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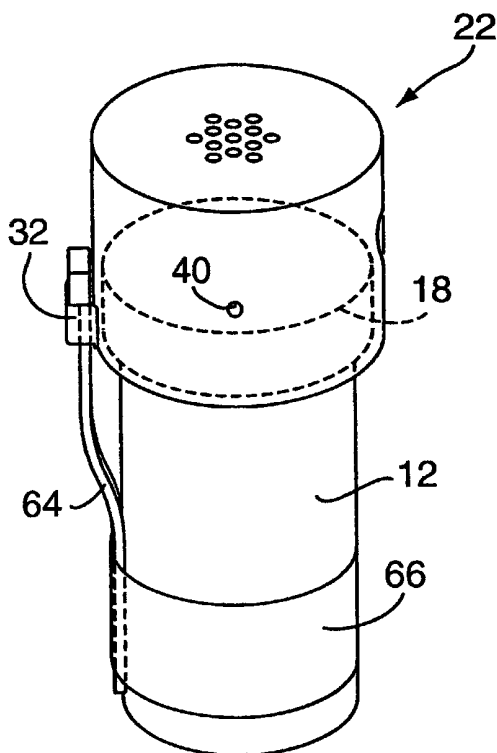
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(54) Title: AUDIO DEVICE FOR MEDICATION CONTAINER



(57) Abstract: The present invention is directed to a device that attaches to a medication container (10) and has a built-in audio recording and playback feature for recording and listening to instructions. The self-contained device has a power supply (56), an audio input component (i.e., microphone (58)), an audio output component (speaker (60)), audio recording storage in the form of electronic data memory (54), control buttons (51) in communication with a microprocessor (53), and associated electronic circuitry (48). The device is adapted to clip onto the cap (18) of a medication container (10) or to slide over the lower end (16) of a medication container (10). The device thus physically adapted to enable use of a conventional medication container cap in its ordinary fashion, without interfering with safe and proper operation thereof which is strictly regulated.



WO 01/22399 A1

## AUDIO DEVICE FOR MEDICATION CONTAINER

### Related Patents

This patent application is related to United States Patent number  
5 5,815,586, which is incorporated herein by reference.

### Technical Field

The present invention relates to medication containers and, more  
particularly, to a device for recording and playing back audio messages that  
10 attaches to a medication container.

### Background Of The Invention

Medication containers, particularly those for prescribed  
medications, require specific written instructions for a patient with regard to  
15 dosages and other special instructions to be printed on a label and affixed to the  
container, or to be packaged with the container. Instructions may be provided  
from the patient's physician, the drug manufacturer, or the distributor.

Written instructions that are provided with medications are  
subject to various shortcomings attributable to various factors including limited  
20 writing space, poor vision, low literacy level of the patient, primary spoken  
language of the patient, potential for physical damage to or smudging of written  
labels, and misplacing of enclosed instructions. For example, written  
instructions that are required to be fixed to the outside of the medication  
container on a label must be printed in letters large enough to be seen by the  
25 reader, yet small enough to enable the complete instructions to be printed on  
the label which is relatively limited in writing area. This may result in  
medication labels that are in print that are too small to be read by people with  
poor vision, without the need for magnifiers or other vision aids. In some  
situations it may be necessary for instructions to be written very concisely to fit  
30 on a label. This sometimes results in language being omitted for the sake of  
brevity thereby rendering the instructions deficient or difficult to comprehend.  
In other situations, where the label or instructions are written in a language that  
is not the native or first language of the patient, it may be difficult for the

patient to understand the instructions. Labels fixed to medication containers are subject to wear, smudging, and moisture, which may result in damage to the label so that it cannot be read. Lastly, certain enclosed instructions and warnings that may have been enclosed in the manufacturer's packaging, but not printed on a label, may be misplaced or otherwise separated from the medication container.

### Objects And Summary Of The Present Invention

It is an object of the present invention to provide a device associated with a medication container for delivering instructions and warnings to patients using a medication. It is a further object to provide such a device in a manner that overcomes the shortcomings discussed above with conventional printed labels and instruction enclosures. These objects and others are achieved by the present invention as will be described herein.

The present invention is directed to a device that attaches to a medication container and has a built-in audio recording and playback feature for recording and listening to instructions. The self-contained device has a power supply, an audio input component (i.e., microphone), an audio output component (speaker), audio recording storage in the form of electronic data memory, control buttons in communication with a microprocessor, and associated electronic circuitry. In one embodiment, the device is adapted to clip onto the cap of a medication container. In another embodiment, the device is adapted to slide over the lower end of a medication container. The aforementioned embodiments of the present invention are physically adapted to enable use of a conventional medication container cap in its ordinary fashion, without interfering with safe and proper operation thereof which is strictly regulated.

In operation, a physician and/or a pharmacist can verbally instruct a patient by recording a voice message into the device of the present invention. The device is attached to a medication container. A playback feature enables the patient, upon receiving the medication container and the device of the present invention, to playback the recording to receive verbal, audio instructions and warnings. This system can be used in lieu of or in association with

conventional, written instructions and warnings on a printed label or printed enclosures.

### **Brief Description Of The Drawings**

5           Fig. 1 is a schematic, front view of a conventional, cylindrical medication container having a rotatable cap and an adhesive label thereon.

          Fig. 2 is a front, top perspective view of a first embodiment of the present invention.

          Fig. 3 is a front, bottom perspective view of the first embodiment of  
10   the present invention.

          Fig. 4 is a schematic, partial, front, cross-sectional view of the first embodiment of the present invention.

          Fig. 5 is a schematic, top view of a circuit board and related components of the first embodiment of the present invention.

15           Fig. 6 is a front, top perspective view of a first embodiment of the present invention attached to a medication container.

          Fig. 7 is a top view of a modified component of the first embodiment of the present invention.

          Fig. 8 is a front, top perspective view of a second embodiment of  
20   the present invention.

          Fig. 9 is a schematic, partial, front, cross-sectional view of the second embodiment of the present invention.

          Fig. 10 is a schematic, partial, front, cross-sectional view of the second embodiment of the present invention shown receiving a medication  
25   container.

          Fig. 11 is a front, top perspective view of a third embodiment of the present invention.

          Fig. 12 is a schematic, block diagram of a fourth embodiment system according to the present invention.

30           Fig. 13 is a cross-sectional, side elevational view of the present invention.

### Description Of The Preferred Embodiments

A conventional medication container (10) of the type used to dispense and store prescription medication comprises a cylindrical body (12) with an open top end (14) having threads (not shown) and a closed bottom end (16) is illustrated in Fig. 1. A rotatable cap (18) is provided to engage the threads on the body (12) of the container (10) to securely close the container (10). The cap (18) may be of the type having child-proof or safety locking configurations. An adhesive label (20) of the type ordinarily used to display written instructions, warnings and patient and physician information is applied to the body (12) of the container (10).

A recording and playback device (22) according to a first embodiment of the present invention is illustrated in Figs. 2 - 3. The device (22) has a cylindrical wall (24), a top surface (26), and an open bottom end (28). A set of speaker holes (30) are provided on the top surface (26) to accommodate an internal speaker (discussed below). Optionally, the speaker holes could be positioned on the cylindrical wall (24). A safety tie hook (32) is provided on the cylindrical wall (24) to accommodate safety means (discussed below) for securing the device (22) to a medication container. The cylindrical wall (24) includes a recessed portion (34) to accommodate a playback button (36) for playing back audio messages, as will be discussed below. A series of flexible teeth (38) are formed on the inner circumferential surface of the open bottom end (28) in order to flex upon contact with a medication container cap, to surround and engage the same. A recessed microphone hole (40) is provided for receiving sounds to be recorded, as will be discussed below.

Referring to Fig. 4, a schematic, cross-sectional view of the device (22) described in Figs. 2 - 3 is provided. As shown, a horizontal, internal wall (42) is provided above and generally parallel to the open bottom end (28) of the device (22). The internal wall (42) is provided to serve to seal off the internal chamber (44) that houses the recording and playback components (46), shown schematically. The internal wall (42) also functions as a stop for engagement with a medication container cap to secure the cap and prevent it from damaging internal components (46). A set of internal tabs (48) can be provided to securely hold the internal wall (42) in place relative to the inner surface of the cylindrical

wall (24). A record-command opening (50) is provided through the internal wall (42) to engage a recessed record button (52). The record button (52) is recessed so that it may be activated by pressing a pointed object, such as a ball point pen, into the record-command opening (50) in order to activate the record function, as discussed below, to record audible instructions.

The internal components (46) are now illustrated schematically in Fig. 5. A circuit board (48) adapted to be securely contained in the internal chamber (44) includes a switch contact element (51) for engagement with the playback button (36). The circuit board (48) may be fixed to the internal wall (42) or otherwise fixed in the internal chamber (44). The switch element (51) is in communication with a microcontroller (53) which includes a data storage element (54) for storing sound data. The microcontroller (53) may comprise one or more commercially available, programmable microchips. A power source, such as a battery (56), is provided to power operation of the electrical components. A microphone (58) and speaker (60) are also provided.

In operation, the device (22) is initialized by a physician or pharmacist. The physician or pharmacist grasps the device (22) and inserts a ball point pen or other pointed object into the record command opening (50) to press the record button (52). At the same time, the physician or pharmacist speaks into the microphone hole (40) to deliver an audible message containing instructions for the medication to which the device will be attached. When the message is completed, the physician or pharmacist releases the record button (52).

The audible message is received through the microphone (58) and transformed into digital signals by the microcontroller (53) and stored. A timer may be set to control the maximum allowable length of the audible message. If desired, the device (22) may be programmed to store and selectively play more than one audible message. For example, the microcontroller (53) may be programmed to operate a calendar function or a timer and an associated alarm system to automatically emit audible signals or messages to remind a patient when it is time to take a dosage of medication. After the audible messages are stored and, if applicable, any timer or calendar functions are programmed, the device (22) is ready to be attached to a medication container as shown in Fig. 6.

The device (22) is press-fitted over the top of a medication container cap (18) by engaging the flexible teeth (38) of the bottom, open end (28) of the device (22) with the container cap (18). By applying downward force to the device (22), the flexible teeth (38) will flex and slip past the container cap (18), so that the container cap (18) resides in a secondary chamber (62) formed in the device (22) between the internal wall (42) and the flexible teeth (38). The internal wall (42) prevents the container cap (18) from penetrating into the internal chamber (44). As shown in Fig. 6, a tether (64) in the form of a flexible plastic rod or tie is attached at one end to the safety tie hook (32). The other end of the tether (64) is fixed to the body of the device (22), such as at the cylindrical wall (24) by adhesive tape (66) or other suitable means. The tether (64) prevents the device (22) from becoming separated from the medication container (10) when, for example, the device (22) is removed from the container cap (18) to allow the container cap (18) to be removed from the medication container (10). The body of the device (22) is preferably molded from a suitable plastic material, such as polyurethane, that is water-resistant and durable. If desired, the speaker (60) can be of the commercially available water-resistant type.

When a patient receives the medication container (10) having the attached device (22) according to the present invention, the patient can activate playback of the audio instructions by depressing the playback button (36). The audio message will be played by the controller (53) and associated electronic components, and emitted from the speaker holes (30).

As shown in Fig. 7, the device (22) may include a display screen (66), such as a liquid crystal display (LCD), and programming buttons (68) for displaying and inputting information relating to programming of optional modes and functions such as a calendar, a timer and alarm, and a clock display.

An alternative embodiment of the present invention is illustrated in Figs. 8 - 10. Referring to Figs. 8 - 9, the second embodiment device (100) comprises a cylindrical wall (102), a bottom wall (104), an open top end (106), and an interior wall (108) with a microphone hole (109). An inner chamber (110) is adapted to receive a circuit board (48) having equivalent functional components as described with respect to Fig. 5. A playback button hole (112) is provided in the cylindrical wall (102) to accommodate a playback button (114). A set of

speaker holes (116) is provided to accommodate an audible speaker of the type described with respect to Fig. 5. The speaker holes (116) are preferably positioned on the cylindrical wall (102), though they could be positioned on the bottom surface of the bottom wall (104). A microphone hole (118), and an optional LCD display (120) and control buttons (122) are provided on the cylindrical wall (102). However, the present invention is not limited in this regard as the display 120 and buttons 122 can be positioned in other suitable areas, such as on the bottom surface of the cylindrical wall, without departing from the broader aspects of the present invention. An optional safety tie hook (124) can be provided. The inner circumferential wall (126) decreases in diameter beginning from the top opening (106) and moving toward the interior wall (108). This provides a wedge-type fit around the bottom section of a medication container.

As illustrated in Fig. 10, a cylindrical medication container (10) is press-fitted into the device (100) in a downward direction, as shown by the arrow (128). The inner circumferential wall (126) has decreasing diameter in the downward direction such that it is slightly larger than the diameter of the medication container (10) at the top opening (106) and it is slightly smaller than the diameter of the medication container (10) at the interior wall (108). This causes the circumferential wall (126) and/or the wall of the medication container to flex slightly so that the device (100) grips the medication container (10) in a wedge-like manner with sufficient force to be retained therewith. The optional safety tie hook (124) may be tethered to the medication container (10) in a manner similar to that described with respect to Fig. 6.

Operation of the device (100) is essentially the same as described above with respect to the first embodiment device (22) of the present invention. The primary difference is that the second embodiment device (100) is generally inverted, enabling it to remain fixed to and in place with respect to the medication container (10) even when the container cap (18) is being opened or closed.

A third embodiment of the present invention is illustrated in Fig. 11. The present invention device (200) is essentially similar to that described with respect to Fig. 1, except that instead of having a microphone hole for directly delivering audible messages from the physician or pharmacist directly



into the microphone element (58), an electrical input jack (202) is provided. The electrical jack (202) can receive a plug that is connected to a microphone, a recorded medium player, a data storage device, or similar means for delivering sound data into the circuitry of the device (200) for processing and delivery as an audible message through the speaker holes (204). Thus, in one instance, a physician or pharmacist may use a microphone that can be attached to the device (200) only when it is necessary to deliver verbal instructions. In another instance, a source of delivering an audible message, such as a machine or a person, may deliver verbal instructions into one recording machine in order to later transfer the message to a device (200) according to the present invention by using an electrical connector through the jack (202). In yet another instance, illustrated in Fig. 12, a sound source (300), such as a person or a machine, may remotely produce an audible message that is recorded by a machine (302) and subsequently transmitted to a remote location where it can be received by another machine (304) and input into a device (200) according to the present invention for use as described above. In this instance, the recorded message may be sent physically on a recording medium, or it may be sent electronically. For example, the recorded message may be converted to digital signals and sent to a remote location via modem or RF.

A fourth embodiment of the present invention is directed to a device (400) similar to that described with respect to the third embodiment, but including additional retaining means for retaining a medication container in the device (400). The retaining means are, preferably, in the form of a retaining spring (406) that may be a metallic spring in the form of a loop, or a rubber ring, or the like. The device (400) may be constructed with separate internal wall components (402, 404) to form a channel (408) for holding the spring (406) relative to the device (400). Alternatively, the channel (408) may be molded into the inner wall (412). When a medication container is received in the device (400), the outer circumferential wall of the container contacts the inner surface (410) of the spring (406) which protrudes past the inner wall (412), thereby causing the spring (406) to compress and exert a retaining force on the container. In a manner similar to that described above with respect to the previous embodiments, various components (414) are stored in the device (400).

While the preferred embodiments have been herein described, it is acknowledged that variation and modification may be made without departing from the scope of the presently claimed invention.

## WHAT IS CLAIMED IS :

1. A device for recording and playing audible signals relating to medication contained within a container, said device comprising:
  - a body adapted to be selectively attached to and detached from said container;
  - 5 data input means fixed to said body for inputting sound data;
  - data storage means contained in said body for storing said sound data;
  - processing means contained in said body for processing said sound data into said audible signals; and
  - 10 sound emitting means fixed to said body for delivering said audible signals into an environment surrounding said device.
2. A device according to claim 1, further comprising control means contained in said body for selectively operating said data input means and said sound emitting means.
3. A device according to claim 2, further comprising timer means associated with said control means for selectively timing the operation of said sound emitting means.
4. A device according to claim 2, further comprising display means for displaying information relating to the operation of said device.
5. A device according to claim 1, wherein said body is generally cylindrical in shape, having one open end and one closed end, whereby said open end is adapted to receive a portion of said container therein.
6. A device according to claim 1, wherein said data input means comprise a microphone.
7. A device according to claim 1, wherein said data input means comprise an electronic connector jack.

8. A device according to claim 1, wherein said sound emitting means comprise a speaker.

9. A device according to claim 5, further comprising a plurality of radially-inward facing, flexible teeth located around an inner circumferential surface of said open end of said body, whereby said flexible teeth are adapted to flex upon engagement with said portion of said container when said portion is received in said open end.

10. A device according to claim 1, further comprising at least one hole in said body associated with said data input means to facilitate input of said sound data into said data storage means.

11. A device according to claim 1, further comprising at least one hole in said body associated with said sound emitting means for directing said audible signals from said device into said environment.

12. A device according to claim 5, wherein said body has an inner, generally cylindrical chamber having a gradually decreasing diameter that has a maximum diameter dimension at said open end, and thereby decreases in a direction toward said closed end, such that said body is adapted to receive said container in a press-fitted manner through said open end.

13. A system for recording and playing audible signals relating to medication contained within a container, said system comprising:

sound recording means for recording audible sounds;

5 data;

sound data transmission means for transmitting said data;

sound data receiving means for receiving said data;

sound data delivery means for delivering said data to a device that is selectively attached to said container;

10 processing means contained within said device for processing said data into audible signals;

sound emitting means contained within said device for emitting said audible signals into an environment surrounding said device; and

15 control means for controlling the operation of said sound emitting means.

14. A method of creating and playing an audible set of instructions on a device attached to a medication container, said method comprising:

activating a record mode of said device;

5 delivering sound signals into electronic data storage means;

fixing said device to said medication container; and

activating a playback mode of said device wherein said sound signals are played aloud as audible signals.

15. A method according to claim 14, wherein said sound signals are delivered into electronic data storage means through a microphone.

16. A method according to claim 14, wherein said sound signals are digital signals.

17. A method of creating and playing an audible set of instructions on a sound device attached to a medication container, said method comprising:

- 5           activating a record mode of a recording device at a first location;
- delivering sound signals into said recording device;
- converting said sound signals into digital signals;
- transmitting said digital signals to a receiving device at a second location remote from said first location;
- 10          transferring said digital signals from said receiving device to said sound device;
- fixing said sound device to said medication container; and
- activating a playback mode of said sound device wherein said sound signals are played aloud as audible signals.

18. A method according to claim 17, wherein said digital signals are transmitted to said receiving device at a second location via a modem.

19. A method of creating and playing an audible set of instructions on a sound device attached to a medication container, said method comprising:

- 5           activating a record mode of a recording device at a first location;
- delivering sound signals into said recording device;
- storing said sound signals on a removable data storage module located in said recording device;
- removing said data storage module from said recording device;
- inserting said data storage module into said sound device;
- 10          transferring said sound signals from said data storage device to said sound device; and
- activating a playback mode of said sound device wherein said sound signals are played aloud as audible signals.

20. A device according to claim 5, further comprising a flexible retaining ring positioned inside said body open end and adapted to compress between said body and said container when said container is received in said body.

1 / 2

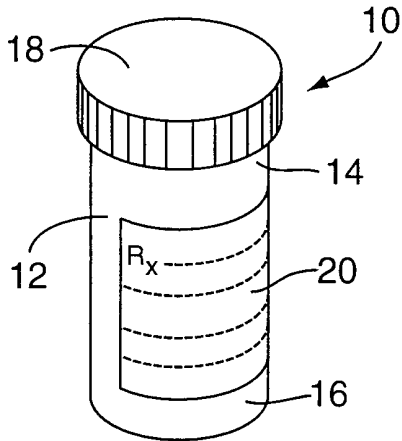


FIG. 1

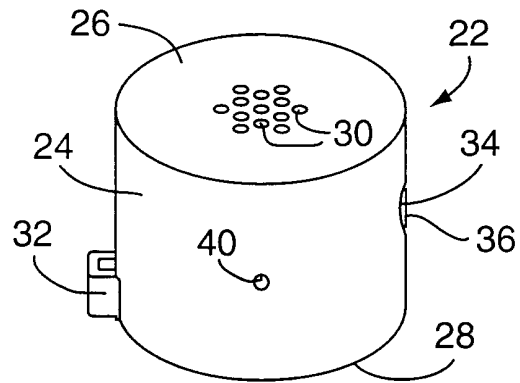


FIG. 2

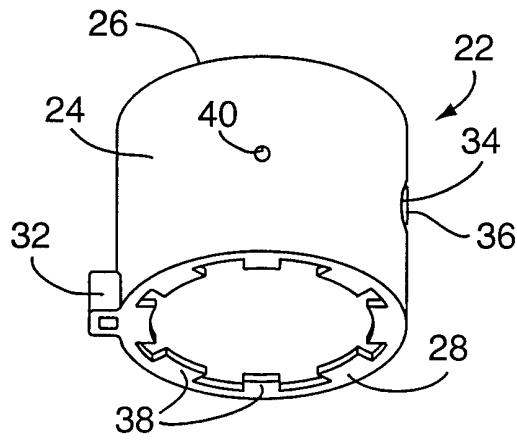


FIG. 3

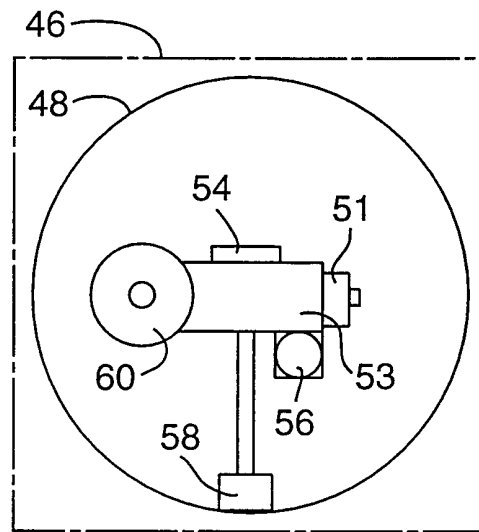


FIG. 5

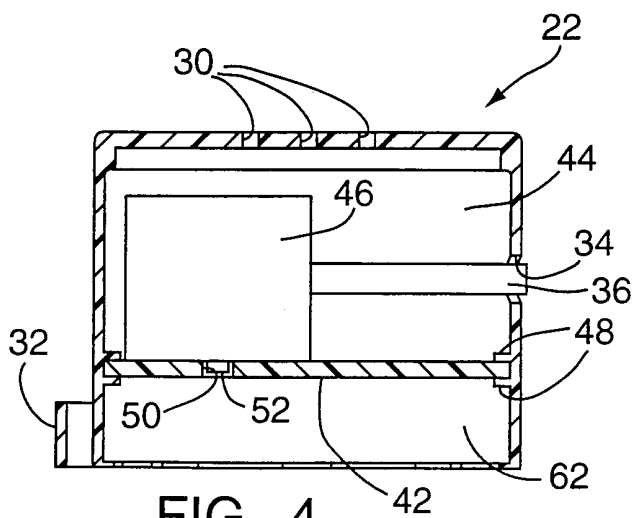


FIG. 4

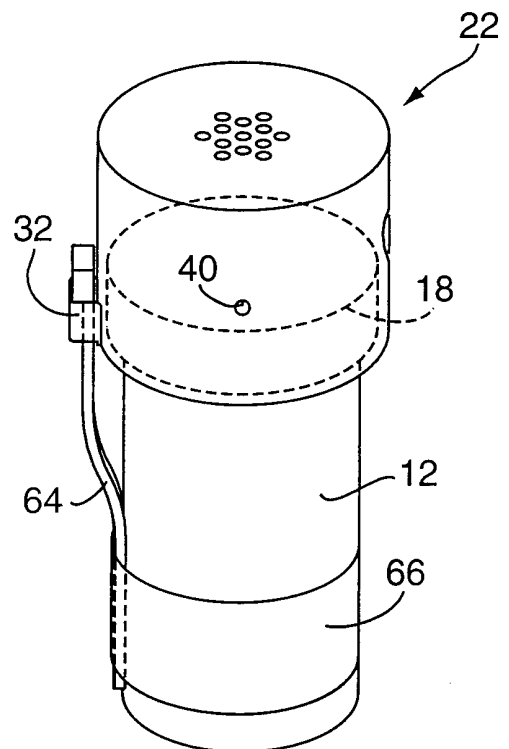


FIG. 6



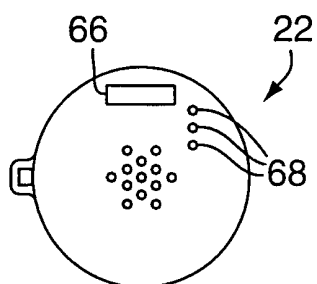


FIG. 7

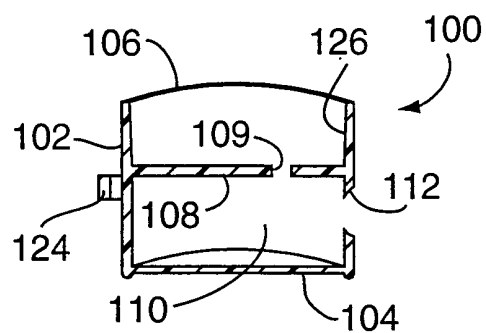


FIG. 9

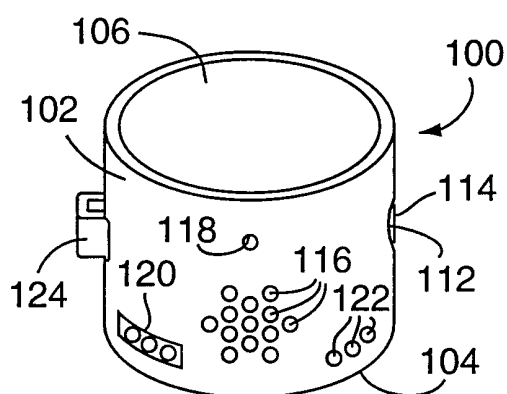


FIG. 8

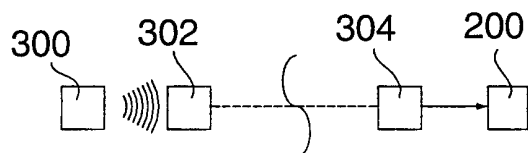


FIG. 12

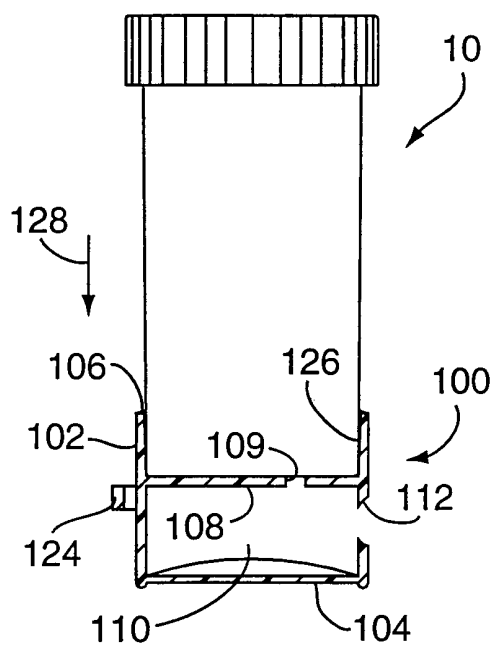


FIG. 10

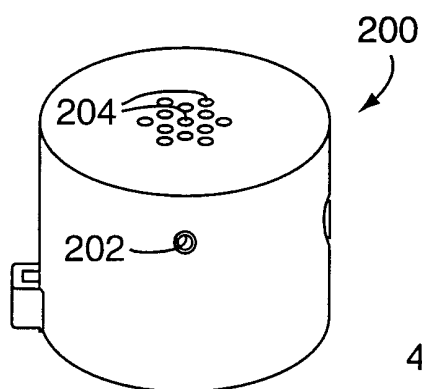


FIG. 11

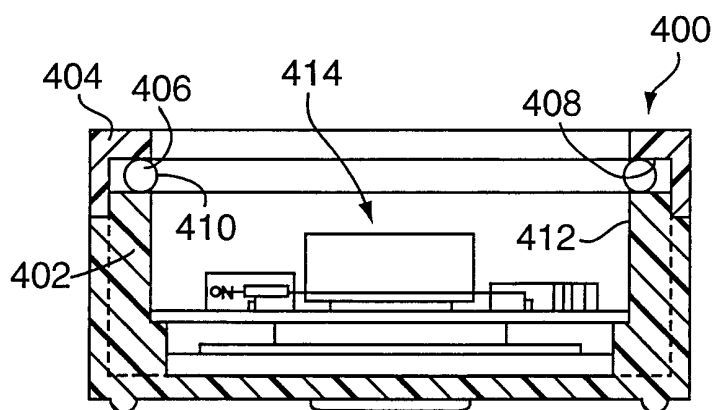


FIG. 13

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US00/12192

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : G10L 11/00; B65D 45/00, 23/00

US CL : 381/124; 700/272; 215/273, 400

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)

U.S. : 381/124, 61, 334, 118; 700/272, 270, 271, 278; 215/273, 400, 291, 336, 277, 280, 230; 221/2, 3

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
None.

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

BRS

Search terms: medication, medicine, container, bottle, recorder, audio/sound, display, microphone.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,815,586 A (DOBBINS) 29 September 1998, see entire document.	1-20
A	US 4,361,408 A (WIRTSCHAFTER) 30 November 1982, see entire document.	1-20
A	US 5,011,032 A (ROLLMAN) 30 April 1991, see entire document.	1-20
X --- Y	US 5,835,455 A (HANSON et al) 10 November 1998, see entire document.	1-2, 4, 6-8, 10-11, 13-15 ----- 16-19
A	US 5,890,121 A (BORCHERDING) 30 March 1999, see entire document.	1-20

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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*O* document referring to an oral disclosure, use, exhibition or other means	
*P* document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

05 JULY 2000

Date of mailing of the international search report

24 JUL 2000

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## INTERNATIONAL SEARCH REPORT

International application No.  
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,950,632 A (REBER et al) 14 September 1999, see entire document.	1-20