related criticalities. To this end, REMSs implementations presented in Section 2 are examined, considering the fact that these are indicative of some state-of-art recent studies on remote health monitoring applications for elderly individuals.

Table 2 projects the results of our examination, whether the identified tasks and their corresponding criticalities, identified in Table 1, are supported and to which extent. The tasks performed by the actors (e.g., wear device, etc) are either accommodated by the services offered by a system (represented as a tick image) or is not fulfilled (cross image). Regarding the criticalities, we use three different colour dots as our notation to illustrate whether the corresponding criticality is supported (black dot), partly supported (grey dot), and not supported (white dot). In case a task is not performed by the system actors and, thus, is absent from the system implementation, the related criticalities are not examined by it; only a dash covers the corresponding cell of the table.

Patient Task	Criticality	Research-based System			Commercial System	
		Smartstone	senSave	Textronic	Medtronic	Biotronic
Acquire device		✓	✗	✗	✓	✓
	Affording devices	●	-	-	○	○
Wear device		✓	✓	✓	✓	✓
	Complying with regulations	○	○	○	●	●
	Restricting size, weight and power	●	●	●	●	●
Activate device		✓	✓	✓	✗	✓
	Operating with ease/flexibility	●	●	●	-	●
Measure vital signs		✓	✓	✓	✓	✓
	Monitoring in real-time	○	○	●	●	○
View vital signs		✓	✓	✓	✓	✓
	Monitoring in real-time	○	○	○	○	○
Manage personal data		✓	✓	✓	✓	✓
	Maintaining data privacy	○	○	○	○	○
	Handling information	○	○	○	○	○
Communicate on emergency		✓	✓	✓	✓	✗
	Reassuring confidentiality	○	○	○	○	-
	Ensuring information protection	○	○	○	○	-
Deactivate device		✓	✓	✓	✗	✓
	Operating with ease/flexibility	○	○	○	-	○
<b>Caregiver Task</b>						
Monitor vital signs		✓	✓	✓	✓	✓
	Operating with ease/flexibility	○	○	●	●	●
	Monitoring in real-time	○	○	○	○	○
	Handling information with ease	○	○	○	○	○
Review patient records		✗	✓	✓	✗	✓
	Maintaining data privacy	-	○	○	-	●
	Handling information with ease	-	○	●	-	●
Act on emergency		✗	✓	✓	✓	✓
	Reassuring confidentiality	-	○	○	○	○
	Ensuring information protection	-	○	○	○	○

Table 2. Summarizing Existing REMS Implementations Characteristics.

## 5.1 Discussion

Based on Table 2, some useful observations are highlighted in the following, regarding the accommodation of tasks and criticalities –identified in section - in the REMS implementations examined.

To begin with, most identified tasks are accommodated for both the patient and the caregiver in all the systems under study. One could comment that a few tasks are not supported, but this fact can be considered as an exception that enhances our claim, as these represent just a minority of REMS. Moreover,

regarding the patient tasks, some crucial activities, such as wearing the device and monitoring the vital signs are completely embedded in all implementations. As for the caregiver, the ability to monitor the patient's vital signs and physiological information is considered a prerequisite in all REMS systems.

In contrast, the criticalities, restricting the actors' tasks, are not adequately addressed in all REMS implementations. Thus, it is observed that the notion of criticalities is not well studied, in a sense that they are hardly supported, even though the tasks are well-defined. This fact generates a considerable amount of issues that should be explored.

First of all, criticalities related to emergency handling tasks, such as the ability of the patient to communicate with the caregiver during an urgent situation and in reverse, the ability of the caregiver to act on an ad hoc manner, are not emphasized. The latter does not conform to the nature of the Healthcare domain and related health systems, like the REMS. Thus, more focus should be casted on a seamless, effective, secure and confidential communication mediated between the actors; in the REMS, the communication is subject to the constraints of doctor-patient confidentiality.

Moreover, there is an inconsistency among the systems in handling the privacy and protection of sensitive patient health data, when the caregivers are reviewing patient records. Some, like Biotronic (Biotronik 2018) REMS, support these criticalities completely, ensuring the security, privacy as well as the access-to-view authorization of these data, while others have taken into consideration the fulfillment of some of them (e.g., privacy only). Systems like Smartstone or Medtronic, are not considering privacy and security at all when handling patient records.

In addition, although the monitoring tasks are accommodated adequately for both REMS actors, their corresponding criticalities lack of support from the examined REMS. Only ease of use is partially supported. This fact opposes to the necessity of monitoring in real-time as a core characteristic of REMSs.

Furthermore, although these systems provide the patient with the capability to perform data management tasks, they do not cover the actors' concerns about the privacy of their personal data. In addition, it is unclear whether most of these systems provide an easy way for the actors to handle and manage their data; these features are for them, enhancing their confidence of data ownership and self-monitoring.

As a minor exception, criticalities related to hardware (device, sensor etc) could be fully identified, mainly because these refer to basic design requirements of IoT devices.

## **6 Conclusions**

Nowadays, when considering systems design, actors' concerns are often neglected, and criticalities generated by them, which should restrict system functionality, are dismissed. Thus, functionality provided by the system fails to satisfy users requirements. The goal is to describe how a transition from the system view to the human view could be made, in order to identify ways to further improve the system. For this purpose, a human-centric perspective for designing systems is introduced. In particular, we describe all the concepts related to this approach, i.e. actors performing tasks, as well as the actor's concerns generating system criticalities, and showed their interrelations. During this work, we examined REMS as our use case, where patients' and caregivers' concerns were identified, and related criticalities, associated with performed tasks, were derived. To validate the proposed perspective, existing REMS implementations were explored, based on the tasks supported and criticalities addressed. Through this exploration, it was observed that while most of the systems provide the majority of identified tasks, several criticalities, such as data privacy and confidentiality are neglected, while others are partly satisfied. The fulfillment of such criticalities may contribute to a more effective design and implementation of such systems and, consequently, enhance user satisfaction and wider adoption of Health systems.

As future research directions, a further analysis of the proposed human-centric perspective should be conducted, utilizing standardized methodologies for modeling processes in human-centric domains, like the REMS use case. This can be also applied to other sensitive Healthcare systems, such as Smart A balance Services (SAS), and Remote Robotic Surgery (RRS), as well.

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