(19) DANMARK

(10) DK/EP 3567563 T3

(12) Oversættelse af europæisk patentskrift

Patent- og Varemærkestyrelsen

(51) Int.Cl.: *G 08 B 21/22 (2006.01)* *A 61 B 5/00 (2006.01)* *A 61 B 5/11 (2006.01)*
G 08 B 21/04 (2006.01)

(45) Oversættelsen bekendtgjort den: **2024-03-11**

(80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2023-12-13**

(86) Europæisk ansøgning nr.: **19173609.9**

(86) Europæisk indleveringsdag: **2019-05-09**

(87) Den europæiske ansøgnings publiceringsdag: **2019-11-13**

(30) Prioritet: **2018-05-11 IT 201800005262**

(84) Designerede stater: **AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR**

(73) Patenthaver: **Innovazione Tecnologica Srl, Via dei Conti Falluc, 70/A, 88100 Catanzaro (CZ), Italien**
Ricci, Luciano, Via B. Musolino, 46, 88100 Catanzaro (CZ), Italien

(72) Opfinder: **RICCI, LUCIANO, VIA B. MUSOLINO, 46, 88100 CATANZARO (CZ), Italien**

(74) Fuldmægtig i Danmark: **Novagraaf Brevets, Bâtiment O2, 2 rue Sarah Bernhardt CS90017, F-92665 Asnières-sur-Seine cedex, Frankrig**

(54) Benævnelse: **SYSTEM OG METODE TIL OVERVÅGNING AF PATIENTER MED KOGNITIVE LIDELSER**

(56) Fremdragne publikationer:
US-A1- 2003 236 474
US-A1- 2006 017 558
US-A1- 2016 140 827
US-A1- 2017 193 180

DESCRIPTION

[0001] The present invention relates to a system for monitoring patients with cognitive disorders.

[0002] The present invention also relates to a method for monitoring patients with cognitive disorders.

[0003] In particular, the present invention relates to a system and a method for monitoring patients with cognitive disorders subject to a risk of injuries due to falls and/or loss of consciousness and/or confusion.

[0004] In particular, the present invention relates to a system and a method for monitoring patients with cognitive disorders, of the type suffering from a disease such as Alzheimer.

[0005] It is known how serious the issues caused by Alzheimer, a disorder which is the most common cause of dementia, are. In fact, Alzheimer constitutes 60% of all cases of dementia and creates, as well as other degenerative neurological disorders, a state of total dependency of the patient, so creating a really complicated and difficult situation for the family who has to assist and also for the health facility that has the task to assist and cure the patient. The assistance weighs for 80% of all cases on the family who has to commit the entire day to cure the patient, with a great psychological stress and expenditures. By the way, even when the treatment of the patient is entrusted to health facilities, these ones suffer from increasing expenditures due to the continuous monitoring that such a disease involves. It is necessary, in fact, to set aside resources and healthcare professionals day and night, with inevitable implications, both technical and economical.

[0006] A first example of known system is described in the patent application US2003236474A1 whose subject are an apparatus and a method for monitoring the movements of a patient. If movements of the patient are detected and exceed predetermined thresholds, a detector assembly determines that a seizure condition is present, and an alarm may be generated. In one arrangement, a sensor assembly includes one or more sound detectors to detect sound caused by a patient's movement. The detector assembly monitors the movement of the patient for determining if an abnormal movement or a seizure condition is present. In another arrangement, an image sensor is used. A detector assembly monitors images produced by the image sensor to determine if the movements exceed predetermined thresholds. Other types of sensors can be used in other arrangements. The sensors can either be placed on a surface common to the patient or they can be attached to the patient's body.

[0007] Still, the patent application US2016140827A1 describes a person support apparatus, such as a bed, a stretcher, a cot, or the like, and includes a fall detector. The fall detector is adapted to detect when a person associated with the person's support apparatus has fallen and to issue a fall alarm. In some embodiments, the person support apparatus also includes

an exit detection system that issues an exit alarm when the person exits from the person support apparatus. The fall alarm is given a higher priority than the exit alarm. The fall detector may include a camera, a thermal image sensor, a device worn by the person, or another sensor. The person support apparatus may also, or alternatively, include a timer for measuring how long an occupant remains out of the person support apparatus.

[0008] A further solution published in the patent application US2016/0063846 describes a system for determining the position of a patient in a hospital bed comprising: at least a deformation sensor, able to generate a signal indicating a deformation of the structure of the bed; a unit able to determine the position, in order to determine a lateral and/or longitudinal position of the patient depending on the deformation of the structure. The application also describes a method for monitoring the exit of a patient from a hospital bed comprising the steps of: determining the position of the patient on the bed depending on the measured deformation and generating a warning signal if the determined position is out of a preset area. A system for detecting the weight of a hospital bed comprises a base with a frame suspended with respect to a fixed frame comprising: a load sensor which connects the suspended frame and the fixed frame by means of a suspension element which allows a free vertical movement of the suspended frame with respect to the fixed frame.

[0009] Finally, the international application published as WO2014165798 describes a method and an apparatus for detecting and alerting about a patient leaving the bed, this being a factor which causes stress to those who take care of patients who often wander out of bed due to dementia, Alzheimer's disease or other medical conditions. According to an aspect, the apparatus comprises a sock provided with a pressure sensor and a battery-powered microcontroller unit provided with a radiofrequency module. Once the patient leaves the bed and touches the floor, the sensor immediately detects the pressure caused by his body weight and activates by a wireless connection a sound audible at a monitoring unit which can be a smartphone, a tablet or a PC. According to an aspect, the sensor and the microcontroller unit can be assembled in a single assembly to be mounted on a normal sock, slipper or shoe. The device also counts the steps and measures the time interval between them accurately. According to an aspect, the pressure sensor and/or the sensor/microcontroller assembly can adhere to a foot.

[0010] However, the known systems are complex and expensive.

[0011] The purpose of the present invention is to provide a system and a method for monitoring patients with cognitive disorders that is able to control and monitor the patient in real-time in a reliable, fast and efficient manner, so optimizing the human resources acting both in a clinic and in a family, therefore having characteristics so as to overcome the limits that still affect the actual known systems.

[0012] According to the present invention a system for monitoring patients with cognitive disorders is provided, as defined in claim 1.

[0013] According to the present invention a method for monitoring patients with cognitive disorders is also provided, as defined in claim 7.

[0014] For a better understanding of the present invention, it is now described a preferred embodiment, purely by way of non-limiting example, with reference to the accompanying drawing, in which:

- figure 1 shows a schematic view of a system for monitoring patients with cognitive disorders, according to the invention.

[0015] With reference to figure 1, a system 100 for monitoring patients with cognitive disorders is shown, according to the invention.

[0016] In particular, the system 100 for monitoring patients with cognitive disorders comprises:

- at least one bed 101 comprising a plurality of weight sensors 101b configured to detect the presence of a patient in the bed 101;
- a plurality of sensors 101c configured to detect the descending of the patient from the bed 101;
- a plurality of acoustic sensors 101e able to detect environmental noises near the bed 101 of the patient;
- a plurality of flame sensors 101d able to detect smoke and flames near the bed 101 of the patient;
- a plurality of shock sensors 101f able to detect sudden movements of the bed 101;
- at least a wearable sensor 102 placed on the garment of the patient;
- at least a processing unit 101a provided with an Internet access and with a control system configured to acquire, digitize and analyze the signals coming from the sensors 101b, 101c, 101e, 101d, 101f, 102 through a machine learning algorithm and to generate visual or acoustic alarms, said visual and acoustic alarms being remotely notified to healthcare professionals provided with mobile devices;
- a video camera mounted on the processing unit 101a;
- a computer 103 provided with an Internet access and configured to receive the data transmitted by the at least a processing unit 101a through a wired or a wireless local network.

[0017] According to an aspect of the invention, the weight sensors 101b configured to detect the presence of the patient in the bed 101 are weight sensors of the oleo dynamic type mounted into the feet of the bed 101 and are configured to measure the weight of the bed 101.

[0018] Advantageously according to the invention, the use of weight sensors 101b of the oleo dynamic type allows a more accurate measure of the weight of the bed 101 in the presence

and in the absence of the patient, compared to weight sensors realized through other technologies.

[0019] Another advantage allowed by the use of the weight sensors 101b of the oleo dynamic type according to the invention is that they can be used in any hospital or domestic bed.

[0020] Advantageously according to the invention, the acoustic sensors 101e allow to detect environmental noises, for example screams emitted by the patient, whose sound intensity is higher than a preset threshold.

[0021] According to the invention, the processing unit 101a is mounted at the foot of the bed.

[0022] According to the invention, the sensors 101c, 101e, 101d, 101f are housed into the processing unit 101a.

[0023] Advantageously according to the invention, the use of flame sensors 101d allows to detect promptly the presence of fume or flames near the bed 101 of the patient.

[0024] According to an aspect of the invention, the control system implemented by the at least a processing unit 101a is based on a machine learning algorithm developed on the basis of the behavioral analysis of the sampled and analyzed data and is able to process through a comparison with known models the signals generated by the sensors 101b, 101c, 101e, 101d, 101f and 102, generating visual and acoustic alarms.

[0025] Advantageously according to the invention, said machine learning algorithm allows to obtain a synergic effect on the detections carried out by all the sensors, discriminating and correlating them in a smart way, so minimizing the risk of generating false alarms and notifying the concerning warnings.

[0026] The sensor group, in particular, composed as illustrated above, bases its behavior on the analysis of events and is designed depending on said logic of machine learning aiming at discriminating false positives.

[0027] The machine learning algorithm that supervises the behavior of the system in its unsupervised learning, used to find a set of frequent behaviors in a given set of data, is based on the "Apriori Machine Learning Algorithm, that is a simple and powerful data mining logic which generates an association rule on the transaction databases and on which some measures have been implemented in order to improve its weak points. The extraction of association rules uses the Candidate-Generation-Based (CGB) and Pattern-Growth-Based (PGB) strategies.

[0028] In particular, speaking of sensors having an output with sudden TTL fronts such as the shock sensors 101f (tilt), the algorithm calculates the number of pulses recorded in a given time span obtained from a database of events recorded during the self-learning phase in order

to determine whether the detected and processed event from the at least one processing unit 101a is a valid positive or a false positive.

[0029] Similarly, although trough different logics, the behavior of the sensors 101c (implemented, for example, through a sonar) is analyzed with regard to detection times and to the speed of the movements through the comparative analysis of predictive models developed experimentally, also crossing data coming from the weight sensors 101b of the oleo dynamic type; the algorithm is however based on a logic capable of self-adaptation in cases where too many false positives are detected.

[0030] With reference to the sensors having a linear analogue output such as the flame sensors 101d, the acoustic sensors 101e and the weight sensors 101b, dedicated functions that digitize their measures are carried out through the ADC (Analog to Digital Converter) of the MCU (MicroController Unit) integrated in the at least a processing unit 101a, at regular intervals and in very short times. If in the average of these measurements the potential alarm signal is present only once for a very short period of time <T (T being preset in advance), the algorithm discards the event. On the contrary, if the alarm event is present in more than one measurement made in a time not longer than 2T, the same alarm is notified.

[0031] Under conditions of high noises, shocks, vibrations, the functions set themselves up to a predetermined value, in order to try to discriminate the false alarm while remaining within unavoidable and constant limits below or above which the algorithm would not work correctly.

[0032] According to another aspect of the invention, each processing unit 101a is associated with a unique identification code which allows the association of the bed and the hospital room with the patient's registry.

[0033] According to one aspect of the invention, the processing unit 101a is equipped with a display able to visualize images or videos.

[0034] Moreover, according to another aspect of the invention, the at least a processing unit 101a allows to make and receive phone calls and video calls, even without the intervention of the patient, by means of a self-call or an auto-reply.

[0035] Advantageously according to the invention, the display allows the patient to visualize images or videos that help him to maintain a connection with his personal memories.

[0036] According to another aspect of the invention, the processing unit 101a sends the data stored therein according to a preset programming to a remote cloud server, not shown in the figure.

[0037] Advantageously according to the invention, this periodic data upload operation allows both to store data of any single patient, and to verify the correspondence of said data with those stored locally in the processing unit 101a, thus detecting possible manipulations of the

same data, voluntary or unintentional, made by patients.

[0038] In detail, the architecture of the software modules has been designed according to a criterion of robustness and reliability by historicizing each event detected by a "Domino" central on two redundant servers (a local server and a cloud server) where the access logs of the authorized operators are recorded in order to be able to verify the events detected and their management without the possibility of tampering.

[0039] According to another aspect of the invention, and in particular for walking patients, the wearable sensor 102 is coupled with a small proximity sensor, not shown in the figure, that, located in the patient's room, allows to verify the presence of the same patient in the room within the operating range of the sensor 102, which can be set as desired, for example from 0 to 15 m.

[0040] Advantageously according to the invention, the voluntary or unintentional departure of the patient from the room can be controlled through the detections of the wearable sensor 102.

[0041] According to one aspect of the invention, said proximity sensor is a miniaturized beacon-type device communicating with the wearable sensor 102 through a short-range wireless connection, for example a Bluetooth LE connection.

[0042] Furthermore, according to another aspect of the invention, the wearable sensor 102 is configured to detect and notify, through the at least a processing unit 101a, sudden accelerations to which the patient is subject by issuing a distress call in case of an accidental fall or in case of fainting.

[0043] According to another aspect of the invention, the system 100 also includes a software application provided with a web user interface that allows to display from afar by the Internet a historical record of the visual and acoustic alarms generated by the processing unit 101a depending on the signals coming from the sensors 101b, 101c, 101d, 101e, 101f and 102, said alarms being sent according to the logic set up by the control system of the processing unit 101a by SMS, instant messaging or e-mail to portable devices, such as smartphones or tablets, of healthcare professionals.

[0044] According to another aspect of the invention, said software application provided with a web user interface is installed on the computer 103.

[0045] According to another aspect of the invention, the at least a processing unit 101a and the computer 103 are connected through a wired or a wireless LAN network.

[0046] As already said, the present invention relates also to a method for monitoring patients with cognitive disorders by means of the system 100, comprising the steps of:

- Detecting the presence or the absence of the patient in a bed through weight sensors of

the oleo dynamic type, sudden movements of the bed, presence of flames and smoke near the bed, an attempt to get off the bed made by the patient, the presence of the patient within a preset range of distances;

- Sending the signals of the aforementioned detecting step to a processing unit mounted at the foot of the bed;
- Providing a connection between the processing unit and a device having a software application provided with a web user interface, said device being configured to show a historical record of visual and acoustic warnings generated by the elaboration unit in the aforementioned detecting step.

[0047] According to one aspect of the invention, each alarm can be notified to a mobile device of a remote user, for example a healthcare professional provided with a smartphone or a tablet, via SMS, instant messaging or e-mail.

[0048] According to another aspect of the invention, the method includes the step of video calling patients.

[0049] Advantageously according to the invention, by using the described system 100 and method, a healthcare professional can receive the alarm from one or more patients, going with certainty into the patient's room from which the alarm was generated and thus carry out the due control. Alternatively, the healthcare professional can make a call to the processing unit 101a to monitor the patient's condition from afar.

[0050] In addition, advantageously according to the invention, the healthcare professional can:

- manage the alarm by reporting and recording its date, time and type;
- reset any possible malfunctioning or setting up one or more peripherals that may have caused false alarms by changing their thresholds;
- generate a historical record of the alarms received by filtering them by patient's name.

[0051] Therefore, the system and method for monitoring patients with cognitive disorders allow a remote monitoring of patients.

[0052] Furthermore, the system and method for monitoring patients with cognitive disorders are efficient.

[0053] Finally, the system and method for monitoring patients with cognitive disorders allow a real-time monitoring in a reliable, fast and efficient manner, optimizing the human resources acting both in the clinic and in the family, so reducing the effort of a caregiver.

[0054] It is finally clear that the system and method for monitoring patients with cognitive

disorders described and illustrated herein can be subject to modifications and variations without departing from the scope of the present invention, as defined in the appended claims.

REFERENCES CITED IN THE DESCRIPTION

Cited references

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US2003236474A1 [0006]
- US2016140827A1 [0007]
- US20160063846A [0008]
- WO2014165798A [0009]

Patentkrav

1. System (100) til overvågning af patienter med kognitive lidelser, der omfatter:
- mindst en seng (101) omfattende et antal vægtsensorer (101b), der er konfigureret til at detektere tilstedeværelsen af en patient i sengen (101)
- en flerhed af sensorer (101c) konfigureret til at detektere, hvis patienten forlader sengen (101)
- en flerhed af akustiske sensorer (101e) i stand til at detektere omgivelsesstøj nær patientens seng (101)
- en flerhed af flammesensorer (101d) i stand til at detektere røg og flammer nær patientens seng (101)
- en flerhed af stødsensorer (101f) i stand til at detektere pludselige bevægelser af sengen (101)
- mindst en bærbar sensor (102) placeret på patientens beklædning

Karakteriseret ved at omfatte:
- mindst en behandlingsenhed (101a), der er installeret ved foden af sengen (101), og som indeholder sensorer (101c) konfigureret til at detektere, hvis patienten forlader sengen (101), nævnte akustiske sensorer (101e), nævnte flammesensorer (101d) og nævnte stødsensorer (101f) forsynet med internetadgang og med et kontrolsystem konfigureret til at registrere, digitalisere og analysere signalerne fra nævnte vægtsensorer (101b), nævnte sensorer (101c) konfigureret til at detektere, hvis patienten forlader sengen (101), nævnte akustiske sensorer (101e), nævnte flammesensorer (101d), nævnte stødsensorer (101f) og nævnte bærbare sensor (102) konfigureret gennem en maskinlæringsalgoritme til at sammenligne signalerne med kendte modeller og data relateret til de nævnte signaler med en database over hændelser registreret i en selvlæringsfase, der genererer visuelle og akustiske alarmer, som fjernunderrettes til sundhedspersonale forsynet med mobile enheder, hvilket minimerer risikoen for at generere falske alarmer
- et videokamera monteret på behandlingsenheden (101a)
- en computer (103) forsynet med internetadgang og konfigureret til at modtage de data, der overføres af mindst en behandlingsenhed (101a) via et kablet eller trådløst lokalt netværk

2. System (100) ifølge krav 1, **karakteriseret ved**, at vægtsensorerne (101b) er vægtsensorer af oleodynamisk type og monteret i sengens fødder.

3. System (100) ifølge krav 1, **karakteriseret ved**, at behandlingsenheden (101a) er forbundet med en entydig identifikationskode for sengen (101) og patientens hospitalsrum.

4. System (100) ifølge krav 1, **karakteriseret ved**, at behandlingsenheden (101a) er udstyret med et display, der er i stand til at visualisere billeder, og er konfigureret til at foretage og modtage telefonopkald og videoopkald.

5. System (100) ifølge krav 1, **karakteriseret ved**, at den bærbare sensor (102) er forbundet med en nærhedssignalsensor via en trådløs kortdistanceforbindelse og er konfigureret til at detektere og underrette om pludselige accelerationer, som

patienten udsættes for.

6. System (100) ifølge krav 1, **karakteriseret ved** at omfatte en softwareapplikation forsynet med en webgrænseflade installeret på computeren (103) og konfigureret til at vise en historisk registrering af visuelle og akustiske alarmer genereret af udarbejdelsesenheden (101a).

7. Fremgangsmåde til overvågning af en patient med kognitive lidelser ved hjælp af systemet (100) ifølge krav 1, omfattende følgende trin:

- detektering af patientens tilstedeværelse eller fravær i en seng gennem vægtsensorer af oleodynamisk type, pludselige bevægelser af sengen, tilstedeværelse af flammer og røg nær sengen, forsøg på at komme ud af sengen lavet af patienten, patientens tilstedeværelse inden for et forudindstillet afstandsområde
- udsendelse af signaler fra det førnævnte detekteringstrin til en behandlingsenhed (101a) installeret ved sengen
- tilvejebringelse af en forbindelse mellem behandlingsenheden (101a) og en enhed med en softwareapplikation forsynet med en webgrænseflade, idet enheden er konfigureret til at vise en historisk registrering af visuelle og akustiske advarsler genereret af udarbejdelsesenheden i det førnævnte detekteringstrin

8. Fremgangsmåde ifølge krav 7, **karakteriseret ved**, at hver alarm kan meddeles en mobil enhed hos en fjernbruger.

9. Fremgangsmåde ifølge krav 7, **karakteriseret ved** at omfatte trinet med at foretage et videoopkald.

DRAWINGS

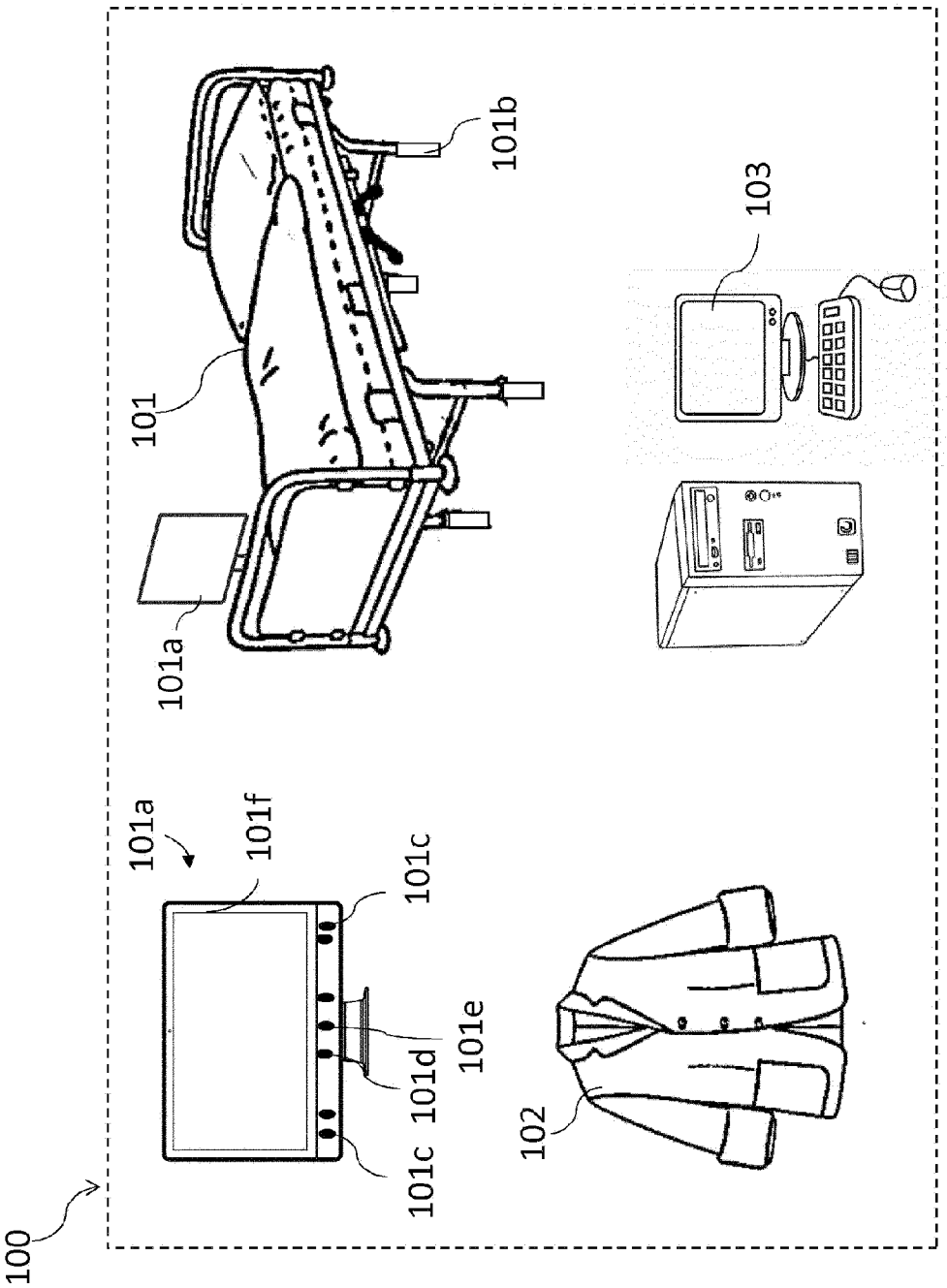

FIG.1