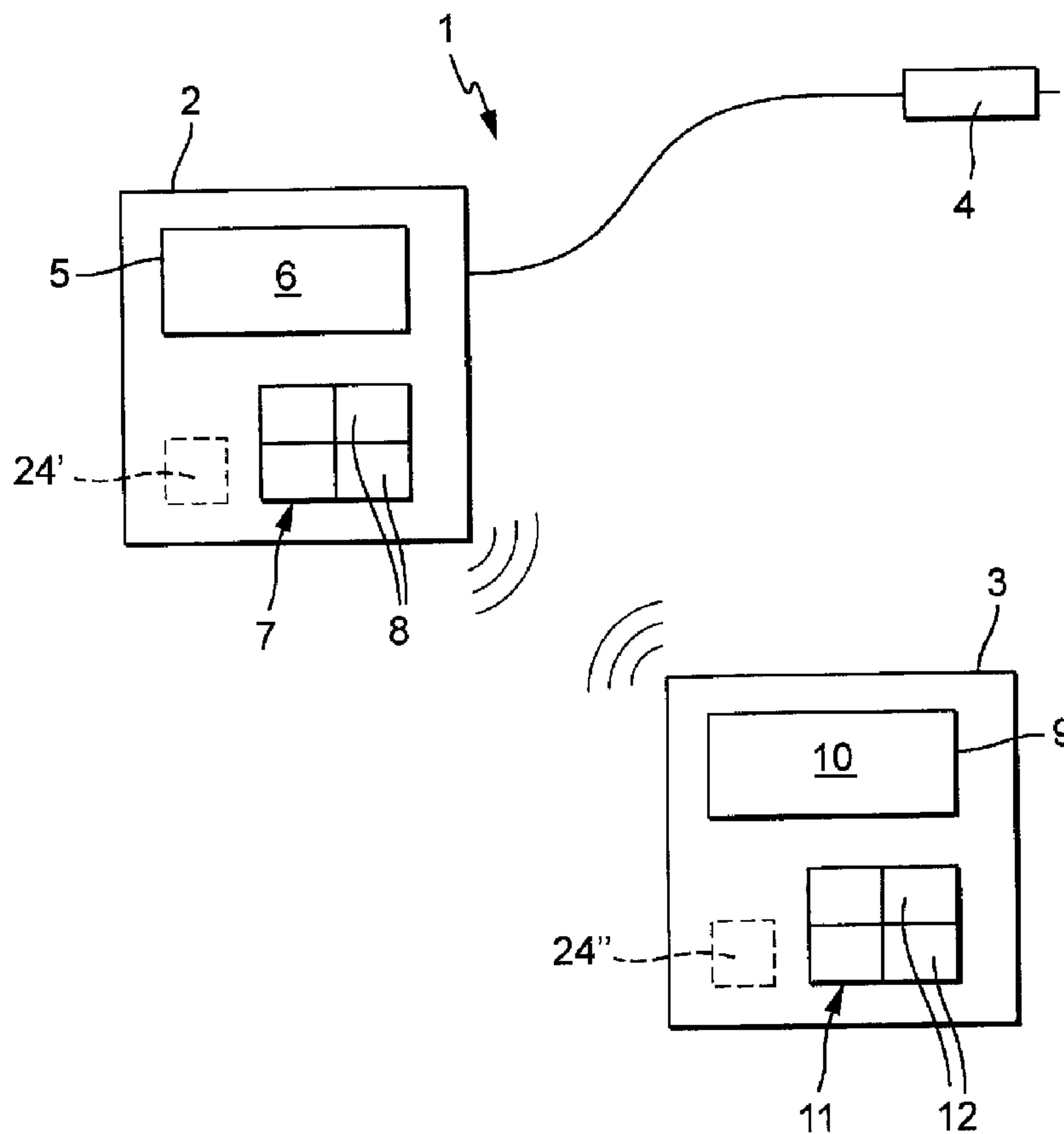




(22) Date de dépôt/Filing Date: 2007/03/28
 (41) Mise à la disp. pub./Open to Public Insp.: 2007/09/30
 (45) Date de délivrance/Issue Date: 2009/11/10
 (30) Priorité/Priority: 2006/03/30 (EP06 006 679.2)

(51) Cl.Int./Int.Cl. *A61M 5/172* (2006.01),
G08C 17/00 (2006.01)
 (72) Inventeurs/Inventors:
RASCH-MENGES, JUERGEN, DE;
HAAR, HANS-PETER, DE;
POREDDA, ANDREAS, DE;
HAUETER, ULRICH, CH
 (73) Propriétaire/Owner:
F. HOFFMANN-LA ROCHE AG, CH
 (74) Agent: OGILVY RENAULT LLP/S.E.N.C.R.L.,S.R.L.

(54) Titre : SYSTEME DE PERFUSION MUNI D'UN DISPOSITIF DE PERFUSION ET D'UNE TELECOMMANDE
 (54) Title: INFUSION SYSTEM HAVING AN INFUSION UNIT AND A REMOTE CONTROL UNIT



(57) Abrégé/Abstract:

An infusion system has an infusion unit and a remote control unit. The infusion unit is adapted to be located outside the body and to infuse a liquid into the body and includes a housing with a fluid reservoir, in which the liquid may be received, an input device for



(57) **Abrégé(suite)/Abstract(continued):**

inputting infusion control commands, an output device, and a communication device for wirelessly transmitting signals to and receiving signals from the remote control unit. The remote control unit includes an input device for inputting infusion control commands, an output device and a communication device for wirelessly transmitting signals to and receiving signals from the infusion unit. The infusion system is adapted for operating in two different operating modes, namely in a remote control mode and a direct control mode.

ABSTRACT

An infusion system has an infusion unit and a remote control unit. The infusion unit is adapted to be located outside the body and to infuse a liquid into the body and includes a housing with a fluid reservoir, in which the liquid may be received, an input device for inputting infusion control commands, an output device, and a communication device for wirelessly transmitting signals to and receiving signals from the remote control unit. The remote control unit includes an input device for inputting infusion control commands, an output device and a communication device for wirelessly transmitting signals to and receiving signals from the infusion unit. The infusion system is adapted for operating in two different operating modes, namely in a remote control mode and a direct control mode.

RDG 172/00/EP

5

Infusion system having an infusion unit and a remote control unit

10 The present invention relates to an infusion system having an infusion unit and a remote control unit, the infusion unit being arranged and adapted to be located outside the body and to infuse a liquid into the body. The infusion unit has a housing having a fluid reservoir for receiving the liquid, an input device for inputting infusion control
15 commands, an output device and a communication device for wirelessly transmitting signals to and receiving signals from the remote control unit. The remote control unit has a housing, an input device for inputting infusion control commands, an output device and a communication device for wirelessly transmitting signals to and receiving signals to and
20 from the infusion unit. At least one of the infusion control commands generated by actuating one of the input devices is a command requiring verification, whose transmission and/or execution is verified by a verification signal perceivable by the user, which is outputted by one of the output devices.

25

Such devices are used in diabetes treatment to equalize the insulin balance of the patient by injecting insulin. The equalization of the insulin balance is important because both an insulin dose being too high and also an insulin dose being too low are quite harmful for the patient.

30

Therefore, multiple devices are known in the prior art, which operate either as "stand-alone devices", i.e., as individual devices, or additionally have a remote control for controlling the infusion device. Remote control has the advantage that the infusion device can be worn on the body under the clothing and can be operated and controlled comfortably via the remote control. A device of this type is disclosed, for example, in EP 0 048 423 A2.

WO 01/70307 A1 suggests an infusion unit with a shaft which is worn on the body. A "communication key" can be inserted into the shaft to control the infusion unit by a remote control. The remote control can communicate with the infusion unit either via a cable connection or via a wireless connection. In addition to a special remote control device, the possibility of using a computer or a handheld computer for the remote control is also provided for programming the infusion unit. This is preferable, in particular, if more complex programming of the infusion unit is to be performed by medical personnel. The specific remote control is sufficient for simple operation of the infusion unit. Only the bolus rate or the basal rate can be changed and/or set. The communication key can also be removed, however. In this case, the infusion unit operates as an individual device and can not be remote controlled.

A remote controllable infusion apparatus is also known from EP 1109586 B1. In addition to the infusion device, a remote commander (remote control unit) is part of the system described therein. The infusion device can be operated and programmed via the remote control unit. Since maintaining the infusion quantity is very important for the health of the patient, it is suggested that the infusion control commands transmitted to control the infusion unit be acknowledged. For this purpose, verification signals in the form of a visual or acoustic display or a vibration are outputted at the infusion device when a command has been received from the remote control unit. A further verification signal is outputted when the command received from the remote control unit is executed. Thus, the user can, also with remote control of the infusion device, monitor the transmission of the commands to and the execution

of the commands by the infusion device via the verification signals. The infusion pump is continuously ready to receive in order to recognize and acknowledge the signals transmitted by the remote control unit.

5 It is an object of the present invention to suggest an infusion system which is improved in its operation, to make the operation more secure and tolerant of errors. In particular, the uncertainty factor of the overall system given by the man-machine interface is to be reduced.

10 The object is achieved by an infusion system with the features of Claim 1.

The infusion system according to the present invention having an infusion unit and a remote control unit having the features defined in the
15 preamble of Claim 1 is distinguished in that the infusion system is adapted for operating in two operating modes. The system includes a trigger device, which switches between the two operating modes, namely a remote control mode and a direct control mode. In the remote control mode, at least one infusion control command, which requires verification,
20 is generated by the input device of the remote control unit and the corresponding verification signal is outputted by the output device of the remote control unit. In the direct control mode, at least one infusion control command, which requires verification, is generated by the input device of the infusion unit and the corresponding verification signal is
25 outputted by the output device of the infusion unit. The system operates either in one or the other mode.

The commands for controlling the infusion, for example, for setting the "basal rate" or for a temporary infusion increase ("bolus") are referred to
30 as infusion control commands. Those commands are inputted at either the input device of the remote control unit or the infusion unit. Of course, other commands can also be inputted at the input devices, for example, to change a display or to set an internal clock. However, these are not infusion control commands in the meaning of the present invention.

A significant improvement of the operating safety is achieved by the present invention, the special problems existing in this field having to be taken into consideration:

- Diabetes is a severe illness having high, ultimately fatal risks.
- 5 - Any operating errors must therefore be avoided with the greatest possible reliability.
- The users are restricted in their operational reliability because of the illness and their usually advanced age. The restrictions relate in many cases to the short-term memory. The transmission of tactile
10 stimulations is also frequently reduced.
- The operation of an infusion system suitable for diabetes treatment must therefore be as simple as possible. A "robust" operation is required in the meaning that errors are avoided as much as possible through intuitive operability.

15

In the context of the present invention, it has been established that a significant improvement is achieved in this regard if the verification signal for acknowledging the input of an infusion control command is always (at least also) outputted to the unit of the system at which the command
20 input has occurred. Although the change of the output location of the verification signal first appears to be a reduction in comfort, which apparently results in greater complexity and thus makes it more difficult to assign the verification signals, it was established in the context of the experiments, which the present invention is based on, that a significant
25 increase of the operational reliability is achieved. The user receives a direct confirmation by the "locally generated" verification signal that he has performed an input at the appropriate unit (remote control unit or infusion unit). This information is redundant - from the viewpoint of information theory - because the user himself has inputted the command
30 at the corresponding unit. However, it has been established that this redundancy increases the operational reliability. It is to be considered that an infusion control command typically comprises a sequence of individual commands which are inputted by pressing keys. It has been established that the capability of the user to input this sequence correctly

and completely at the particular selected input device is significantly improved by the present invention by the locally outputted verification signal. For example, an additional insulin infusion ("bolus") is programmed by a series of key presses, which are each verified. The local feedback given, if the present invention is used, intuitively ensures that the user also performs the further key presses of a command sequence consequently (at the same input unit).

In addition to this improvement of the operation, the present invention typically also results in savings of the power consumption, because the components not required in the particular operating mode can be turned off. For example, in the direct control mode, the communication device of the infusion unit is expediently turned off. In the remote control mode, the output device of the infusion unit can be disconnected from the power supply. This power savings is important because the operating time at a given battery capacity is thus increased.

The system is preferably configured in such a manner that the switch between the operating modes does not occur completely automatically, but rather requires an action of the user. The user can (and must) consciously decide whether he wishes to operate the infusion system in the remote control mode or in the direct control mode. Thus, the operator has the freedom of always acting correctly in a situation. This freedom is connected with the security that due to the clear either-or principle, i.e., either remote control mode or direct control mode, his action is intuitively correct. Preferably, these aspects are also supported in that the system can optimally react to customer requirements due to identical operating sequences both when operating via the remote control unit and also when operating the infusion unit in the direct control mode. Due to, in known systems, operation is possible in parallel both at the remote control unit and also via key presses at the infusion unit, the user is frequently confused. This can result in incorrect inputs and incorrect operations of the infusion system.

In the remote control mode, all infusion control commands requiring verification are preferably generated by the input device of the remote control unit and all corresponding verification signals are outputted (in any case also) by the output device of the remote control unit. No
5 verification signals are preferably outputted at the infusion unit.

In the direct control mode, all commands requiring verification are preferably generated by the input device of the infusion unit and all corresponding verification signals are outputted (in any case also) by the
10 output unit of the infusion unit. The user operates the infusion pump as a standalone device and inputs all commands directly at the infusion unit. Here, preferably, the verification signals for the infusion control commands, which control the infusion pump, are also outputted only at the infusion unit. The remote control unit is not required. It can be turned
15 off. This is advantageous, for example, if the remote control unit has broken down due to a defect or if it was lost and/or forgotten by the patient. In this case as well, the infusion system according to the present invention can be operated further in the typical manner, so that the life-supporting functions executed by the system can be performed securely.

20 The verification signals can be outputted as visual signals (for example, using one or more control lights or by displaying clear text on a display), as acoustic signals (e.g., in the form of tones or as speech output), or as tactile signals (e.g., vibrations). A combination of these signal forms is
25 also possible. If different signal types are used in a system, the output can depend on a user setting or on the location of the output, i.e., whether the verification signal is outputted at the infusion unit or at the remote control unit.

30 Preferably, the verification signal, that can be recognized by the user, is a "command verification signal" indicating that an infusion control command has been received by the infusion unit.

35 According to another preferred embodiment, the verification signal distinguishable by the user is an "execution verification signal" indicating

when an injection control command has been executed by the infusion unit. It can further be differentiated whether the execution of the injection control command has just been started or whether the execution has been ended. Both can be indicated in the form of an execution verification signal.

It is also possible to output multiple verification signals one after another. If an execution verification signal is outputted after the output of a command verification signal. This is referred to as a "double indication". If two execution verification signals are generated after the command verification signal, one to indicate that the execution of the infusion control command has been started, and one to indicate that the execution of the infusion control command has been finished, this is referred to as a "triple indication".

In the remote control mode, a double indication is preferably outputted to the remote control unit when a command requiring verification has been generated by the input device of the remote control unit. Optionally, an additional verification signal can be outputted at the infusion unit. In the direct control mode, the same principle can be performed. Here also, a double indication is preferably outputted. In addition, a verification signal can optionally be outputted at the remote control unit. The different output possibilities can be implemented directly by the manufacturer in the infusion system; however, they can also be selected and/or set by the user. In addition to the situational switching of the operating modes by the user, situational determination of the output of the verification signals is thus also possible.

7a

In accordance with another aspect of the present invention, there is also provided, an infusion system having an infusion unit and a remote control unit, the infusion unit being adapted to be located outside the body and to infuse a liquid into the body and comprising: a housing with a fluid reservoir for the liquid; an input device for inputting infusion control commands; an output device; a communication device for wirelessly transmitting signals to and receiving signals from the remote control unit; the remote control unit comprising: a housing; an input device for inputting infusion control commands; an output device; a communication device for wirelessly transmitting signals to and receiving signals from the infusion unit; wherein at least one infusion control command generated by actuating one of the input devices is a command requiring verification, and transmission and/or execution of said command is verified by a verification signal perceivable to the user, said verification signal being outputted by one of the output devices; and wherein the infusion system is adapted for operating in two different operating modes, namely a) a remote control mode, in which at least one command requiring verification is generated by the input device of the remote control unit and the corresponding verification signal is output by the output device of the remote control unit, and b) a direct control mode, in which at least one command requiring verification is generated by the input device of the infusion unit and the corresponding verification signal is outputted by the output device of the infusion unit, and includes a trigger device for switching between the remote control mode and the direct control mode.

Preferred exemplary embodiments are described in the following drawing. The technical features illustrated therein can be used individually or in combination to provide preferred embodiments of the present invention.

Fig. 1 shows a schematic diagram of an infusion system having an infusion unit and a remote control unit;

Fig. 2 shows a more detailed block diagram of the infusion unit and the remote control unit from Figure 1;

Fig. 3 shows a block diagram of an alternative remote control unit;

5 Fig. 4 shows a block diagram to explain the function of a trigger device;

Fig. 5 shows a schematic diagram of an alternative embodiment of the infusion system with an infusion unit and remote control unit.

10 Figure 1 shows an infusion system 1 having an infusion unit 2 and a remote control unit 3. The infusion unit 2 pumps a liquid, in particular insulin, through thin tubing to an injection unit 4 having a needle. The injection unit 4 is attached to the body of the patient. As shown in a schematic illustration, the infusion unit 2 has an output device 5
15 implemented as a display 6. Verification signals can be displayed on the display in visual form to acknowledge infusion control commands for controlling the infusion unit 2.

An input unit 7 has keys 8 for controlling the infusion unit 2. The basal
20 rate of the infusion unit 2 can be changed and a bolus can also be set via the keys 8. The complete functional control of the infusion unit 2 can also be performed using the keys 8.

The remote control unit 3 also has an output unit 9, which is implemented
25 as a display 10 for visual display. In addition to the verification signals generated as an answer to the infusion control commands, further indications are also output on the display 10. For example, the time of day or other relevant data can also be displayed.

30 An input device 11 of the remote control unit 3 substantially corresponds to the input device 7 of the infusion unit 2. The input device 11 is implemented with keys 12. Due to a similar design of the input devices 7, 11 and the output devices 5, 9, the operation at both the remote control unit 3 and also the infusion unit 2 is identical for the user. There is no

difference for the patient whether he operates the infusion system 1 via the infusion unit 2 or the remote control unit 3. In this way, operating errors are minimized and the operating comfort is increased.

5 Figure 2 shows a block diagram of the infusion unit 2 and the remote control unit 3. The infusion unit 2 has a fluid reservoir 13 receiving the liquid, which is applied via the injection unit 4 into the body of the patient. A pump 14 is connected to the fluid reservoir 13. Controlling the pump regulates the infusion quantity to be applied. In particular, the basal rate
10 set in the infusion unit 2 is fixed by the speed of the pump delivery. A bolus optionally to be applied additionally can be controlled by the duration and the amount of a temporary increase of the pump speed.

15 Furthermore, the infusion unit 2 comprises a power supply unit 15, a microprocessor 16, and a communication device 17 for wirelessly transmitting signals to and receiving signals from the remote control unit 3. The power supply unit 15 supplies all components of the infusion unit 2 with power. The output device 5 is shown as a block. The output device 5 comprises a loudspeaker 5' that is used for the acoustic output of
20 verification signals at the infusion unit 2. A trigger device 18 is used for switching between the remote control mode and the direct control mode of the infusion system 1.

25 In addition to the input device 11 and the output device 9, the remote control unit 3 comprises a loudspeaker 9' for the acoustic output of verification signals. A microprocessor 19 processes the inputs of the input device 11 and the signals transmitted wirelessly from the infusion unit 2, which are received by a communication device 20. The communication device 20 operates bidirectionally. It also transmits
30 signals from the remote control unit 3 to the infusion unit 2. A power supply unit 21 supplies the remote control unit 3 and all components with the required power.

35 The communication devices 17 and 20 are preferably implemented as transceivers; therefore, they comprise a transmitter for transmitting

signals and also a receiver for receiving signals. The transmitted signals are preferably electromagnetic waves. Alternatively, the communication between the communication devices 17 and 20 can be performed via optical signals (in particular via infrared signals). The signals can be coded in the usual ways.

Figure 3 shows an alternative embodiment of the remote control unit 3 also comprising a trigger device 22 in addition to the components already described. Then, no trigger device 18 has to be provided in the infusion unit 2.

In a preferred embodiment of the infusion system 1, the communication device 17 of the infusion unit 2 is deactivated upon the switch into the direct control mode. It is not required in the direct control mode, because no signals have to be transmitted to the remote control unit 3.

The communication device 17 of the infusion unit 2 is especially preferably disconnected from the processor 16 when it is deactivated. Then, the processor 16 transmits no signals to the communication device 17. Additionally or alternatively, the communication device 17 can be disconnected from the power supply unit 15. The deactivation of the communication device 17 is advantageous for multiple reasons. On the one hand, energy is saved, so that the energy stored in the power supply unit 15 lasts longer for operating the infusion unit 2. In addition, interfering influences on the system and the environment are reduced. For example, the shutdown of the communication device 17 can be executed by simple interrupt-controlled routines in the microprocessor 16 monitoring all keys 8 of the input unit. For this purpose, one simple switching transistor per line to be switched can be used.

The output device 5 of the infusion unit 2 is preferably deactivated upon the switch into the remote control mode. Since all verification signals are outputted to the output device 9 of the remote control unit 3 and/or 3a in the remote control mode, the output device 9 does not have to be active. The output device 5 can therefore be shut down. For this purpose, the

microprocessor 16 causes a disconnection from the power supply unit 15. When the trigger device 18 or 22 switches the infusion system 1 into the direct control mode, the output device 5 is then reactivated, i.e., supplied with power.

5

When the microprocessor 16 does not output any signals to the output device 5, the output device 5 can also be deactivated. In addition, the loudspeaker 5' can also be deactivated. Alternatively, however, it is possible for the loudspeaker 5' to remain active, so that additional verification signals can be outputted at the infusion unit 2 in the form of acoustic signals. In addition, in spite of the shutdown of the output device 5, a warning tone can be outputted at the loudspeaker 5' if the liquid quantity in the fluid reservoir 13 falls below a critical value or the voltage outputted by the power supply unit 15 is too low, for example.

15

The function of the trigger device 18 is explained on the basis of Figure 4. In order to cause the switch between the remote control mode and the direct control mode, it generates a control signal for the infusion system at its output 18a, which causes the switch between the operating states using known electronic means. The control signal typically forms a command for the microprocessor 16, which in turn causes the operating mode switch.

The trigger device 18 is in turn controlled by a trigger signal which is transmitted to its input 18b. The means for generating the trigger signal react in some manner to actions of the user or changes in the surroundings of the infusion system. Therefore, they are generally referred to as a trigger sensor 24. Different embodiments of the present invention differ due to the type of the generation of the trigger signal or, in other words, due to different embodiments of the trigger sensor 24.

a) In the simplest case, a manually operable input key specially provided for this purpose (dedicated input key) is used as a sensor for generating the trigger signal. Such an input key may be provided both on the infusion unit 2 and also on the remote control unit 3 (cf.

35

Figures 1 and 2; optional input keys 24' and 24", respectively). Of course, numerous variations are possible, for example, a pressure sensitive area in a display 6, 10 designed as a "touch screen" (Figure 1).

5

b) The sensor 24 can comprise a combination of the keys 8, 12 of the input devices 7, 11, which are provided in any case, with a logic circuit. Then, a combination of key presses (for example, the simultaneous pressing of two specific keys) is interpreted as a manually generated command for switching the operating modes. As a result, a trigger signal is generated and transmitted to the input 18a of the trigger device 18.

10

c) The sensor 24 can be formed by input change detection electronics. The electronics detect when the user changes the operation from the infusion unit 2 to the remote control unit 3 or vice versa. Therefore, when the system is in the direct control mode and the user inputs an infusion control command at the remote control unit 3, this is recognized by the input change detection electronics and a trigger signal is transmitted to the trigger device 18. All verification signals being used to acknowledge an infusion control command are now outputted to the remote control unit. Thus, such input change detection electronics also form a sensor 24 for generating a trigger signal for the trigger device 18.

15

20

25

d) Finally, the sensor 24 can also be formed by remote control function detection electronics. These recognize when the conditions for the communication between a remote control unit 3 and an infusion unit 2 (both devices turned on, communication devices of both units in operation, secure data transmission ensured) exist. Under these conditions, such remote control function detection electronics generate a trigger signal. The transmission of the trigger signal to the trigger device 18 causes the remote control mode to be turned on.

30

35 In cases a) and b), the trigger signal is a manually generated signal.

Case c) is an example of how the trigger signal can be generated as a result of the input of any arbitrary command at one of the input devices 7, 11, preferably as a result of the input of an infusion control command. Such a trigger signal is also referred to as a semi-automatically generated signal.

Case d) shows that the trigger signal can also be generated by detecting a signal exchange between the communication devices 17, 20 of the remote control unit 3, 3a, 3b and the infusion unit 2, 2a. A trigger signal of this type is also referred to as an automatically generated signal.

In each of the embodiments described, the switch from a standard mode (such as the direct control mode) into the other mode (remote control mode) can only be triggered by a special trigger signal, while the return into the standard mode is triggered by an (optional) time-dependent control element 23 shown by dashed lines in Figure 4. The time interval, after which the time-dependent control element 23 causes the switch into the standard mode, can be permanently programmed into the system by the manufacturer or changeable by the user.

The means for implementing the configurations of the sensor 24 described can be implemented very differently by electronics and are known. In particular, the functions implemented in the form of separate electronic components (sensor 24, trigger device 18, and possibly time-dependent control element 23) explained on the basis of Figure 4 can be implemented partially or completely by software. The above explanations apply in the same manner if the trigger device is located in the remote control unit, of course.

Figure 5 illustrates a further embodiment of an infusion system 1, comprising an infusion unit 2a and a remote control unit 3b. A recess 26 is provided in the housing 25 of the infusion unit 2a for inserting a communication device implemented as a transceiver module 27. The recess 26 forms a reception chamber 28 fitting to the transceiver module

27. A contact 29 is located in the lower area of the reception chamber 28 for detecting the presence or absence of the transceiver. As soon as the removable transceiver module 27 is inserted into the infusion unit 2a, the contact 29 is closed. Thus, the contact 29 forms a sensor generating a trigger signal. Said trigger signal is applied to the input of the trigger device 18, so that the operating mode is switched into the remote control mode.

The removal of the transceiver module 27 from the reception chamber 28 opens the contact 29. The trigger device 18 switches into the direct control mode. Then, communication with the remote control unit 3b is no longer possible. All inputs are expected at the input device 7 of the infusion unit 2a. Therefore, the trigger signal is manually generated by plugging in and/or removing the transceiver module 27.

During the direct control mode of the infusion system 1, the transceiver module 27 can be stored in a corresponding recess 30 in the remote control unit 3b. In this way, it can not be lost. The transceiver module 27 is only required when the patient wishes to operate his infusion system 1 via the remote control unit 3b and therefore the system must be switched into the remote control mode. The patient then has both the remote control unit 3b and also the transceiver module 27 directly together on hand. He only still has to plug the remote control unit 3b into the infusion unit 2a.

Instead of the transceiver module 27, a removable antenna module can also be provided. The antenna module is used in the same manner as the transceiver module 27.

CLAIMS:

1. An infusion system having an infusion unit and a remote control unit, the infusion unit being adapted to be located outside the body and to infuse a liquid into the body and comprising:
 - a housing with a fluid reservoir for the liquid;
 - an input device for inputting infusion control commands;
 - an output device;
 - a communication device for wirelessly transmitting signals to and receiving signals from the remote control unit;the remote control unit comprising:
 - a housing;
 - an input device for inputting infusion control commands;
 - an output device;
 - a communication device for wirelessly transmitting signals to and receiving signals from the infusion unit;wherein at least one infusion control command generated by actuating one of the input devices is a command requiring verification, and transmission and/or execution of said command is verified by a verification signal perceivable to the user, said verification signal being outputted by one of the output devices; and
wherein the infusion system is adapted for operating in two different operating modes, namely
 - a) a remote control mode, in which at least one command requiring verification is generated by the input device of the remote control unit and the corresponding verification signal is output by the output device of the remote control unit, and

b) a direct control mode, in which at least one command requiring verification is generated by the input device of the infusion unit and the corresponding verification signal is outputted by the output device of the infusion unit,

and includes a trigger device for switching between the remote control mode and the direct control mode.

2. The infusion system according to claim 1, wherein, in the remote control mode, all commands requiring verification are generated by the input device of the remote control unit and all corresponding verification signals are output by the output device of the remote control unit.
3. The infusion system according to claim 1, wherein, in the direct control mode, all commands requiring verification are generated by the input device of the infusion unit and all corresponding verification signals are output by the output device of the infusion unit.
4. The infusion system according to any one of claims 1 to 3, wherein the trigger device switches between the operating modes when a trigger signal is transmitted to its input.
5. The infusion system according to claim 4, wherein the trigger signal is a manually generated signal.
6. The infusion system according to claim 4, wherein the trigger signal is generated as a result of the input of any arbitrary command at one of the input devices.

7. The infusion system according to claim 6, wherein the trigger signal is generated as a result of the input of an infusion control command
8. The infusion system according to claim 4, wherein the trigger signal is generated by detecting a signal exchange between the communication devices of the remote control unit and the infusion unit.
9. The infusion system according to any one of claims 1 to 8, wherein the communication device of the infusion unit is deactivated upon the changeover into the direct control mode.
10. The infusion system according to claim 9, wherein the communication device of the infusion unit is disconnected from at least one of a processor of the infusion unit and a power supply unit of the infusion unit when the communication device is deactivated.
11. The infusion system according to any one of claims 1 to 10, wherein the output device of the infusion unit is deactivated upon the switching into the remote control mode.
12. The infusion system according to any one of claims 1 to 11, wherein the verification signal perceivable to the user is a command verification signal, indicating that an infusion control command has been received by the infusion unit.
13. The infusion system according to any one of claims 1 to 12, wherein the verification signal perceivable to the user is an execution

verification signal, which indicates when an infusion control command has been executed by the infusion unit.

14. The infusion system according to any one of claims 1 to 13, wherein the trigger device comprises a time-dependent control element, so that after switching over into the direct control mode, the system is switched back automatically into the remote control mode after a predetermined time.

1/3

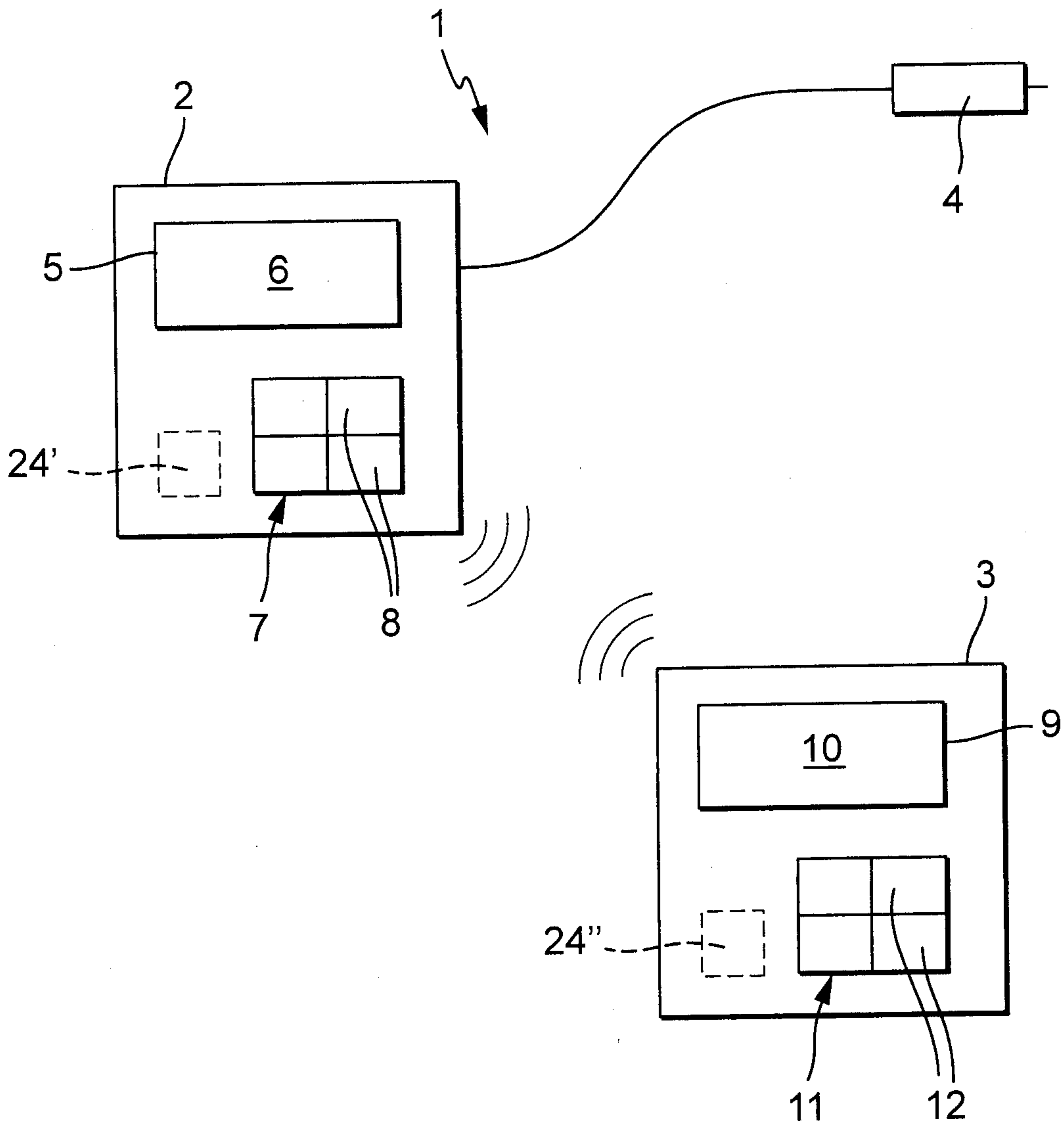
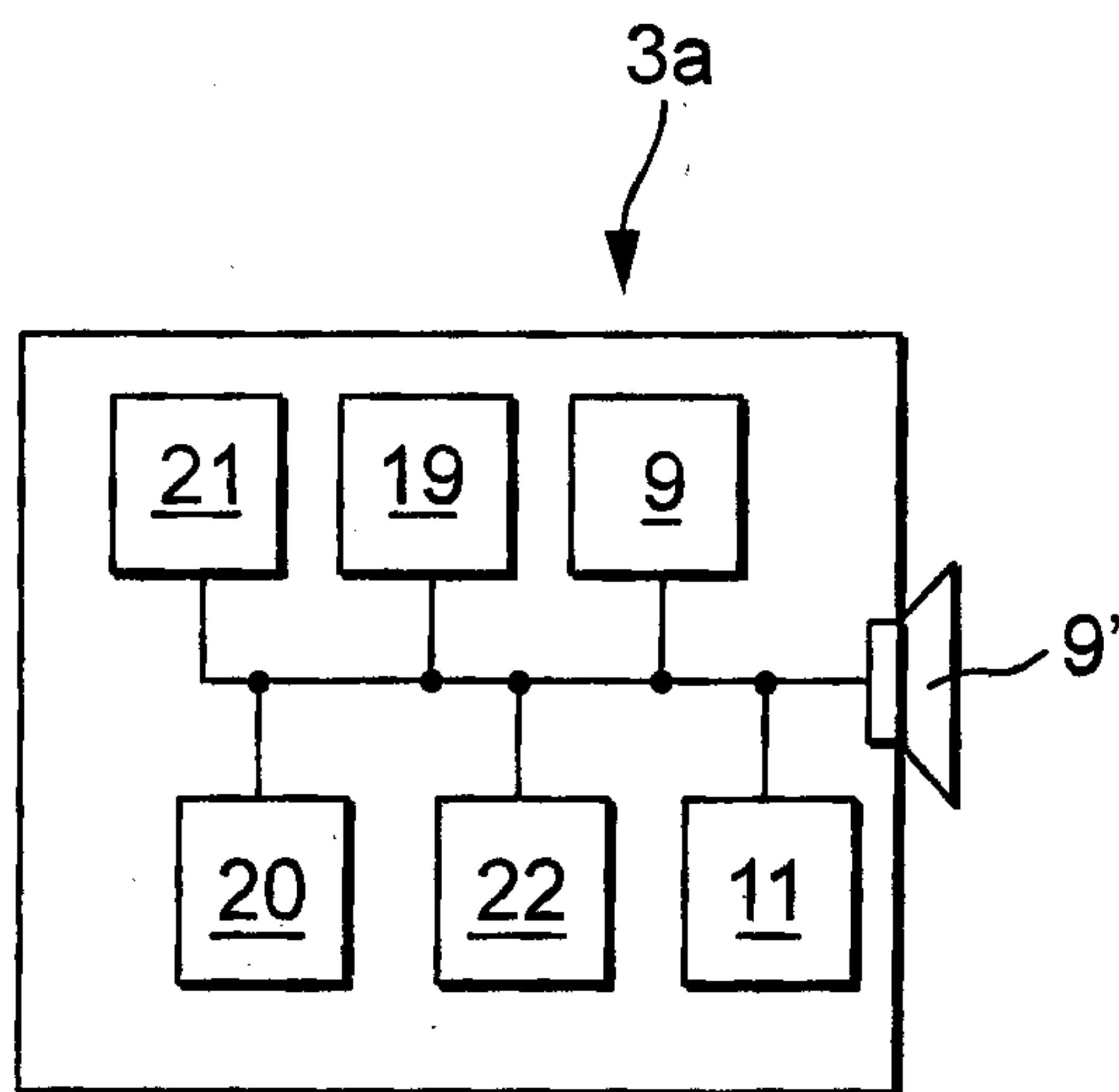
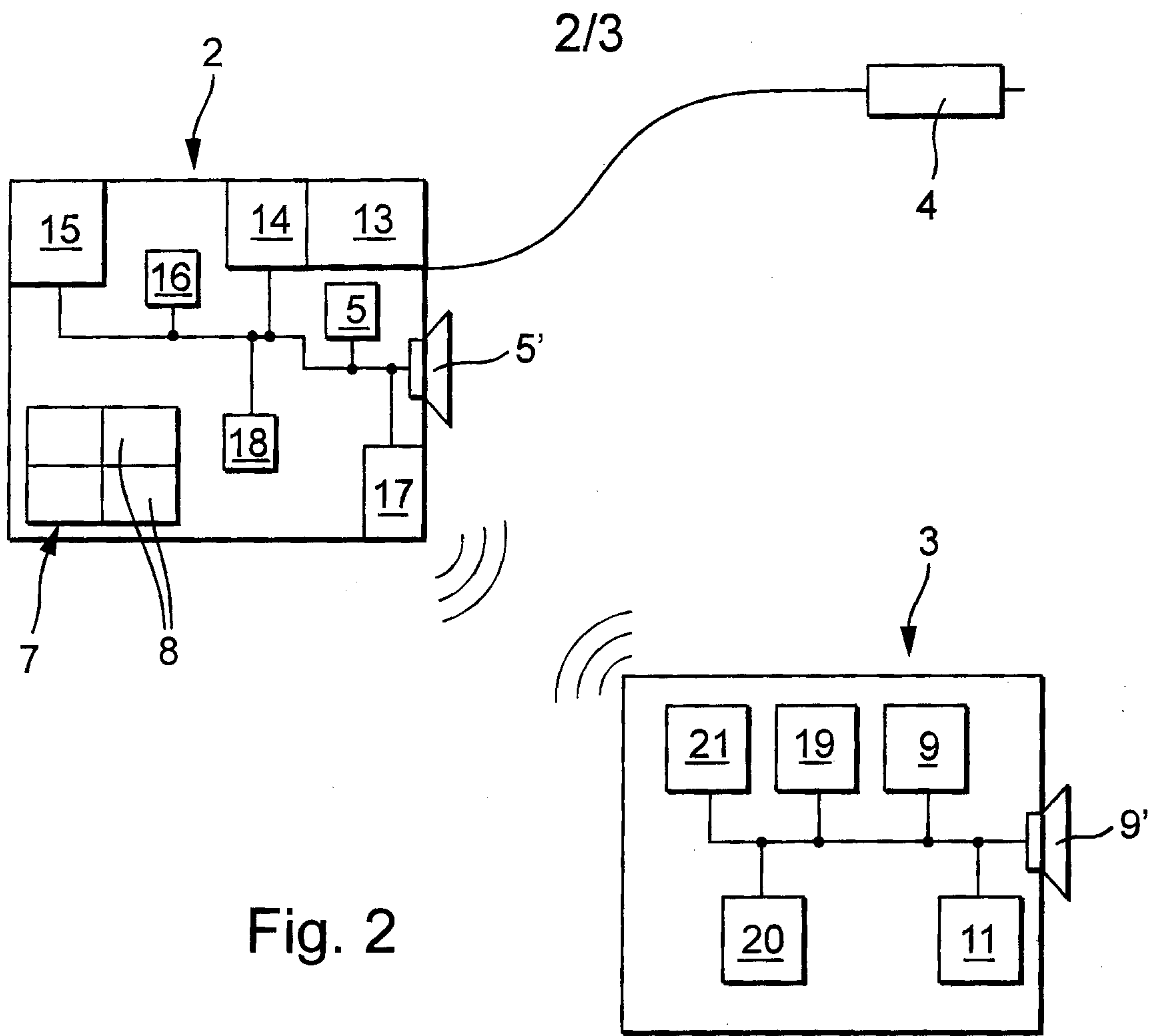


Fig. 1



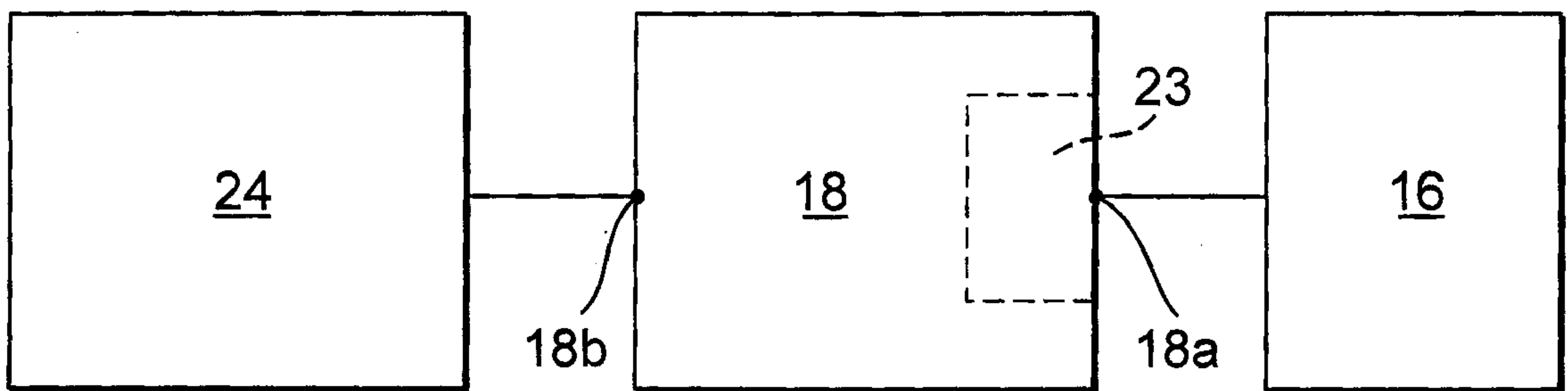


Fig. 4

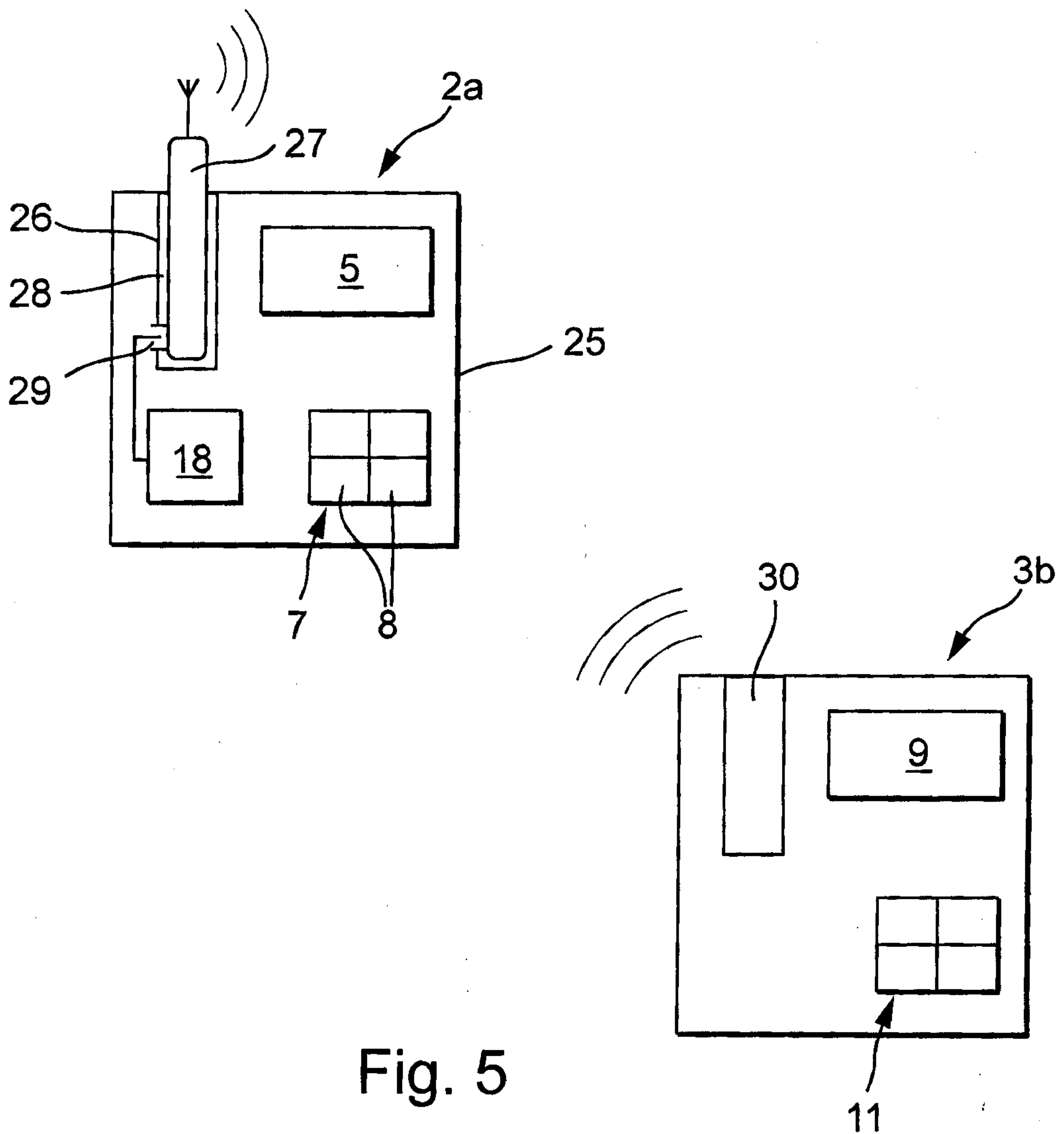


Fig. 5

