(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 629 822 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
01.03.2006 Bulletin 2006/09

(51) Int Cl.:
A61J 7/04 *(2006.01)*

(21) Application number: **05107739.4**

(22) Date of filing: **23.08.2005**

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR
Designated Extension States:
AL BA HR MK YU

(30) Priority: **23.08.2004 FI 20040302 U**

(71) Applicant: **Dose Control Oy**
03400 Vihti (FI)

(72) Inventor: **KORANDER, Kari**
03400, Vihti (FI)

(74) Representative: **Hakola, Unto Tapani**
Tampereen Patenttitoimisto Oy,
Hermiankatu 12 B
33720 Tampere (FI)

(54) Device for monitoring the administration of doses

(57) A device for monitoring the administration of doses is intended to be used in connection with a container unit (S) of n × m matrix form, preferably equipped with a set of compartments. The monitoring unit comprises a space in which the container unit (S) of n × m matrix form can be placed in a releasable way, to cooperate with the alarm and reminder system of the device for monitoring the doses.

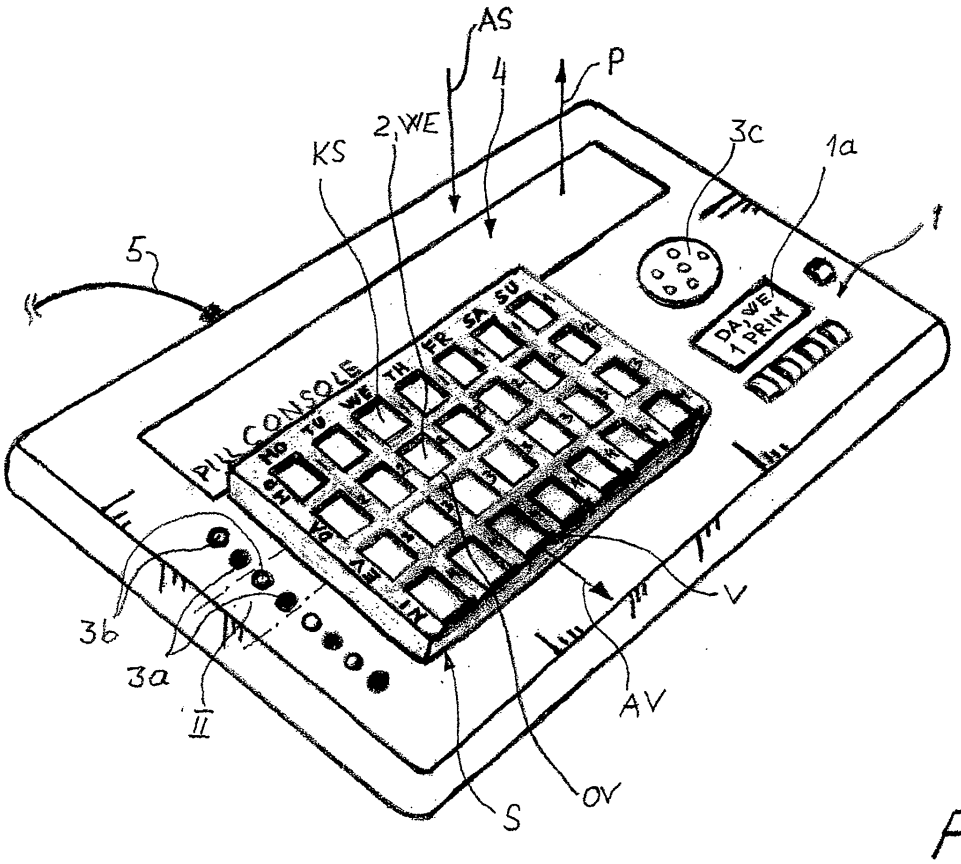

Fig.2

EP 1 629 822 A2

Description

[0001] The invention relates to a device for monitoring the administration of doses, defined in more detail in the preamble of the independent claim.

[0002] For doses of medicine to be taken at intervals, it has been customary to use various alarm systems based on a timer in connection with various container units for doses of medicine. Normally, the doses of medicine are in the form of pills, tablets or corresponding doses to be taken orally. Examples to be mentioned in this context include alarm systems for medicament boxes disclosed in application publications GB 2179919 and FR 2666225.

[0003] In addition, patent US-5200891 discloses a container unit of orally administered doses of medicine, intended for home use, comprising spaces for storing each drug and also including a reminder function to alarm of the time when each dose of medicine is to be administered. The container unit also detects if the dose of medicine has been administered appropriately from the space corresponding to the time of administration. The storage spaces in the container unit are arranged as a set of compartments in the box-like frame of the container unit, wherein each compartment in turn can be pulled out, like a drawer, for the administration of a dose of medicine.

[0004] In practice, however, alongside with these container units equipped with reminder and/or alarm functions, container units, so-called "dosette" boxes, are commonly used, which are equipped with an openable and closable set of compartments that is arrayed in a matrix form (generally n × m matrix, n being the number of rows and m the number of columns, and n being equal to or different from m), wherein each compartment in the set of compartments can be separately opened for administering a dose of medicine according to instructions in connection with the container unit. The container unit is typically made of a plastic material, for example, by a method of deep drawing and/or injection moulding. The matrix form is typically based on the principle of weekly filling; in other words, the number of columns in the matrix form is seven, corresponding to the days of a week, and the number of rows varies typically from four to six, even eight. Each row is intended for a dose of medicine to be administered at a given time each day, and different times of administration are assigned to different rows for the dose of medicine in question; for example, seen from the top down in the use position of the container unit, four rows of the container unit define the purpose of use for the row in question: the morning dose, the daytime dose, the evening dose, and the night dose. Container units of this kind are presented in the publications US 5,174,451 and US 5,379,899. The container unit according to the latter publication is commercially available (registered trademark DOSETT).

[0005] For example the container unit according to US 5,379,899 comprises structurally an integral compartmented base of a rectangular shape to be placed inside a box-like container unit and to be closed inside by an openable lid part. The compartmented base is designed to comprise four horizontal rows and seven vertical columns in the use position of the container unit, wherein the compartmented base thus consists of twenty-eight (n = 4 and m = 7) compartments joined together. The top part of the frame of the container unit is equipped with seven preferably transparent lid strips that are manually movable on the support of guides in the frame in the longitudinal direction of each column. By gripping the free end of said lid strip and by suitably pulling the lid strip outside the container unit, the upper part of the compartment in turn for use can be opened and the dose of medicine can be removed from the compartment. The edge parts of the frame of the container unit are equipped with markings of the day of the week by the columns and with markings of the time of administration of the dose by the rows.

[0006] There is also known a set of compartments of the above-described type, comprising integrated visual and acoustic reminder functions, *i.e.* the electronics for controlling them. Such a device is described in the document FR 2818124.

[0007] It is an aim of the invention to present a device for monitoring the administration of doses by utilizing known container units of matrix form, for example the structures according to the above-mentioned documents US 5,174,451 and US 5,379,899, and thereby promoting the reliability of such container units of matrix form and medical safety in general. For achieving this aim, the device for monitoring the administration of doses according to the invention is primarily characterized in that the device for monitoring the administration of doses comprises a space in which a container unit of n x m matrix form can be placed in a releasable manner to cooperate with an alarm and reminder system of the device of monitoring the administration of doses.

[0008] Thanks to the solution, it is possible to significantly increase the reliability of a commercially available container unit equipped with an openable and closable set of compartments but having no integrated alarm and reminder system. An additional advantage is that the wearing or damage of the container unit that is primarily subjected to daily handling does not affect the actual device for monitoring the administration of doses, but in such cases, the container unit, which has a reasonable price, can be replaced at low cost. All the required electronics and possible data transmission connections can be included in the electronic monitoring device. By designing the space where the container unit is to be placed in the device for monitoring the administration of doses to be functionally easy to use, it is easy to take along the container unit with simple measures when leaving the location where the device for monitoring the administration of doses is kept, as well as it is easy to remove the container unit for the administration of a dose of medicine and further for the weekly refilling of the container unit.

[0009] Consequently, by means of the invention, it is

possible to utilize existing container units, made at low production costs, for example those sold under the trademark DOSETT.

[0010] In the following, the invention will be described in more detail with reference to the appended drawings, in which

Fig. 1 is a perspective view showing an application of the device for monitoring the administration of doses according to the invention,

Fig. 2 is another perspective view showing the application of the device for monitoring the administration of doses according to Fig. 1, equipped with a container unit of n x m matrix form, and

Fig. 3 is a principle view showing a monitoring device that can be varied according to the size of the container unit.

[0011] In particular, the application of the device for monitoring the administration of doses, shown in Fig. 1, has the general design of a rectangular plate. On the upper surface of the frame of the monitoring device, the main elements visible to the user are, from the right-hand side of Fig. 1, a programming and display unit 1, a field 2 for receiving a container unit S (Fig. 2) in connection with the monitoring device, and an alarm and reminder unit 3. The elements 1 to 3, together with the programmable data processing unit inside the casing of the monitoring device and advantageously with remote connections provided in the device, constitute the alarm and reminder system of the monitoring device. The container unit S, shown in Fig. 2 and placed in the monitoring device, contains doses of medicine (not shown) arranged in different compartments according to the schedule of administration of the doses.

[0012] Furthermore, the upper surface of the monitoring device may comprise text 4 or corresponding information to explain the use of the monitoring device. The device for monitoring the administration of doses can be coupled via a transformer (not shown in the figures) to an electrical power network by a connection cord 5. Preferably, the device comprises a battery as a backup power supply.

[0013] A data processing unit consisting of programmable electronic circuits is placed inside the casing. The programming and display unit 1 comprises a display 1 a, programming and function keys 1b (in the application, four keys in a row) and an alarm key 1c, all connected to the data processing unit. By using the programming and function keys 1b, programming data of the data processing unit as well as various instructions and data for the user of the monitoring device, for example, about the dose of medicine to be administered at the time, can be displayed on the display 1a.

[0014] The field 2, which is preferably a planar rectangular recess 2a extending downwards from the upper surface of the monitoring device and having the size corresponding to the rectangular bottom surface of the container unit S, comprises a coupling element 2b connected to the data processing unit and indicating that the container unit S is either placed in the field S for the monitoring device, or detached from it. The coupling element 2b may be, for example, a mechano-electrical micro-switch, or a sensor operating on contactless principle.

[0015] Alternatively, the field 2 may be an area limited by elevated stoppers, such as elongated edges, normally a structure formed in the upper surface of the device of a type in which the container unit can be placed in a given position defined by the stoppers. Consequently, the monitoring device comprises a space in which the container unit S can be placed in a given position to cooperate with the automatic alarm and reminder system of the device.

[0016] In the presented embodiment, the alarm and reminder system 3 coupled to the data processing unit consists, in its visual appearance, of four pairs I to IV of indicators, preferably electrical colour indicators 3a, 3b. They are aligned in the upper surface of the monitoring device in the longitudinal direction of the edge parallel with the columns of the n x m matrix form of the container unit of the field 2. Preferably, the colour indicators 3a, 3b (for example, 3a green and 3b red) may be, for example, colour LEDs (light-emitting diodes). The monitoring device shown in the figures is thus intended for such an application of the container unit S that comprises, for each day of the week, four times of administering a dose of medicine; in other words, the n x m matrix form is 4 x 7. Each colour indicator pair 3a, 3b is placed by a given row in the matrix form, for example in such a way (Fig-2) that I, II, III and IV correspond to the locations of the compartments for doses of medicine to be taken in the morning, in the daytime, in the evening and at night, respectively, when the container unit is placed in the field 2. Preferably, the alarm and reminder unit 3 also comprises a buzzer device 3c, which can be used to support the alarm and reminder functions in the form of acoustic signals.

[0017] In the figure, the indicators are arrayed in a vertical row on the left-hand side of the field, but alternatively, they can be arrayed on the right-hand side of the field.

[0018] In the presented embodiment, the device for monitoring the administration of doses operates in the following way:

[0019] The container unit S is refilled weekly with the doses of medicine prescribed for each day and time of administration in such a way that the medication for the whole week is stored in the container unit S. The container unit S is then placed in the field 2 (Fig. 2), wherein the monitoring device receives this information by means of the coupling element 2b. The container unit can be filled by a person other than the user, for example by a home aid. Consequently, the container unit S is a container unit for doses of medicine, which can be used several times and which can be refilled from the actual packages of medicine.

[0020] The data processing unit of the monitoring de-

vice comprises a timer in which the times of the day when a given dose of medicine should be administered can be programmed with the keys 1b of the programming and display unit 1, in advance when the monitoring device is taken into use, or when the medication regime is changed. When, during the use of the monitoring device, a time matches with the time of administration of a dose of medicine programmed in the timer, the monitoring device gives an alarm; in other words, the first LED 3a, preferably a LED with green colour, placed by the row corresponding to the time of administration of said dose of medicine, is lit. The green colour thus indicates that the dose of medicine is available to be administered. Preferably, this visual alarm signal is also combined with an acoustic signal from the buzzer device 3c. In the normal situation, after the detection of the alarm, the container unit S is detached from the field 2 of the monitoring device for the administration of the dose of medicine. Thus, the time of detachment is recorded by the coupling element 2b, preferably a micro-switch. The administration of the dose of medicine is recorded in the data processing unit as being completed after the container unit S has stayed detached from the field 2 for a required minimum time recorded in the programming and display unit 1. At this point, the first, green LED 3a is turned off and the second LED 3b, preferably of red colour, is lit to indicate that the dose of medicine has been administered. The programming may suitably comprise a function that the second, red LED 3b is turned off after a given time; in other words, none of the LEDs 3a, 3b (I-IV) is on, wherein the status indicated by the monitoring device is: the preceding dose of medicine has been taken, a certain time has passed from its administration, and it is not yet time to administer the next dose of medicine.

[0021] Yet another alternative is that when it is not time to take any dose, all the indicators have the colour indicating a warning, preferably red; in other words, when the indicator is a pair of visual indicators, the second indicators (LEDs) 3b are on. When it is time, *i.e.* allowable, to administer a dose from a given compartment, the indicator of the respective compartment (the indicator at the end of the row of compartments containing said compartment) is turned to a state in which it has the colour allowing the administration, preferably green; that is, when the indicator is a pair of visual indicators, the first indicator (LED) 3a is lit and the second one 3b is turned off.

[0022] An auxiliary function programmed in the data processing unit of the monitoring device is that if the administration of a dose of medicine is not recorded within a given time after the above-presented first alarm, a second alarm, a "reminder alarm", will be given, which may be of a different type, for example a different acoustic signal and/or a different visual signal; for example, a blinking function begins in the green LED 3a.

[0023] Furthermore, a special alarm function is preferably programmed in the data processing unit of the device, which will be activated when a given time has passed from the time of the first alarm (the programmed time of administration of the dose). This special alarm is programmed to be sent outside the location where the monitoring device is kept, via a wired or wireless communication line (for example, GSM) (not shown in the drawings). Such a special "remote alarm" may be a third alarm; in other words, it follows the above-described reminder alarm, or it may be directly the second alarm. The telephone number, to which the remote alarm will be sent, can be programmed in the device in advance. Such a remote alarm may also be combined with an audio and/or light signal given by the device. Thus, by means of the remote alarm function, it is possible to give indirectly information that the user of the device may have problems, because a deviation from the normal daily routines may be an indication of such a problem.

[0024] The data processing unit of the monitoring device may also comprise other programmable properties; for example, if the container unit is re-detached from the monitoring device before it is time to take the next dose of medicine, the monitoring device may indicate, in the absence of other operations, a malfunction by giving a visual and/or acoustic warning signal which may be, for example, a blinking function of the second, red LED 3b and/or a sound different from the above-mentioned acoustic signals via the buzzer 3c. Furthermore, if the container unit S has stayed detached from the field 2 during the administration of the dose of medicine for a longer time than allowed by the programmed time for detachment, this may be interpreted, in the absence of other operations, as a malfunction, of which an acoustic and/or visual signal can be given to the user, or an alarm can be sent outside the location where the monitoring device is kept, via a wired or wireless communication line (for example, GSM). To avoid the occurrence of the above situations interpreted as malfunctions, the programming of the monitoring device also comprises a by-pass function; that is, if the container unit S is taken along when leaving the location where the monitoring device is kept, this information can be entered in the data processing unit of the monitoring device. The by-pass function can be set to last for a short time or a longer time, to avoid unnecessary alarms.

[0025] The programming may comprise a function, by which data relating to the dose of medicine which is being taken can be shown on the display 1a. The monitoring device also comprises an alarm key 1c, which can be pressed preferably continuously, for example for 0.5 seconds, to send a special alarm as a remote alarm outside the location where the monitoring device is kept, for example to an emergency centre, an outpatient department, the doctor in charge of the treatment, a nurse, and/or a home aid. Consequently, the monitoring device may communicate with one or more external supervisors having different authorizations to change the programming of the monitoring device and/or to monitor the function of the monitoring device, wherein e.g. a wired or wireless data transmission connection (for example, GSM)

is used in the communication. Thus, for example a doctor can monitor the treatment, and in the case of a duplex connection, the doctor can also program the monitoring device by remote control. Thus, via the data transmission line, it is possible to program various instructions in the data processing unit of the monitoring device, such as the quantities of doses of medicine, other instructions such as instructions for meals and excercises which can be shown on the display 1 a, *etc.* Furthermore, it is possible to change the times of administering the doses of medicine (new alarm and reminder times) by using the communication connection. Although the communication connection is protected as well as possible, the monitoring device contains a security function for backup, said security function allowing only a change of a given quantity, one way or the other, in the values relating to the administration of the drug dose (time of day, quantity of the dose of medicine), i.e. an upper limit is determined for the changes. The methods and targets of data transmission described here can also be used for implementing the above-described automatic remote alarm function following a failure to administer a dose.

[0026] With reference to Fig. 2, the above-described functions thus occur normally in such a way that, for example on Wednesday, at the time to take the daytime dose, the first, green LED 3a of the pair of indicators 11 is lit, wherein the user removes the container unit S from the monitoring device in the direction of arrow P. At the same time, the display unit shows the corresponding data as well as a notice of the content of the dose of medicine. Next, the user grips the handle V of a lid strip KS by the column corresponding to Wednesday, and pulls the lid strip KS outwards, as shown by arrow AV, outside the container unit S so that the opposite end of the lid strip passes the row corresponding to the placement of the daytime dose of medicine, *i.e.* down to the point OV in Fig. 2. Thus, the upper part of said compartment 2,WE is open and the dose of medicine can be removed for administration. After this, the lid strip KS is returned to its initial position and the container unit S is placed in the direction of arrow AS into the field 2 of the monitoring device. Thus, the second, red LED 3b of the pair of indicators II is lit, and said administration of the dose of medicine is recorded in the data processing unit of the monitoring device as being correctly completed. After a given time, the second, red LED 3b of the pair of indicators II is also turned off.

[0027] Alternatively, the visual and acoustic signals can be designed and programmed to function in such a way that during the time of administering a dose of medicine and the removal of the container unit S, only one visual indicator is used, for example a green LED, and after a given time, an acoustic reminder is given, if the administration of the dose of medicine has not been recorded in the data processing unit before that. Thus, the functions corresponding to those described above can be substantially implemented by only one visual indicator placed by each row.

[0028] Naturally, it is also possible to equip the edge of the field 2 parallel with the rows with a row of indicators on the upper surface of the monitoring device (a total of seven indicators, one by each column, place 6 in Fig. 1), which indicates the actual day of the week with, for example, red colour.

[0029] Figure 3 shows an embodiment that takes into account the possibility of container units S of different sizes. In this case, the field 2 is dimensioned according to the largest thinkable container unit, and its structure may be the above-mentioned recess or area defined by stoppers. The coupling element 2b is placed in that part of the field which is covered by the smallest thinkable container unit S. A container unit S smaller than the size of the field is placed in one corner of the field, and the rest of the field 2 can be covered by a separate angle piece KP. Alternatively, the stoppers limiting the field from above and from the side can be arranged to be movable on two sides of the field (the sides joined in the corner opposite to said corner of placement of the container unit). The figure also shows how the visual portion of the reminder unit 3, which is parallel to one side of the field and simultaneously the container unit, may consist of a continuous visual structure, such as a display screen, which can be provided, by means of display technology, with a visual indicator 3a, 3b placed by the respective row and operating in a way similar to above-mentioned colour indicators, and which does not necessarily need to be coloured but may also be black-and-white. The locations, in which the indicators will exist, can be programmed by means of the data processing unit of the device.

[0030] Similarly, the invention is not limited solely to the described container unit type. If use is sometimes made of units in which the locations corresponding to different times of the day are arranged in the matrix form in different columns, the indicators in the monitoring device designed for this purpose may be placed next to each column, that is, in a row above or below the field.

Claims

1. A device for monitoring the administration of doses, intended to be used in combination with a container unit (S) in n x m matrix form, preferably equipped with a set of compartments, **characterized in that** the device for monitoring the administration of doses comprises a space in which the container unit (S) in n x m matrix form can be placed in a releasable way to cooperate with an alarm and reminder system of the device of monitoring the administration of doses.

2. The monitoring device according to claim 1, **characterized in that** the space forms a field (2) for placing the container unit (S).

3. The monitoring device according to claim 1 or 2,

characterized in that the space of the monitoring device is equipped with a coupling element (2b) to indicate if the container unit (S) is connected to the monitoring device or detached from it.

4. The monitoring device according to claim 2 or 3, **characterized in that** the field (2) is designed to correspond, in its bottom area, the bottom area of the container unit (S), wherein the field (2) is preferably formed as a recess (2a) in connection with the upper surface of the monitoring device, or as an area limited by elevated stoppers.

5. The monitoring device according to claim 4, **characterized in that** the coupling element (2b) is placed in the bottom of the recess (2a) or inside the area limited by the stoppers, wherein it is preferably, in its structure, a mechano-electrical micro-switch or a sensor operating on contactless principle.

6. The monitoring device according to any of the preceding claims, **characterized in that** the upper surface of the monitoring device is equipped, at least by each row or column of the container unit (S) in n x m matrix form, with at least one indicator (3a, 3b) arranged to give alarm and reminder signals in visual form and/or audio form.

7. The monitoring device according to any of the preceding claims, **characterized in that** it comprises an indicator (3a, 3b) of the administration of a dose, operating on visual and/or acoustic principle.

8. The monitoring device according to claim 7, **characterized in that** the indicator consists of two elements, wherein the first one (3a) is arranged to remind, particularly with a visual signal, of the time of administering a dose of medicine and to alarm the user if the dose of medicine has not been administered within a given time from the reminder, and wherein the second one (3b) is arranged to indicate the completion of the administration of a dose of medicine.

9. The monitoring device according to claim 7 or 8, **characterized in that** the indicator (3a, 3b) of the administration of a dose is a coloured LED.

10. The monitoring device according to any of the preceding claims, in which the container unit (S) of n x m matrix form for doses of medicine is placed.

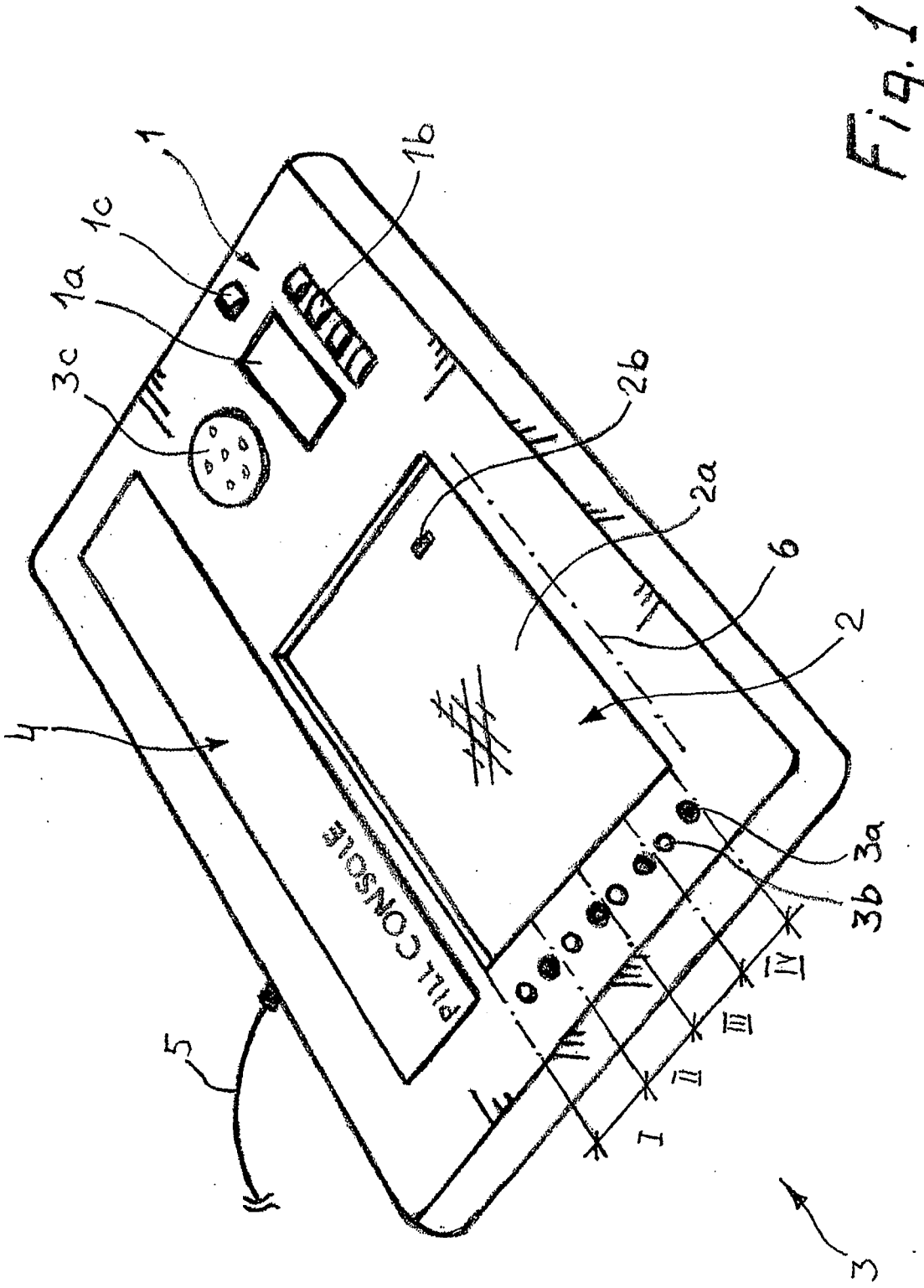

Fig. 1

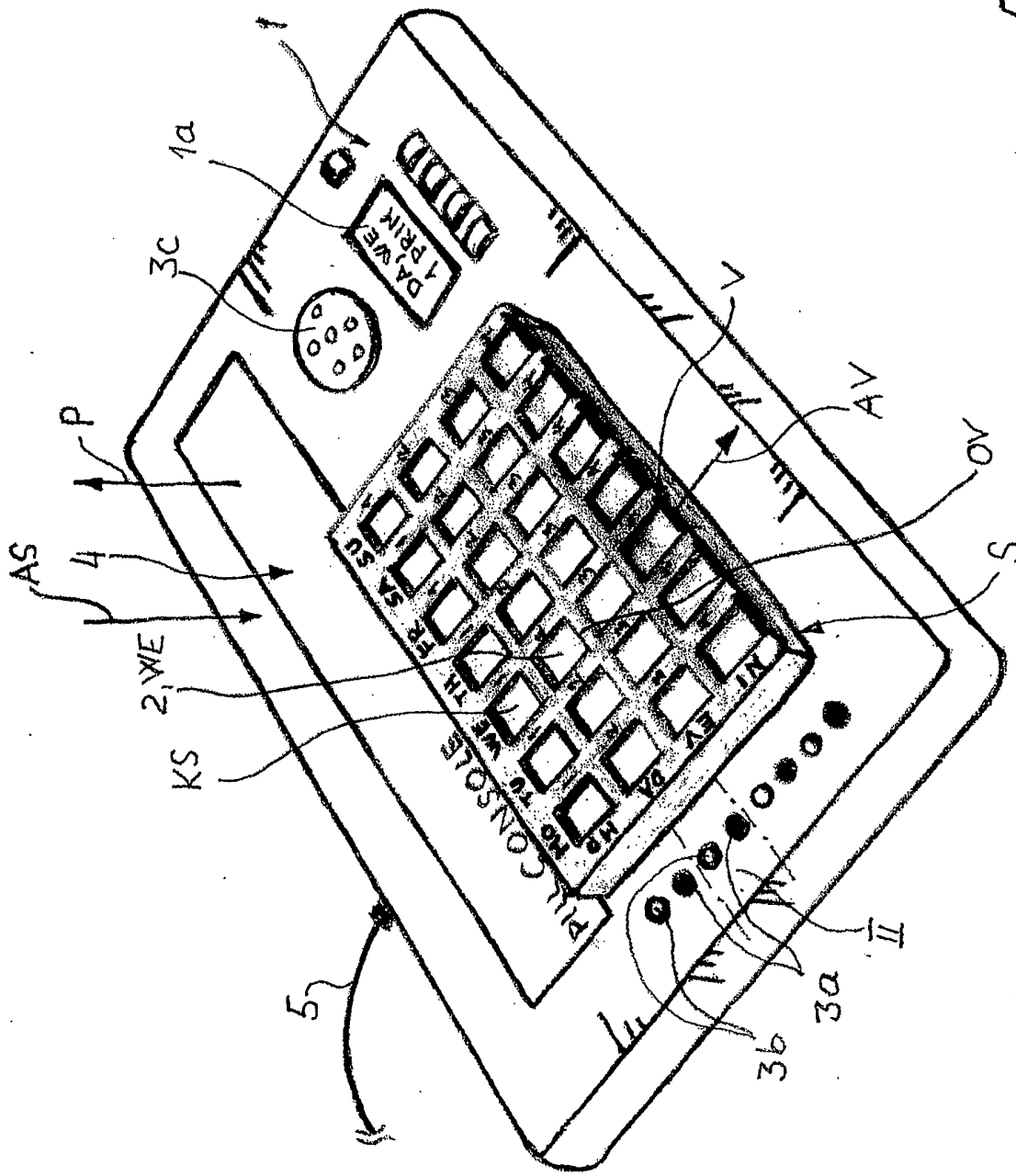

Fig.2

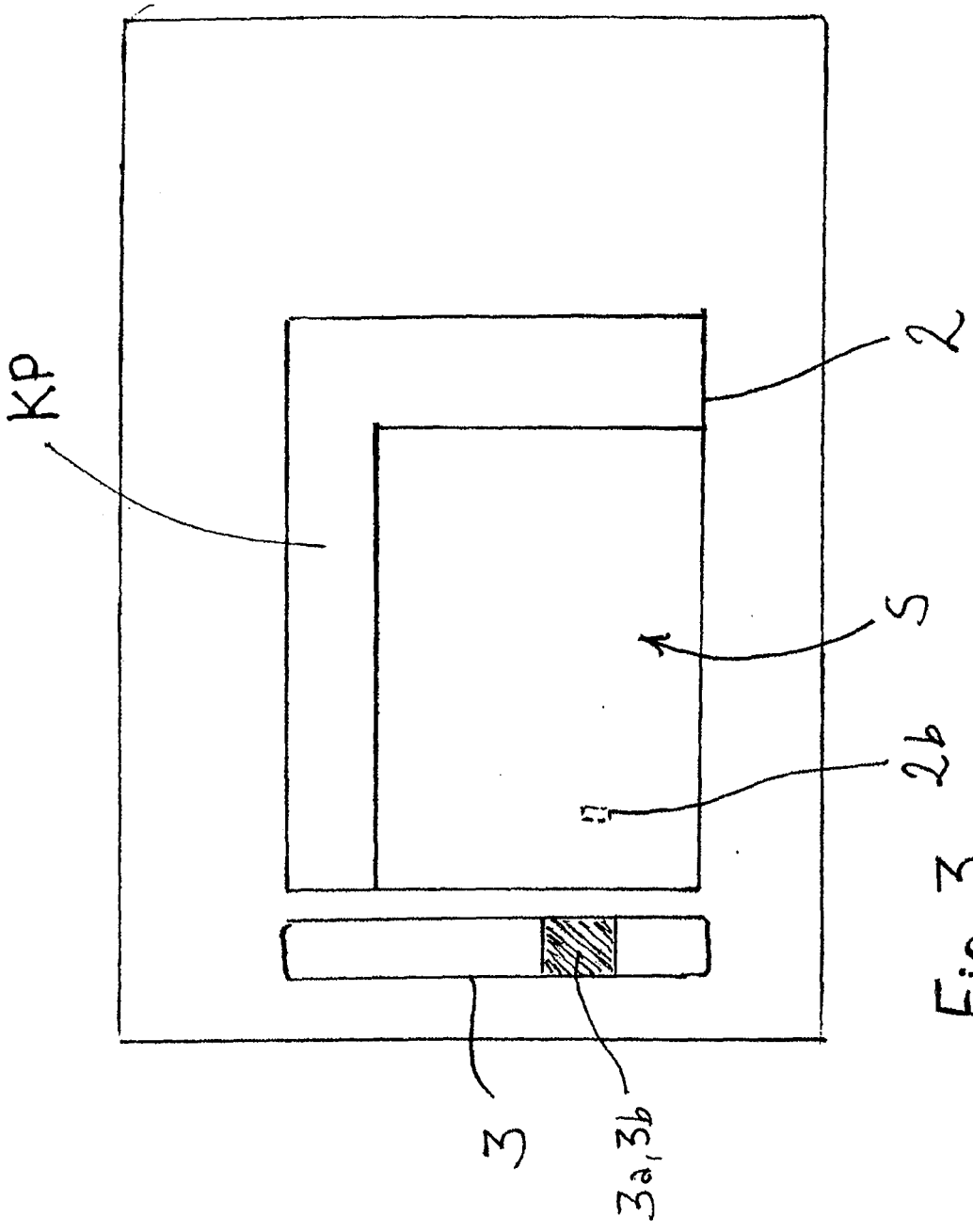

Fig. 3