

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
6 April 2006 (06.04.2006)

PCT

(10) International Publication Number
WO 2006/035351 A2

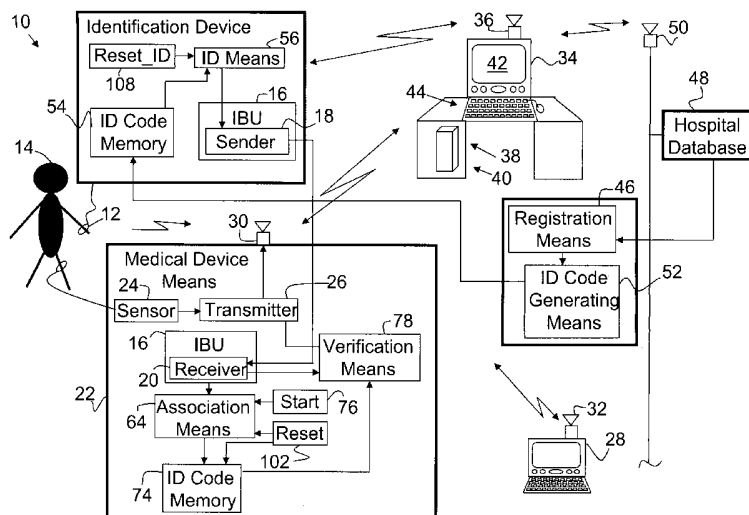
- (51) International Patent Classification:
G06F 19/00 (2006.01)
- (21) International Application Number:
PCT/IB2005/053075
- (22) International Filing Date:
19 September 2005 (19.09.2005)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/614,629 30 September 2004 (30.09.2004) US
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- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))

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(54) Title: SYSTEM FOR AUTOMATIC CONTINUOUS AND RELIABLE PATIENT IDENTIFICATION FOR ASSOCIATION OF WIRELESS MEDICAL DEVICES TO PATIENTS



(57) Abstract: The medical communication system comprises a plurality of medical identification devices (12). Each identification device (12) is attached to one particular patient (14). A registration processor generates a unique patient identification data that is stored in an electronic patient identification code memory (54). Each identification device (12) includes an intra-body wireless communication device (16) which transmits the patient's identification on the patient's body. A medical device (22), which is linked to the patient (14) to measure a vital function, periodically automatically receives the patient's identification code to continually ensure association to a correct patient.

WO 2006/035351 A2



Published:

— without international search report and to be republished upon receipt of that report

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**SYSTEM FOR AUTOMATIC CONTINUOUS AND RELIABLE
PATIENT IDENTIFICATION FOR ASSOCIATION OF WIRELESS MEDICAL
DEVICES TO PATIENTS**

DESCRIPTION

The present invention relates to the medical monitoring systems and methods. It finds particular application in conjunction with the patient's identification and association to medical devices in health care facilities and will be described with particular reference thereto. However, it is to be appreciated that the invention will also find application in conjunction with patient monitoring in retirement communities, assisted living, at home, and the like.

Worldwide, the health care facilities employ new flexible care giving scenarios which allow the clinicians in the emergency units, for example, to quickly use a monitoring or diagnostic system. Traditionally, vital sign sensors were connected by wires with associated monitors and equipment. Telemetry patients, as another example, can locally be monitored by temporarily assigning a portable monitor or a PDA. Due to the inconvenience of the myriad of wires, there is an increasing demand for wireless telemetry. The care everywhere paradigm employs various wireless medical devices and sensors around the patient at the point-of-care.

Typically, a wireless sensor is attached to a patient to measure certain vital functions of the patient. The wireless medical sensors and devices use radio links for communication and transmission of data to other devices within the hospital system. Wireless devices allow an increased mobility of patients and clinicians through a more flexible usage of medical devices at different places, for different patients, or by different clinicians. In emergency treatment facilities, wireless communications can save time connecting and disconnecting sensors as a patient moves from ambulance, to trauma assessment station, to surgery, to recovery, to a hospital room, etc.

In the health care facilities, where the hardwired devices are used, it is easy to monitor which patient is associated to which medical device. In the wireless system, it is more difficult to verify which identification signal is coming from which patient. Several techniques have been proposed to associate a wireless device to the patient. One such technique is a single assignment through manual input of the patient information via

keyboard or during a device start up process. Another such technique is a single assignment through a barcode marker which contains a unique identification number (ID) and is attached to the patient's body, e.g. with a wrist band. When a new device is used for a specific patient, the patient's ID is read with a special barcode reader and assigned to the new device. Yet another such solution is a single assignment through RFID – corresponds to barcode solution; the information (ID) is stored in an RFID-tag. These solutions have the problem of reliance on a manual process which is subject to a human error. In addition, the automatic association of the device to the patient is not feasible. It is also not possible to regularly check the association.

Automatic association of a wireless identification system is possible using Bluetooth or other short-range RF technology. The Bluetooth technology is well known in the art. E.g., a short-range RF-sender is attached to the patient's body to continuously send out the patient identification. Wireless medical devices in the environment of the patient can automatically receive the identification information and check/verify it regularly. However, because of the large spreading of the RF signal, sensors associated with the nearby patients can also receive the identification and associate with the wrong patient. Unambiguous association to a specific patient cannot be guaranteed.

The frequent and mobile usage of wireless/mobile medical equipment at the patient's bedside requires an efficient and safe procedure for association of the medical equipment to the respective patient. The present invention provides a new and improved apparatus and method which overcomes the above-referenced problems and others.

In accordance with one aspect of the present invention, a medical communications system is disclosed. The medical communication system comprises a plurality of medical identification devices. Each device is connected with one patient and includes an electronic patient identification code memory and a short-range, wireless communication device for communicating the patient identification. The medical communication system further comprises at least one medical device which is linked to a patient. A means automatically associates the medical device with the electronic patient identification code of the medical identification device connected to the same patient. A means automatically verifies the association of the medical device to the patient.

In accordance with another aspect of the present invention, a communication method is disclosed. A wireless patient identification device is assigned to a selected patient. The identification device is encoded with an electronic patient identification code that uniquely identifies the selected patient which it is assigned to. The wireless patient identification device is automatically associated to at least one medical device which is linked to the selected patient to measure at least a vital function. The association of the medical device to the selected patient is automatically verified.

One advantage of the present invention resides in automatic association of medical devices to patients with no need for a manual input of patient identification.

Another advantage resides in periodic automatic verification of the association of the medical device to the patient.

Another advantage resides in continuous secure and reliable patient identification on or close to the patient's body.

Another advantage resides in speeding up the use of medical devices.

Another advantage resides in non-contact transmission of the patient information.

Still further advantages and benefits of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating the preferred embodiments and are not to be construed as limiting the invention.

FIGURE 1 is a diagrammatic illustration of an identification system;

FIGURE 2 shows a process flow of the identification system;

FIGURE 3 is a diagrammatic illustration of a second identification system;

and

FIGURE 4 shows a process flow of the second identification system.

With reference to FIGURE 1, a patient identification system **10** includes a plurality of identification devices or **IDDs 12**. Each identification device **12** is attached to a patient or patient's body **14** as a band at a wrist, leg, or the like. Alternatively, the identification device **12** is a non-contact device and is attached in a close proximity, e.g. within 10cm, of the patient's body **14**. Each identification device **12** includes a sender **18** of an intra-body communication unit or **IBU 16**. The intra-body communication unit **16** utilizes a near-field body-communication technology, which is based on capacitive coupling and well known in the art, to transmit the patient's ID. In regular time intervals **T**, e.g. every 1 sec, the sender **18** sends a unique identification signal. The ID signal is received by a receiver **20** of another intra-body communication unit **16**, which is connected to a medical device or **PWD** or medical device means **22**. The medical device means **22** such as ECG, blood oxygen sensor, pulse monitor, injection pump, a drip monitor, or the like, has a sensor **24** which is typically disposed in close proximity to or contacting the patient **14** for continuous vital sign measurements. The medical device **22** includes a transmitter **26**, which wirelessly transmits the vital sign measurements to a bedside-monitor **28** via a transmitting/receiving link **30, 32** or to a central station **34** via transmitting/receiving link **30, 36**. The central station **34** is equipped with an appropriate hardware **38**, software **40**, monitor **42** and input means **44**. In one embodiment, the medical device means **22** is a mobile device that can be directly attached to the patient **14**, such as a wireless vital sign sensor, or positioned permanently or temporarily in close proximity of the patient **14**, such as a spot-measurement unit, and can be equipped with the intra-body unit receiver **20**.

Typically, when the patient **14** is admitted to the health care facility, a registration means **46** configures a corresponding identification device **12**. More specifically, the registration means **46** is connected with a Departmental, Clinical or Hospital Information system which includes a hospital database **48**, preferably wirelessly via communications link **36, 50**. An ID code generating means **52** generates a unique patient's identification number which is associated to a corresponding patient record in the information system **48**. Optionally, the ID code generating means **52** generates a comprehensive patient identification code by a use of a set of patient data, e.g. patient's name, date of birth, and/or other hospital data or medical patient data. The generated

unique identification number or comprehensive patient identification code is stored in an ID code memory 54 of the patient's associated identification device 12. An ID means or identification process 56 performs an initial identification of the identification device 12. After the identification process 56 is completed, the identification device 12 is attached to the patient's body 14. As each medical device 22 is attached to the patient 14, the identification device 12 sends the patient ID to the medical device 22 to associate it with the same patient ID. Periodically, the patient's ID is verified.

With continuing reference to FIGURE 1 and further reference to FIGURE 3, the ID code is received 58 by the identification means 56 from the ID code memory 54. The identification process 56 is started 60. The ID code is transmitted 62 to the medical device 22 by the intra-body unit sender 18. An association means or process 64 automatically starts 66 the association of the medical device 22 to the patient 14 when the ID code is received 68 by the intra-body unit receiver 20. More specifically, the association means 64 waits 70 for receiving the ID code. The intra-body unit receiver 20 disposed at the medical device 22 receives 68 the patient's ID code. The ID code is stored 72 in an ID code memory 74 of the medical device 22. Optionally, the ID code is transmitted via the communication link 30, 32; 30, 36 to the bedside monitor 28 and/or to the central station 34 to automatically display the patient ID number, patient name, etc., so that the device association process can be recorded or verified by a human. In one embodiment, the association process 64 is optionally manually initiated with a use of a start button 76.

Once the medical device 22 is associated with the patient's ID, it starts communicating the sensed information by communication link 30, 32; 30, 36 to the bedside monitor 28 and/or the central station 34. Alternatively, all of the information sensed by all of the medical devices 22 associated with the same patient 14 can be communicated with the near body technology to a common medical device or the ID device which, in turn, transmits all of the monitored information to the bedside monitor 28 and/or central station 34. Communications with the bedside monitor 28 and the central station 34 include the patient ID code to keep the information segregated by the patient.

A verification means or process 78 verifies the association of the medical device 22 to the patient 14 on a regular basis during the normal operation of the medical device 22. More specifically, the verification means 78 waits 80 for the ID code. In one embodiment, so long as the medical device 22 is at the patient 14 or close to the patient 14,

the medical device 22 receives 68 the ID code in regular T_1 time intervals 82. Alternatively, the medical device 22 can periodically query the identification device 12 to request the transmission of the patient's ID. The ID code is checked 84. If the received ID code is different from the stored ID code, an alarm "wrong ID" is raised 86 locally at the medical device 22 as well as at the bedside monitor 28 and/or central station 34. If no ID code is being received 88, the medical device 22 waits for reception for the pre-specified period of time T_2 , e.g. ID timeout 90 such as 15 sec. If no ID code is received during the T_2 period, an alarm "no ID" is raised 92. After any alarm 86, 92, an explicit re-execution of the association process 64, which preferably is manually triggered by the start button 76, is performed. If after the alarm is raised 86, 92, the ID code is being received again, it is slayed until the association process 64 is re-executed. The association of the medical device 22 to the patient 14 is preferably terminated 100 manually by a reset button 102. As a result, the ID code is erased from the ID code memory 74. It is also contemplated that the association of the medical device 22 to the patient 14 can be manually terminated through a control device such as a dedicated user interface at the bedside monitor 28, central station 34, clinician's PDA, or other like device. Each termination or disassociation is reported to the central station 34. When the patient leaves the facility or the identification code is to be terminated 104, the ID device 12 can be destroyed or it can be reset by deleting 106 the ID code in the identification device memory 54. It is performed manually by a use of a reset_ID button 108. Optionally, the identification process 56 is terminated by deleting the stored information via a dedicated procedure at the central station 34, or other appropriate procedure. If the device is reusable, it is preferably reprogrammed by the registration means 46 as it is given to another patient.

With reference to FIGURES 2 and 4, each patient 14 is equipped with the identification device 12, which is attached to the patient's body 14 or close to the patient's body. The identification device 12 includes a first intra-body unit sender/receiver 110, 112. Each medical device 22, which is attached to the patient 14, includes a second intra-body unit sender/receiver 114, 116. The ID code is transmitted 62 via the first intra-body unit sender 110 upon request 120 of the medical device 22.

More specifically, the identification device 12 waits 122 for an ID code request to be received 124 by the first intra-body unit receiver 112. The medical device 12 submits the ID code request via the second intra-body unit sender 114. When the first intra-

body unit receiver 112 receives the request 124, the first intra-body unit sender 110 sends 62 the ID code to the medical device 22. The second intra-body unit receiver 116 receives 68 the ID code, after which the ID code is stored 72 in the medical device ID code memory 74. The verification process 78 verifies the continued association of the medical device 22 to the patient 14 on a regular basis during the normal operation of the medical device 22. More specifically, in regular time intervals T_3 , the second intra-body unit sender 114 submits 130 the ID code request to the identification device 12. Upon receiving 124 of the request by the first intra-body unit receiver 112, the first intra-body unit sender 110 sends 62 the ID code to the medical device 22. The ID code is received 68 by the second intra-body unit receiver 116. The received ID code is checked 84. If the received ID code is different from the stored ID code, an alarm "wrong ID" is raised 86 locally at the medical device 22 as well as at the bedside monitor 28 and/or central station 34. If no ID code is being received 88 during the preset time T_2 , the medical device 22 repeats the ID code request 130 for a pre-defined number of times N.

For security and privacy, the communications between the identification device 12 and the medical device 22 are preferably encrypted. Preferably, a group of identification devices 12 and medical devices 22 is pre-configured with a shared security key which might be specific for each medical department, or for the overall hospital. The shared key is used for encrypting/decrypting the ID code. This ensures that only authorized devices can send/receive the valid ID code.

The invention has been described with reference to the preferred embodiments. Modifications and alterations may occur to others upon a reading and understanding of the preceding detailed description. It is intended that the invention be constructed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

CLAIMS

Having thus described the preferred embodiments, the invention is now claimed to be:

1. A medical communications system (10) comprising:
a plurality of medical identification devices (12), each connected with one patient (14) and including:

an electronic patient identification code memory (54), and
short-range, wireless communication device (16) for communicating the patient identification; and
at least one medical device (22) which is linked to a patient (14), each medical device (22) including:

a means (64) for automatically associating the medical device (22) with the electronic patient identification code of the medical identification device (12) connected to the same patient (14), and

a means (78) for automatically verifying the association of the medical device (22) to the patient (14).

2. The system as set forth in claim 1, wherein the short-range communication device (16) includes:

an intra-body communications transmitter (18) that transmits the electronic patient identification code on the patient's body, and
the medical device (22) includes:

an intra-body communication receiver (20) for receiving the patient identification code being transmitted on the patient's body.

3. The system as set forth in claim 2, wherein the medical device (22) further includes:

a means (76) for causing the associating means (64) to trigger storing the received patient identification code in a second ID code memory (74).

4. The system as set forth in claim 2, wherein the medical device (22) further includes:

a second ID code memory (74) in which the associating means (64) stores the patient's identification code received by the receiver (20).

5. The system as set forth in claim 4, wherein the medical device (22) further includes:

a verification means (78) for comparing the patient identification code stored in the second ID code memory (74) and patient identification codes subsequently received by the receiver (20).

6. The system as set forth in claim 5, wherein the identification device periodically triggers the transmitter (18) to retransmit the patient identification code stored in the ID code memory (54).

7. The system as set forth in claim 5, wherein the medical device periodically requests to transmit the ID code stored in the ID code memory (54).

8. The system as set forth in claim 5, further including:

a means (102) for terminating the association of the medical device (22) to the communication device (12) when one of:

the received identification code is different from the stored patient's identification code,

the identification code is not received within a pre-specified time period (T_2), and

manual actuation.

9. The system as set forth in claim 1, further including:

a means (52) for generating an electronic patient identification code based on at least a record data of the patient (14) in an information database (48) and loading the electronic patient code into the identification code memory (54) of the identification device (12) to be connected with the patient (14).

10. The system as set forth in claim 1, wherein the medical device (22) further includes:

a means (26) for one of measuring a vital function and administering a medication.

11. A communication method comprising:

assigning a wireless patient identification device (12) to a selected patient (14) which identification device is encoded with an electronic patient identification code that uniquely identifies the selected patient (14) which it is assigned to;

automatically associating the wireless patient identification device (12) to at least one medical device (22) which is linked to the selected patient (14) to measure at least a vital function; and

automatically verifying the association of the medical device (22) to the selected patient (14).

12. The method as set forth in claim 11, wherein the assigning step includes:

generating a unique electronic identification code for the patient (14) based on at least a record data of the patient (14) in an information database (48); and

storing the patient identification code in a communication device ID code memory (54).

13. The method as set forth in claim 11, wherein the associating step includes:

periodically wirelessly transmitting the patient identification code from the patient identification device.

14. The method as set forth in claim 13, further including:

receiving a first transmitted patient identification code at the medical device (22);

and

storing the first received patient identification code in an ID code memory (74) of the medical device.

15. The method as set forth in claim 14, wherein the verifying step includes:

periodically receiving the patient identification codes subsequently transmitted by the patient identification device; and

comparing the stored patient identification code and the subsequently received patient identification codes.

16. The method as set forth in claim 15, further including:
terminating the association of the medical device (22) to the patient (14) when one of:

the received identification code is different from the stored identification code,

the identification code is not received within a pre-specified time period (T_2), and

manual actuation.

17. The method as set forth in claim 16, wherein the termination step includes:
erasing the patient identification code from the medical device ID code memory (74); and

reporting the termination to at least one of a bedside monitor and a central station.

18. The method as set forth in claim 11, wherein the communication device (12) is attached to the patient.

19. The method as set forth in claim 11, further including:
communicating the electronic patient identification code to the medical device via an intra-body communication sensor.

20. A patient identification system for performing the method of claim 11.

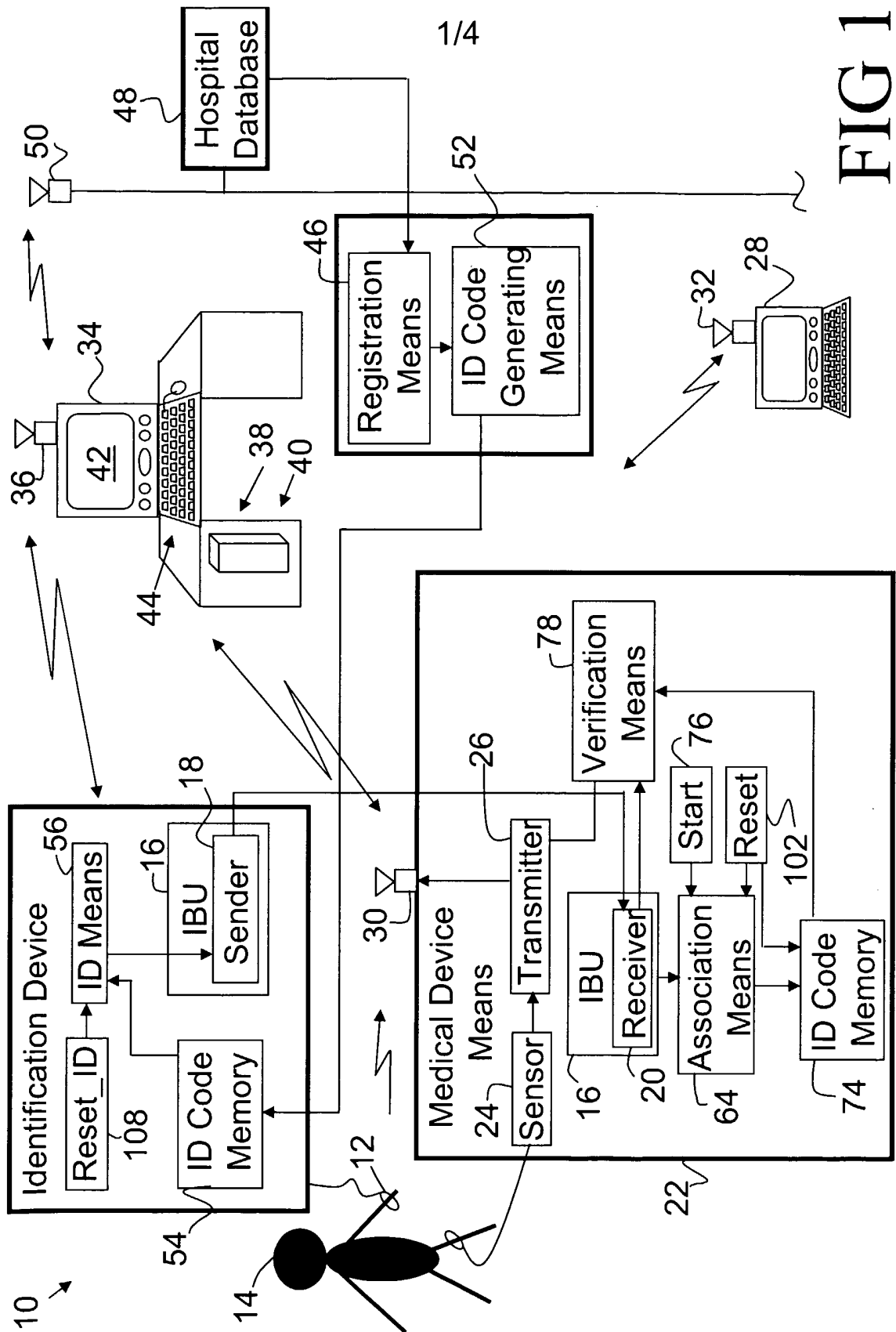


FIG 1

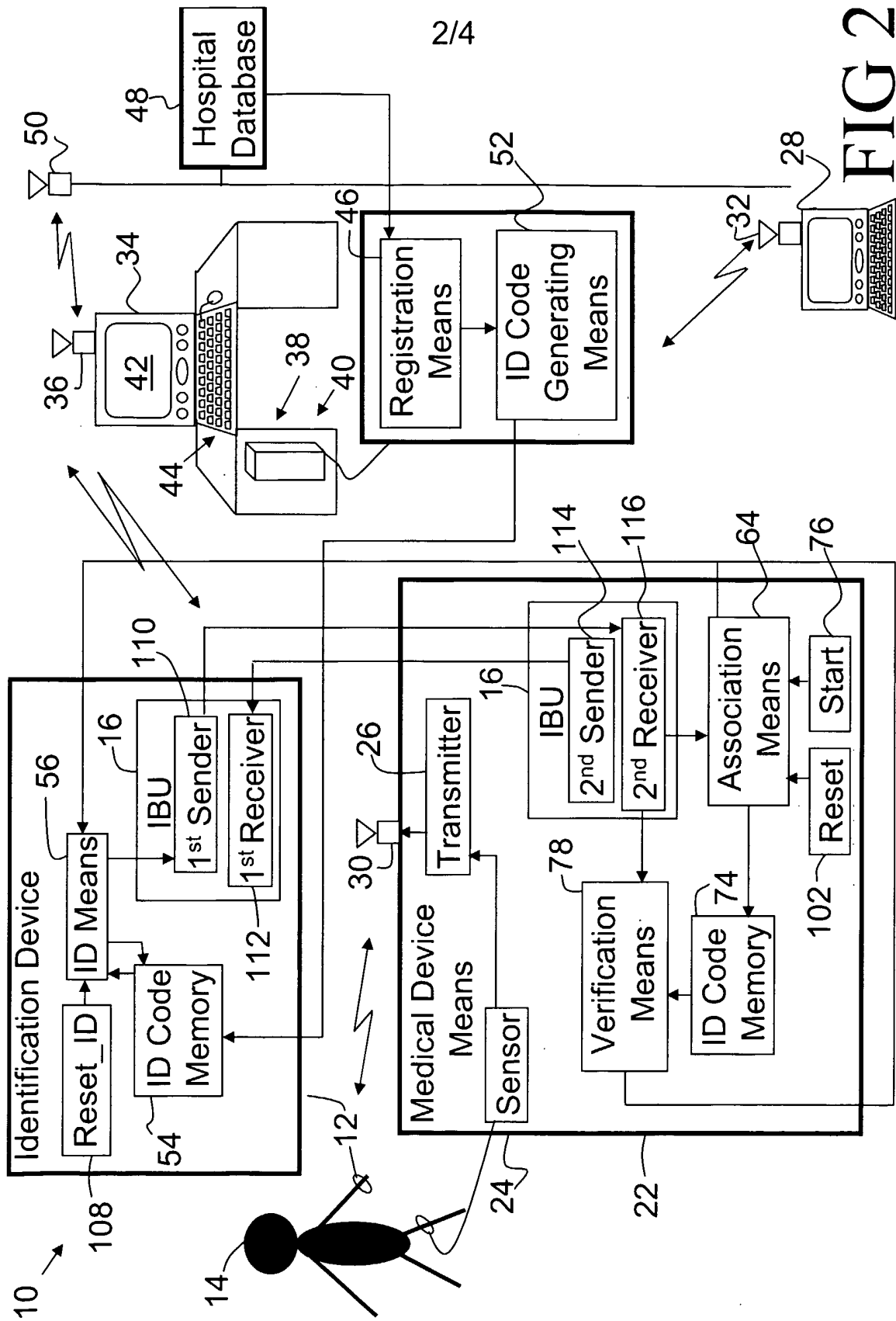


FIG 2

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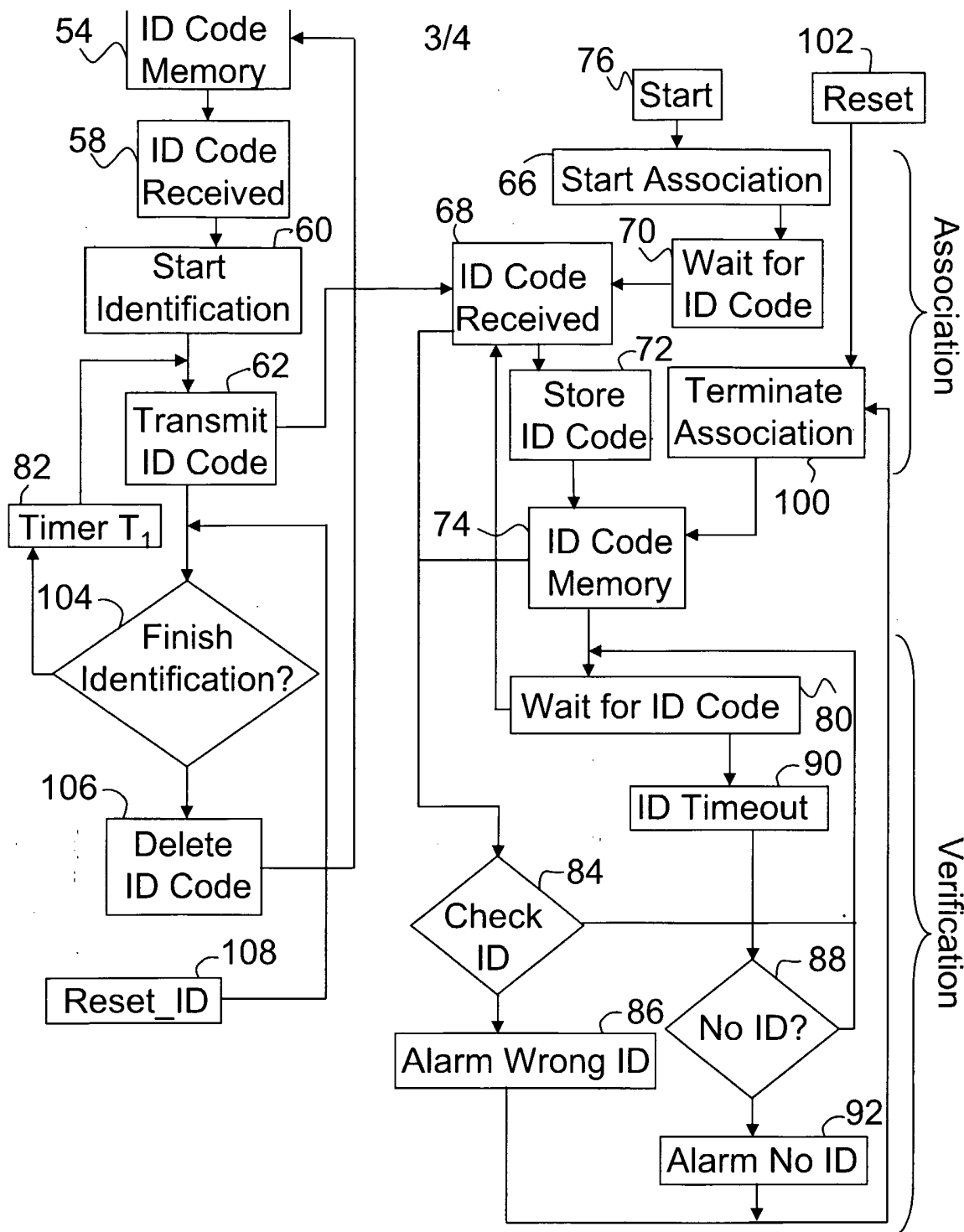


FIG 3

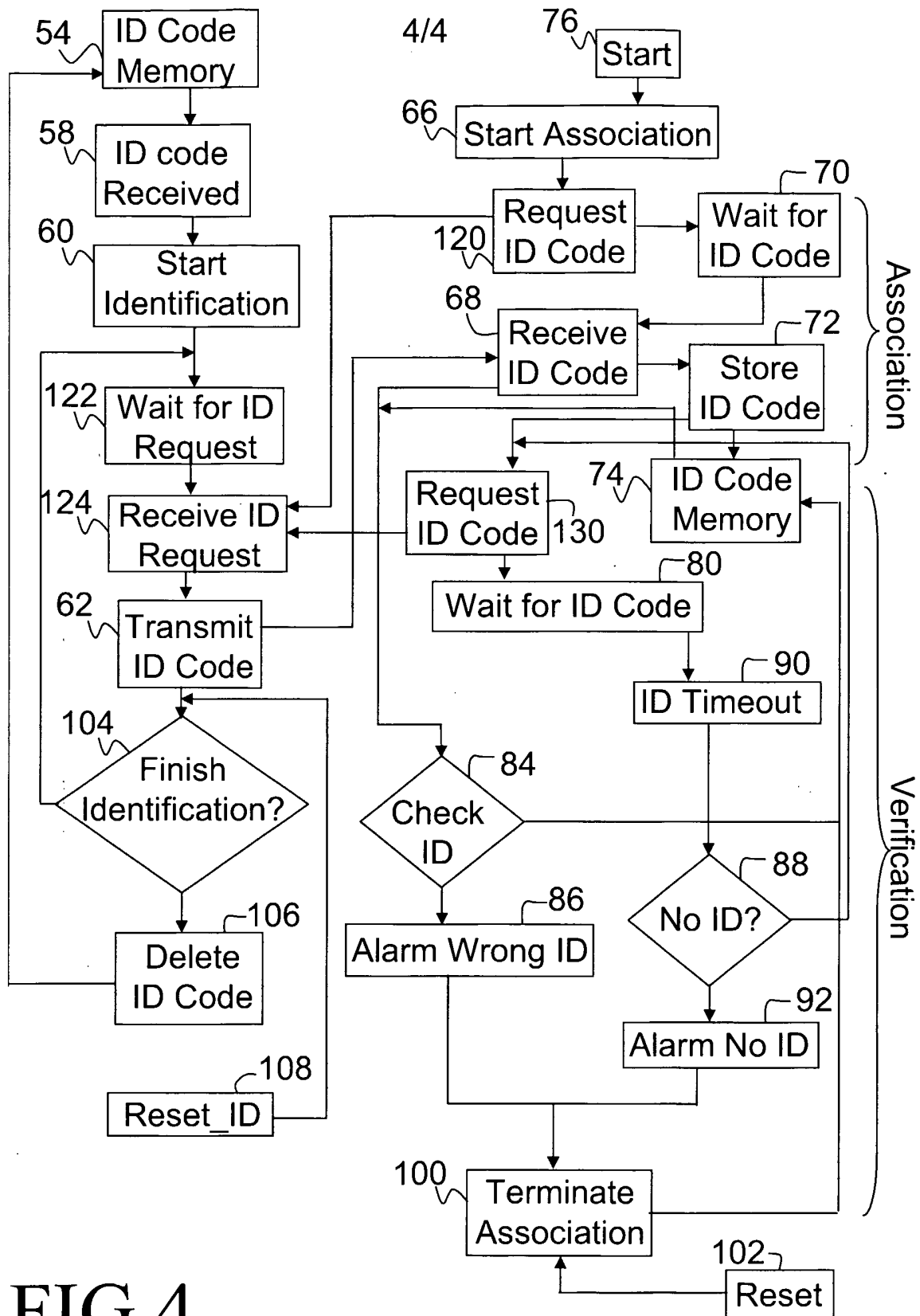


FIG 4