Requirements for Ambient Sensors that Enhance the Safety of Artificially Ventilated Patients

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Abstract— In the sophisticated setting of artificially ventilated persons at home errors or miscues can be lethally for the patients. Therefore, the joint research project "MeSiB" aims at implementing an Ambient Sensor System (ASS) that detects, among other things, care procedures and the state of the patients. Within MeSiB, these sensor values are further examined in a so-called "SafetyBox". If a critical situation is detected, an alarm will be generated and sent to an emergency alert or telemedicine station. This work focuses on the requirements for the ASS. Therefore, two different scenarios are presented. Furthermore, the process of the requirement extraction is described. The results of this work are comprised of the functional and the non-functional requirements for the ASS.

Keywords—Artificial Ventilation, Safety Systems, Ambient Sensors, Requirements Engineering, Home Mechanical Ventilation

I. Introduction

In the sophisticated setting of artificially ventilated persons at home, critical situations, which can be lethally for the patient, may arise [1]. Therefore, the research project MeSiB aims at implementing a safety system for these patients that also relieve their caregivers. As a part of this system, ambient sensors are used to identify the state of the ventilation device, the number of persons around the patient's bed and their activity. This sensor data will be transmitted to an Ambient Process Analyzer (APA) [2] that estimates the situation and transmits status values to a rule engine. The rule engine sends an alarm notification to an emergency alert station if a critical situation is detected.

As the bedroom area is a highly private space and the overall setting of artificially ventilated patients is complex, it is essential to follow a standardized requirement analyzation procedure for sensors in this area. In this work, the requirements for the ambient sensor system (ASS) are presented. Therefore, section 2 focuses on the background and the objective of this work. The methods for the definition of the requirements are presented in the third section. Finally, the requirements are presented in section 4 and discussed in section 5.

II. Background and Objective

There are numerous possible miscues or errors that may happen in a care setting at home. Therefore, it is impossible to define all errors or miscues that might happen and to tackle those within the project presented here. As this work focuses on patients that are ventilated at home, it was necessary to restrict the approach to error or miscue scenarios that are related to home ventilation. Therefore, two exemplary scenarios were defined at the beginning of the project MeSiB with the help of professional caretakers. These scenarios present two characteristic and dangerous situations for home ventilated persons and were used as a guideline to explicitly define the sensor requirements for the ASS.

A. Scenario 1: Disconnection

A disconnection of the patient from the ventilation device is a highly critical procedure, as it may be lethally for the patient if the patient is not reconnected early enough. However, some care procedures contain an intentional disconnection of the patient. In these cases, it is important that the caregiver does not forget to reconnect the patient. A similar problem exists with the deactivation of the ventilation device, which may happen intentionally or unintentionally.

To distinguish between intentional and unintentional disconnections and deactivations, general information about the situation in the room where the ventilation takes place is necessary. For instance, the SafetyBox needs to know whether caretaking activities are performed or whether there is somebody in the room while the patient is disconnected from the respiratory device. Summarizing, the SafetyBox needs insight in the situation within the patient's room.

B. Scenario 2: Blackout

The ventilation can be disconnected from the current supply due to a local or external blackout. In these cases, the ventilation device is supplied by the integrated battery. However, the ventilation is in this case only insured for several hours. Every home ventilated patient should have a second, fully charged, ventilation device at home but there are no structured procedures to monitor this [3]. Additionally, the second ventilation device is not sufficient if the blackout last longer, e.g. several days.

These scenarios are the background for the derivation of the requirements, even though they do not represent all of the errors or miscues that might occur in the complex setting of home ventilation.

III. Methods

To frame the requirements for sensors, discussions with experts were conducted, use cases were specified, and the guidelines for noninvasive and invasive ventilation from the German Respiratory Society [3] were analyzed. Additionally, interviews with caretakers were conducted. The requirements were defined based on the IEEE 803-29148:2011 standard [4]. Therefore, each requirement is described with a unique acronym, a name, a specific description and a priority. Additionally, it was ensured that the requirements are realistic and free of contradictions.

Three priority classes are used: "High", "Mid" and "Low". Requirements are considered to be of high priority if their non-fulfillment prevents the MeSiB system totally from working correctly. Mid-priority requirements denote parameters or preferences that are important for the MeSiB system, but not as critical as high-priority requirements. Finally, low-priority requirements describe mainly system parts that are used for further research purposes and are not critical for the MeSiB system.

IV. Results

The resulting requirements list can be divided into two subsections. The first contains the functional requirements, which consist of the requirements concerning the ventilation device, the number of people in the bed area, the detection of caregiving activities, the patient state, and the communication with the SafetyBox. The second subsection is comprised of quality, organizational, and ethical requirements.

A. Functional Requirements

In this subsection, the functional requirements are presented.

1) Ventilation Device State Change

Both described scenarios show that changes in the state of the ventilation device can have a significant impact on the safety of the patient. Therefore, five requirements were defined that specify which ventilation device state changes need to be monitored to enhance the safety of the patient.

Based on scenario 2, two requirements (F_E_1 and F_E_2) were defined: The local blackout and the external blackout requirement. These requirements define that the ASS should detect the occurrence of local or external blackouts. In addition to these requirements, scenario 2 constitutes the need to monitor whether the ventilation device is charged or not. As this cannot be measured directly with ambient sensors, it has to be monitored whether the ventilation device is in battery mode (F_E_3).

Another two state changes are the ventilation stop (F_E_4) and the device deactivation (F_E_5). These requirements are based on scenario 1 as the deactivation of the respiratory device may have the same consequences for the patient as a disconnection.

Table 1 summarizes the requirements concerning possible state changes of the ventilation device.

TABLE 1 Electricity Failure Requirements

No.	Name	Description	Priority
F_E_1	Local Blackout	The ASS shall detect whether a local blackout occurs.	High
F_E_2	External Blackout	The ASS shall detect whether an external blackout occurs.	High
F_E_3	Battery mode	The ASS shall detect whether the ventilation device is in battery mode.	Mid
F_E_4	Ventilation stop	The ASS shall detect whether the ventilation is ongoing or stopped.	High
F_E_5	Device Deactivation	The ASS shall detect whether the ventilation device is deactivated.	High

2) Person Count

As described in scenario 1, a disconnection can be critical if the patient is alone and this disconnection is not part of a caretaking procedure. Otherwise, a disconnection can be harmless. One possibility to provide information about the situation in the patient's room is to count the number of persons in the room (F_P_1) and in the bedroom area (F_P_2). Apparently, if there is no person present, a disconnection of the ventilation device has to be critical because it cannot be part of a caretaking procedure. Additionally, it is necessary to know whether one or more persons are present as this may change the alarm handling. If only one person is present, an alarm that forces this person to leave the room, e.g. to bring a new respiratory device, may not be appropriate. This is different if more persons are present.

For obvious reasons; it is also necessary to detect whether the patient is in bed (F_P_3). Otherwise, false alarms could be generated.

Table 2 summarizes the person count requirements.

TABLE 2 Person Count Requirements

No.	Name	Description	Priority
F_P_1	Number of Persons in Room	The ASS shall detect how many persons are in the room where the ventilation takes place.	High
F_P_2	Number of Persons in Bed are	The ASS shall detect the number of persons in bed area of the patient.	High
F_P_3	Patient in Bed	The ASS shall detect whether the patient is in bed.	High

3) Detection of Nursing Procedures

Following scenario 1, information about ongoing nursing procedures is necessary for the SafetyBox. However, it is necessary to formulate realistic requirements that can be accomplished with sufficient quality (see section quality requirements IV.B.1: Quality requirements). Therefore, only elements of caretaking procedures that supposedly can be measured with sufficient quality, like the bending over the patient (F_N_1) or contact between caregiver and patient

(F_N_2) are inserted with a high priority in the requirement list.

In addition to these high priority requirements, two more complex requirements were formulated: The detection of turning procedures (F_N_3) and endotracheal suctioning (F_N_4). Furthermore, it should be detected whether kinks emerge in the ventilation tube after these nursing procedures (F_N_5) were performed. As these requirements are difficult to achieve with sufficient quality they will be addressed with a somewhat lower priority during the implementation phase of the project.

The usage of an artificial lung (F_N_6) needs to be detected to be able to inform the SafetyBox that the patient is disconnected although the ventilation device is in an active state.

Table 3 shows the nursing procedure requirements.

TABLE 3 NURSING PROCEDURES REQUIREMENTS

No.	Name	Description	Priority
F_N_1	Bending of caregiver over the patient	The ASS shall detect whether a caregiver bends over the patient.	High
F_N_2	Contact between patient and caregiver	The ASS shall detect whether there is physical contact between the caregiver and the patient.	High
F_N_3	Turning procedure	The ASS shall detect whether a turning procedure is performed.	Low
F_N_4	Endotracheal suctioning	The ASS shall detect whether endotracheal suctioning is performed.	Low
F_N_5	Kinks in ventilation tube	The ASS shall detect whether kinks in the ventilation tube exist.	Low
F_N_6	Artificial Lung usage	The ASS shall detect whether an artificial lung is used.	High

4) Patient State

To achieve a high confidence that the patient is really ventilated, physical parameters of the patient have to be measured. Therefore, the measurement of the frequency of the rib cage movement can be used to determine whether the patient is actually ventilated (F_S_1). Additionally, the position of joints of the patient provides additional knowledge to whether a caretaking activity is performed (F_S_2). Finally, the measurement of the SP02 value (F_S_3) of the patient ensures that the patient receives sufficient oxygen.

Table 4 lists the requirements regarding the state of the patient.

TABLE 4 PATIENT STATE REQUIREMENTS

No.	Name	Description	Priority
F_S_1	Rib cage movement	The ASS shall detect the frequency of the ribcage movement.	Mid
F_S_2	Position of joints	The ASS shall detect the position of joints of the patient.	Low
F_S_3	SP02 Measurement	The ASS shall detect the SPO2 value of the patient.	High

5) Communication with the APA

Table 5 shows the communication parameters between the ASS and the APA. Every value will be transmitted with 1 Hz. Most values are implemented as Boolean values, while only few will be implemented as strings or integers.

TABLE 5 COMMUNICATION REQUIREMENTS

No.	Name	Data type	Frequency
F_E_1	Local Blackout	boolean	1 Hz
F_E_2	External Blackout	boolean	1 Hz
F_E_3	Battery mode	boolean	1 Hz
F_E_4	Ventilation stop	boolean	1 Hz
F_E_5	Device Deactivation	boolean	1 Hz
F_P_1	Number of Persons in Room	Integer	1 Hz
F_P_2	Number of Persons in Bed area	Integer	1 Hz
F_P_3	Patient in Bed	boolean	1 Hz
F_N_1	Bending of caregiver over the patient	boolean	1 Hz
F_N_2	Contact between patient and caregiver	boolean	1 Hz
F_N_3	Turning procedure	boolean	1 Hz
F_N_4	Endotracheal suctioning	boolean	1 Hz
F_N_5	Kinks in ventilation tube	boolean	1 Hz
F_N_6	Artificial Lung usage	boolean	1 Hz
F_S_1	Rib cage movement	int (frequency in Hz)	1 Hz
F_S_2	Position of joint	List of 3-dimensional float vectors	1 Hz
F_S_3	SP02 Measurement	Int	1 Hz

B. Non-Functional Requirements

In this subsection, the non-functional requirements are described.

1) Quality

As this work focuses on the implementation of a safety system, the parts of the ASS with high priority should have a high accuracy. Therefore, it is required that the precision and the recall of the high-priority measurements are at least 99 %. Accordingly, their false positive rate should not exceed 1 %. Still, with the measurement rate of 1 Hz, false positives could occur every 100 s, according to this requirement. However, as many sensors are used simultaneously in the MeSiB system, these false positives will be filtered with validation routines.

For the mid- and low-priority requirements the quality requirements are less restrictive as shown in Table 6 where the quality requirements are summarized.

TABLE 6 QUALITY REQUIREMENTS

No.	Name	Description	Priority
N_Q_1	High Priority Precision/ Recall	High Priority Measurements shall have a precision and recall of at least 99%.	High
N_Q_2	Mid Priority Precision/ Recall	Mid Priority Measurements shall have a precision and recall of at least 95%.	High
N_Q_3	Low Priority Precision/ Recall	High Priority Measurements shall have a precision and of at least 90%.	High
N_Q_4	High Priority False Positives	High Priority Measurements shall have a maximum false positives rate of 1%.	High
N_Q_5	Mid Priority False Positives	Mid Priority Measurements shall have a maximum false positives rate of 5%.	High
N_Q_6	Low Priority False Positives	Low Priority Measurements shall have a maximum false positives rate of 10%.	High

2) Organisational Requirements

The organisational requirements are important for two different reasons. First, they define necessities that ensure that the quality requirements will also be met in the long-run. Second, good organisation during the installation may improve the acceptance of the ambient sensor system. For instance, the installation may be disturbing for caretakers and patients, and should, therefore not take longer than four hours (N_O_1). Additionally, the sensor should be placed such that they do not disturb caretaking activities (N_O_2) and attached such that the sensors cannot be displaced unintentionally (N_O_3). To minimize the installation effort and the usage of cables, the sensors of the ASS should be powered by a battery (N_O_4).

Table 7 contains the list of the organisational requirements.

TABLE 7 ORGANISATIONAL REQUIREMENTS

No.	Name	Description	Priority
N_O_1	Installation Time	The Installation of the ASS shall not take longer than 4 hours.	Low
N_O_2	Placement	The components of the ASS shall be placed such that they do not disturb the regular. Care	Mid
N_O_3	Attachment	The components of the ASS shall be attached such that they can not be displaced unintentionally.	Mid
N_O_4	Battery powered	The components of the ASS shall be powered by a battery.	Low

3) Ethical Requirements

As cameras and microphones are not well accepted in Germany [5], where the MeSiB system will be tested, they should not be used. Another reason to not use these highly invasive devices is the recently published EU data protection regulation [6]. Therefore, requirements restricting the use of cameras and microphones are part of the ASS requirement list. Additionally, the caregiver and the patient should always be able to turn all monitoring systems down.

The ethical requirements are presented in Table 8.

TABLE 8 ETHICAL REQUIREMENTS

No.	Name	Description	Priority
N_E_1	Cameras	The ASS shall not contain cameras	Mid
N_E_2	Microphones	The ASS shall not contain Microphones	Mid
N_E_3	Disabling	The Caregiver and the patient shall be able to turn the ASS off.	High

V. DISCUSSION

The requirements presented in this work are the basis for the development of the ambient sensor system within the research project MeSiB. However, the requirements are subject to changes during the implementation phase of the project, what is typical for requirement lists in research projects.

Based on the requirement list, it was decided that the ambient sensor system will be comprised mainly of four sensor types:

- RGB-D (RGB + Depth)
- Power Sensor
- Infrared Array Sensor
- Passage Detector

Additionally, an oximeter will be used to measure the SPO2 value of the patient.

The RGB-D sensor will be used to monitor caretaking activities according to the nursing procedure requirements. Although the usage of this sensor is contrary to the ethical requirement N_E_1, the sensor will be used because otherwise the requirements for detection of nursing procedures were not achievable. However, the algorithms for this sensor will be implemented such that the ASS is not able to identify persons and only the minimum amount of data, which ensures the detection of nursing procedures according to the quality requirements, will be generated.

The power sensor will detect the state of the respiratory device and detect whether local or external blackouts occurred. Therefore, a central power sensor will be used that measures the current supply of the whole apartment and detects the state of the respiratory device using techniques of nonintrusive load monitoring [7].

The Infrared array sensor and the passage detector will be used to derive general information about the status of the room (number of persons, patient in bed,…). The passage detector will be placed at the entrance of the room. The infrared array sensor will be placed on the ceiling above the bed area. Machine learning algorithms will be trained to analyze the data from the infrared array sensor.

Within the SafetyBox, filtering algorithms will be implemented to reduce false alarms. It is known that multi-modal sensor systems can achieve high accuracy if used with ensemble methods [8].

The complete setup will be tested in two environments during the next two years. First, it will be tested in a hospital where caretakers are trained for the caretaking of artificially ventilated persons. Second, the system will be evaluated in a field study at artificially user's homes.

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