

## Requirement Specification and Modeling a Wearable Smart Blanket System for Monitoring Patients in Ambulance

### Abstract

**Background:** Nowadays, the role of smart systems and developed tools such as wearable systems for monitoring the patients and controlling their conditions consistently has increased significantly. The present research sought to identify the factors which are essential for designing a wearable smart blanket system and modeling the proposed systems. **Methods:** To this aim, the requirements for creating the proposed system in ambulance were described after determining the features related to wearable systems by conducting on a comparative study. First, some studies were performed to identify the wearable system development. Then, the elicited questionnaire was given to the physicians and medical informatics specialists. Finally, the extracted requirements were implemented for modeling a smart blanket system. **Results:** Based on the results, the wearable smart blanket system includes some specific characteristics such as monitoring the important signs, communicating with the surroundings, processing the signals instantly, and storing all important signs. In addition, they should involve some nonfunctional characteristics such as easy installment and function, interactivity, error fault tolerance, low energy consumption, and the accuracy of sign stability. Then, based on the requirements and data elements extracted from the questionnaire, the system was modeled as a detailed design of the proposed technical blanket system. Based on the results, the architecture of the designed system could provide expected scenarios by using the Active Review for Intermediate Design-oriented scenario-based evaluation method. **Conclusion:** Today, smart systems and tools have considerably developed in terms of monitoring the patients and controlling their conditions. Therefore, wearable systems can be implemented for monitoring the health status of patients in ambulance.

**Keywords:** Smart sensors and fibers, vital signs, wearable smart blanket requirements, wearable systems

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### Introduction

Today, the smart systems and advanced tools have significantly increased for monitoring the patients and controlling their conditions immediately. The ability of such smart systems in storing and transferring data has attracted a lot of attention in different fields of health care (e.g., telemedicine). Wearable technology is one of the recent technologies in this regard.<sup>[1]</sup>

Wearable systems are mainly used for monitoring the symptoms and status of patients, follow-up, telemedicine, nursing and medical team systems, surgery robots, and many other systems.<sup>[2]</sup> One of the special features of wearable systems is that they are continuously associated with

the patient since the physician has always access to his patients and receives their information everywhere.<sup>[3]</sup>

Monitoring refers to the action of watching the patients and warning the serious and threatening events, fatal diseases, and the like.<sup>[4]</sup> The term “monitoring” is normally used in the emergency ward of medical centers because the conditions of emergency patients are unstable and monitoring their symptoms helps the patients with diagnosis and treatment. Patient monitoring announces the threatening events to caretakers, and most of such systems use the physiological input data for controlling the support tools directly.<sup>[4]</sup>

The continuous monitoring of disease symptoms is needed in ambulance due to the emergency and unstable conditions of

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patients. Thus, the timely and managed intervention can reduce the consequences due to disease and sudden death if the patient is in emergency conditions.<sup>[5]</sup> In addition, monitoring the patient in emergency conditions requires the fast and accurate decisions to help the patient survive. For this reason, the medical team in ambulances is in charge of monitoring the patients in emergency conditions.<sup>[4]</sup> Thus, the immediate information of life-threatening events is considered as one of the objectives of clinical monitoring of the patients in ambulance under emergency conditions so that they should be treated to prevent from causing any harm or disabling the patient's body.<sup>[3]</sup>

Accordingly, the time and speed of monitoring these patients in ambulance under emergency conditions are highly critical.<sup>[6]</sup> On the other hand, connecting different devices in the ambulance to the patient's body is time-consuming. In such conditions, time is highly important. Furthermore, using different monitoring systems for recording the symptoms occupies the whole space of ambulance due to its small space. Some of these current monitoring systems have limited measurement accuracy. Further, recording the accurate data are regarded as one of the main fundamental parameters of monitoring. Sometimes, such systems make errors in recording the data. Thus, using these systems in ambulance leads to some problems such as difficult installment, reliability, energy consumption, installment time, and vital data transfer. Thus, the present study aimed to seek for the tools to monitor the vital signs in the emergency conditions due to the development of medical technologies. Portable smart monitoring tools should involve specific features. An accurate needs assessment should be conducted for designing wearable smart blanket system appropriately to monitor the vital signs of patients in ambulance. The fundamental capabilities should be extracted, along with all key features. Therefore, the present study seeks to monitor the vital signs of patients in emergency conditions with an integrated and wearable sensor-based system.

Therefore, the use of wearable sensors for monitoring vital health-related biomarkers in humans has been considered with respect to the advancement of computer science and communication. In this regard, a large number of studies have been conducted on wearable systems, among which some of these wearable wireless networks are listed below. Anliker *et al.* introduced a multi-parameter wearable medical monitoring and warning system, specifically for respiratory and cardiac patients. The designed system could perform continuous evaluation and monitoring of various vital signs, and identify multiple emergency parameters.<sup>[7]</sup> Eom K *et al.* introduced a smart blanket in Japan including a collection of wireless sensing units which only captured and transmitted vital parameters to the body.<sup>[8]</sup> The BASU Consortium gathered science and technology experts from the field of electronics, communications, and medical engineering to develop a distributed wireless system for monitoring chronic patients in health centers and homes

continuously. The BASUMA project was primarily designed for improving the treatment of patients with pulmonary obstruction, due to the global progression of the disease.<sup>[9]</sup> In another study, Lorussi *et al.* introduced a wearable textile platform for assessing stroke patient treatment in daily life by developing wearable sensing platform based on the sensor fusion among inertial, knitted piezoresistive sensors, and textile electromyography electrodes.<sup>[10]</sup> Mokhlespour Esfahani *et al.* designed a printed body-worn sensor for measuring the human movement orientation, based on conductive flexible nylon/lycra fabric strain gauge.<sup>[11]</sup> In addition, Chae *et al.* concluded usability evaluation of smart clothing and proposed evaluation factor and object through user-centered evaluation process. In fact, they examined some empirical data obtained from observation evaluation and wearability evaluation (WE).<sup>[12]</sup> In another study, Schall *et al.* discussed some barriers to the adoption of wearable sensors in the workplace including the related concerns with regard to the privacy/confidentiality of the collected data among the employees and their compliance, sensor durability, the cost/benefit ratio of using wearables, and good manufacturing practice requirements.<sup>[13]</sup> Further, Claudio *et al.* focused on the usefulness and ease of using wearable sensor-based systems in emergency departments, which was evaluated based on the viewpoints of patients and nurses in emergency departments.<sup>[14]</sup>

By considering the above-mentioned studies, the present study aimed to analyze the facilities and capabilities provided for wearable smart blanket for monitoring the patients and suggest the appropriate design requirements of an integrated monitoring system for different groups in healthcare. In addition, the proposed system was modeled based on functional and nonfunctional requirements by using the Unified Modeling Language (UML). Therefore, the relationships between components, systems, and users in the proposed system were designed and accordingly the structural and behavioral aspects of the proposed system were modeled by implementing UML diagrams.

## Methods

The present study is based on a descriptive and development design. First, the necessary requirements for designing a wearable smart system were discussed to satisfy most of the needs in healthcare after evaluating the features presented by the current wearable systems with respect to monitoring the health status of patients and classifying these systems to fiber-based systems based on a comparative study.

## Instruments of the study

First, the data were collected to specify the expected capabilities from the wearable smart blanket. A number of 20 studies and electronic books with keywords "design requirements of wearable system," "capabilities of wearable systems," "wearing comfort and acceptability," and "usefulness and ease of using wearable systems"

were studied for extracting the capabilities. Then, a researcher-made questionnaire including data elements and capabilities obtained from the study steps was used to determine the functional and nonfunctional requirements. The questionnaire was designed based on a 5-point Likert scale for evaluating the significance of elicited requirements in three main areas including the functional features of the system software, structural features of smart blanket, patient portable unit, and nonfunctional requirements of the system software. The questionnaire had 60 items, scored from 1 to 5 (totally disagree, disagree, no idea, agree, and totally agree). In order to collect the related data, a total of 20 physicians and technicians were selected based on convenience nonprobability sampling (the total score of each question was 100). The items with the score (Absolute frequency) higher than 80 were considered as prioritized requirements. Then, Cronbach’s alpha was used to measure the reliability of the questionnaire ( $r = 0.82$ ). In addition, the content validity was used to investigate the validity of the questionnaire. To this aim, the designed questionnaire was studied by a group of experts including two physicians and one faculty member of Medical Informatics to confirm the validity.

Finally, the data obtained from the questionnaire were analyzed by SPSS 16 software (SPSS Inc.). For this purpose, the absolute frequency values for each question were calculated based on the descriptive statistics.

### Modeling method

All requirements extracted from the previous steps were developed in the form of a software requirements specification (SRS). Designing and modeling the smart wearable blanket system were discussed based on the document template. To this aim, the UML language was used. The class diagram was designed based on the system components and their relationships, and the system interaction with its environment was designed based on the use case diagram. Further, the activities in critical processes were mapped using activity charts and sequence diagrams for the sequence of events. Finally, the deployment diagram indicated the establishment of the system modules and the component diagram illustrated the relationship between the components of the system.

### Results

The requirements of software system were divided into functional and nonfunctional requirements.<sup>[15]</sup> The requirements specifying the services provided by the system, the response to specific inputs, and the reaction in specific conditions are called “functional requirements.” Nonfunctional requirements are the limitations which are applied to the system services or influence the system.<sup>[15]</sup>

Defining an appropriate scenario is required for the early phase of modeling the wearable smart blanket system for monitoring the ambulance patients. For this purpose, the

**Table 1: The main factors for developing the wearable systems in the field of health care**

Requirement/characteristics	Requirements/characteristics
Wearability	The system should be based on low weight and small size <sup>[11]</sup>
Easy use	The system should be designed in such a way that it can be easily and effortlessly designed and user-friendly <sup>[12]</sup>
Appropriate replacement of sensors to the areas of body anatomy	The sensors should be easily located in different areas without obstructing the movement and daily activity of the individual <sup>[13]</sup>
Security and data encryption	The transmission of medical signals should be encrypted and the requirements for identification should be considered for the privacy of the individual <sup>[13]</sup>
Warning ability	The system should have alert and warning capabilities for the user <sup>[13]</sup>
Reliability/functionality	Medical signals should be recorded with enough accuracy to ensure that they are reliable and that results can be obtained <sup>[12]</sup>
Reliability	The monitoring system should be designed in such a way that it can be used for long-term monitoring <sup>[12]</sup>
Cleansing/disinfecting ability	The system should be designed in such a way that it can be cleaned and disinfected <sup>[13]</sup>
Proper appearance	The system should be designed to have a proper appearance, without creating any discomfort for the person <sup>[14]</sup>
Data transfer/storage	The transmission of data should be performed by standard communication protocols and sufficient memory to store the vital signs <sup>[13]</sup>
Affordability	Sufficient budget should be considered for designing and modeling <sup>[15]</sup>
Fault tolerance (tolerability)	The system should produce reliable results under all circumstances such as patient movement <sup>[12]</sup>
Scalability	The system should have the ability for upgrading, and the software components should be updated for the developed system <sup>[13]</sup>
Ability to support decision	The system should be designed to be smart enough to provide the user with sufficient performance <sup>[13]</sup>
Ability of receiving signals	Biomedical sensors play an important role in designing wearable systems in the health domain and they should be able to record vital signs, assess comprehensively, and predict patient conditions <sup>[13]</sup>
Efficiency	The system should operate correctly at the same time during difficult conditions. For example, inadequate skin contact, poor communication, poor battery should not create artifacts for the system <sup>[13]</sup>
Instant processing	The system should be able to transfer and process the data received from the patient’s body <sup>[12]</sup>

electronic books on the wearable system requirements in the field of health care were studied. The main factors for designing and implementing the health wearable systems were extracted from the papers as shown in Table 1.

First, the general structure of the proposed system was evaluated, and then, the selected requirements were shown in Table 2. The general structure of wearable smart blanket system has the following subsections:

### Blanket bedding with the sensors installed on

- Smart blanket bedding includes the antibacterial and antiallergy materials to guarantee the long term and safe use
- The connections between the sensors are created through conductive yarns to make it easy for wearing. The blanket is in the standard size to work for males and females (but small sizes should be made for children).

### Portable patient system

It is a device which is used for receiving, storing, and transferring the data collected by sensors. All sensors and fibers installed on patients are connected as wireless or through conductive yarns to the portable patient unit. Such units receive all of the data related to vital signs and make some processes. After the relative processing, the portable patient unit sends the received information to the physician with the help of physician assistant. The above-mentioned unit can send the information to the system software through Bluetooth.

- This device is connected to the blanket through conductive yarns, and some sensors transfer the data as wireless
- This device receives the data through sensors/electrodes
- This device measures the voltage through the piezoelectric sensors
- This device processes the electrocardiography (ECG), respiration rate, and photoplethysmogram (PPG) to obtain the heart rate, blood pressure, changes of heart rate, and respiration signals.

### Complete software

The physician assistant or the physician system has complete and comprehensive software, which is able to analyze, compare, and process at a high level by complicated algorithms. All data related to vital signs and medical signals are sent from the portable patient unit to the physician assistant. In addition, the physician assistant announces all required warnings at the time of vital risk event for each person and displays all medical signals graphically and numerically to the physician. The general tasks of the wearable system software are as follows:<sup>[16]</sup>

- Recording the data through the data flow
- Downloading the data on physician assistant (the

data which were stored and collected by the portable patient system)

- Analyzing the recorded data graphically and numerically
- Transferring the data as wireless to the hospital system
- The complicated signals processing algorithms.

Controlling some physiological and vital signs is necessary for monitoring the health status of the patient in ambulance. Thus, recording the ECG, blood pressure, temperature, blood oxygen saturation, heart rate, and respiration rate are essential for such patients.<sup>[15]</sup> Finally, this study recorded five vital signs of the body by using the wearable smart blanket after analyzing the questions responded by the physicians.

### Identifying suitable sensors for recording vital signs

#### Temperature

The platinum thermistor inside the elastic ambient can be used for recording the body temperature of the person in emergency conditions. In this proposed system, the sensor with its ambient was installed on the auxiliary. Axillary had the closest skin temperature to the central temperature of the body.

#### Respiration rate

Electroactive polymer fiber can be used for recording the respiration rate of the patient in ambulance. Since the person in emergency conditions is fixed, the artifact of moving will not be involved with the respiration rate. However, the strings with sensor connected to the blanket were used due to the significance and location of sensors. Such elastic strings should be tied firmly on the back to let the sensors record the respiration rate signals appropriately.

#### Heart signals

The silver-coated polymer foam fibers can be used for recording the heart signals by the wearable smart blanket because these fibers have some significant properties such as high conductivity, elasticity, and are antibacterial. The algorithms of filters such as an adaptive impulse correlation filter should be used to reduce the noise in the recorded signals. In recording the ECG, the signal should be standard, and all noises on the signals should be removed if the R peaks are identified. For this reason, the adaptive filter can be used, along with the low-pass filter. The heart arrhythmia can be evaluated, and heartbeat should be obtained by using the R\_R peak distance when the R peaks are appropriately identified.

#### Oxygen level of blood

Thin light sensors, which are stuck to the fingers like adhesive bandage, can be used to monitor the blood oxygen level, and announce the shortage of oxygen. In this case, the green and red light emitting diodes made of organic matter and integrated on resilient plastic piece can be used. Such sensors include a wrap for wrapping the finger. This

wearable probe has a photodetector receiving the emitted light and converting it to an electric signal.

### Blood pressure

In order to record the blood pressure, the other tools and parameters can be used for reducing the cuff and attack. In this system, the blood pressure is estimated by ECG and PPG signals. Pulsed pulse time (PPT) is considered as a potential parameter for estimating the blood pressure without cuff. The distance from the electrocardiogram peak to the peak of the PPG signal and the distance from the peak of the electrocardiogram to the valley (lowest point) of the PPG signal were used for the diastolic blood pressure of at least PPT.

### Describing the requirements for wearable smart blankets

The requirements of the wearable smart blanket system as functional and nonfunctional requirements, along with the absolute frequency of questionnaire items, were discussed from the perspective of all respondents. Table 2 indicates the requirements of wearable smart blanket system.

According to the studies and analysis of the responses provided by physicians and specialists, a questionnaire designed for all subjects with a score of over 80 was selected as the requirements for designing a wearable smart blanket. These requirements were divided into functional, nonfunctional, and physical requirements, as shown in Table 2, along with the score for each item.

Now, the case-application charts, component, deployment, class, activity, sequence, and UML software are plotted for modeling a wearable smart blanket. Some of these graphs are illustrated by the example below. Figure 1 displays all classes related to wearable smart blanket system.

The component diagram in this study indicated the relationship between the system components. A component is a changeable unit of the system with hidden details, and its behavior is shown through some interfaces. In addition, it describes a set of classes, which are packed physically in the object-oriented method.<sup>[11]</sup> Figure 2 illustrates the components of wearable smart blanket system.

The deployment diagram shows the deployment of software and hardware systems in physical modes and technology context.<sup>[13]</sup> Such a diagram is used for modeling the deployment of systems (configuration) at the implementation time. The deployment of proposed system is illustrated in Figure 3.

### Discussion

In the present study, UML diagrams were demonstrated in different views. Now, the designed architecture is discussed by using the Active Review for Intermediate Design (ARID) scenario-based method.

Unlike the other scenario-based evaluation methods for analyzing the complete architecture of a system, the ARID method focuses on the partial design of different parts of

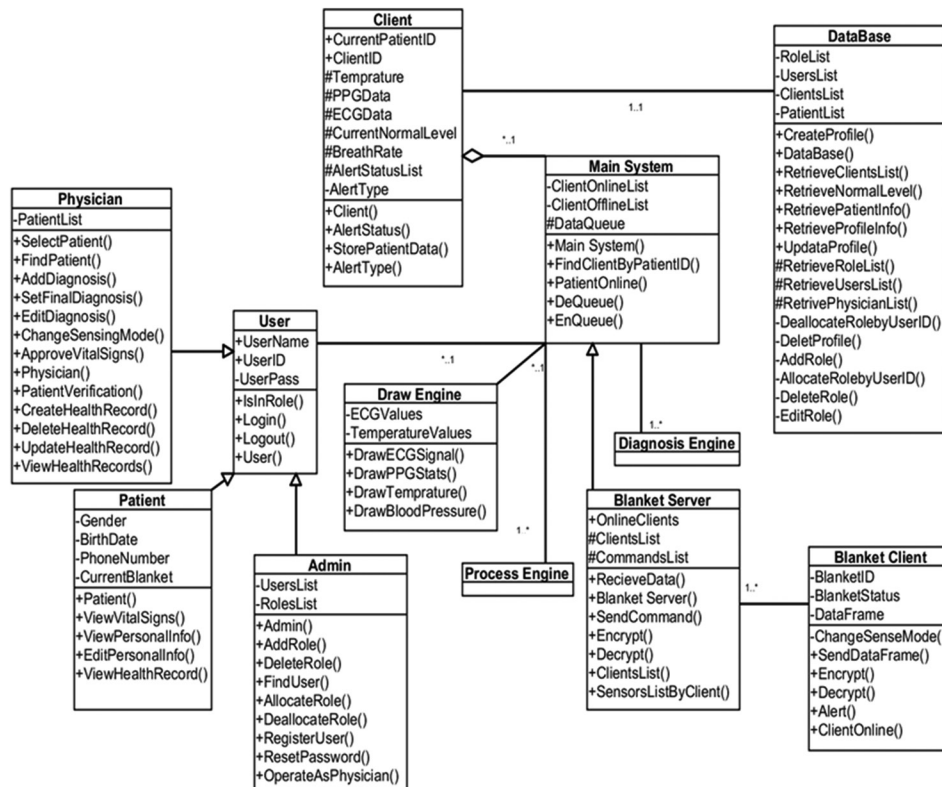


Figure 1: The classes and relationships between the variables

**Table 2: Wearable smart blanket system requirements**

Absolute frequency of each item	The requirements of system software (physician assistant)	
	Description of requirements	System functional requirements
97	The ambulance physician should be able to do the registration by username and password, and log in and out	The ability of registering, logging in, and logging out of the system software
83	Due to the fact that a person in an emergency condition may not be able to tell his national code, his history is displayed to the physician by using the patient fingerprint for all the medical information	The possibility of communication between the system software and the electronic health record for biometric authentication by patient fingerprints
90	The ambulance physician should insert the age and gender of the patient into the system software so that normal and abnormal findings (e.g., heart rate based on age and gender) are processed and presented accurately	The ability to record the age and sex in the system software by the physician
90	The physician should be able to determine, if applicable, the threshold values for all vital signs. Otherwise, the default settings of the system are applied	The ability to set threshold limits for all vital symptoms by physician in the system software
81	The software system should receive all the vital signs from the central node, and the portable unit of the patient wirelessly	The ability to receive information from a sensor set (patient portable unit) by software
93	The software system should display graphical and numerical symptoms, and report the health status of the individual	The ability to display vital signs and medical signals and patient status by software
96	Some alerts should be made when the vital signs exceed the normal thresholds. In other words, the system software should allow immediate feedback to the physician	The ability to generate alert by system software to alert emergency conditions to physicians (alarm module)
95	-	The ability to record differential diagnosis, diagnosis, and treatment by the physician
97	The software system should display the signals and vital data numerically and graphically so that the physicians can easily make their own diagnosis	The ability to analyze the data recorded in numerical and graphical form by software system
90	All patient clinical information is transmitted to the hospital through the internet infrastructure in the case of needing any counseling	The ability to communicate system software between ambulance physician and health center physicians
96	In the system software, the patient file is saved in the treatment center after storing his name	The ability to store symptoms and file for the patient in the software system
92	Having an acceptable level of intelligence for analysis Extracting useful knowledge and information from the raw data Extracting vital features such as extracting heart rhythm, QRS period, heart rhythm fluctuations, detecting cardiac waves, identifying minimum and maximum PPG signals	Filterability, feature extraction, optimization, high level processing by software
<b>Wearable smart blanket system (fiber/sensors) and portable patient unit</b>		
81	-	Selecting the exact number of sensors to record each symptom
82	Long-term installation of the sensors should not cause allergy and inflammation	Non-allergy sensors and fibers (fiber and sensors)
85	Correct placement of sensors and electrodes	Selecting the exact location of the sensor installation to record vital signs precisely
86	The individual state and position of his limbs are important for recording medical signals	Considerations about the individual's state when signing up
87	The person is asleep and his hands are altitude with his body Fixed and ideal contact between the patient's body and sensors to get the correct data (very close and continuous contact without any movement)	Ensuring the constant and ideal contact between the sensors and the patient's body
80	The wearable system should be standardized for different ages and gender. In this context, the body size and anatomical shape of the male and female body should be standardized to design a blank blanket. Measuring the physical characteristics of the body and identifying gender differences is considered as important stages	Perfect blanket size
83	Sensors, microcontrollers, fibers, and lightweight devices should be used for designing. Heavy weight will cause the patient's discomfort	Suitable blanket weights

*Contd...*

**Table 2: Contd...**

Absolute frequency of each item	Wearable smart blanket system (fiber/sensors) and portable patient unit	
	Description of requirements	System functional requirements
83	Considering that wearable wearing system is used for patients in certain circumstances, you need to be able to rinse and disinfect different sensors. This action prevents the transmission of contagious diseases. However, washing and disinfection should not result in irreversible damage to the system	Washing and disinfecting ability for wearable blankets
81	In designing a smart blanket, shoulder width, body length, upper chest width should be standard for adults	Required dimensions to design standard blankets Shoulder width Body length Top chest width
80	The blanket should be as jumbled, flexible, lightweight as possible so that the sensors can be placed at the desired location for recording signs and provide the elasticity of the blanket contact between the electrode	Blankets made of soft cloth, polyester, knitted linen
82	The sensors having relative conductivity should be used. In some cases, wetting electrodes is beneficial for receiving the signals quickly	The selection of fibers and sensors with relative conductivity*
95	The body temperature should be recorded every 15 min	The ability of recording and storing body temperature cycles
82	The armpit has the closest temperature to the central body temperature. The thermistor is in a perfect contact with the skin. The sensor is stationary in a blanket area, which is easy to hold and record the temperature of the body	The exact location of the thermostat as an anatomical area of the armpit
83	Recording respiratory rate: Continuous recording	The ability of recording and storing the respiratory rhythm
90	These sensors record the movements of the chest and abdomen, by which the respiratory signals of the individual are obtained	The detailed location of the sensor installation of several anatomical regions Electrode in the chest between the electrodes of the ECG Electrode in the abdomen between the electrodes of the ECG
90	Electrocardiogram recording: Continuous recording	The ability of recording and storing ECG signals continuously
95	RA: The right side along the arm LA: The left side along the arm LL: The left side of the stalk RL: Right side of stroke V1: In the interdental space, the right side of the chest near the jib	The exact location of installing ECG electrodes in order to have higher quality signals: RA, LA, LL, RL, V1
90	Oxygen saturation registration: Continuous recording	The ability of storing and storing oxygen saturation continuously
90	As the fingers have a thin skin, the changes in blood volume and saturation of oxygen at the tip of the finger and the radial artery should be linear for recording the oxygen saturation and PPG signals	Precise location of PPG recorder installation, SpO2 finger pointer
96	Blood pressure record: Continuous recording	The ability to record and maintain blood pressure permanently
81	A wearable oximeter is used for PPG signals. Fiber electrodes are used to record ECG signals. Thus, continuous blood pressure is obtained through computational signals in the above signals	Measuring the blood pressure of the PPG and recording the ECG signals as follows An infrared light sensor with a wavelength of 900 nm for recording PPG signals Individual ECG by smart electrodes
90	Heart rate record: Continuous recording	The ability of recording and saving continuous heart rate

*Contd...*

**Table 2: Contd...**

Absolute frequency of each item	Wearable smart blanket system (fiber/sensors) and portable patient unit	
	Description of requirements	System functional requirements
82	The physician's smart system recognizes the distance of the R-rays and examines the patient's heart rate, along with heart rate fluctuations. Due to the energy constraints and the intelligence of the patient's system, the patient's electrocardiogram can be used to identify indicators such as heart rate, heart rate fluctuations without having to install a separate recording sensor	The use of an electrocardiogram which is processed and optimized to monitor heart rate
<b>Nonfunctional requirements for wearable smart blanket system**</b>		
90	All information about the age, sex, vital signs, mental illnesses, and sexually transmitted infections should be encrypted using encryption techniques	The use of some techniques such as encryption to transmit data safely to a health facility
83	Secure information should be sent between an ambulance doctor and a doctor at a treatment center	The possibility of secure electronic communication
83	Identifying who, when and, what access to the system has been made available to the system, and where and when the operation is performed on the system	Providing audit capabilities to access and use the system
85	Using some methods such as the use of a username and password for physicians, identifying patients, and entering a national code in a situation where a person can tell his own person (if a person is sick and cannot tell his own national code, using the fingerprint can be done with the system for contacting him and his code will be extracted and his clinical information will be obtained and authenticated)	The authentication of some entities such as patients, ambulance physicians, and medical center physicians
84	Modifying the system administrator access to the system	The ability to remove access to each person's information by the system administrator
87	A unique username and password should be at least 10 characters for each physician	The allocation of unique password for each person
88	The amount of work done per unit time	Response time
92	The time should be minimized for the various operations such as signing, transfer, storage, and processing	The speed of the operation
83	The restoration and recovery time should be as sensitive as possible	Restoration and recovery time
94	The system availability is available 24 h a day, 7 days a week	Availability
96	Algorithms and software can be upgraded in certain circumstances (open source)	Interactivity
86	The accuracy of the system functionality is important for personnel and users	The data should be recorded in a way that health personnel can ensure their accuracy
87	The system should be designed in such a way that the defects can occur with the least repeat	The repetition and severity of defects and faults
88	The existence of educational documentation for system application and installation of sensors is necessary	The accessibility, accuracy, and clarity of the training system

\*Conductive fibers; \*\*WSBS. WSBS – Wearable smart blanket system; PPG – Photoplethysmogram; ECG – Electrocardiography

the system. Thus, this method can be used for evaluating the incomplete architectures. The ARID method aims at supplying the user's requirements.<sup>[17]</sup>

In this study, two software experts and two ambulance physicians formed the review sessions. The above-mentioned scenarios expressed the services, which could be provided by the system. Such scenarios were categorized based on the system services. The evaluation scenarios of the proposed system included logging into the system, monitoring the vital parameters, processing the vital signs, consulting, treating, and interacting between the physicians and the system.

In the scenario of logging into the system, the ambulance physician logs in the system software by entering his

username and password. In case of any problem in entering the username, the physician's information will not be saved as the system user. If all identity and personnel information of the physician is correct, the username and password will be sent to his E-mail. The ambulance physician enters the system by entering his username and password. If necessary, the relevant physician can receive a training program about how to install sensors, activate and deactivate them, and change the number of sensors.

Then, the scenario of monitoring vital parameters was examined based on the wearable smart blanket system. Wearable smart blanket is a system, which is put on as a



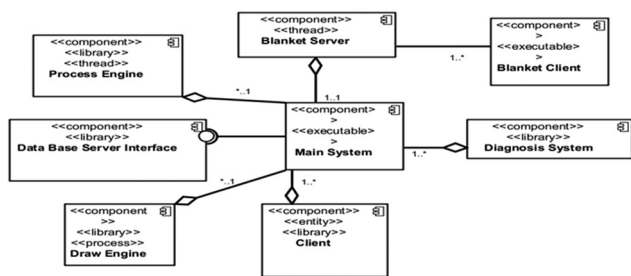


Figure 2: The component of the proposed system

dress on the person and has fabric sleeves to fix the blanket on the patient. Such a blanket has medical sensors measuring the vital signs of the body, along with the electrocardiogram, and these vital signs include respiratory rhythms, body temperature, heart rate, blood pressure, and blood oxygen levels when the ambulance is moving. A sensor set is required to record any of the vital parameters. The size of each parameter is often collected and transmitted wirelessly to a central node. The individual biological signals are recorded and sent to a portable unit. Depending on the monitoring command (active or inactive), the sensor set starts to receive the signals from the patient’s body. All recorded vital parameters are sent to the patient’s portable unit providing the local storage and preprocessing the signals and signs. All preprocessed information is transmitted wirelessly to the physician assistant having a high level of interpretation, processing (noise reduction), stream control coordination, and visualization of information. The reminder is one of the most effective control classes affecting the monitoring, counseling, and treatment of patients. Such a class declares the reminder based on the request form of the physician. The physician can apply the changes to the reminder settings after entering his username and password and accordingly enter the patient’s age and gender in the system to process the patient’s vital signs based on his age and gender. Furthermore, the physician can record all his final and differential diagnosis on the system. The physician assistant system (system software) displays the vital signs and medical signals of the patient numerically and graphically. The ambulance physician sets the threshold for the entire patient’s vital signs based on the patient’s conditions. Otherwise, all thresholds for the symptoms are compared with the defaults of the monitoring system. In order to continuously monitor the patient, the smart blanket system has the function of continuously recording the electrocardiogram signals, blood oxygen saturation, blood pressure, heart rate, and respiratory rate presenting the body temperature periodically (once every 15 min) to the current physician.

Regarding the scenario of processing vital signs, the raw data are sent to the patient’s portable unit, and preprocessing is applied to the information after recording vital signs of the body with sensors installed on the smart blanket. All information is sent wirelessly to the system software. The ambulance physician enters the patient’s gender and age in

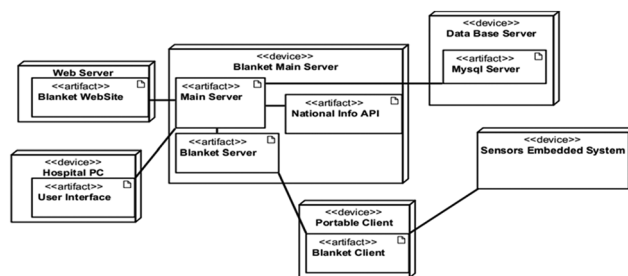


Figure 3: The deployment of the proposed system

the software to process and present normal and abnormal findings accurately (e.g., heart rate based on age and gender). In addition, the ambulance physician sets the maximum and minimum vital signs to warn the system when it exceeds the threshold. The ambulance physician can activate or deactivate each sensor set and change the number of sensors (electrodes) to record the signs. The system software receives all information from the sensor set. All vital signals are interpreted by complex implementation algorithms. For example, the system software should be able to interpret electrocardiogram signals, display distances between waves, name the waves (wave detection), and identify and classify the heart rate in 60 s. In addition, the software can calculate the percentage of saturation of oxygen in the blood and displays it in a numerical order. This software should display graphical rhythm disturbances and maximum and minimum respiratory rates over time. The system can calculate the blood pressure indirectly from the ECG and PPG signals and display the pulse pressure. Furthermore, the physician’s interactions with the system are as follows:

- Setting the threshold for recording the vital signs: The ambulance physician can change the threshold for each vital sign after entering the system, in case of worsening the patient’s current condition, or he can the normal and abnormal findings of the patient based on the above-mentioned factors by entering the patient’s age and gender
- Recording the patient-related diagnosis: After recording and saving the vital signs and medical signals by the different sensors of wearable smart blanket, all relevant interpreted information is displayed to the ambulance physician. After examining the interpretations provided by system, the physician enters the patient’s final and differential diagnosis in his temporary file and enters all medical decisions with the limits of clinical measures in the system
- Receiving the patient information from the electronic health record: Since the person in emergency conditions cannot express his national code, all medical information is displayed to the ambulance physician by the patient’s fingerprint. All patient records, drug allergy, health information, and mental health information are shown to the physician so that he can make his medical decisions based on the received information
- Requesting for a consultation: If the ambulance

physician requires consultation with the physicians of medical centers while transferring to the hospital, he can request for a consultation with the relevant physicians. The ambulance physician can send the patient's vital information to the system in the center to provide a voice, video, text message, and help the physician with the differential diagnosis of the patient and provide short-term treatments (during the patient's transfer) to the hospital. According to ARID scenario-based evaluation, the designed architecture and considered relations in the proposed system can provide the functions and scenarios desired by the users of the system. Therefore, it is possible to monitor the patient's vital signs better and more effectively and provide the biosignals of the patient by using smart and blanket, which can provide the quality health care, reduce the care costs, and increase the patient satisfaction with the received care.

In this regard, the present study aimed to model the wearable systems to control the vital signs of the patients in ambulance. The wearable smart blanket system includes the capabilities and designing requirements which allow for the continuous monitoring of vital signs of the patient such as heart rate, blood pressure, oxygen, blood, and so on. The smart wearable blanket collects the data from the sensor on the blanket on the medical signals while such data are processed and interpreted by the intelligent system. The information obtained from the patient's conditions helps the ambulance physician to provide adequate intervention without delay. The proposed wearable smart blanket system allows the continuous patient monitoring in emergency conditions. Further, the above-mentioned system registers all the vital signs needed to control individuals and provides interpretive data for the ambulance team, compared to other wearable systems. All sensors and electrodes installed on the proposed smart blanket are connected through the conductive yarn and sometimes wireless to the portable unit of the patient while the total energy consumption of the system is provided through this unit. All systems for registering symptoms in the ambulance environment require direct intervention by the physician in the ambulance. Furthermore, recording the information is absolutely instantaneous, and the only function of the set of systems available in the ambulance is related to recording some limited symptoms such as blood pressure, oxygen saturation, glucagon, and heart rate (in some cases, electrocardiogram recording). In this study, a fiber-based smart blanket system was described, along with a wearable smart blanket system. Based on the results, all requirements for designing and modeling were described in the standard SRS document. Furthermore, a wearable system architecture was designed in the present study. The design of this system makes monitoring and controlling the patients in risky conditions possible and integrates the vital signs in a higher quality. The wearable systems can be used easily. In addition, such systems have some sensors, which can be fit on anatomically correct areas. Medical signals are recorded accurately enough to allow the users to assure the recorded

data. Further, the similar systems are designed to allow individuals to receive alerts on physiological risk conditions. Data transferring by communication protocols is considered as one of the design requirements, which are standardized in similar systems. The sensors and fibers installed on the wearable bedding can record the symptoms and processes performed on these symptoms by software systems. Compared to similar systems, the proposed wearable smart blanket includes some requirements, which are consistent with the requirements considered for investigation. The proposed wearable smart blanket system includes a blanket bedding with sensors, a comprehensive software package, along with a physician assistant and a portable patient system. The sensors and electrodes installed on a smart blanket should meet the requirements such as the reception of medical signals, ideal blankets, proper weight, number and type of sensors and electrodes, adequate contact with the patient's body, blanket, and the ability of recording and storing the vital signs. By the proposed wearable smart blanket, the individual body temperature can be measured by platinum thermistors within the elastic ambient, individual respiration rates by piezoelectric sensors, heart signals by silicone rubber, and individual oxygen levels by wrapped sensors and blood glucose with separate eardrop sensors. Finally, a continuous blood pressure can be performed by analyzing the heart signals and photoplethysmography. The smart blanket software, like some similar systems, has certain functional features such as monitoring and recording vital signs, communicating with the environment, interpreting the vital signs, recording medical signals, and considering nonfunctional features such as installation and performance, fault tolerance, optimal power consumption, charging capability, accuracy of signing, software upgradeability, and so on.

Compared to other wearable systems which were already mentioned, the above-mentioned system records all vital signs to control individuals in an integrated way and provides interpreted data to the medical team in ambulance. Thus, all medical, diagnostic, and individual health records are stored in the physician assistant system enabling the ambulance physician to take early diagnosis without any delay.

However, lack of participants was considered as one of the limitations of the present study. In addition, the participants were followed routinely since they did not spend enough time for filling in the questionnaire. In the future, this smart blanket system can be designed and produced for improving patient monitoring in emergency conditions.

## Conclusion

Since many illnesses and disabilities require constant monitoring, monitoring the patients continuously for timely intervention is considered as an essential requirement, which is especially important for the patients in unstable emergency conditions. Today, smart systems and advanced devices have grown considerably in terms of monitoring the patients and controlling their conditions. Therefore,

wearable systems can be used for monitoring the health status of patients in ambulance. Obviously, optimizing the time and speed of monitoring the patients in ambulance under emergency conditions is considered as two essential factors. Therefore, designing a smart tool such as wearable smart blankets plays a significant role in monitoring, recording, and transferring the vital signs.

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### Conflicts of interest

There are no conflicts of interest.

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