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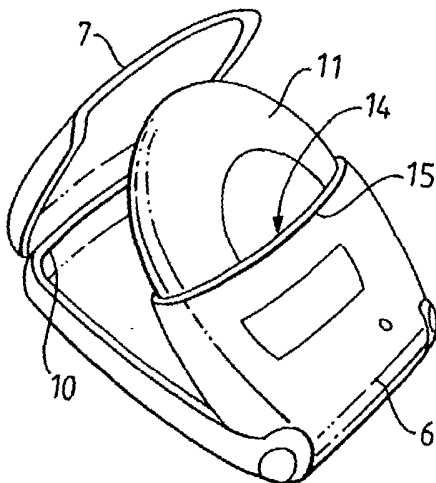
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(54) Title: COMPLIANCE AID



(57) Abstract: There is provided a compliance reminder aid for prompting a user to take doses of a medicament at prescribed periods. The compliance aid comprises a holder for holding a medicament delivery device. The holder includes an electronic dose reminder system comprising a detector for detecting the presence of a medicament delivery device within the holder: a timer for timing a time period; a dose interval, a dose interval memory for storing data relating to a prescribed dose interval; and a patient alerter for alerting a user to take a dose of medicament.

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COMPLIANCE AID

This invention relates to aids for people who need to remember to take, at prescribed times, doses of palliative, curative and/or remedial medicaments in order to comply
5 with a treatment programme for a medical condition and it relates in particular, though not exclusively, to such aids as may be used by people suffering from conditions, such as chronic asthma, which require treatment by regular dosages of medicament.

10 It is difficult for people who lead busy lives to remember to take medicaments at prescribed times and it is particularly difficult for those on the move, and especially when travelling, to work out and remember dosage times and inter-dose periods.

This invention seeks to address such difficulties by providing a holder for an
15 independent (i.e. separate or separable) medicament delivery device, the holder incorporating an electronic system for providing dose reminder information to the patient.

One advantage of the present invention is that because the electronic reminder
20 system is comprised within the holder, rather than the medicament delivery device itself, it may be used with existing (e.g. non-electronically-enabled) medicament delivery devices, including inhalation devices for delivery of medicament for treating asthma.

25 According to one aspect of the present invention there is provided a compliance aid for assisting patient compliance with the taking of medicament doses at prescribed periods, the compliance aid taking the form of a holder for holding a medicament delivery device, said holder including an electronic dose reminder system comprising a detector for detecting the presence of a medicament delivery device within the
30 holder; a timer for timing a time period; a dose interval memory for storing data relating to a prescribed dose interval; and a patient alerter for alerting a user.

In one aspect, the timer acts such as to time a holding time period corresponding to the time that the medicament delivery device is held by the holder; said dose interval memory stores data relating to a prescribed (i.e. defined) dose interval time period; and the alerter activates when said holding time period exceeds said prescribed dose interval time period.

In another aspect, the timer is a standard clock; said dose interval memory stores data relating to a prescribed (i.e. defined) dose time; and the alerter activates when the time registered by said clock corresponds to said prescribed dose time. Thus, in one example where a medicine is due to be taken once in the morning and once in the evening, the prescribed dose time may be set at say 6am and 6pm and the alerter will alert when the clock registers this time. The alerter may be set to alert for a defined maximum time period (e.g. for three hours after the prescribed dose time) and then to stop alerting until the next prescribed dose time is registered by the clock.

The medicament delivery device can have any suitable form and may be configured to deliver medicament in any known form, including powder, aerosol, tablet, liquid, solution, gel and paste form. In its simplest form, the medicament delivery device may simply comprise a medicament container (e.g. a blister pack or tablet bottle) that enables user access to enable delivery of the medicament. More complex medicament delivery devices are also envisaged including inhalation devices such as dry powder inhalers (DPIs), metered dose aerosol inhalers (MDIs) and inhalers for delivering medicament in solution form (e.g. nebulisers). Also envisaged are injectable medicament delivery devices, including needle-based and needle-less syringe delivery devices.

The holder can have any suitable form. Functionally, it must be capable of releasably holding the medicament delivery device such that it may be removed therefrom to enable delivery of the medicament. The holder may in aspects, be configured as a

standalone or wall-mountable device be in a form suitable for carrying in the pocket or luggage of a user.

The holder may incorporate one or more lock-release features which act such as to
5 releasably lock the delivery device into a holding position. The lock is releasable by a simple user action, which may be mechanical (e.g. releasing a catch) or electronic (e.g. inserting a password into a control system).

In one preferred aspect, the holder is in the form of a 'docking station' for receipt of
10 the medicament delivery device. When so-received, the medicament delivery device is partly housed by the holder and partly stands proud therefrom (e.g. in display fashion).

In another preferred aspect, the holder comprises a casing configured to house the
15 medicament delivery device. Suitably, the casing is capable of being configured by the user so as to assume any of: a closed condition, in which the medicament delivery device is housed wholly within the casing, an opened condition, in which the medicament delivery device can be removed therefrom to permit a dose of the medicament to be taken, or a display condition, in which the medicament delivery
20 device is supported in the casing so as to partially protrude therefrom.

In one aspect, the casing comprises a generally clam-shaped shell which is hinged for opening and closure, and is dimensioned to house a substantially discoidally-shaped delivery device (e.g. the inhalation device sold under the trade mark DISKUS
25 by GlaxoSmithKline Inc.). It is further preferred that the top of the shell-like casing is split transversely thereof, creating respective front and rear sections of the top which are separately hinged for opening for access to and removal of the dosage container. Such a configuration usefully permits the casing to be used to support the container in an alternative, display mode, rather like the configuration commonly
30 adopted for travel alarm clocks, in which the delivery device can be repositioned so as to partially protrude from the casing, being held in place partially at least by the

reclosure of the rear portion of the top, which provides a support surface supporting the discoidal delivery device at an angle inclined to the vertical. The support for the delivery device may be enhanced by the provision of a groove in the base of the shell-like casing.

5

In preferred embodiments, the holder (e.g. the casing) receives an adaptor device, to house and/or support other kinds of medicament delivery device, such as metered dosage applicators of forms differing from discoidal. In particular, an adaptor may be provided to enable the casing to support a generally L-shaped Metered Dose Inhaler (MDI) of the kind well known in the treatment of asthma. The casing may or may not be capable of closure when the adaptor and L-shaped container are used.

In aspects, the casing may be provided with a controlled release opening mechanism which aids or assists the smooth opening thereof. For example, the opening mechanism may be sprung load, or controlled by a clutch such as a damping grease type.

The casing may be made of any suitable material but is preferably of elastomeric material, and it may if desired incorporate bright colouring or patterning to render the compliance aid readily visible, or merely to enhance its visual attractiveness.

Particularly for compliance aids intended for use by children, the colouration or patterning may be specifically designed to make the device attractive and friendly. Surface texturing can moreover be used to achieve desired visual and/or tactile effects.

25

In one aspect, the casing is formed with at least one transparent or translucent area which provides a window enabling the user to readily check that a dosage container is in place within the casing. In this respect, the container may be brightly coloured, or a brightly coloured region may be provided, opposite the window, on the base of the casing interior; the bright region being obscured when the delivery device is installed, and thus visible only when the casing is empty.

The holder includes an electronic dose reminder system. This may be configured to have any suitable form and may be powered by mains, stored (e.g. battery) or self-regenerating (e.g. solar) energy power sources.

5

The electronic dose reminder system comprises a detector for detecting the presence of a medicament delivery device within the holder; a timer for timing a time period; a dose interval memory for storing data relating to a prescribed dose interval; and a patient alerter for alerting a user.

10

The detector detects the presence of a medicament delivery device within the holder. In one aspect, the detector comprises a switch (e.g. a mechanical switch) that is triggered in response to the insertion of a delivery device into the holder.

15 Suitably, the detector comprises a suitably configured sensor such as a proximity sensor which acts such as to detect the proximity of the medicament delivery device thereto.

In one aspect, the sensor comprises a radiative emitter and detector. Suitably, the
20 emitter emits electro magnetic radiation and the detector detects the electromagnetic radiation. The emitted radiation may be infrared, visible or ultraviolet radiation. Suitably, radiation in the range 0.95 μ m to 0.35 μ m is used. More suitably, the radiation is in the infrared range.

25 Suitably, the emitter is selected from the group consisting of light emitting diode, laser, incandescent lamp, electroluminescent and fluorescent light sources. In one embodiment, the emitter may include a filter, suitably an optical filter and preferably a polarising filter (particularly if the emitter is an incandescent source) in order to select a particular wavelength, a narrow range or ranges of wavelength.

30

Suitably, the detector is selected from the group consisting of photodiode, phototransistor, light-dependent resistor and bolometer. In one embodiment, the detector additionally comprises a filter, suitably an optical filter and preferably a polarising filter. The use of a filter will enable the wavelength/wavelengths
5 detectable by the detector to be pre-determined. For example, the detector could be made sensitive only to the wavelengths chosen for the emitter so the detector could be less sensitive to extraneous light sources, such as room light/sun light. In a further embodiment, the detector is associated with an amplifier, since the output from the detector can be very small (of the order of micro Amps). Suitably, the
10 amplifier is positioned as closed to the detector as possible to avoid amplifying any extraneous noise e.g. any electrical noise picked up in the connecting wires. In one particular embodiment, the amplifier is integrated with the detector, for example the detector and amplifier are positioned on the same integrated circuit or "chip".

15 Suitably, the sensor is integral with the holder, for example moulded into the holder or attached hereto.

The electronic dose reminder system is suitably associated electronically with the sensor(s), such that when the detector detects removal of the medicament delivery
20 device from the holder, a signal is sent to record that the device has been removed. In one aspect, the system comprises a microprocessor. Suitably, the microprocessor performs operations on the data from the sensor and produces a signal output relating to the data or the outcome of an operation on the data.

25 The timer can have any suitable form including that of an electronic timer.

It will of course, be appreciated that the timer can be arranged to communicate with the detector such that for example, a particular timing operation commences on detection of the presence of a medicament delivery device in the holder and ceases
30 when the device is removed. The timer may also be configured to include an

automatic reset or re-zeroing feature such that on subsequent reinsertion of the device the timer count starts again from zero.

The dose interval memory stores data relating to a prescribed dose interval, in particular a prescribed dose interval time or time period. By way of examples, if the medicament is to be taken twice a day at a regular interval, the prescribed dose interval time period may be set as twelve hours, or for a once daily treatment the value may be set at twenty four hours. In aspects, the system may be configured to allow for ready readjustment of the prescribed dose interval time or time period, or it may be configured in secure fashion such that any readjustment may be made only by a designated prescriber (e.g. a medical professional or pharmacist). Password and/or other security means may be employed. The prescribed dose interval data may be configured to be variable over a particular course of treatment, or alternatively it may be fixed at a set dose interval over the full course of treatment.

15

The patient alerter is designed to communicate an alert to the user. In one aspect, the alerter activates only when the holding time period exceeds the prescribed dose interval time period. By way of an example, for a once daily treatment with a prescribed dose interval of twenty four hours, the alerter would activate only when the relevant time period exceeds twenty four hours since at this point another dose is due to be taken. It may thus, be appreciated that the alerter acts functionally as a reminder to the patient that a dose is due to be taken.

The alerter may in aspects, comprise a visual device, such as a liquid crystal display (LCD) or an array of light-emitting diodes (LEDs), connected to a battery-driven timing device of any convenient kind known to those skilled in the art. The visual device may be configured to display information such as the actual time or the elapsed time from the taking of a previous dosage and may have superimposed thereon additional messages, such as a textual instruction to take a dose of the medicament. Alternatively, the instruction to take the medicament may be conveyed

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merely by displaying a warning colour or by causing the display to flash or in any other way.

In a further alternative arrangement, no specific time or elapsed time information is displayed, but the alerter merely provides a warning signal that indicates the necessary action to the user.

Depending upon the lifestyle of the user, additional or alternative warnings may be of greater assistance than purely visual warnings. Accordingly, the invention envisages that the alerter may provide audible and/or tactile warnings, such as vibration, instead of (or in addition to) visual warnings.

The alerter may provide a single, one-off alert. More preferably, the alerter is configured to provide the alert over a set period of time (the 'alerting time period' or 'alerting window'). In one aspect, the alerting time period is calculated as a function of (e.g. fraction of) the dose interval time period. For example, for a twice daily treatment with a dose interval time period of twelve hours, the alerting time period may be set as half that period (i.e. six hours). In this case, the alert is then provided for the six hours immediately following the activation of the alert.

The system may be configured such that the alerting signal cuts off when the user removes the medicament delivery device from the holder to enable dosing of medicament there from or when the device is replaced after use. The system is then reset. Other manual cutoffs / overrides may also be included.

The compliance aid herein may be configured to act in two subtly different modes, termed herein the 'clock time independent' and 'clock time dependent' modes.

In the 'clock time independent' mode the relevant timeframe (to which all subsequent timings relate) is set by the relationship of system elements, and in particular by the relationship of the medicament delivery device to the holder. In this mode, the timer

acts such as to time a holding time period corresponding to the time that the medicament delivery device is held by the holder. The dose interval memory stores data relating to a prescribed dose interval time period and the alerter activates when the holding time period exceeds the prescribed dose interval time period.

5

In the 'clock time independent' mode, it may therefore be appreciated that the relevant timeframe for detecting, timing and alerting are determined by user action in relation to the system, and in particular by user action to remove and reinsert the medicament delivery device into the holder. The dose reminder capability is

10 therefore independent of any particular defined external time zone (e.g. the local time zone relative to Greenwich Mean Time, as defined by the twenty four hour clock) because the user action defines its own 'reminder timeframe'. This provides an advantage over reminder systems, which are reliant on user reference to defined external time frames. The advantage is particularly great for the international traveler
15 since complex calculations involving different local time zones are avoided.

Conversely, in the 'clock time dependent' mode, the relevant timeframe (to which all subsequent timings relate) is determined by an external time zone (e.g. the local time zone relative to Greenwich Mean Time, as defined by the twenty four hour
20 clock). In this aspect, the timer is a standard clock set to a particular time zone. The dose interval memory stores data relating to a prescribed dose time and the alerter activates when the time registered by said clock corresponds to the prescribed dose time. At the time of setting the standard clock, suggested dose-taking times (e.g. once in the morning, once in the evening) may be entered into the dose interval
25 memory or triggered from earlier pre-set inputs to that memory.

Optionally to provide additional functionality to the user, the compliance aid may also be provided with a standard time-keeping clock with clock alarm feature. The clock may be set to any particular 'timeframe' but is conventionally set to the local time
30 zone.

It will be appreciated from the above description that the various components of the electronic dose reminder system interrelate with each other to provide the required functionality. The system may be configured in any suitable fashion using known electronic components and circuitry methods.

5

Optionally, other system aspects may also be included. In one aspect, there is included a system for reading and/or writing information from the electronic dose reminder system of the holder to the medicament delivery device inserted therein. In aspects, such a system may be used to verify the identity of the inserted device.

10

In one aspect, the holder is provided with a first transceiver for transmitting and receiving data. In this aspect, the medicament delivery device will be provided a second transceiver for transmitting and receiving data. Data will thus, be transferable in two-way fashion from the first transceiver to the second transceiver.

15

Suitably, the data is preferably in digital form and suitable for transfer by e.g. electronic or optical means. Data is transferable when the medicament delivery device is held wholly or partly by the holder. A defined data transfer position in which there is specific registration between the holder and medicament delivery device

20 received thereby may be established.

The data could include a unique serial number stored in encrypted form or in a password protectable part of the memory which uniquely identifies the product or basic product information such as the nature of the medicament and dosing

25 information.

The information written to the memory may be provided in a particular language (e.g. French, English) including a non-latin typescript language (e.g. Mandarin Chinese or Thai) or it may be provided in multilingual form. In one aspect, the system of the holder is provided with the capability (e.g. by way of appropriate software) to display information read from the medicament delivery device in any selected language.

30

In one aspect, the information/language is defined by what is written to the medicament delivery device (e.g. at the traditional point of labelling in the manufacturing process). The medicament delivery device then has the form of a
5 geography and/or language-specific product.

In another aspect, the medicament delivery device has multi-geographic and /or linguistic information written thereto (e.g. at the traditional point of labelling point in the manufacturing process). The delivery device then has the form of an
10 'international' product. The holder may then be configured (e.g. by the patient or by the pharmacist at the time of prescribing) to read/display to the patient only that information/language data set that is relevant to the particular market (or patient) of interest.

15 In a further aspect, the delivery device has information written thereto (e.g. at the traditional point of labelling in the manufacturing process) in a default (e.g. standard) language/character set. The delivery device then has the form of a 'standard' product. The holder is then provided with the capability translate that standard dataset into any local format such that it displays to the patient only the
20 information/language data set that is relevant to the particular market (or patient) of interest.

On loading or reloading the holder with a delivery device, the first transceiver may, for example, read the unique serial number, batch code and expiry date of the
25 delivery device and any other information on the second transceiver. In this way the nature and concentration of the medicament, together with the number of doses used or remaining within the delivery device, may be determined. This information can be displayed to the patient on a visual display unit. Other information, such as the number of times the holder has been reloaded with a delivery device, may also
30 be displayed.

Other information, such as the date and time of administration of the drug, or environmental exposure data such as the minimum / maximum temperatures or levels of humidity the holder and/or delivery device has been exposed to, may also be read and displayed to the user.

5

Data may be transferred each time the patient uses the device. Or alternatively, data may be stored in a database memory of an electronic data management system of the holder and periodically downloaded to any transceiver. In either case, a history of the usage of the delivery device may be built up in the memory of a transceiver.

10

Suitably, the first and second transceiver each comprise an antenna or equivalent for transmitting or receiving data and connecting thereto a memory. The antenna can, in embodiments, also transfer energy to the passive receiver. The memory will typically comprise an integrated circuit chip. Either transceiver may be configured to have a

15 memory structure that allows for large amounts of information to be stored thereon.

The memory structure can be arranged such that parts of the memory are read-only, being programmed during/after manufacture, other parts are read/write and further parts are password protectable. Initial transfer of information (e.g. on manufacture or one dispensing) to or from any transceiver can be arranged to be readily achievable

20 by the use of a reader which is remote from the medical dispenser, thereby minimising the need for direct product handling. In further aspects, the reader can be arranged to simultaneously read or write to the memory of multiple transceivers on multiple medicament dispensers.

25 Suitably, data is transferable in two-way fashion between the first and second transceiver without the need for direct physical contact therebetween. Preferably, data is transferable wirelessly between the first and second transceiver.

30 Suitably, the first transceiver is an active transceiver and the second transceiver is a passive transceiver. The term active is used to mean directly-powered and the term passive is used to mean indirectly-powered.

Suitably, the second transceiver comprises a label or tag comprising an antenna for transmitting or receiving energy; and an integrated circuit chip connecting with said antenna, and the first transceiver comprises a reader for said label or tag. In this
5 case the label or tag is a passive transceiver and the reader is an active transceiver. Preferably, the reader will not need to be in direct contact with the tag or label to enable the tag or label to be read.

The tag may be used in combination and/or integrated with other traditional product
10 labelling methods including visual text, machine-readable text, bar codes and dot codes.

The tag may be associated with the delivery device in any suitable fashion. In one aspect, the tag is somehow attached or fixed to the delivery device by any suitable
15 means including adhesive fixing, welding, snap-fit arrangements or through the use of various mounting means. The mounting means may for example, comprise an adhesive label, wrap-round tape or collar arrangement.

In another aspect, the tag is located within the delivery device, for example, as a
20 loose component together with any medicament contents thereof or within a separate compartment or housing within the medicament container. An advantage of placing the tag within the delivery device is that it can be 'hidden from view' thereby improving its utility as a security feature. Additionally, the tag and delivery device may be configured (e.g. shaped and sized) such that the tag may only be removed
25 by rupture or other degradation of the delivery device or tag.

Suitably, the tag is on a carrier and the carrier is mountable on the holder or the delivery device.

30 In one aspect, the carrier is a flexible label. In another aspect, the carrier is a rigid disc. In a further aspect, the carrier is a rectangular block. In a further aspect, the

carrier is a collar (e.g. in the form of a ring) suitable for receipt by (e.g. for mounting to) the delivery device. Other shapes of carrier including those defining chip housings or enclosures are also envisaged.

- 5 Suitably, the carrier encases the tag. More preferably, the carrier forms a hermetic seal for the tag. In one aspect, the carrier comprises an insulating material such as a glass material or, a paper material, a ceramic material or an organic polymeric material such as polypropylene. Alternatively, the carrier includes a ferrite material.
- 10 The energy to power any transceiver may be in any suitable form including ultrasonic, infrared, radiofrequency, magnetic, optical and laser form. Any suitable channels may be used to channel the energy including wave guide and fibre optic channels.
- 15 In one aspect, the second transceiver comprises a radiofrequency identifier comprising an antenna for transmitting or receiving radiofrequency energy; and an integrated circuit chip connecting with said antenna, and the first transceiver comprises a reader for said radiofrequency identifier. In this case the radiofrequency identifier is a passive transceiver and the reader is an active transceiver. An
- 20 advantage of radiofrequency identifier technology is that the reader need not be in direct contact with the radiofrequency identifier tag or label to be read.

The radiofrequency identifier can be any known radiofrequency identifier. Such identifiers are sometimes known as radiofrequency transponders or radiofrequency

25 identification (RFID) tags or labels. Suitable radiofrequency identifiers include those sold by Phillips Semiconductors of the Netherlands under the trade marks Hitag and Icode, those sold by Amtech Systems Corporation of the United States of America under the trade mark Intellitag, and those sold by Texas Instruments of the United States of America under the trade mark Tagit.

Suitably, the antenna of the RFID tag is capable of transmitting or receiving radiofrequency energy having a frequency of from 100 KHz to 2.5 GHz. Preferred operating frequencies are selected from 125 KHz, 13.56 MHz and 2.4 GHz.

5 In one aspect, the second transceiver comprises a magnetic label or tag comprising an antenna for transmitting or receiving magnetic field energy; and an integrated circuit chip connecting with said antenna, and the first transceiver comprises a reader for said magnetic label or tag. In this case the magnetic label or tag is a passive transceiver and the reader is an active transceiver.

10

A suitable magnetic label or tag comprises plural magnetic elements in mutual association whereby the magnetic elements move relative to each other in response to an interrogating magnetic field. A magnetic label or tag of this type is described in U.S. Patent No. 4,940,966. Another suitable magnetic label or tag comprises a
15 magnetorestrictive element which is readable by application of an interrogating alternating magnetic field in the presence of a magnetic bias field which results in resonance of the magnetorestrictive elements at different predetermined frequencies. A magnetic label of this type is described in PCT Patent Application No. WO92/12402. Another suitable magnetic label or tag comprising plural discrete
20 magnetically active regions in a linear array is described in PCT Patent Application No. WO96/31790. Suitable magnetic labels and tags include those making use of Programmable Magnetic Resonance (PMR) (trade name) technology.

In another aspect, the second transceiver comprises a passive microelectronic
25 memory chip and the first transceiver comprises an active reader for said microelectronic memory chip. The microelectronic memory chip may comprise an Electrically Erasable Programmable Read Only Memory (EEPROM) chip or a SIM card-type memory chip. In this case the microelectronic memory chip is a passive transceiver and the reader is an active transceiver.

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Any transceiver herein, particularly a passive transceiver may be mounted on or encased within any suitable inert carrier. The carrier may comprise a flexible sheet which may in embodiments be capable of receiving printed text thereon.

- 5 Suitably, the holder additionally comprises an electronic data management system, wherein the electronic data management system is in association with at least the first transceiver. The electronic data management system has input/output capability and comprises a memory for storage of data; a microprocessor for performing operations on said data; and a transmitter for transmitting a signal relating to the
- 10 data or the outcome of an operation on the data.

Suitably, the electronic data management system is arranged to be responsive to or activated by the voice of a user. Thus, for example the system may be switched on or off in response to a voice command.

15

In the event that the compliance aid is to be used unsupervised by a child used to adult supervision, developed forms of holder can incorporate facilities for remote stimulation of the reminder, such as by radio messaging from the child's parent.

- 20 The electronic dose reminder system including the timer and the visual display and/or other warning mechanisms are in one aspect, battery operated, and circuitry of known kind is preferably provided to monitor the condition of the battery or batteries used and provide a warning of the need for change well before any drop in performance occurs. In some circumstances, it is preferred that (bearing in mind
- 25 that a timing device is incorporated) a warning to change the battery or batteries is generated after a set time irrespective of the actual condition of the battery or batteries.

- If desired, the holder may be provided with a suitable socket from which it can be
- 30 powered via an adaptor connected to the mains power supply when the aid is being

used at home for long periods, for example by someone who is bed-ridden. As a further alternative, rechargeable batteries can be used in known manner.

In order that the invention may be clearly understood and readily carried into effect,
5 one embodiment thereof will now be described, by way of example only, with reference to the accompanying drawings of which:

Figure 1 shows, in perspective view and in sequential format the closed, open and display conditions of a compliance aid in accordance with one example of the
10 invention;

Figure 2 shows, in view and format similar to Figure 1, the conversion of a compliance aid in accordance with said example of the invention to accommodate medicament delivery devices of differing form;

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Figure 3 shows in perspective view a cradle form holder in accordance with another aspect of the invention; and

Figure 4 shows a system diagram of an electronic dose reminder system for use in
20 accordance with the invention.

Referring now to Figure 1, and specifically to Figure 1(a), there is shown a compliance aid 1 in accordance with one example of the invention. In this example, the compliance aid 1 comprises a casing 2 of elastomeric material, the casing 2
25 being coloured, patterned and/or textured as described hereinbefore to create a desired visual and/or tactile effect.

The casing 2 has a top portion 3 and a bottom portion 4; the top portion 3 being transversely split along a break-line 5 to define front and rear sections 6 and 7
30 respectively. Both sections 6 and 7 of the top portion 3 are independently hinged to the bottom portion 4; the arrangement being such that the rear section 7 is intended

to be closed first and a latching arrangement is provided to snap the casing shut in its closed condition once the front portion 6 has been closed also. The hinge for the rear section 7 (not shown in Figure 1(a) but visible at 10 in Figures 1(c) and 1(d)) is a simple, freely mobile hinge of any convenient construction whereas the hinge for the front section 6 (not shown) is preferably resiliently urged towards its closure position, for a reason which will become clear hereinafter.

When it is desired to open the casing 2, pressure is applied to a pair of release buttons 8 and 9 disposed to either side of the compliance aid 1, near the front thereof. This action causes the front section 6 of the top portion 3 to open slightly, enabling the rear section to be opened as shown in Figures 1(b) and 1(c), permitting a dosage container 11 to be grasped and removed, if it is time to take a dose of the medicament, and/or repositioned if it is intended to convert the compliance aid into its display condition.

15

If the user of the compliance aid 1 is traveling, for example, and wishes to keep it closed at times when the container is not being used to take doses of the medicament, the container 11 which, in this case is a Diskus DPI device, as sold by GlaxoSmithKline Inc., comprising a somewhat discoidal container that is capable of supplying a set number of well-defined doses of the medicament, is merely removed for the dosage to be taken and then re-inserted into the casing 2. The casing is then re-closed.

If, on the other hand, it is more convenient for the compliance aid to be configured in its display mode, wherein the dosage container 11 is presented ready for use, for example on a bed-side table, the casing 2 can be so converted, as shown in Figures 1(d) and 1(e), merely by using the dosage container 11 to pull the front section 6 of the top portion 3 farther open against the resilient closure urging of its hinge, closing the rear section 7 behind it and then allowing the resilient hinge of the front section 6 to hold the container 11, against the front edge of the rear section 7, in an inclined position, protruding from the casing 2. The support for the Diskus DPI device may

be enhanced by the provision of a groove (not shown) in the base of the shell-like casing.

Preferably at least a portion of either or both sections 6 and 7 of the top portion 3 are
5 made transparent or translucent to provide a viewing window whereby the presence
of a dosage container such as 11 can be readily confirmed visually when the casing
2 is closed. To aid in this, it is preferred that a portion of the interior base of the
bottom portion 4 which can be seen through the window when the container is
closed but which is obscured when a dosage container is installed, is brightly
10 coloured and/or fluorescent.

Importantly, the compliance aid 1 supports electronic circuitry (not shown, but of
known kind) that includes an electronic timer for timing (e.g. a holding time period
corresponding to the time that the medicament delivery device is held within the
15 casing). In this example, the time recorded by the electronic circuitry is displayed on
an LCD 12 and a reset button 13 is provided whereby, if an elapsed time is recorded,
the count is reset to zero after a dose of the medicament has been taken. Other
controls may be provided to set the time, and possibly also the date, if absolute time
is to be recorded, or the button 13 may be actuated in specific sequences and/or for
20 selected durations if other information is to be imparted to the circuitry. Preferably
the circuitry is incorporated into a microprocessor.

The presence of the dosage container 11 within the casing 2 in either the closed or
display configurations is detected by a proximity sensor 14 located on the interior
25 side of the forward lip 15 of the front section 6 of the casing. The proximity sensor is
capable of sending a signal to the electronic circuitry, and in particular to the
electronic timer. A new holding time period commences on initial detection of the
presence of the dosage container 11 in the casing 2 (e.g. after reinsertion of the
dosage container following a particular dosage event).

Assuming that an elapsed time count is to be displayed, the button 13 or an additional control button (not shown) is actuated to select an appropriate inter-dose period and the arrangement is such that, upon the inter-dose period elapsing, the compliance aid 1 provides an alert that the next dose is due to be taken. The

5 warning may be visual, provided by the LCD, or by an associated LED, audible (such as a beeping tone, music or a verbal instruction) and/or tactile, such as a vibration. Any or all of the foregoing warnings may be provided in a compliance aid according to the invention.

10 In any event, the user is warned that a dose is due to be taken, and the dosage container 11 is duly removed from the casing 2, as described above, and replaced with the casing in its same condition, or reconfigured from its closed condition to its display condition or vice-versa. The timing circuitry is reset and the process begins again.

15

The electronic circuitry may be powered in any convenient manner, for example by one or more batteries (disposable or rechargeable) and/or by adapted mains electricity.

20 Where the electronic circuitry and the visual display and/or other warning mechanisms are battery operated, it is preferred that the circuitry is configured to generate a warning to change (or charge) the battery or batteries after a predetermined number of resetting operations have occurred irrespective of the actual condition of the battery or batteries. As an alternative, the circuitry can
25 incorporate a battery monitoring function of known kind, thereby to provide a replace (or recharge) warning ahead of any significant deterioration in battery performance.

Figure 2 shows a slightly modified version 101 of the compliance aid 1 shown in Figures 1(a) to 1(e). In Figure 2, components that are the same as, or directly
30 equivalent to, components shown in Figure 1 have their reference numbers increased by 100.

Figure 2(a) shows the compliance aid 101 in its display condition, equivalent to Figure 1(e). Figure 2(b) shows an adapter device 116 which can be placed in the casing 102 to reconfigure the interior of the casing so as to accommodate, in the display condition as shown in Figure 2(c), a dosage container 118 of the well-known L-shape (e.g. an MDI inhaler) as opposed to the Diskus DPI device 111. Depending upon the dimensions of the casing 102 and its internal configuration, it may or may not be possible to close the casing 102 when it houses the L-shaped container 118. Either arrangement may be chosen in dependence upon the overall design criteria for the compliance aid 101 and its intended usage.

As previously, the presence of the dosage container 111 or 118 within the casing 102 in either the closed or display configurations is detected by a proximity sensor 114 located on the interior side of the forward lip 115 of the front section 106 of the casing. It will be appreciated that with this choice of location of the proximity sensor 114 detection of both a discoidal 111 or L-shaped 118 type inhaler is enabled. The proximity sensor 114 is capable of sending a signal to the electronic circuitry, and in particular to the electronic timer.

Figure 2(a) shows a window 119 provided, as explained earlier, to enable the presence of the dosage container 111 to be readily ascertained.

In developed forms of the invention, the electronic circuitry may be rendered capable of responding to remote stimuli, such as a parental message sent via a radio or other telecommunications link to which the compliance aid 1 or 101 is receptive.

Figure 3 shows compliance aid 201 herein in which the top portion 203 thereof is provided with a holder in the form of a cradle 202 for receipt of a medicament delivery device (not shown). The bottom portion 204 of the compliance aid 201 forms a base that enables the compliance aid 201 to sit on a horizontal surface such as a bedside table or mantelpiece (not shown).

The interior of the cradle 202 is provided with a mechanical switch 214, in the form of a lever balance, which acts such as to detect the weight of a medicament delivery device (not shown) held within the cradle 202. The cradle 202 has a generally cross-shaped form that enables it to receive either a discoidally-shaped delivery device (e.g. the Diskus DPI device as sold by GlaxoSmithKline) in the lateral part of the cross, or an L-shaped delivery device (such as the well-known MDI aerosol devices) in the vertical part of the cross. Insertion of either sort of device into the cradle results in triggering of the switch 214.

10

The compliance aid 201 includes electronic timing circuitry (not shown) and a dose interval memory for storing dose interval data (also not shown). A patient alert is provided by both an LCD display 212a and an LED light emitter 212b.

15 The compliance aid of Figure 3 may be arranged to act in either 'clock time independent' or 'clock time dependent' mode (as defined hereinbefore).

In the 'clock time independent' mode, the timer acts such as to time a holding time period corresponding to the time that the medicament delivery device is held by the cradle 202. The alert is triggered when the period for which the delivery device has been held within the cradle 202 exceeds a prescribed dose interval time period held in the memory. In this case, the alert comprises a flashed LCD display 212a of the message 'Dose Reminder' and also illumination of the LED light emitter 212b. The alert is switched off when the delivery device is replaced in the cradle 202 which action triggers the switch 214.

In the 'clock time dependent' mode, the timer is a standard clock set to a particular time zone. The alert is triggered when the time registered by the clock corresponds to a prescribed dose time. In this case, the alert comprises a flashed LCD display 212a of the message 'Dose Reminder' and also illumination of the LED light emitter 212b. The alert is switched off when the delivery device is replaced in the cradle 202

thereby triggering the switch 214. The system may also be configured to automatically switch off the alert after a set time period of alerting has been exceeded (e.g. after three hours of alerting activity) regardless of whether the delivery device has been removed from the cradle 202. The next alert will then occur
5 at the next prescribed dose time.

Figure 4 shows the structure of a suitable electronic dose reminder system herein 110, which for example could be used in any of the compliance aids as shown in the previous figures. The electronic dose reminder system 330 comprises a central
10 processor unit (CPU) 340, RAM 341 and ROM 342. The CPU 340 also receives patient data from sensor 350, which may for example be a proximity sensor or electronic switch for detecting the presence of the medicament delivery device in the holder. The CPU 340 is also associated with clock 345. In the 'clock time independent' mode aspect, the clock may be configured to start a timing event in
15 response to detection of the delivery device by the sensor 350. The CPU can receive and transfer data to data storage device 343 which includes two databases, one for storage of dose interval data 343a and one for storage of compliance data 343b relevant to patient compliance with the prescribed regime. The CPU 340 also interacts with man machine interface 344 for receipt of patient input commands (e.g.
20 relating to the relevant dosage regime); and display driver 311 and display 312 for display of alerting information to the patient. The display may for example, be in the form of an LED display (as shown in Figure 3).

In addition to the basic features of the electronic dose reminder system, further
25 capability is also provided by the system of Figure 4. In one aspect, the CPU 340 is further associated with communications port 355 which links via modem 356 to a network computer system (not shown) to enable communication therewith. In another aspect, the CPU 340 is capable of two-way data transfer with reader 330. The reader, which is typically located on the holder, is capable of reading and writing
30 information to a passive transceiver in the form of a tag 320 (e.g. on a medicament delivery device). The tag 320 may comprise an RFID tag or a magnetic tag. In a

preferred system herein, the reader 330 will form part of the holder of the compliance aid and the tag 320 will be mounted on a medicament delivery device receivable thereby.

5 The compliance aid and holder of the present invention is in aspects suitable for use with medicament delivery devices for dispensing medicament for the treatment of respiratory disorders such as disorders of the lungs and bronchial tracts including asthma and chronic obstructive pulmonary disorder (COPD), bronchitis and chest infections.

10

Appropriate medicaments may thus be selected from, for example, analgesics, e.g. codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate (e.g. as the sodium salt), ketotifen or nedocromil (e.g. as the sodium salt); antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone (e.g. as the dipropionate ester), fluticasone (e.g. as the propionate ester), flunisolide, budesonide, rofleponide, mometasone e.g. as the furoate ester), ciclesonide, triamcinolone (e.g. as the acetoneide) or 6 α , 9 α -difluoro-11 β -hydroxy-16 α -methyl-3-oxo-17 α -propionyloxy- androsta-1,4-diene-17 β -carbothioic acid S-(2-oxo-tetrahydro-furan-3-yl) ester; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol (e.g. as free base or sulphate), salmeterol (e.g. as xinafoate), ephedrine, adrenaline, fenoterol (e.g. as hydrobromide), formoterol (e.g. as fumarate), isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol (e.g. as acetate), reproterol (e.g. as hydrochloride), rimiterol, terbutaline (e.g. as sulphate), isoetharine, tulobuterol or 4-hydroxy-7-[2-[[2-[[3-(2-phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl-2(3H)-benzothiazolone; adenosine 2a agonists, e.g. 2R,3R,4S,5R)-2-[6-Amino-2-(1S-hydroxymethyl-2-phenyl-ethylamino)-purin-9-yl]-5-(2-ethyl-2H-tetrazol-5-yl)-tetrahydro-furan-3,4-diol (e.g. as maleate); α_4 integrin inhibitors e.g. (2S)-3-[4-({[4-(aminocarbonyl)-1-piperidiny]carbonyl}oxy)phenyl]-2-[[[(2S)-4-methyl-2-{[2-(2-methylphenoxy) acetyl]amino}pentanoyl]amino] propanoic acid (e.g. as free acid or

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20

25

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potassium salt), diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium (e.g. as bromide), tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and
5 peptides, e.g., insulin or glucagon; vaccines, diagnostics, and gene therapies. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

10

Preferred components of the combinations comprise medicaments selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

15

Preferred components of combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) or formoterol (eg as the fumarate salt) in combination with an anti-inflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g.,
20 the propionate) or budesonide. A particularly preferred combination of components comprises fluticasone propionate and salmeterol, or a salt thereof (particularly the xinafoate salt). A further combination of components of particular interest is budesonide and formoterol (e.g. as the fumarate salt).

25 Generally, powdered medicament particles suitable for delivery to the bronchial or alveolar region of the lung have an aerodynamic diameter of less than 10 micrometers, preferably less than 6 micrometers. Other sized particles may be used if delivery to other portions of the respiratory tract is desired, such as the nasal cavity, mouth or throat. The medicament may be delivered as pure drug, but more
30 appropriately, it is preferred that medicaments are delivered together with excipients (carriers) which are suitable for inhalation. Suitable excipients include organic

excipients such as polysaccharides (i.e. starch, cellulose and the like), lactose, glucose, mannitol, amino acids, and maltodextrins, and inorganic excipients such as calcium carbonate or sodium chloride. Lactose is a preferred excipient.

5 Particles of powdered medicament and/or excipient may be produced by conventional techniques, for example by micronisation, milling or sieving. Additionally, medicament and/or excipient powders may be engineered with particular densities, size ranges, or characteristics. Particles may comprise active agents, surfactants, wall forming materials, or other components considered
10 desirable by those of ordinary skill.

The excipient may be included with the medicament via well-known methods, such as by admixing, co-precipitating and the like. Blends of excipients and drugs are typically formulated to allow the precise metering and dispersion of the blend into
15 doses. A standard blend, for example, contains 13000 micrograms lactose mixed with 50 micrograms drug, yielding an excipient to drug ratio of 260:1. Dosage blends with excipient to drug ratios of from 100:1 to 1:1 may be used. At very low ratios of excipient to drug, however, the drug dose reproducibility may become more variable.

20 Aerosol formulations suitable for use with metered dose inhaler (MDI) dispensers typically comprise a propellant. Suitable propellants include P11, P114 and P12, and the CFC-free hydrofluoroalkane propellants HFA-134a and HFA-227.

The MDI aerosol formulation may additionally contain a volatile adjuvant such as a
25 saturated hydrocarbon for example propane, n-butane, isobutane, pentane and isopentane or a dialkyl ether for example dimethyl ether. In general, up to 50% w/w of the propellant may comprise a volatile hydrocarbon, for example 1 to 30% w/w. However, formulations, which are free or substantially free of volatile adjuvants are preferred. In certain cases, it may be desirable to include appropriate amounts of
30 water, which can be advantageous in modifying the dielectric properties of the propellant.

A polar co-solvent such as C₂₋₆ aliphatic alcohols and polyols e.g. ethanol, isopropanol and propylene glycol, preferably ethanol, may be included in the MDI aerosol formulation in the desired amount to improve the dispersion of the formulation, either as the only excipient or in addition to other excipients such as surfactants. Suitably, the drug formulation may contain 0.01 to 30% w/w based on the propellant of a polar co-solvent e.g. ethanol, preferably 0.1 to 20% w/w e.g. about 0.1 to 15% w/w. In aspects herein, the solvent is added in sufficient quantities to solubilise the part or all of the medicament component, such formulations being commonly referred to as solution formulations.

A surfactant may also be employed in the MDI aerosol formulation. Examples of conventional surfactants are disclosed in EP-A-372,777. The amount of surfactant employed is desirable in the range 0.0001% to 50% weight to weight ratio relative to the medicament, in particular, 0.05 to 5% weight to weight ratio.

The final aerosol formulation desirably contains 0.005-10% w/w, preferably 0.005 to 5% w/w, especially 0.01 to 1.0% w/w, of medicament relative to the total weight of the formulation.

20

The compliance aid and holder of the invention is in one aspect suitable for use with devices for dispensing medicament for the treatment of respiratory disorders such as disorders of the lungs and bronchial tracts including asthma and chronic obstructive pulmonary disorder (COPD). In another aspect, the compliance aid and holder of the invention is suitable for use with devices for dispensing medicament for the treatment of a condition requiring treatment by the systemic circulation of medicament, for example migraine, diabetes, pain relief e.g. inhaled morphine.

Accordingly, there is provided the use of a compliance aid and holder according to the invention in combination with a suitable medicament delivery device for the treatment of a respiratory disorder, such as asthma and COPD. Alternatively, the

present invention provides a method of treating a respiratory disorder such as, for example, asthma and COPD, which comprises administration by inhalation of an effective amount of medicament product as herein described from a suitable medicament delivery device used in compliant fashion making use of a compliance
5 aid and holder of the present invention.

The medicament delivery device is in another aspect a syringe for the delivery of injectable medicament to a patient. Traditional syringes rely on puncturing of the patient's skin by a hollow needle through which the injectable medicament (in
10 solution or suspension form) is delivered to the muscle or tissue of the patient. Recently developed needleless systems for the delivery of injectables employ high velocity injection of particle formulated drugs or vaccine through the skin and into any physically accessible tissue. Other needleless systems employ similar high velocity injection of drug or vaccine coated on to a suitable carrier particle.

15

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

The application of which this description and claims form part may be used as a
20 basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

25

CLAIMS:

1. A holder for holding a medicament delivery device, said holder including an
5 electronic dose reminder system comprising

a detector for detecting the presence of said medicament delivery device within the holder;

10 a timer for timing a time period;

a dose interval memory for storing data relating to a prescribed dose interval; and

a patient alerter for alerting a user.
15
2. A holder according to claim 1, wherein said timer is for timing a holding time period corresponding to the time that the medicament delivery device is held by the holder; said dose interval memory stores data relating to a prescribed dose interval time period; and the alerter activates when said holding time period exceeds said
20 prescribed dose interval time period.
3. A holder according to claim 1, wherein the timer is a standard clock; said dose interval memory stores data relating to a prescribed dose time; and the alerter activates when said clock registers said prescribed dose time.
25
4. A holder according to any of claims 1 to 3, in the form of a docking station for receipt of the medicament delivery device.
5. A holder according to any of claims 1 to 3, in the form of a casing configured
30 to house the medicament delivery device.

6. A holder according to any of claims 1 to 5, configured to receive an adaptor device enabling the holding of an alternative medicament delivery device thereby.

7. A holder according to any of claims 1 to 6, wherein the detector comprises a
5 switch which is triggered in response to placing of the medicament delivery device into the holder.

8. A holder according to any of claims 1 to 6, wherein the detector comprises a sensor for detecting the proximity of the medicament delivery device thereto.

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9. A holder according to claim 8, wherein the sensor comprises an emitter and detector.

10. A holder according to claim 9, wherein the emitter emits electro magnetic
15 radiation and the detector detects said electromagnetic radiation.

11. A holder according to any of claims 1 to 10, wherein the timer includes an automatic re-zeroing feature.

20 12. A holder according to any of claims 1 to 11, wherein the dose interval memory is configured in secure fashion such that any readjustment to the dose interval data may be made only by an authorised prescriber.

13. A holder according to any of claims 1 to 11, wherein the dose interval memory
25 is configured to enable variation of the dose interval over a particular course of treatment.

14. A holder according to any of claims 1 to 11, wherein the dose interval memory is securely configured to fix the dose interval over a particular course of treatment.

30

15. A holder according to any of claims 1 to 14, wherein the alerter comprises a visual device.

16. A holder according to claim 15, wherein the visual device is selected from the
5 group consisting of a liquid crystal display (LCD) and an light emitting diode (LED).

17. A holder according to claim 16, wherein the visual device is configured to display textual information thereon.

10 18. A holder according to any of claims 1 to 17, wherein the alerter provides alert signals selected from the group consisting of visual, audible and tactile signals.

19. A holder according to any of claims 1 to 18, wherein the alerter is configured to provide the alert over a defined alerting time period.

15

20. A holder according to claim 19, wherein the alerting time period is calculated as a function of the dose interval time period.

21. A holder according to any of claims 1 to 20, wherein the alerter is configured
20 such as to cut off when the medicament delivery device is removed from the holder or replaced therein.

22. A holder according to any of claims 1 to 21, additionally comprising a system for reading and/or writing information from the electronic dose reminder system of
25 the holder to the medicament delivery device held thereby.

23. A holder according to claim 22, wherein the holder is provided with a first transceiver for transmitting and receiving data when the medicament delivery device is held wholly or partly by the holder.

24. Kit of parts comprising a holder according to any of claims 1 to 23 and a medicament delivery device capable of being held thereby.

25. Kit of parts according to claim 24, wherein the holder is provided with a first
5 transceiver for transmitting and receiving data and the medicament delivery device is provided with a second transceiver for transmitting and receiving data.

26. Kit of parts according to claim 25, wherein the first transceiver is an active transceiver and the second transceiver is a passive transceiver.

10

27. Kit of parts according to claim 26, wherein the second transceiver comprises a label or tag comprising an antenna for transmitting or receiving energy and an integrated circuit chip connecting with said antenna; and the first transceiver comprises a reader for said label or tag.

15

28. Kit of parts according to claim 27, wherein the second transceiver comprises a radiofrequency identifier comprising an antenna for transmitting or receiving radiofrequency energy and an integrated circuit chip connecting with said antenna; and the first transceiver comprises a reader for said radiofrequency identifier.

20

29. Kit of parts according to claim 28, wherein the second transceiver comprises a magnetic label or tag comprising an antenna for transmitting or receiving magnetic field energy and an integrated circuit chip connecting with said antenna; and the first transceiver comprises a reader for said magnetic label or tag.

25

30. Kit of parts according to any of claims 24 to 29, wherein the holder additionally comprises an electronic data management system in association at least the first transceiver.

30

31. Kit of parts according to claim 30, wherein the electronic data management system comprises a memory for storage of data; a microprocessor for performing

operations on said data; and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data.

32. Use of the holder according to any of claims 1 to 23 for holding a medicament
5 delivery device.

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FIG. 1(a)

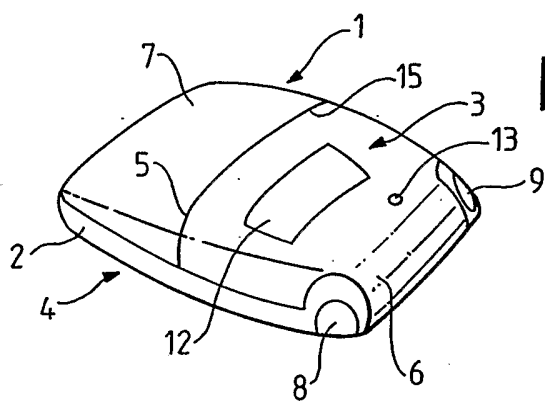


FIG. 1(b)

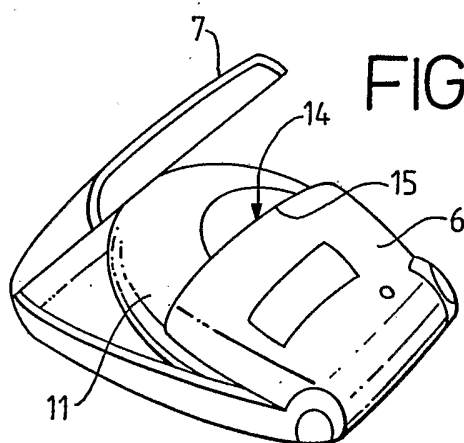


FIG. 1(c)

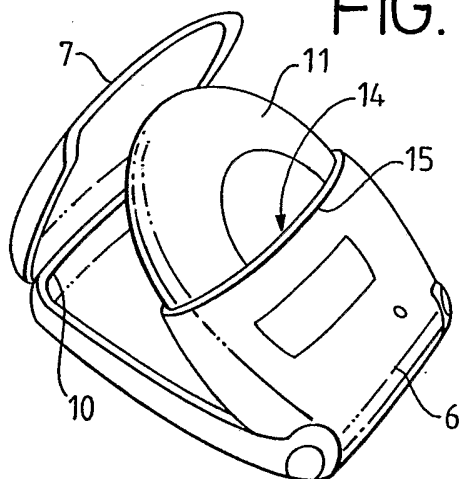


FIG. 1(e)

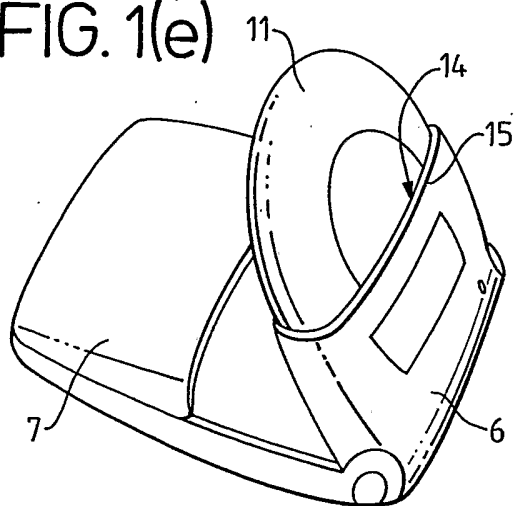
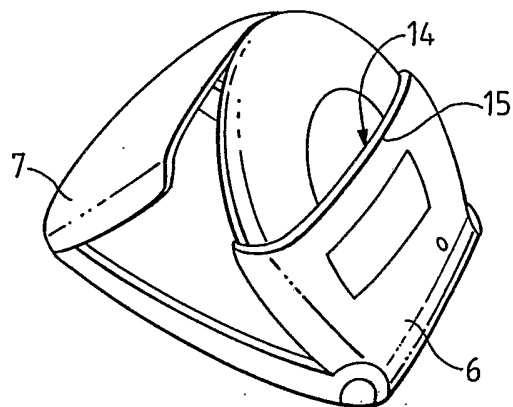


FIG. 1(d)



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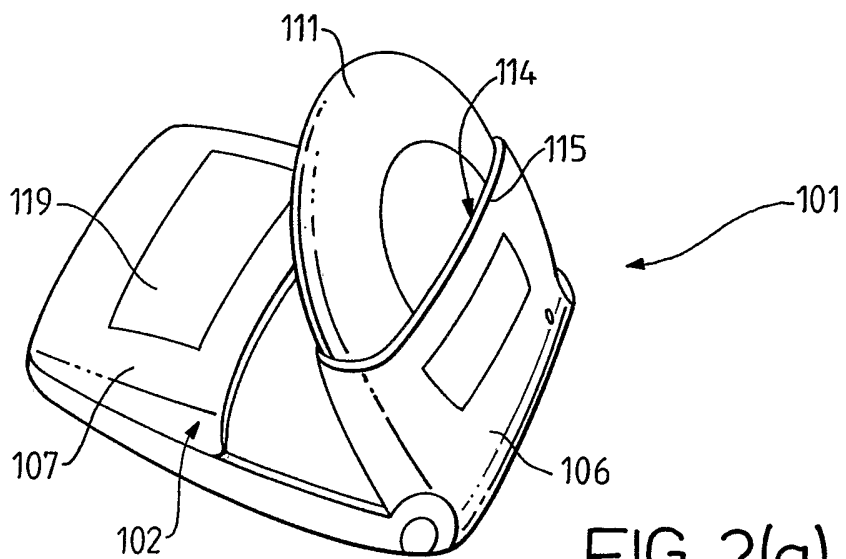


FIG. 2(a)

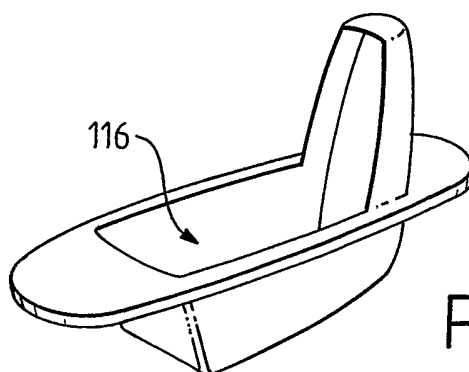


FIG. 2(b)

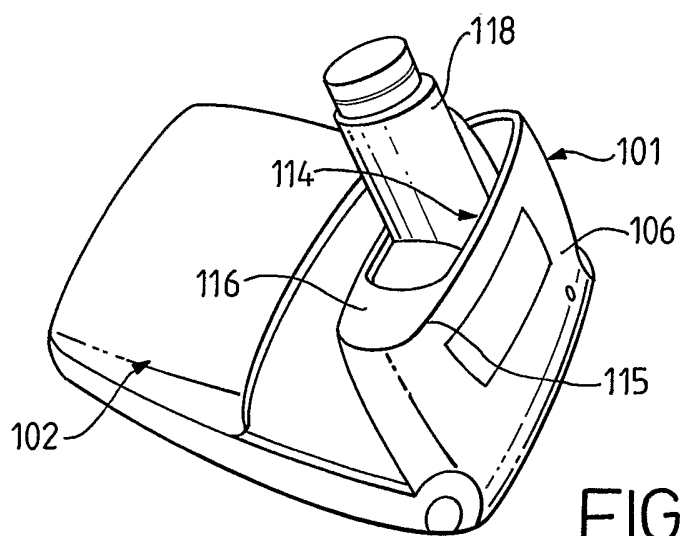


FIG. 2(c)

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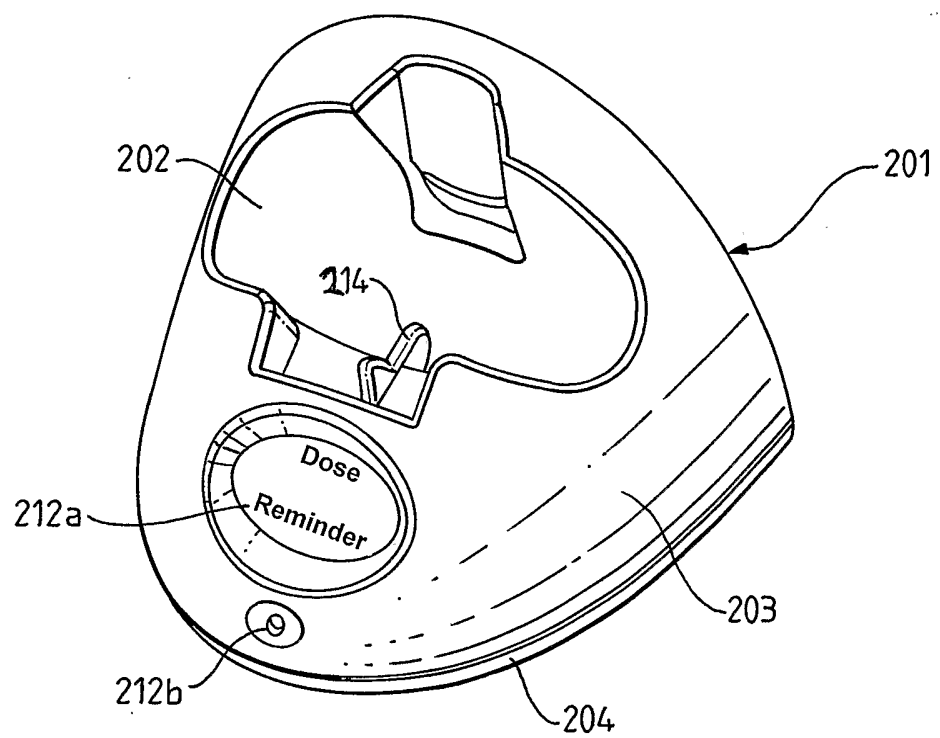


FIG. 3

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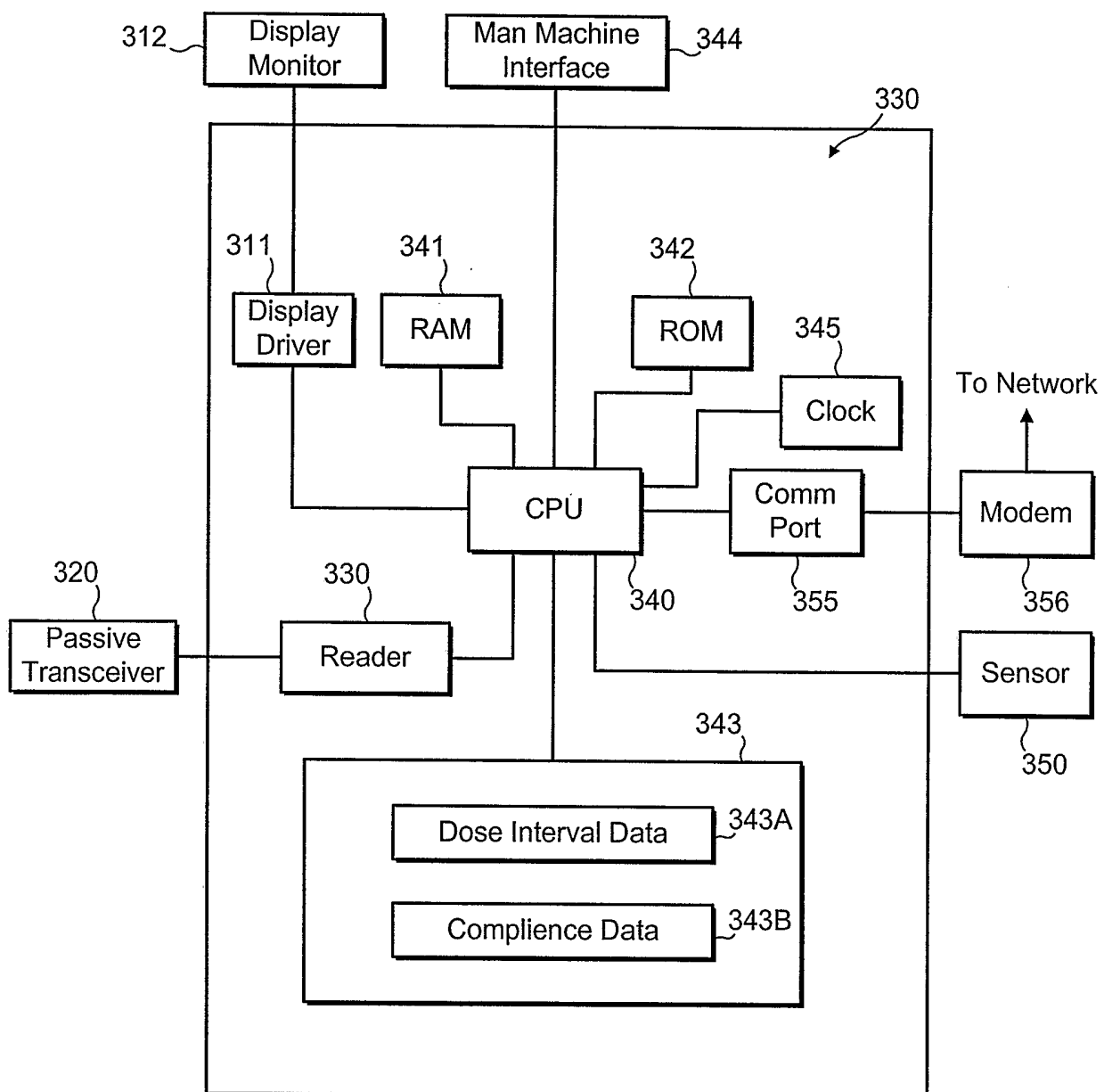


FIG. 4

INTERNATIONAL SEARCH REPORT

Internati plication No

PCT/EP 03/00597

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61J7/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 170 380 A (HOWARD JAMES M ET AL) 8 December 1992 (1992-12-08) column 2, line 53 -column 3, line 39 column 4, line 6 - line 10 column 5, line 8 -column 6, line 57 column 7, line 36 -column 8, line 49; figures 1-6 ---	1-7, 11-21, 24,32
X	US 6 294 999 B1 (DIPISA JOSEPH ET AL) 25 September 2001 (2001-09-25) column 5, line 23 -column 8, line 42 column 10, line 40 -column 11, line 27; figures 3,5,6 --- -/--	1-5,7-32

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

° Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

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PCT/EP 03/00597

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 099 463 A (LLOYD HARRY A ET AL) 24 March 1992 (1992-03-24) column 2, line 67 -column 5, line 39 column 6, line 1 - line 11; figures 1,2 ---	1-5, 7-21, 24, 32
X	US 6 150 942 A (O'BRIEN CHARLES T) 21 November 2000 (2000-11-21) column 4, line 28 -column 9, line 56; figures 1,6 ---	1-5, 8-32
X	US 5 774 865 A (GLYNN KENNETH P) 30 June 1998 (1998-06-30) column 2, line 48 -column 6, line 39; figures 1-4 -----	1-5, 7-24, 30-32

INTERNATIONAL SEARCH REPORT

Internat. Application No

PCT/EP 03/00597

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5170380	A	08-12-1992	CA 2083107 A1	18-05-1994
US 6294999	B1	25-09-2001	AU 2283901 A	09-07-2001
			EP 1242035 A1	25-09-2002
			WO 0147466 A1	05-07-2001
			US 2002027507 A1	07-03-2002
			US 2002067270 A1	06-06-2002
US 5099463	A	24-03-1992	NONE	
US 6150942	A	21-11-2000	US 5963136 A	05-10-1999
			AU 4982199 A	07-02-2000
			CA 2306998 A1	27-01-2000
			EP 1023711 A1	02-08-2000
			TW 439048 B	07-06-2001
			WO 0004521 A1	27-01-2000
US 5774865	A	30-06-1998	NONE	