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(54) MEDICATION ADHERENCE CONTROL SYSTEM FOR PATIENTS

(57) Medication adherence control system for patients.

The system comprises: - a weekly pill organizer (1) provided with alveoli for the placement of a blister pack (5) of pills; an extra compartment (122) to mend incorrect dosages; electronics for the alert and dosage control; - a cavity (123) to lodge a daily pill organizer (2) removable when not in use; - a removable daily pill organizer (2),

with Bluetooth, GPRS and Wi-Fi connections to allow receiving/sending information, and electronics for the management of the alerts and; - a web platform (6) with a (WEB MODULE), a mobile application (MOBILE APP) and a (HARDWARE MODULE), that have at their disposal real-time information about the patient taking the medication,

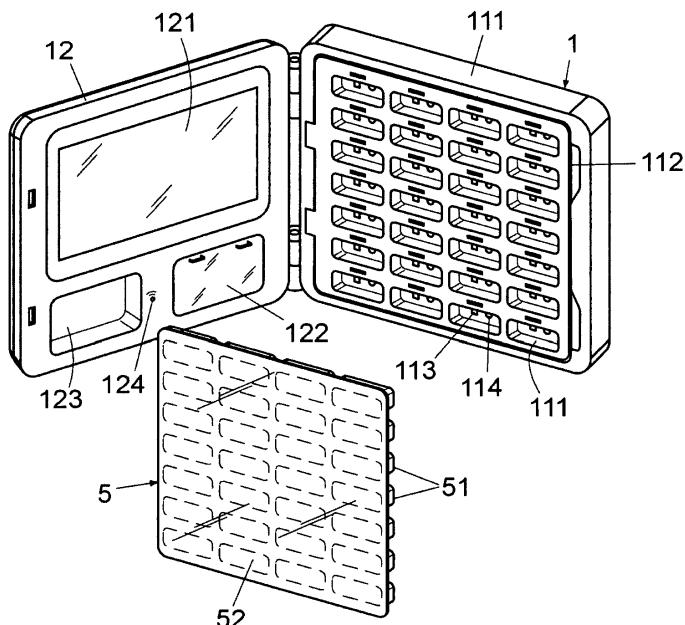


Fig. 2

Description**Object of the invention.**

[0001] The object of the present invention is a medication adherence control system for patients; comprising: a weekly pill organizer, electronic, usable by the patient, provided with a plurality of compartments for lodging the alveoli of a blister pack containing the medication corresponding to different daily dosages; and a control unit with means to warn about the dosages to be taken, and means of communication with a web platform containing a control program of patient data, medication and dosages assigned to the said patient, and of tracking the dosages taken by the aforementioned patient.

[0002] This system additionally incorporates a pharmaceutical pill organizer to fill the blister packs with the prescribed medication for each patient; and a bracelet wearable by the patient to receive the notifications related to taking the medication.

Prior art

[0003] Currently, different types of medication pill's dispensers are known; they can be grouped into four distinct types:

a) Automatic and temporally programmable dispensers for the administration of a single type of pill.

b) Medical dispensers with containers for different types of pills in which the device itself automatically selects the pills to be taken from each different container and dispenses the treatment according to the previously established schedule. In this type of device the human intervention is limited to programming the system and the equipment assumes full responsibility for providing the medication.

c) Multi pill dispensers based on blister packs or refillable matrix containers in which previously the pharmacist or the patient placed different dosages of treatment. In this case, although the devices are provided with indicator means, the responsibility for selecting the right compartment containing the dose for each time rests with the patient.

d) Circular pill organizers equipped with alarm means to remind the dosage time.

[0004] Among prior arts belonging to the group c) which is the most related to the electronic pill organizer of the present invention, one might mention the documents listed below:

The document WO 2015021543 describes a method to remind a patient to take a dose of a medicine comprising: providing an electronic pillbox that has a cas-

ing with a plurality of chambers with a moveable door, a lighting device to light the door of each chamber and a switch coupled to each lighting device; providing a reminder schedule to a microprocessor in the pillbox casing; loading the chambers with the proper dose of medication to match the schedule reminder and monitoring in real time, in connection with the reminder program, providing a first reminder to the patient to take a particular dose of medication from a particular chamber when the real time corresponds to a time on the reminder schedule; issuing a second reminder to the patient if the door to the particular chamber is not opened within a pre-set period of time, changing the light emitted from the lighting device associated with the particular chamber from the first colour to a second colour, or to a flashing light.; emitting a reminder audible sound; linking the device, directly or through an associated electronic device, to a remote server and entering data related to the patient and the reminder calendar in the aforementioned remote server as well as the control of the reminder agenda of the remote schedule; entering data into a website operably linked to the server or entering the data into a medical server and synchronizing it with the aforementioned server; electronically linking the caregiver's electronic device to the server and contacting the caregiver through his electronic device if the patient does not take the dose of medication after a second reminder.

[0005] In the European patent EP 1446085A1 a pill dispenser device comprising a lid and a bottom part is provided with means for adjusting dosage times, means for indicating dosage times, means for placing a blister pack containing pills; means for ejecting a pill from the blister pack and a printed circuit placed on the lid to confirm the removal of pills; the bottom part of the device incorporates a printed circuit board to program the pill dosage cycle.

[0006] The patent US 2007272583 consisting of a smart device (pillbox) that keeps track of the pills taken and a method and device to acquire data related to the health care of the individual and transmission of data to a remote location where they can be processed to facilitate the medication reminder, the data collection uses primary analogue and digital telephones.

[0007] The utility model ES 1052269 U describes a device provided with compartments for the classification of different pills and which has acoustic and luminous alarm means for the dosage notification.

[0008] The utility model ES 1064960 U consists in a warning pill organizer provided with recesses for the placement of pills, and reports the incorporation of programming means for the dosage schedule and a warning alarm.

[0009] The patent US 2015083742 describes a device to provide a pill comprising a body and a unit containing a pill pack and a drive assembly for its removal into a

discharge box, this device also comprises a control unit that controls operations of the drive assembly, a camera located on one side of the body and a communication module for transferring the image taken by the camera to a server connected to the network or computer.

[0010] Moreover, it should be noted that documents disclosing alternative solutions pillboxes are known in the prior art, at least by the applicant, one has not been found that presents similar technical, structural and constitutive features presented by the electronic pill organizer applicable to medication adherence control systems, object of this invention.

Description of the invention

[0011] The medication adherence control system for patients of this invention, comprising an electronic pill organizer, of weekly usage, of the previously described type and mentioned in the pre-characterizing portion of the first claim, presents a series of constructive particularities oriented towards making possible two modes of use for the patient: daily or weekly, for this purpose it is provided of a daily pill organizer, detachably connected to a weekly pill organizer, both weekly and daily pill organizer can be used together or independently.

[0012] Another purpose of the invention is to enable the error correction in medication dosage, in case the patient would remove the medication from a compartment corresponding to the incorrect dosage; for this purpose the weekly pill organizer is provided with a specific compartment to store, until consuming time, the dosage removed by mistake.

[0013] Another purpose of the invention is to allow the monitoring and export, via web, of the results of using the device for monitoring the treatment by the prescribing physician or health-care personnel in charge.

[0014] Additionally, this system comprises a pharmaceutical pill organizer to fill the blister packs with the prescribed medication for each patient; and a bracelet wearable by the patient to receive the notifications related to the medication dosage; being both elements optional, although they significantly facilitate the pharmacy the refilling of the blister packs with the medication corresponding to each patient; and the patient receiving possible notifications regarding the medication dosage.

[0015] This system has two types of web development associated: a web platform and a mobile application.

[0016] The different devices generate information flows that will allow us to know the adherence of the patient to the treatment in real time. The real-time information is made possible due to the communication of the pill organizer wearable by the patient with the platform via GPRS and Wi-Fi, this platform is designed to receive, process, treat and adapt the information in such a way that the medical or pharmaceutical personnel can assess easily and intuitively that information and act accordingly.

[0017] To this end, and according to the invention, this pill organizer has a book-like configuration, provided with

a base and a lid.

[0018] The base comprises:

- A space with a plurality of alveoli, intended for the placement of the blister pack of pills and a grid to correctly hold the blister pack.
- Electronics comprising lighting means to alert to correct or incorrect dosage (RGB LEDs) and sensors, specifically photocells that will allow us to know whether the alveolus has been accessed or not.

[0019] The lid comprises:

- A touchscreen to allow communication with the patient and the related personnel.
- An extra compartment to mend the incorrect dosages; the aforementioned work is provided with the necessary electronics to detect the opening, or not, of the alveolus and communicate it.
- A cavity to lodge the daily pill organizer whenever its use is needed.
- An interior cavity in which are located electronic boards (PCB) responsible for generating actions, treating information and externally communicating.
- This weekly pill organizer has the ability to communicate via Bluetooth, Wi-Fi or GPRS.
- A buzzer to produce alert sounds.

[0020] As for the daily pill organizer, it is designed to give autonomy to patients who will spend the whole day out of home and do not want to carry their medication all week.

[0021] The patient will use a simple and fast process:

- Remove the daily pill organizer of the weekly block.
- Activate on the weekly pill organizer touchscreen the option of daily pill organizer.
- Select the dosages that will be taken (from 1 to 4).
- Carry out the removal protocol; depending on the dosages taken, the alveoli from which the medication has to be removed will get lightened one by one and, at the same time, the screen will display in which compartment of the daily pill organizer it will have to be placed.

[0022] This device is provided with Bluetooth, GPRS and Wi-Fi connections to allow receiving/sending information.

[0023] Regarding the alerts, this device is able to get illuminated, sound and vibrate when required.

[0024] The pharmaceutical pill organizer has a similar appearance to the weekly pill organizer, and shows a difference in the level of intelligence since it does not need to be as sophisticated as the patient's pill organizer.

[0025] The pharmaceutical pill organizer is aimed to improve the process of refilling the blister packs with the accurate medication for each patient.

[0026] The improvement is mainly based on two con-

cepts:

- Physical device where the empty blister pack is inserted and, depending on the medicine to be refilled, the illumination of the alveoli in which the pills should be placed, based on the treatment prescribed by the medical personnel.
- Protocol via the web, which will guide the pharmacy personnel in the process, both to complete all the data, as to see on the screen a graphical simulation of how to refill the blister pack.

[0027] This platform, with the data required when refilling, allows full monitoring of dosed medicines and also the ability to keep track of medication stock for each patient.

[0028] The bracelet wearable by the patient has a Bluetooth connection to both the weekly and individual pill organizer, with a memory enabling it to store the weekly treatment. It will also be able to receive signals in order to alert the patient when needed, thus the system makes sure that the patient will always receive the dosage alert.

[0029] This bracelet is provided with the necessary electronics to register and send another type of data, such as the heart rate.

[0030] The blister pack to be used consists of two parts: a plastic sheet in which the compartments to lodge the medication are defined, a complex sheet (with a sheet of foil) that adheres to the blister pack, so the access to medication is only allowed by breaking the foil

[0031] The names of the days of the week and of the dosages are marked on the front area of the blister pack. At the top of the front area there is a space reserved for the date and the name of the patient so that both the pharmacist and the patient can identify them.

[0032] The blister pack has the space to attach an RFID (Radio Frequency) tag that allows automatic recognition by the Pill-box due to a radio frequency that will have the weekly Pill-box incorporated.

[0033] The sealing between the two sides of the blister must ensure the leak-tightness of each of the compartments. This sealing, along with the characteristics of foil, neutralizes the entry of dirt, dust or moisture into the compartments or the alveoli containing the medication.

[0034] The mobile application module included in the system consists of a mobile application (APP MOBILE) available for both patients and caregivers. The features of this mobile application are:

- Entry screen: displays the patient medicines program along with medicines to be taken at all times.
- Adherence check: In this screen the system displays a list of days and in each of them two elements: missed and taken, in which will be indicated the number of both missed and properly taken dosages.
- Sending messages: This feature allows the patient or caregiver to send the HPC a message related to

the dosages.

- Alarms: warns those people who programmed so, about the time the patient should take the medication. In the case of the patient the alarm helps him taking his dosage; in the case of the caregiver, some time (programmable) after the taking of the medicine, if the platform does not detect that the patient has made a correct decision, an alarm will warn about the possible failure.

[0035] The system is provided with a platform web that allows sharing the information, generated by the aforementioned physical devices, to all the stakeholders accessing the system, such as: Health Council or its equivalent, health centres; doctors / nurses (HCPs); pharmacies, patients and caregivers

[0036] The accessibility will depend on the level of each user, allowing for example:

- 10 - The health council to access the platform to report about the adherence program of all assigned hospitals or those dependent on it.
- 15 - Health centres to access the platform for the administration of their physicians/nurses, and creating reports related to their area of action: statistics about adherence of patients related to the concerned health centre.
- 20 - Physicians/nurses to access the information of the patients assigned to each of them individually, to modify the patient's information, his treatment, caregivers, ailments, etc.; obtaining reports about the adherence of the assigned patients; receiving alerts on the platform about adherence failures and statistics about the behaviour of their group of patients.
- 25 - Pharmacies to access the alarm of lack of adherence and the treatment data and the adherence of the patients who have decided to use them as their pill organizer management centre; the pharmacies being able to manage the manipulation of the pill organizers, their assignation to patients, the refilling of said modules and delivering and receiving the modules, concerning the patients. In addition, the system also allows pharmacies to have a channel of direct communication with the patient's physician in order to indicate any situation that arises in relation to patient treatment via the internal messaging system of the platform. They will have access to reports allowing the management of patients.
- 30 - The ability of patients through mobile phone, to see their medication adherence program, to send to the platform information related to the dosage, to receive alarms they have to take the medical treatment, indicate whether the dosage has been made in the suited way, receive messages related to the changes
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in their treatment.

- The caregivers receiving: alert messages in case the assigned patient takes the wrong medication or, at a pre-programmed time, the patient has not taken the medication correctly; and the possibility to revise, through their mobile phone, the adherence data of the patient at their care through the same mobile interface as the patient.

[0037] Since currently health councils already have their own patients management systems and appointment management systems; many autonomies are implementing the format of "electronic prescription" for the assignment of medicines; and pharmacies have already created and installed management systems, a modular platform has been developed, in which each of the parts can operate independently of the others but, when integrated with the others, can work as a whole.

[0038] In view of the above, the proposed architecture is based on layers, where the foundations for the upper layers start laying on a nucleus.

Description of the figures.

[0039] To complement the description being made, and in order to facilitate understanding of the invention characteristics, the present specification is accompanied by a set of drawings in which, with illustrative and non-limitative character, the following has been represented:

- The figure 1 shows a scheme of an example of embodiment of the medication adherence control system for patients.
- The figure 2 shows a perspective view of an example of embodiment of the weekly pill organizer, in open position and the blister pack intended to be placed in it.
- The figure 3 shows a perspective view of an example of embodiment of the daily pill organizer
- The figure 4 shows a perspective view of an example of the bracelet receiving the notifications, wearable by the patient.
- The figure 5 shows a perspective view of an example of embodiment of the pharmaceutical pill organizer, used to refill the blister packs with the medication.
- The figure 6 shows a block diagram of an example of embodiment of the system web platform.

Preferred embodiment of the invention.

[0040] Figure 1 schematically represent the different elements constituting the medication adherence control

system for patients, according to the invention, interrelated with each other.

[0041] In the example shown, the medication adherence control system of this invention, comprises a weekly pill organizer (1), a daily pill organizer (2) attachable to the weekly pill organizer and a bracelet (3) to receive notifications, being said elements associated with the patient.

[0042] In addition, the system comprises a pharmaceutical pill organizer (4) for the refilling of the blister pack (5) with the medication for each patient prescribed by the corresponding physician.

[0043] This system has associated a web platform (6) with a (WEB MODULE); a mobile application (MOBILE APP) and a (HARDWARE MODULE) that allow having real-time information thanks to the communication of the weekly pill organizer (1), via GPRS/Ni-Fi, with the web platform (6) that is designed to receive, process, treat and adapt the information in such a way that the medical or pharmaceutical personnel can assess that information easily and intuitively, and act accordingly. If it detects that the patient is not following the treatment, this system sends messages to the different stakeholders, communicating this issue to the patient's mobile phone (M) and to relatives or individuals (P) in charge of him.

[0044] Figure 2 represents the embodiment of the weekly pill organizer (1), provided with a book-like configuration, provided with a base (11) and a lid (12). Figure 2, the number 111 appears doubled and number 11does not appear.

[0045] The base (11) comprises: a space with a plurality of alveoli (111), intended for the placement of the pill blister pack (5) and a grid (112) to hold the blister pack (5). It is inwardly provided with electronics comprising lighting means (113) (RGB LEDs) placed inside the alveoli (112) to alert to correct or incorrect dosage and sensors (114), specifically photocells, responsible for detecting the access to the alveoli and whether the medication therein contained has been removed.

[0046] The lid (12) comprises: a screen (121) to allow communication with the patient and the related personnel; an extra compartment (122) to mend the incorrect dosages and store, until consuming time, the dosage incorrectly removed from one of the alveoli (112); and the necessary electronics to detect the opening, or not, of the aforementioned compartment, and to notify the system; a cavity (123) to lodge the daily pill organizer (2) when not in use; electronic boards (not represented) placed in an interior cavity and responsible for generating actions, treating information and externally communicating via Bluetooth, Wi-Fi or GPRS; and a buzzer (124) to produce alert sounds.

[0047] Additionally this system comprises a pharmaceutical pill organizer (figure 5) to fill the blister packs with the prescribed medication for each patient; and a bracelet (3) wearable by the patient to receive the notifications related to the medication dosage. Both elements significantly facilitate the pharmacy to refill the blister

packs with the medication corresponding to each patient, and the patient to receive possible notifications regarding the medication dosage.

[0048] The daily pill organizer (2), shown in figures 1 and 3, is designed so the patient can carry a daily dosage without having to transport the weekly pill organizer (1): in order to use it, the patient has to remove it from the cavity (123) of the main pill organizer, activate the option of "daily pill organizer" on the screen (121) and select the dosage that he will take with him (from 1 to 4), thus, depending on the dosages, the alveoli (111) from which the medication has to be removed will lit one by one, and, at the same time, the screen will display in which compartment of the daily pill organizer it has to be placed.

[0049] The daily pill organizer (2) has Bluetooth, GPRS and Wi-Fi connections to allow receiving/sending information and with the necessary electronics to manage the alerts, lighting, ringing and vibrating when required.

[0050] Additionally, the bracelet (3) wearable by the patient and schematically represented in the figures 1 and 4, is provided with a Bluetooth connection (not represented) to establish communication with the weekly pill organizer (1) as well as the daily one (2), and receive signals in order to alert the patient when needed, the system will make sure the patient always will receive the dosage alert; and electronics suited to register and send another type of data, such as the heart rate.

[0051] The pharmaceutical pill organizer (4) shown in figures 1 and 5 has features and appearance similar to those of the weekly pill organizer (1), with a base (41) and a lid (42), and its purpose is to improve the process of refilling the blister packs (5) by the pharmacy. The aforementioned pharmaceutical pill organizer (4) is provided with alveoli (411) for positioning the empty blister pack (5), a grid (412) and some lighting elements (413) to light those alveoli where each medicine should be placed, based on the treatment prescribed by the medical personnel, and a screen (414) to fill correctly all the data related to the blister pack refilling and to see a graphical simulation of how to refill the blister pack.

[0052] The data required when filling the blister pack, such as data of the patient, contact data of relatives of the patient, prescribed medicines, physician, health centre etc., are accessible through the web platform (6), which allows the complete monitoring of the dosed medicines and also the possibility of keeping track of stock for each patient.

[0053] The blister pack (5) to be used comprises a plastic sheet in which the compartments (51) to lodge the medication are defined and a complex film (52) that adheres to the blister pack and only allows the access to medication by breaking the film.

[0054] The system has a platform that allows sharing information, generated by different devices of the system, to all stakeholders that have access to the system; depending on the accessibility of each of their user level.

[0055] Figure 6 shows a diagram of the different components of the architecture of the web platform (6) includ-

ing a (WEB MODULE), a module of mobile application (MOBILE APP) and a (HARDWARE MODULE).

[0056] Said components comprise:

5 - CORE OBJECTS (BACKEND): Represents all classes and methods of low level that provide the necessary services for the execution of the application, it also manages the connection with the databases needed for the data manipulation.

10 **[0057]** Among the features of this module there are:

- Access Management Platform
- Creation of statistics and reports
- Communication with the databases
- Alarms management
- Integration management of the platform with external systems
- Control of schedules and appointments
- Creation and management of the board
- Internal messages management
- Sending of messages to external sources (email, SMS, etc.)

15 25 - REST MESSAGING (BACKEND): a service that allows the exchange of information via HTTP between the different elements of the platform; furthermore, enables receiving and delivering information to external systems.

30 - WEB MODULE (FRONTEND): This module is actually the description of the model and the technology with which the information will be presented to the different components of the platform. It consists of the following parts:

- ADMIN: it is the interface for the administrators of the platform, in it there must be:

35 Functionality that allows the platform management at a macro level:

- Health Centres Management
- Management of physicians / nurses (HCPs)
- Management of Pharmacy affiliated to the scheduled
- Management of internal databases of medicines 1
- Generation of predefined reports, both at health council and health centres level
- Management of tracking and auditing events inside the platform
- Integration utility (optional)

- HCP: will be the interface for health professionals (physicians/nurses).

In it, the following functionalities have to be

considered:		
<ul style="list-style-type: none"> • Information board for patient management • Interventions management (sending SMS messages, email or recording the reasons of phone calls) • Patients management • Patients reports • Appointment schedule 	5	
◦ PHARMACY: is the module that will be available and installed for pharmacies.		
The features on this module will be:	10	
<ul style="list-style-type: none"> • Information board for patients management • Management of the patients modules • Assignment of modules to patients • Registration of delivery of modules to Patients • Management and support of filling the patients modules • Module activation deactivation • Agenda of module withdrawal by the patient • Reports 	15	
◦ PATIENT: would allow the patient to know the status of their adherence on a main board, on the other hand, it would allow the patient to refer to his HCP any incidence with the assigned medication and to see a schedule of dosages based on the programming done in his device	20	
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	35	
[0058] The platform comprises a module of mobile application (MOBILE APP) available both for patients and caregivers, and a (HARDWARE MODULE)		
Claims		
1. Medication adherence control system for patients, comprising:	40	
- a weekly pill organizer (1), comprising:		
<ul style="list-style-type: none"> • a space with a plurality of alveoli (111), intended for placing a blister pack (5) of pills and a grid (112) to hold the blister pack (5); • electronics comprising lighting means (113) (RGB LEDs) to alert to the correct or incorrect dosage placed inside the alveoli (112) and sensors (114) responsible for detecting the access to the alveoli and whether the medication therein contained has been removed. 	45	
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2. System, according to claim 1, characterized in that a bracelet (3) wearable by the patient for him to receive notifications regarding the medication dosage; the aforementioned bracelet is provided with an internal memory to store the weekly treatment and a Bluetooth connection to establish communication with the weekly pill organizer (1) as well as the daily one (2), and receive signals in order to alert the patient when needed.		
3. System, according to claim 1, characterized in that the bracelet (3), comprises electronics suited to register and send another type of data, such as the heart rate.		
4. System, according to claim 1, characterized by comprising a pharmaceutical pill organizer (5) to fill the blister pack with the prescribed medication for each patient; the aforementioned pharmaceutical pill		

organizer (4) is provided with alveoli (411) to place an empty blister pack (5), a grid (412) holding the blister pack and lighting elements (413) to light those alveoli where medicine has to be placed, based on the treatment prescribed by the medical personnel and a screen (414) to display data related to the re-filling of the blister pack, to access the information of the web platform (6) of the system and to see a graphical simulation of how to refill the blister pack.

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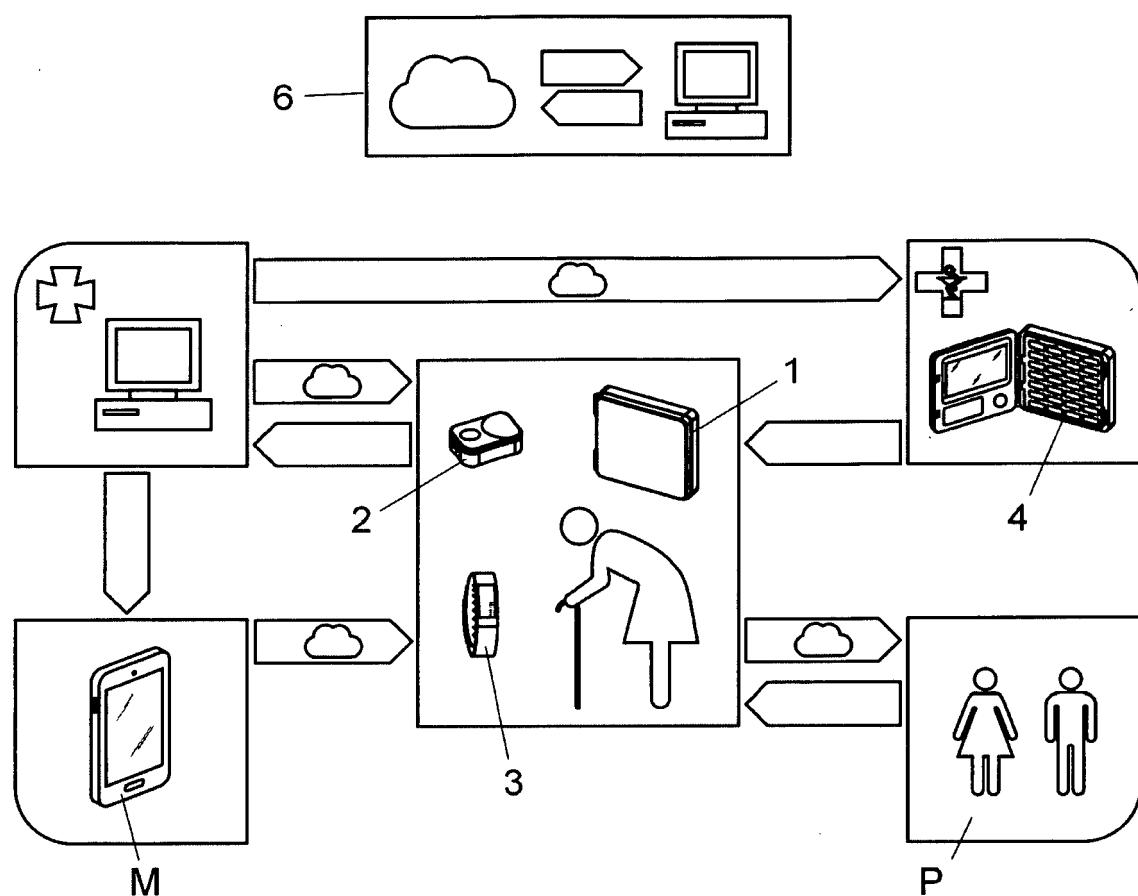


Fig. 1

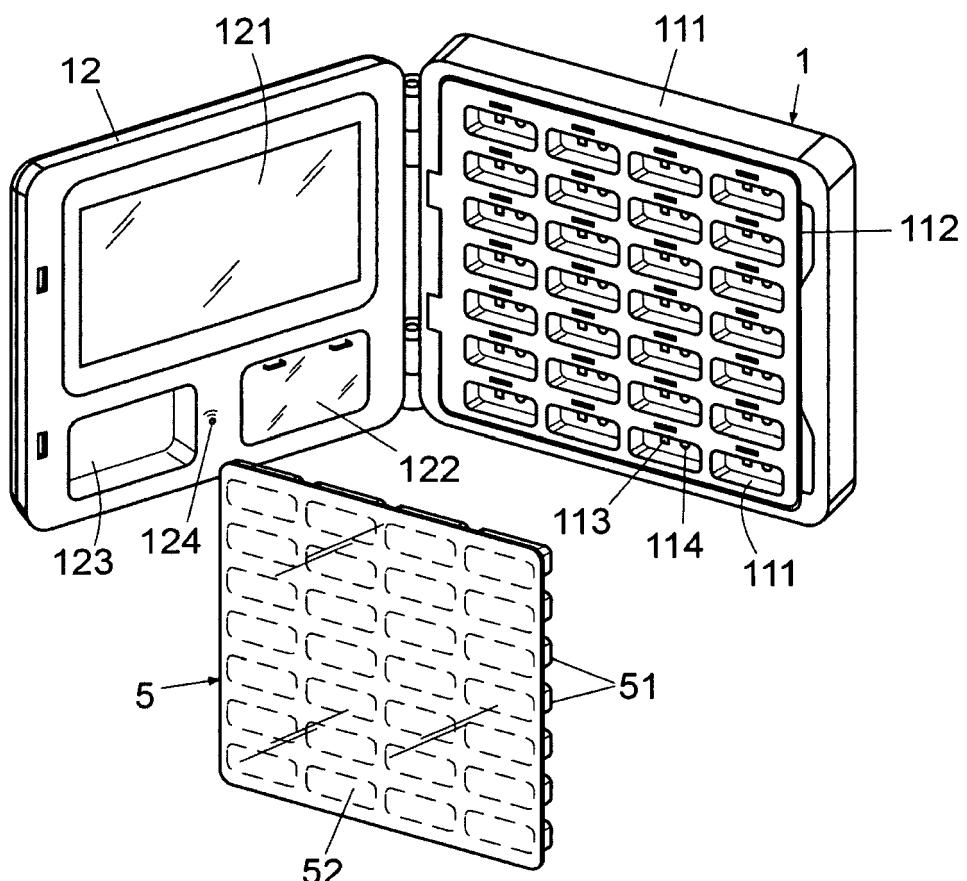


Fig. 2

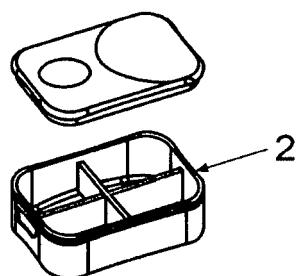


Fig. 3

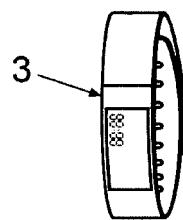


Fig. 4

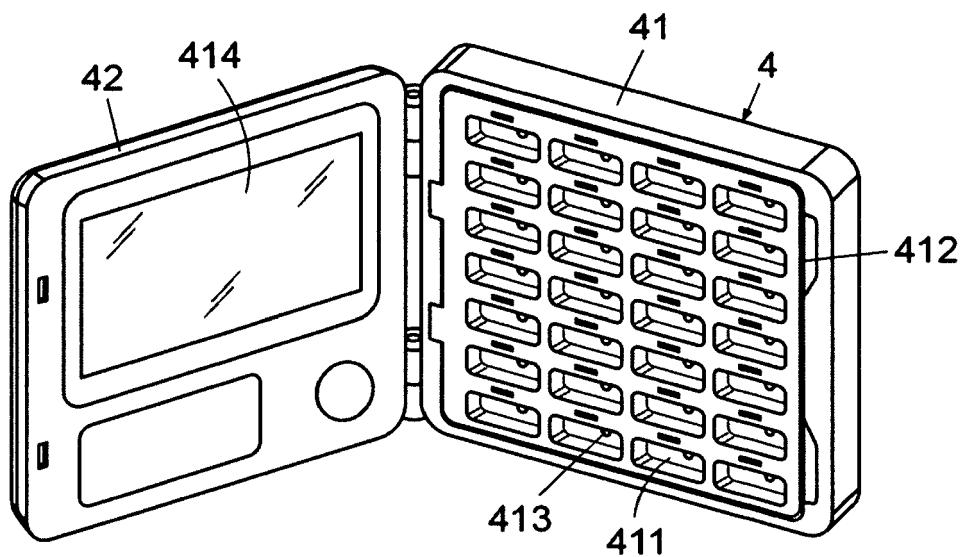


Fig. 5

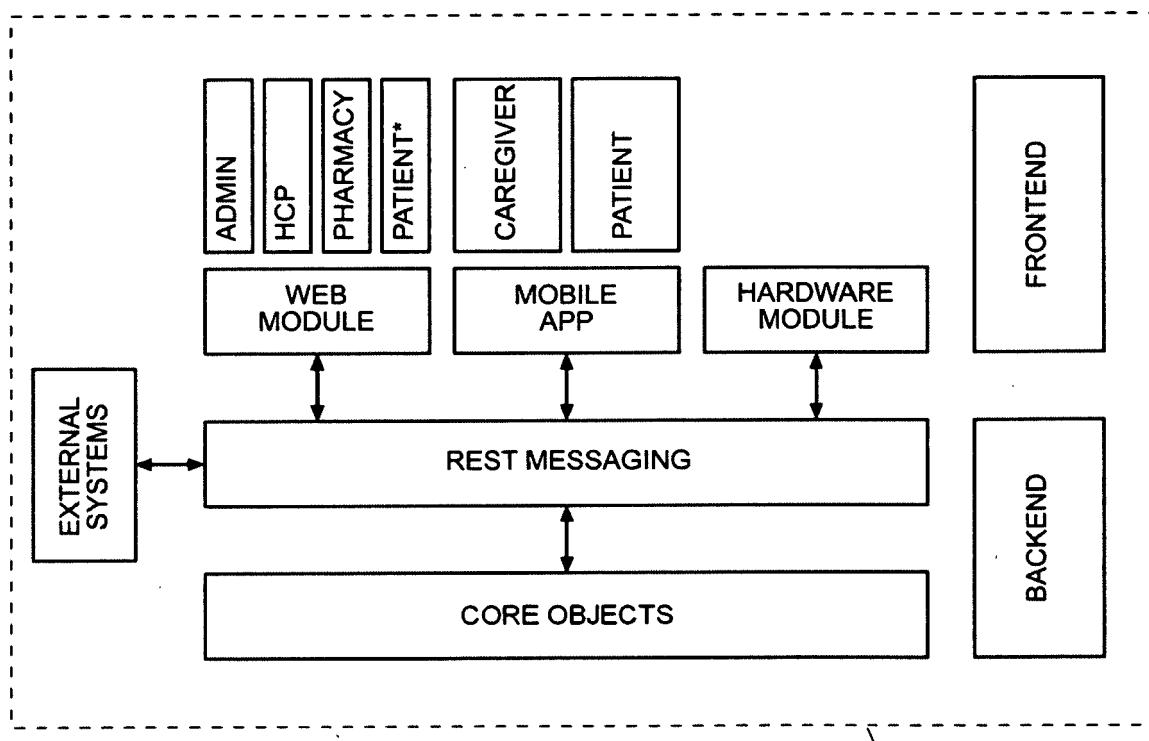


Fig. 6

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EUROPEAN SEARCH REPORT

Application Number
EP 16 00 1569

5

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
10 Y	US 2016/158109 A1 (NOVA EDWARD [CA] ET AL) 9 June 2016 (2016-06-09) * paragraph [0036] - paragraph [0079] * * figures * -----	1-4	INV. A61J1/03 A61J7/00 A61J7/04
15 Y	US 2013/002795 A1 (SHAVELSKY ERAN [US] ET AL) 3 January 2013 (2013-01-03) * column 0064 - column 0117 * * figures * -----	1-4	
20 A	US 2016/008229 A1 (DICKIE ROBERT G [CA] ET AL) 14 January 2016 (2016-01-14) * the whole document * -----	1-4	
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45			
50 1	The present search report has been drawn up for all claims		
55	Place of search The Hague	Date of completion of the search 4 January 2017	Examiner Edlauer, Martin
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 16 00 1569

5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

04-01-2017

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