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(54) Title: Dispensing system for medicament regime

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Title

[0001] Dispensing System for Medicament Regime

Field of the Invention

[0002] The present invention relates to the field of dispensing systems for medicament regimes for patients. In particular the present invention relates to a medicament tray which is compartmentalised for the purposes of a medicament dosage regime.

Background to the Invention

[0003] Of particular interest is a dispensing system which is suitable for use with different medicaments for different administration regimes. For example a patient on more than one medicament will have to take one or more medicaments at any given time of day (e.g. morning, afternoon, evening or with meals/before meals/after meals). The medicaments to be taken at any given time may vary depending on dosage/frequency etc. One medicament may be taken over a longer term (e.g. a medicament for treating high blood pressure) while a second medicament may be taken over a shorter term. Furthermore, people can be on single or multiple dosage forms for short term or long term prescribed courses, for example antibiotics or blood pressure tablets. The complexity of the regime may increase as a patient is prescribed one or more medicaments or as the dosage regime gets more complicated. Accordingly, there is a need for dispensing systems which hold the medication in compartmentalised form for administration at a given time. Generally, one compartment will hold the medication to be taken by a patient at a given time. Such systems are referred to as Monitored Dosage Systems or Multicompartment Compliance Aids (MCA).

[0004] Because of the potential complexity of the dosage regime, many systems for monitoring patient medication intake have been developed. These systems generally have a series of compartments in which medication to be taken at an indicated time is placed. Many types of dispensing systems are known. These include mechanical or manual devices for filling tablet boxes, blister packs, sachets and the like. They also include dispensers of the type which may be carried by a patient and which are small boxes which have a dispenser which will dispense one tablet at a time by actuating a dispensing mechanism, typically by pushing on a push-button.

[0005] Such systems are used for the administration of pre-packed medication supplied from Pharmacies to patient care centres (such as hospitals, Retirement/Nursing Homes etc). The aim of these systems are to provide daily doses of medication to a patient, or a care giver to the patient, in an easy to administer format in ready-prepared dosage units either in sachets or blister pack containers. The

examples of the current brands of blister packs are Nomad™/ Venalink™/ Manerix™. These systems are usually comprised of two parts, an outer paper or plastic casing or cassette, which acts as a holder into which sits an inner tray which has compartments arranged in a grid format detailing a daily dosage per patient divided into the days of the week with several compartments sectioned into intervals throughout the day (morning dose, midday etc.) and repeated for a week or a month. The pharmacist dispenses medication into separate compartments of each patient's tray according to the (doctor's) prescription and seals the tray closed. (S)He then performs a double-checking procedure and when all is confirmed correct, delivers the trays/cassettes to the patient care centre. The medicaments will be one or more non-liquid forms such as one or more tablets, capsules or other ready prepared dosage units. The compartments in the trays are typically dimensioned to accommodate a plurality of tablets. The patient or caregiver then accesses the tablets according to the correct dosage time (e.g. Monday morning's dose, as in accordance with the original prescription). In general, the contents of a given compartment are transferred from the tray by hand to individual, unlabeled, unidentified medicine pots which are then distributed to the patient. The medicine pots are typically small open mouth plastic cups which are disposed of after use.

[0006] The problems of Monitored Dosage Systems such as those described above are:

- 1) Medication must be removed from each daily compartment by breaking the seals and tipping the tray over or physically removing the tablets by hand and transferring them to medicine pots.
- 2) Tablets can get stuck in the adhesive seal of the tray.
- 3) Paper Trays tend to deteriorate over time due to usage.
- 4) Plastic trays with sliding doors and compartments are bulky and heavy and also deteriorate over time, for example, the trays become unfastened; they can unlock and become loose with wear and tear.
- 5) In general, the medication must be transferred to medicine pots prior to administration to the patient.
- 6) The trays are not re-usable.

[0007] Sachets may also be utilised. These comprise rolls of individually labelled sachets containing daily medication. The problems with these systems are:

- 1) The rolls of sachets are large and bulky.
- 2) Because each dose is removed daily from a packed roll any mistakes in the dosages may not be immediately apparent as it is not clear how the tablets

are distributed throughout the roll and in particular because the repeat pattern of the patient's medicine regime is not readily visible.

- 3) Tablets are stored in lightweight or delicate packages in which transfer of the tablets to a medicine pot may be necessary, in some cases, at the point of administration to avoid loss of the tablets.
- 4) Packaging machinery to create sachets is very expensive.
- 5) Currently there is a patient confidentiality issue concerning the disposal of sachets having personal information on them.

[0008] In summary each system involves an extra stage whereby tablets must be transferred prior to administering to the patient. Sachets systems can be superior to monitored dosage systems as there may not be as much direct handling of the medication, but these have other drawbacks.

[0009] It would be desirable to provide an alternative system for a patient dosage regime.

Summary of the Invention

[0010] The present invention a dispensing system as set out in Claim 1. The dispensing system is for administration of medicaments during a medicament dosage regime and comprising:

a tray comprising:

an interconnected array of compartments, each compartment being dimensioned to accommodate therein a plurality of medicaments; and
a closure for the compartments arranged so that the closure and the compartments form a series of sealed containers for holding medicaments;

the compartments and the closure therefor being arranged so that each sealed container is frangible from the interconnected array so that a sealed container may be broken off the array. This allows each container to be used for administration of medicament contained therein. This provides an easy system for administering medication without requiring medicine pots. The medication remains within a sealed container until it is required.

[0011] The present invention may comprise

a tray comprising:

a frame;
an interconnected array of compartments, each compartment being dimensioned to accommodate therein a plurality of medicaments; and

a closure for the compartments arranged so that the closure and the compartments form a series of sealed containers for holding medicaments;

the compartments and the closure therefor being arranged so that each sealed container is frangible from the frame so that a sealed container may be removed from the frame.

[0012] The frame essentially acts as an interconnecting member to hold the compartments in position in an interconnected array. When each compartment (sealed container) is removed from the frame it may leave an aperture in the frame. This means that the frame will hold remaining compartments in the array even if one or more adjacent compartments have been removed.

[0013] Desirably a holder optionally in the form of a cassette is provided into which the tray fits. Such a holder can be adapted to retain the frame while allowing the containers to be removed. In such an arrangement the holder is provided with one or more retaining members which retain the frame but allow removal of the containers.

[0014] Each closed container desirably comprises patient identification information, which is printed on the closure prior to applying to the compartments. The information printed on the closure identifies a time during the dosage regime at which it is intended to administer the medication in the container. The provision of patient information on the container is advantageous in that the person removing the medication from the system such as a care worker can easily double-check that the correct medication is being provided to the correct patient.

[0015] The compartments are desirably constructed of a substantially transparent material which allows visual inspection of the medicament contained therein. This provides a means for the care worker to ensure that the correct medication prescribed for the patient is contained in the compartment. Desirably the trays or strips are nestable one within the next to allow compact storage and convenient shipping of the inner trays.

[0016] In a desired aspect of the present invention, the compartments are constructed so as to avoid any substantive magnification or reduction of the size of the medicament contained therein. A problem underlying the currently available systems is that the container in which the medicaments are contained can provide a misrepresentation of the actual size and/or colour of the medicaments themselves. This problem can lead to difficulty in identifying medication, in particular based on size, and lead to incorrect medication being given to the patient if incorrectly contained in the container. This issue is avoided in the dispensing system of the present invention.

[0017] The closure of the present invention suitably comprises an adhesive sheet or strip which includes an individual closure for each of the compartments. Patient identification information may be provided on each closure, and optionally additionally identifying a time during the dosage regime at which it is intended to administer the medication in the container.

[0018] It is also desirable that information identifying the medicaments, which should be contained within each container, is provided on each closure via barcode. For example it is desirable that information is provided to account for the number of medicaments which should be contained within each container is provided, for example on each closure. It is also desirable that information pertaining to the patient, which is desirably on each container, is provided on each closure, for example in the form of a barcode.

[0019] In another aspect of the present invention there is provided a dispensing system for administration of medicaments during a medicament dosage regime and comprising:

a tray comprising:

an interconnected array of compartments, each compartment being dimensioned to accommodate therein a plurality of medicaments; the interconnected array comprising a series of rows each row being frangibly connected to the next.

[0020] In this aspect of the present invention, it is desirable that the system comprises a closure for the compartments arranged so that the closure and the compartments form a series of sealed containers for holding medicaments; the compartments and the closure therefor being arranged so that each sealed container is frangible from the interconnected array so that a sealed container may be broken off the array for use in administration of medicament contained therein.

[0021] The dispensing system of the present invention may further comprise indicating means which indicate to a user that a tray is correctly positioned in a holder. Desirably indicating means are provided to indicate when a tray and/or row which has been broken away has been correctly positioned in a holder. The advantages of the indicating means is that the orientation of the tray or row in the holder is correct. This is important because for example incorrect placing can mean the dosage regime is incorrect, for example in reverse order in the holder. In this embodiment it is desirable that the user can only put the tray or row in one orientation which correctly positions the tray or row of compartments containing medicaments in the holder so that the correct medication is given to a patient at the appropriate time. It will be appreciated that

incorrect placing, for example reversal of the order of compartments is more likely when a single row being seated in the holder

[0022] In other words, the indicating means also may indicate to a user that a tray or row which has been broken away has been correctly seated in a holder. The indicating means may also allow the correct application of the closure, for example in the form of a sheet optionally comprising adhesive seals/strips, *in situ*.

[0023] In a desired aspect of the invention, the indicating means comprise one or more protrusions, which interfere with incorrect positioning of the row or tray. Therefore, it would be impossible for the user to misplace the tray or row detached from the tray in the holder.

[0024] It will be appreciated that all aspects of the invention which refer to a tray apply equally to one or more rows of compartments also.

[0025] In a further desired aspect of the present invention, the indicating means comprise one or more alignment protrusions, which assist with correct positioning in the holder and optionally additionally with correct positioning of a closure such as an adhesive sheet. This provides a simple yet effective indicating means.

[0026] In a preferred aspect of the present invention, the holder is a cassette into which the tray sits. This allows the system of the invention to be employed with cassettes which can be easily stacked. Desirably the cassettes allow for removal of the containers while retaining the remainder of the tray, for example a frame thereof.

[0027] In a further preferred aspect of the present invention, the protrusions are on the tray, and the tray is held in a housing of a cassette. The tray may be slid into the cassette. Alternatively or additionally it may be inserted through an open top or base of the cassette which is optionally closed with a flap.

[0028] In the present invention, the cassette is re-usable and comprises at least one openable flap which allows access to the tray. The openable flap is a cover for the top or bottom of the cassette. This is a simple yet highly effective method of allowing re-use of the cassette with different trays/rows.

[0029] In a desired aspect of the present invention, there are two openable flaps one being a cover for the top of the cassette and one being a cover for the bottom of the cassette. This allows for dispensing ease and one flap for example on the base of the cassette can be employed to hold information relating to the medication regime.

[0030] The cassette further comprises a retainer within the housing which retains the tray in position while allowing sealed containers to be manually broken away from the interconnected array. This means that even if containers are removed from the tray the remainder of the tray will be held in place. It also means that even if a closure such

as a cover for the holder is opened the tray is still retained. This means the array can be accessed and closed containers can be removed from the array while the tray is still held in place.

[0031] In one aspect of the present invention, the retainer comprises a cage structure, which is optionally present above and below the tray. The cage structure will retain the array while still allowing the sealed containers to be removed. Desirably the compartments extend through the cage structure. This allows for ease of removal.

[0032] It is desirable that the retainer comprises a seat for the tray. In one aspect of the present invention the seat for the tray may comprise the cage structure. The cage structure of the present invention desirably comprises a grid with openings into which compartments of the tray are received. Desirably the retainer allows removal of the containers while retaining the remainder of the interconnected array. In particular the retainer may retain a frame to which the compartments are connected.

[0033] In a desired aspect of the present invention the retainer comprises a series of members which overlie the tray. This ensures the tray is securely held while still allowing access to remove the containers.

[0034] It is further desirable that the cage structure comprises a series of members, said member overlie the tray while the tray is seated in the holder. The advantage of the cage structure overlying the tray of the present invention is that when a container is being manually removed from the interconnected array, the series of members ensures that the tray remains in the housing of the cassette while the container is broken off.

[0035] In a desired aspect of the present invention said member which overlie the tray while the tray is seated in the holder are in the form of a grid structure containing one or both of horizontal and vertical members.

[0036] It may be desirable in the present invention that the retainer is pivotally connected to the cassette. This can allow for ease of insertion of the tray.

[0037] It may be further desirable that at least a portion of the cage structure is pivotally connected to the cassette. This allows for ease of access and in particular to add or remove a tray. Again all references to a tray apply equally to one or more rows.

[0038] In a further aspect of the present invention, it may be further desirable that the retainer comprises a series of members which overlie the tray and the series of members are pivotally connected to the cassette. Again this allows for ease of insertion and removal of a tray or row.

[0039] In a further aspect of the present invention, there is provided a dispensing system for administration of medicaments during a medicament dosage regime and comprising:

a cassette with a cassette housing and for use with a tray,
the tray comprising: an interconnected array of compartments, each compartment being dimensioned to accommodate therein a plurality of medicaments, the cassette further comprising a retainer within the housing which retains the tray in position. This is a simple arrangement which is particularly suited for use with the systems of the invention described above.

[0040] The dispensing system of the present invention may further comprise a closure for the compartments, the closure and the compartments forming a series of sealed containers for holding medicaments; the compartments and the closure therefor being arranged so that each sealed container is frangible from the interconnected array so that a sealed container may be removed from the array for use in administration of medicament contained therein and the retainer retains the remaining part of the tray within the cassette. This allows for ease of removal of containers while retaining the remainder of the tray.

[0041] It is desirable that the retainer of the dispensing system comprises a cage structure. It may be desirable that a cage structure is present above and below the tray. It may be further desirable that the retainer comprises a seat for the tray. In another aspect of the present invention, it is desirable that the cage structure forms a seat for the tray.

[0042] Optionally the cage structure comprises a grid with openings into which compartments of the tray are received.

[0043] In another aspect of the present invention, it is desirable that the retainer comprises a series of members which overlie the tray. It is further desirable wherein the cage structure comprises a series of members which overlie the tray. In a further aspect of the present invention, the retainer is pivotally connected to the cassette. It may be desirable that at least a portion of the cage structure is pivotally connected to the cassette.

[0044] In another aspect of the invention, a frangible connection is formed between each compartment and the interconnected array by at least one breakable tab, and breaking of the tab releases a sealed container from the array. In a further aspect of the invention, a frangible connection is formed between each compartment and the interconnected array by at least one perforated member and breaking along the perforations releases a sealed container from the array. In an even further aspect of the invention, a frangible connection is formed between each compartment and the interconnected array by at least one tear away strip and tearing away of the strip releases a sealed container from the array.

[0045] The invention may further comprise an actuator which when actuated removes one or more containers from the array. For example, the actuator may comprise a leverage member which acts on the frangible connection to aid removal of a container from the interconnected array, a punch which punches a container away from the interconnected array, a blade which cuts a container away from the interconnected array, and/or a tab which when pushed and/or pulled removes a container away from the interconnected array. The actuator may comprise a finger pull to allow manual breaking of the connection (for example in a manner analogous to various ring pulls which have been present on drinks cans) or dual tabs which when pushed together breaks a container away from the interconnected array. The actuator will generally be arrangeable to act on the frangible connection so that the actuator assists in removing the container.

[0046] The actuator may be on the holder or on the tray. Further desirably the actuator is moveable mounted to allow the actuator to move to (act on respective frangible connection) to remove more than one and desirably all containers.

[0047] It may be further desirable wherein the retainer comprises a series of members which overlie the tray and the series of members are pivotally connected to the cassette. All of the foregoing have the advantages as set out above.

[0048] In another aspect of the present invention, there is provided a method according to Claim 4. The method includes filling a medicament dispensing system with medicaments comprising the steps of:

providing a system as defined above;

dispensing prescribed medication into one or more compartments of the tray according to the required dosage regime;

closing at least the compartments into which the medication is dispensed utilising a closure for the compartments so that the closure and the compartments form a series of sealed containers.

[0049] It is desirable that the method of the present invention further provides patient identification information.

[0050] In the method of the present invention, it is further desirable wherein each closed container is provided with information identifying a time during the dosage regime at which it is intended to administer the medication in the container.

[0051] The method of the present invention desirably provides patient identification information on each closure.

[0053] In a further desired aspect of the method of the present invention, information identifying the medicaments which should be contained within each container is provided on each closure, for example, using barcodes.

[0054] The term medicament when applied to the present invention includes any form of medication prescribed for a patient, for example, a tablet, a pill, a capsule, a suppository, a powder, and the like known to those skilled in the art.

[0055] The term frangible when applied to the present invention includes any means of allowing the required sealed container to be removed or separated from the array when required. This includes breaking a connecting tab, breaking an adhesive seal, use of perforations to allow removal, use of a finger-pull tab, a tear-away strip or the like and any combination of the same.

[0056] The invention allows a pharmacist to provide a patient directly, or through a Patient Care Centre, with a dosage system whereby the Pharmacy supplies the medication in pre-prepared sealed containers. When the closure on the sealed containers is peeled back, the containers also act as medicine pots, that is, the medicaments can be left in the container or medicine pot when given to the patient. In this instance, the terms "medicine pot(s)" and "container" can be used interchangeably.

[0057] The medicine pots are desirably arranged on a rigid transparent tray where each pot is frangibly attached to the tray as described by any of the methods above and for example by a weakened joint. The pots are generally arranged sequentially according to times of administration and optionally also days of the week or weeks per month. A typical configuration is where rows (left to right) relate to different days and columns (top to bottom) relate to different times during the day, or rows (left to right) can relate to a specific daily dosage time and the columns (top to bottom) can relate to weeks in the year, i.e. week 1, week 2, week 3, etc.

[0058] Upon filling the tray in the Pharmacy the medicine pots are sealed by applying a closure which may take the form of lid-labels, which optionally states the patients name and/or photograph on each pot. The labels may be applied via a single sheet or a strip such that once pressed onto the tray the sheet or strip will leave each pot with an individual label. The edges of the label/seal may be adhesive so as to adhere to the rim of the sealed container which now may also act as a medicine pot.

[0059] The tray is then optionally inserted into a reusable cassette. Desirably the cassette is a cassette of the present invention. The cassette may be useful to hold patient information such as a sheet typically a card which lists the patient's medication, and desirably additionally one or more of: identifiers to aid visual identification of a tablet, side effect warnings, dosage regime etc.

[0060] It is easy to deliver the cassette in this form. Once delivered, the patient or a caregiver can remove each individually labelled medicine pot by pressing on the desired container to release the container or pot. An individual labelled pot can be removed for the patient. The cassette can remain behind.

[0061] The advantages of the present invention include:

- Reduced risk of contamination by reducing or eliminating handling for example by staff or patient;
- Ensure an undisturbed pharmacist-to-patient line of distribution of medication so risk of further errors are diminished;
- Provide crucial identification of medication right through the distribution line from pharmacist to patient and thus eliminates the possibility of the wrong medication being given to the wrong patient;
- Frees up time spent cross-checking medication;
- Provides patient with the confidence that the medicine they are taking is actually for them, for example in an embodiment where there is a peel off lid with patient identification information such as a name and/or photo identified clearly on it;
- Reduces the cost as it eliminates the need for separate medicine pots and trays in particular and including costs for their disposal;
- Kinder to the environment by reducing the level of waste per patient;
- Having frangible rows reduces the cost and level of waste per patient when a patient is not on a 5-times a day or 4 weeks per month dosage regime;
- Caregivers or patients do not have to carry entire heavy cassettes about.

Brief Description of the Drawings

[0062] Additional features and advantages of the present invention are described in, and will be apparent from, the detailed description of the invention and from the drawings in which:

[0063] **Figure 1A** illustrates a top view of a tray of the dispensing system of the present invention with one frangible row detached therefrom and one frangible container detached therefrom; **Figure 1B** illustrates a side profile of the interconnected compartments of the tray of the dispensing system of the present invention; and **Figure 1C** illustrates a cross-section of the compartments as illustrated in Figure 1B.

[0064] **Figure 2A to 2E** illustrate a cross-sectional view of the process of filling the empty compartments with medicaments representing a multiple dosage schedule of a patient on five daily dosage regimens, sealing the compartments to form sealed

containers, and seating the sealed containers into a cassette of the dispensing system of the present invention.

[0065] Figure 3 is a side view of three stacked cassettes (holders) of the dispensing system of the present invention.

[0066] Figure 4A illustrates an enlarged and detailed partial cross-section of one of the frangible sealed containers from the interconnected array of sealed containers containing medicaments and positioned *in situ* in the holder of the dispensing system of the present invention. **Figure 4B** illustrates an enlarged detailed partial perspective view of Figure 4A showing in greater detail indicating means for correct alignment of the tray in a cassette (holder).

[0067] Figure 5 illustrates a side sectional view of single sealed container containing medicament being broken away from the tray and removed from the cassette (holder).

[0068] Figure 6 is a perspective view of a closure for a tray comprising rows (and columns) of individually labelled adhesive closures which include patient identification information.

[0069] Figure 7 is an enlarged perspective view of a frangible compartment of the tray of the dispensing system of the present invention showing the frangible connection of the compartment to the interconnected array, the indicating means, and a frangible line for breaking off a row of compartments and further illustrating a tab for indicating the time of the day of the dosage.

[0070] Figure 8A illustrates a cross section of two frangible sealed containers containing medicaments forming part of an interconnected array of compartments, and positioned *in situ* in the holder of the dispensing system of the present invention.

Figure 8B is a top view of the containers of Figure 8A and indicates the position at which the cross-sectional view of Figure 8A is taken; **Figure 8C** is a perspective view of a pair of sealed containers, each containing medicaments, and each broken off from the array, one sealed container having the closure intact, while the other container has the closure partially peeled back.

[0071] Figure 9 is a perspective view of a filled and sealed dispensing system of the present invention for an individual on five daily dosage schedules.

[0072] Figure 10 illustrates the filled and sealed tray of Figure 9 with one frangible sealed container removed.

[0073] Figure 11 is a perspective view of a cassette (holder) of the present invention for receiving an interconnected array of compartments.

[0074] Figure 12 is a perspective view of the cassette (holder) of Figure 11 with two rows of sealed containers housed therein for use for administration of a twice-daily dosage regimen.

[0075] Figure 13 is a perspective view of the underside of the cassette (holder) of Figure 11 with one row of sealed containers housed therein and for administration for a patient on a once-daily dosage regimen and with information on the patient's medication regime on the underside of an openable flap of the holder.

[0076] Figure 14 is a perspective view of a cassette comprising an actuator in the form of a leverage member which aids in removing a container from the interconnected array housed in the holder.

[0077] Figure 15 is a top view of a container with a tear away strip for releasing the container from the interconnected array or frame.

[0078] Figure 16A is a side view of an actuator of the present invention in the form of a punch in position for punching a container (shown in sectional view) away from an interconnected array. **Figure 16B** is a perspective view of a blade actuator, which cuts a container from the interconnected array of the present invention. **Figure 16C** is top view of a container with a finger pull actuator which when pulled removes a container away from the interconnected array of the present invention. **Figure 16D** is a perspective view of a dual tab actuator which when pushed together removes a container away from the interconnected array of the present invention.

Detailed Description of the Drawings

[0079] It should be readily apparent to one of ordinary skill in the art that the examples disclosed herein below represent generalised examples only, and that other arrangements are possible and are embraced by the present invention.

[0080] In **Figure 1** there is illustrated: **Figure 1A** a top view of an interconnected array of compartments in the form of a tray which forms part of the dispensing system of the present invention, the tray is in an unsealed configuration and has had a frangible row removed therefrom, the frangible row being provided with indicating means situated at both ends of the row, and a frangible compartment being removed therefrom, **Figure 1B** is a side profile of the compartments, and **Figure 1C** a cross-section side view of the frangible rows and compartments according to the present invention.

[0081] The dispensing system is generally indicated by the reference numeral 1. The dispensing system 1 comprises a tray 2. The tray 2 comprises an interconnected array 3 of compartments 4. Each compartment 4 is dimensioned to accommodate therein a plurality of medicaments 5 (best seen from **Figures 2B-E**). The interconnected array 3

comprises a series of compartments 4 which are each frangibly connected to a frame 27. A series of frames 27 form the interconnected array. However it will be appreciated that a single frame 27 can hold all of the compartments 4. It will thus be appreciated that having each row frangibly connected to the next, as in the embodiments illustrated, is a desirable feature of the invention and that the frame 27 does not necessarily comprise rows that are each frangibly connected to the next. Thus the frame can be a single frame or backbone structure for supporting the compartments or may comprise a series of frangibly interconnected frames 27 which form a frame or backbone structure for supporting the compartments such as in the present embodiment. Each row 6 is frangibly connected to the next as indicated by the frangible lines 7 in **Figure 1A**.

[0082] The lowermost frangible row 6 has been separated from the remaining part of the interconnected array 3 by snapping off the row 6 along the frangible line 7 as indicated by arrows 14a. This is particularly useful where a full tray is not required, for example where a patient is not on a 5-times a day dosage regime. With previous arrangements a full tray is used even if the patient is on a once-a-day regime. So a pharmacist fills one row of the tray and the remainder remain unfilled. In the present invention the person filling the tray is able to break-off as many rows as are required, typically one to four and utilise those. This means one tray can be used for up to 5 different patients for example when each patient is on a once-a-day regime.

[0083] Each compartment 4 is removably attached to the remainder of a row 6, and in particular frame 27, by a frangible tab 8. The tab 8 is easily frangible. The remainder of the periphery of the compartment 4 is spaced apart from the frame 27 by a peripheral spacing or gap 28. The compartment 4 can thus be removed by applying manual pressure to the frangible tab 8 desirably in either or both of a downwards or upwards direction. Arrow 14b shows one compartment 4 being removed from the tray 2.

[0084] The tray 2 further comprises a series of (seven) labels 9, typically running across the top of the tray 2 which indicate consecutively the days of the week, while a series of labels 10 indicate the time for the administration or dosage schedule, for example, morning, noon, night, week one, week two, before food, *etc.*

[0085] The labels 9 may alternatively be affixed to an openable flap or a wall of a cassette (holder) 20 rather than or in addition to being affixed to the tray 2 (see **Figures 11 to 13**). The advantage of having the labels 9 affixed to the holder 20 is that positioning of the labels 9 on the holder 20 will always ensure that the tray 2 or individual rows 6 are placed in the correct orientation in the holder 20. A peripheral lip 51 on the tray 2 and which extends along the top end and left side thereof is suitable for the affixing of labels.

[0086] The rows 6 each have, at a left and right end 16, 15 thereof, and in particular corners thereof, an indicating means in the form of an aperture 11. The aperture is of a particular shape and size. The purpose of the indicating means 11 of the present invention is to ensure that the rows 6 are placed correctly in the dispensing system 1 and in particular to ensure the weekly sequence is not inadvertently reversed. This negates the possibility of dispensing the incorrect medication at the requisite time because it indicates if a given row 6 is incorrectly oriented in the cassette (holder) 20. This is achieved by ensuring that the row of compartments 4 do not seat properly in the holder 20 if they are not in their correct sequence as will be explained in more detail below. It will be apparent to one skilled in the art that the indicating means 11 can take any suitable form. For example indicating means 11 at both the top end 15 and bottom end 16 of the row 6, can be placed at either or a combination of the left and right corners thereof.

[0087] Figure 1B shows a side view of a series of (three) compartments 4 forming part of the tray 2. The weakened frangible joint (line) 7 between each row of compartments 4 is clearly seen. Figure 1C is a sectional view of the series of compartments 4 shown in Figure 1B.

[0088] The compartments 4 are generally 4-sided substantially flat-bottomed receptacles having sidewalls 24 connected via a bottom end 25. The compartments 4 are constructed of a substantially transparent material, which allows visual inspection of a medicament 5 contained therein (see Figure 2 and Figures 8C, 9 and 10). The sidewalls 24 and a lip 26 form the perimeter of open mouth or (top) opening 13. The lip 26 forms part of a frame 27 of the interconnected array 3. It is connected to the array 3 by the frangible tab 8. The frangible tab 8 (best seen in Figure 1A) is formed as a projection from the lip 26 of the compartment 4. When the compartment 4 is attached to the frame 27 via the frangible tab 8, a peripheral spacing or gap 28 is provided between the edge of the lip 26 and the frame 27. In the event that all compartments 4 are removed from a row 6, or indeed the entire tray 2, the frame 27 is all that will remain seated in the cassette (holder) 20.

[0089] As illustrated in the sequence of figures from Figures 2A to Figure 2E which shows a side sectional view of the tray 2, the tray 2 is provided, and medicaments in the form of tablets 5 are placed into the compartment 4 according to the prescribed dosage regime. In Figures 2A to 2D the dosage regime is one where there is medication given 5 times daily so each of the compartments contain medication. The appropriate medication will be placed in the remainder of the tray for the remaining days of the week. Figure 2A illustrates the tray 2 before the medication is dispensed.

Figure 2B shows the tray 2 with the medication in the compartments, having being dispensed manually or by appropriate dispensing equipment by a pharmacist. **Figure 2C** shows a closure 12 of the type illustrated in **Figure 6** being applied to the tray. The closure 12 is placed over the openings 13 in the direction of arrows A. The closure 12 is a single sheet having an adhesive underside 17 and a topside 18 with patient information 38 provided thereon (see **Figure 6**). The patient information 38 comprises the patients name and/or photograph on each compartment 4 and optionally other information such as an account of what medication should be in a given compartment. The compartments 4 having medicaments 5 therein and the closure 12 applied thereon form sealed containers 19, as indicated in **Figure 2D**. These containers may be broken off in rows 6 or individual sealed containers 19 may be broken off. When broken off individually they will take the form shown in **Figure 8C**.

[0090] The tray 2 comprising the interconnected array 3 of sealed containers 19 is then seated in to a housing 53 of the cassette (holder) 20 of the dispensing system 1 of the present invention (**Figure 2E**), as indicated by the arrow B. An openable flap in the form of a top cover 21 is pivotally connected to one side of the cassette 20 by a hinge 33 of the holder 20 and, once the tray 2 is inserted, the cover 21 is lowered down (from the open position shown in dashed outline) in the direction of arrow C to the closed position shown to cover the tray 2. A similar flap or cover 22 which is also pivotably connected to the cassette by a second hinge 33 closes the underside of the cassette 20.

[0091] Each cover 21,22 further comprises an overhanging lip 34 which releasably engages with a sidewall 35 of the holder cassette when in a closed position, as shown in **Figure 2E**. As shown in **Figure 3**, affixed to the side of the cassette 20 is a patient identification label 23. A plurality of cassettes 20 can be stacked one on top of the other with the patient identification label 23 visible for inspection by a user such as a care worker or pharmacist, and for ease of storage as shown in **Figure 3**.

[0092] An enlarged cross-sectional view of one of the sealed containers 19 *in situ* in the cassette 20 is illustrated in **Figure 4A**. The tray 2 sits in the housing 53 of the cassette 20. The cassette 20 comprises the top cover 21 and bottom cover 22 with the housing 53 generally between the covers. The bottom cover 22 has affixed on an inner face 29 thereof a patient information sheet 30 detailing the patient's identification and dosage regimen, that information typically includes one or more of the following: number of medicaments, types of medicaments, dosage, times of dosage, side effect warnings, descriptions of the visual aspects of the medication *etc.* The top cover 21 is

formed by a series of members 40 which overlie the tray 2. The details of the structure of cassette 20 will be discussed later with reference to Figures 11 to 13.

[0093] As explained previously, the indicating means in the form of apertures 11 are provided and are shown in more detail in **Figure 4B**. The indicating means indicates to a user that when a row 6 which has been broken away has been correctly positioned and seated in the cassette 20. The indicating means further comprise one or more protrusions 37 that interfere with incorrect positioning of the tray 2 and assist with correct positioning in the cassette 20. The protrusion 37 can be on the tray 2, on a retainer 36 within the housing of the cassette 20, or any combination of same. If the aperture(s) 11 and a protrusion(s) 37 do not align then the tray 2 will be raised out of its seated position. In the correct relative position shown in **Figure 4B** the aperture(s) 11 and the protrusion(s) 37 align allowing for correct seating (as protrusion 37 fits into the aperture 11).

[0094] As illustrated in **Figure 5** a retainer retains the tray 2 in position while allowing sealed containers 19 to be manually broken away from the interconnected array 3 in the direction of arrow D. In the embodiment the retainer comprises a grid 36 which has an aperture through which each compartment 4 extends when the tray 2 is seated thereon. The cover 21 also forms part of the retaining means by holding the tray 2 (or a frangible row) to the grid 36. Together the cover (and in particular members 40 thereof) and the grid form a cage structure which traps the tray therebetween but allows individual containers to be manually broken-off and extracted through the cage structure without the necessity to open the cassette. The frame 27 which may frame one or more rows (whether connected or not) will be retained by the retainer of the device while the sealed containers may be easily removed.

[0095] When the frangible tab 8 is disconnected (for example snapped off,) from the frame 27, the container 19 is easily removed. The series of members 40 (best seen in **Figures 11 and 12**) overlie the tray 2, which retains the tray 2 in position while simultaneously permitting the removal of the sealed container 19 from the frame 27 of the row 6. Alternatively, the sealed container 19 can be removed from the cassette 20 through an aperture 32 of the retainer 36 in the direction of arrow E (see **Figure 5**). To allow access to do this, the bottom cover 22 may be opened as indicated by arrow F.

[0096] Now turning to **Figure 6**, there is illustrated the closure 12 that is attached to the compartments 4 *in situ* in the cassette 20 (or alternatively prior to placing the tray 2 or a row 6 of compartments 4 in the cassette 20) to secure and seal the medicaments 5 inside the compartments 4 to form the sealed container 19. The closure 12 comprises a single sheet with an adhesive backing 17. When the sheet 12 is applied to the

compartments 4, the closure 12 adheres to the lip 26 of each compartment 4. The topside 18 of the closure 12 has patient information details 38 printed thereon, which may include personal details (name, age *etc.*) and dosage regime. An individual closure for each container is formed by perforations 39 which allow the closures to be broken away with the compartment 4 during removal of the compartment 4 from the cassette 20. This allows formation of, and easy removal of, a sealed container 19 using the closure 12 which thus provides patient information details 38 on each container 19. It is desirable that the closure 12 has further perforations 65 (as shown in Figure 9 and Figure 10) allowing separation of the closure 12 into strips. This means that even if a frangible row is broken off the entire row will remain covered by a strip of the closure 12.

[0097] Figure 7 illustrates a compartment 4 attached to the frame 27 by the frangible tab 8. The gap 28 can be clearly seen between the lip 26 of the compartment 4 and the frame 27 of the row 6. The indicating means in the form of an aperture 11 is also clearly shown. **Figure 8A** is a side sectional view of two compartments 4 in the plane indicated by arrow H in **Figure 8B**. The compartments 4 in **Figure 8A** now form sealed containers 19 as the compartment contains medicaments 5 and sealed with closure 12. The sealed containers are *in situ* in the cassette 20, as depicted by the presence of the top cover 21, the protrusion 37, and retainer 36. The protrusion 37 has extended through aperture 11 indicating correct orientation of the tray 2 and allowing correct seating of the tray 2 in the cassette 20.

[0098] **Figure 8C** is a perspective view of a sealed container 19 removed from the tray 2 of the present invention. The sealed container 19 is removed from the cassette 20 by applying manual pressure in the direction of arrow J (**Figure 8A**) to disengage the frangible tab 8 from the frame 27. When the sealed container 19 is removed from the cassette 20, the patient information details 38 remain attached to the container 19 and the container 19 remains sealed as shown in **Figure 8C**. The remainder of the closure 12 remains attached to the remainder of the tray 2 as shown in **Figure 10**. The patient information details 38 can be readily peeled back, for example in the direction of arrow J, by either the care-worker or the patient to whom the medicaments are prescribed so as to access the medicaments. This means that there is patient information associated with the medicaments right from the time the pharmacist fills the compartment 4 through to the time the medicament is removed from the compartment to be taken by a patient.

[0099] **Figure 9** illustrates the tray 2 with the closure 12 attached thereto prior to placing the tray 2 into the cassette 20. In the aspect of the invention illustrated in

Figure 9, the labels 9 are attached to the tray 2. When the sealed container 19 is removed from the tray 2, as shown in the **Figure 10**, an aperture 66 is evident in the frame 27 of the tray 2/row 6. As explained above, the perforations 39 surrounding the patient information details 38 permit the removal of the sealed container 19 from the closure 12 while keeping the remainder of the closure 12 intact. The perforations 65 are coincident with the frangible line 7, which allows a row 6 to be broken off the tray 2 while also keeping the remainder of the closure 12 intact.

[00100] The cassette 20 of the dispensing system 1 of the present invention is illustrated in more detail in **Figure 11**, **Figure 12**, and **Figure 13**. The cassette 20 comprises a top cover 21 and bottom cover 22. The top cover 21 has labels 10 attached to an upper surface 41 thereof. The labels 10 are attached along a side 42 of the top cover 21. Labels 9 are affixed to a top side 43 of the top cover 21.

[00101] The top cover 21 is formed by a plurality of spaced-apart members 40 running parallel to each other and dividing the tray into days of the week. The spaced-apart members 40 overlie the tray 2 and retain the tray 2 between the top cover 21 and retainer 36. The retainer 36 comprises a cage structure which forms a seat for the tray 2. The cage structure comprises a grid with openings 32 into which the compartments 4 of the tray 2 are received. When the cassette does not contain a tray 2 of the present invention, the patient information sheet 30 is visible through the top cover 21 and retainer 36 (see **Figure 11**). The top cover 21 is pivotally attached to the cassette 20.

[00102] The overhanging lip 34 on both the top 21 and bottom 22 covers of the cassette 20 forms latches 44. The latches 44 are perpendicular to the covers 21,22 and lie flush with a sidewall 35 of the cassette 20 when in an engaged or locked position. When the covers 21,22 are in a closed position, the latches 44 engage with a recess 47 set in the sidewall 46 of the cassette 20. The latches 44 each have a notch 48 that releasably engages with a depression 49 in the recess 47 (see **Figure 13**).

[00103] **Figure 12** illustrates the cassette 20 of the dispensing system 1 of the present invention in a closed position containing two rows 6 (which have been frangibly removed from a tray 2) of sealed containers 19 for a patient on a twice-daily dosage regimen. In this instance, the labels 9 have the days of the week and the labels 10 have the specific time at which the patient is to receive the medicaments. The patient information 38 is clearly visible through the spaced-apart members 40. The spaced-apart members 40 of the top cover 21, together with the interaction between the apertures 11 and protrusion 37, aid in keeping the rows 6 in position while the user is removing a sealed container 19 from the dispensing system 1.

[00104] **Figure 13** illustrates the cassette 20 of the dispensing system 1 of the present invention in an inverted orientation and with bottom closure 22 in an open position. The cassette 20 contains a row 6 of sealed containers 19 for a patient on a once-daily dosage regimen, with the patient information sheet 30 detailing the medication regime on the underside of the bottom cover 22. The purpose of this is to allow the user such as pharmacist, care worker or patient to inspect the medicaments 5 in the sealed containers 19 and ascertain whether the medicaments 5 match the prescribed medicaments detailed on the patient information sheet 30. The base 25 of the sealed container 19 is constructed of substantially transparent material and without any substantial curvature such that when the medicaments 5 are viewed through the base 25, there is no optical distortion (e.g. magnification or reduction) of the contents. That is, there is no substantive magnification or reduction of the size of the medicaments 5 contained therein, thereby making it easier to tell that the medicaments 5 being seen in the sealed container 19 match the prescribed medicaments on the patient information sheet 30.

[00105] As illustrated in **Figure 13**, the top and bottom covers 21,22 of the cassette 20 are flush with the sidewalls 35 when in a closed position (see **Figure 12** for top cover 21). The width of the top and bottom covers 21,22 is narrower than the width of the cassette 20. The sidewall 35 of the cassette 20 has a step 60,61 which permits the top and bottom covers 21,22 to nest on the step 60,61 when in a closed position. The step 60,61 also has the labels 9 affixed thereto. Abutting the sides of the top and bottom covers 21,22 is a ridge 62,63 which ensures that when the top and bottom covers 21,22 are in a closed position, the covers 21,22 are flush with both the sidewall 35 and sidewalls 54,55.

[00106] **Figures 14 to 16** illustrate a number of means by which the frangible container 19 may be removed from the tray 2 or frame 27 thereof by means of an actuator. The actuator may be a cutting and/or punching tool and/or other actuatable means to remove a container. The following are merely examples and should not be construed as the only means by which to remove the frangible container 19 from the tray 2 of the present invention.

[00107] As illustrated in **Figure 14**, there is provided a series of leverage members 70. In the embodiment the leverage members are on the holder or cassette 20 and in particular members 40 thereof. When a row 6 (or tray 2) is sitting in the holder 20 and members 40 are in a closed position on top of the row 6 or tray 2, a respective leverage member 70 lies against the sealed container 19. When a user wishes to remove a container 19 from the row 6 or tray 2 by pushing the container 19

from beneath, the frangible tab 8 abuts the leverage member 70. This means the frangible tab 8 experiences increased resistance to movement and this in turn allows the frangible tab 8 to be more easily broken away from the frame 27.

[00108] **Figure 15** illustrates a top plan view of a further actuator in the form of actuating means. In the embodiment the actuating means takes the form of a tear-away strip 71. The tear-away strip 71 is positioned in the gap 28 between the lip 26 of the compartment 4 and the frame 27 (not shown). The strip 71 is held in this position by frangible joins 72. A user simply grips tab 73 and pulls the strip 71 around the perimeter of the compartment 4 until a stop 74 is reached. The compartment 4/container 19 is then detached and can be removed.

[00109] **Figure 16A** illustrates a punch actuator, generally indicated by reference numeral 76, which comprises a support frame 77 adapted to support a punch 78. Flexible member 79 attaches the punch 78 to the support frame 77. The support frame 77 has a flange 80, which is adapted to slide along on the holder 20 for example along the members 40. The actuator 76 can thus be manoeuvred to the correct dosage for the correct day. Furthermore, the actuator 76 may also comprise indicating means (such as an indexing member) to indicate when the actuator 76 has positioned itself in the correct position over a container. The punch 78 has a transparent topside through which the adhesive sheet 12 can be clearly seen. The user simply moves the support frame 77 over the container required and presses the punch 78 in a direction indicated by arrow P. The punch 78 applies pressure to the frangible tab 8 and perforations 39 to break the container 19 from a tray 2 or row 6. It should be understood by those skilled in the art that the contact points of the punch 78 may be sharp to aid breaking/cutting of the perforations 39. It should be further understood that the top of the punch 78 may comprise a magnifying material to aid in identifying the correct container to remove.

[00110] **Figure 16B** illustrates a blade actuator, generally indicated by the reference numeral 85. The blade actuator comprises a blade 86 mounted on a retractable arm 87. The retractable arm 87 is slidably mounted on a side of the holder 20. In this way it can be moved to a desired location on the array. A slide 88 holds it in place so that when in use, the blade 86 is perpendicular to the frangible tab 8. The user simply slides the actuator 85 along the side of the holder 20, which optionally further comprises indicating means (such as indexing means) to align the actuator to a correct positioning, and extends the arm 86 to the container to be removed. The user presses the blade 86 down on the frangible tab 8 which then breaks away from the

frame 27 and the container can be removed. The blade actuator 85 may be stowable, for example stored inside the holder 20 when not in use.

[00111] **Figure 16C** illustrates a further embodiment of an actuator in the form of an actuating means. In the embodiment a finger pull actuator is generally indicated by reference numeral 90. The finger pull actuator 90 comprises a tab 91 lying flush with an upper surface of the compartment 4/container 19 and the frame 27. The tab 91 is releasably connected to the frame 27 and/or the lip 26 of the container 19 via a tear-away strip 92. The tear-away strip 92 is connected to the lip of the container 19 and frame 27 by spaced-apart joins 93 and frangible joins 72. When a user lifts the tab 91 and pulls upwards, the tear-away strip 92 comes away from joins 72,93. This releases the main connection of the container to the remainder of the array and the container 19 can be removed easily from the frame 27. The advantage of the present embodiment is that there are no potential sharp edges left on the container 19 which may cause minor injuries to the lips of the patient when taking the medication contained therein.

[00112] **Figure 16D** illustrates an actuator in the form of a dual tab actuator 100 comprising a pair of tabs 101,102 which when pushed together breaks a frangible tab 8 and thus the container 19 is released from the interconnected array.

[00113] It should be further understood by those skilled in the art that the closure, for example adhesive sheet 12 may be modified to accommodate the various actuators described in Figures 15, 16C, and 16D. The closure will be adapted to remain with the compartments to form the sealed containers irrespective of the arrangement for removing a container from the array.

[00114] The words "comprises/comprising" and the words "having/including" when used herein with reference to the present invention are used to specify the presence of stated features, integers, steps or components but does not preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

[00115] It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable sub-combination.

Claims

1. A dispensing system for administration of medicaments during a medicament dosage regime and comprising:

(i) a tray comprising:

a frame;

an interconnected array of compartments, each compartment being dimensioned to accommodate therein a plurality of medicaments;

wherein the frame acts as an interconnecting member to hold the compartments in position in an interconnected array; and

wherein when each compartment is removed from the frame it leaves an aperture in the frame.

(ii) a closure for the compartments arranged so that the closure and the compartments form a series of sealed containers for holding medicaments; the compartments and the closure therefor being arranged so that each sealed container is frangible from the interconnected array so that a sealed container may be removed from the array.

2. A system according to Claim 1 wherein:

(i) the system further comprising a holder into which the tray fits,

optionally wherein the holder is in the form of a cassette,

optionally wherein the holder is provided with one or more retaining members adapted to retain the array while allowing removal of the containers; and

further optionally wherein said one or more retaining members retains the frame in the holder while allowing containers to be removed from the array;

and/or

(ii) each closed container comprises patient identification information; and/or

(iii) each closed container comprises information identifying a time during the dosage regime at which it is intended to administer the medication in the container; and/or

(iv) the compartments are constructed of a substantially transparent material which allows visual inspection of medicament contained therein, and further optionally wherein the compartments are constructed so as to avoid any

substantive magnification or reduction of the perceived size of the medicament contained therein; and/or

(v) the closure comprises an adhesive sheet which includes an individual closure for each of the compartments, and further optionally wherein:

patient identification information is provided on each closure, and/or
information identifying a time during the dosage regime at which it is intended to administer the medication in the container is provided on each closure, and/or

an account for the number of medicaments which should be contained within each container is provided on each closure, and/or

patient information is provided in the form of a barcode on each closure.

3. A dispensing system for dispensing medicaments to be administered during a medicament dosage regime and comprising:

a tray comprising:

an interconnected array of compartments, each compartment being dimensioned to accommodate therein a plurality of medicaments; the interconnected array comprising a series of rows each row being frangibly connected to the next, wherein each row comprises a frame each frangibly connected to the next; and optionally:

(i) further comprising a closure for the compartments arranged so that the closure and the compartments form a series of sealed containers for holding medicaments; the compartments and the closure therefor being arranged so that each sealed container is frangible from the interconnected array so that a sealed container may be removed from the array; and/or

(ii) further comprising indicating means which indicate to a user that a tray or row of compartments has been incorrectly positioned in a holder; and/or,

(iii) wherein the holder comprises at least one openable flap which allows access to the tray, wherein the openable flap is a cover for a top or bottom of the holder, optionally wherein the holder further comprises a retainer which retains the tray in position while allowing sealed containers to be removed from the interconnected array; and/or

(iv) wherein the tray, a tray portion or a row of compartments, comprises a frame to which the compartments are frangibly detached and a retainer is adapted for retaining the frame.

4. A method of filling a medicament dispensing system with medicaments comprising the steps of:
- (i) providing a system as defined in any one of Claims 1 to 3;
 - (ii) dispensing prescribed medication into one or more compartments of the tray according to the required dosage regime;
 - (iii) closing at least the compartments into which the medication is dispensed utilising a closure for the compartments so that the closure and the compartments form a series of sealed containers, and optionally:
 - (a) providing patient identification information on the sealed containers, and/or;
 - (b) providing each closed container with information identifying a time during the dosage regime at which it is intended to administer the medication in the container, and/or
 - (c) providing patient identification information on each closure, and/or
 - (d) providing information identifying a time during the dosage regime at which it is intended to administer the medication in the container is provided on each closure, and/or
 - (e) providing an account of the number of medicaments which should be contained within each container is provided on each closure, and/or
 - (f) providing information in the form of a barcode on each closure.

5. A dispensing system, or tray, or method, substantially as described herein with reference to and as illustrated in the accompanying drawings.

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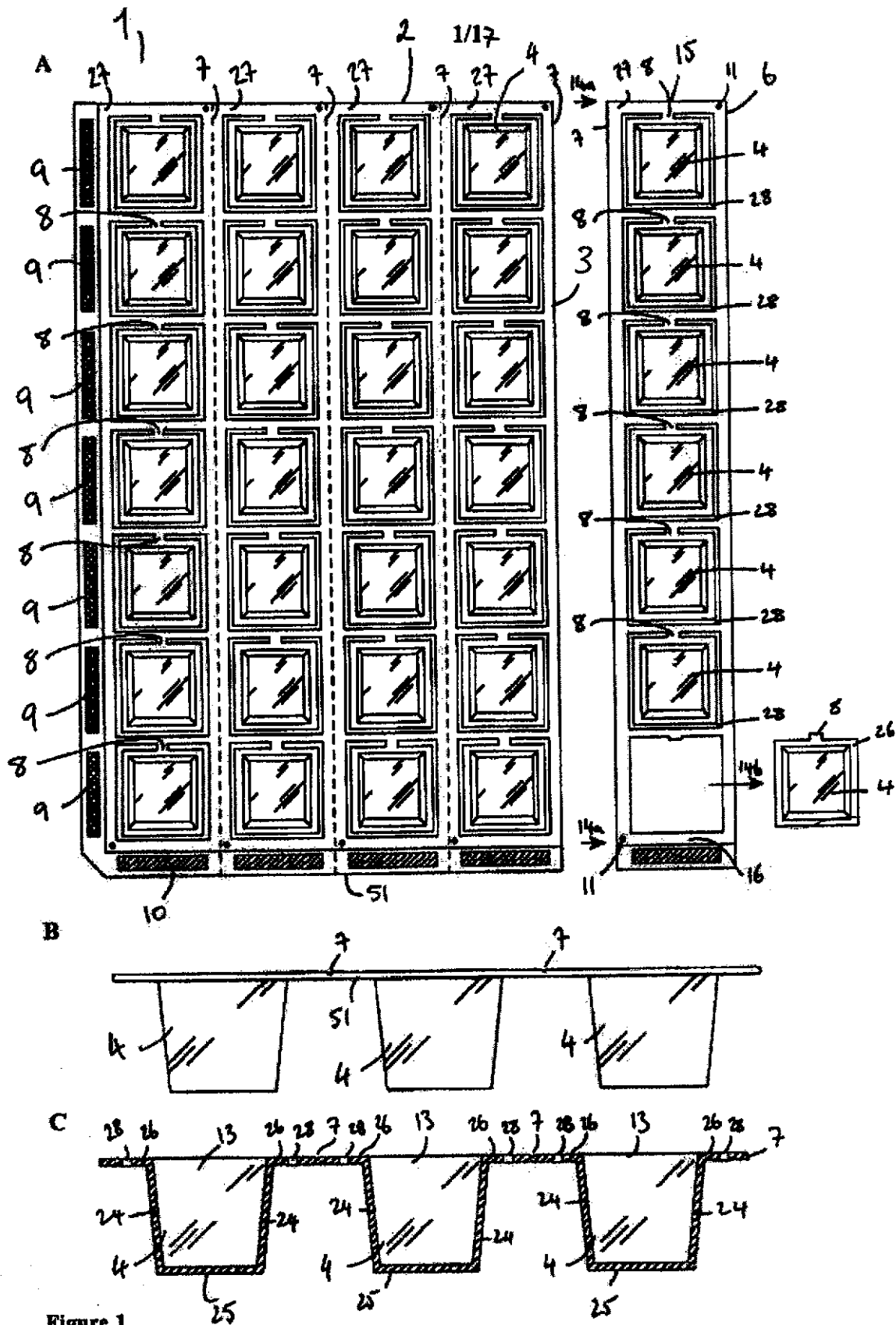
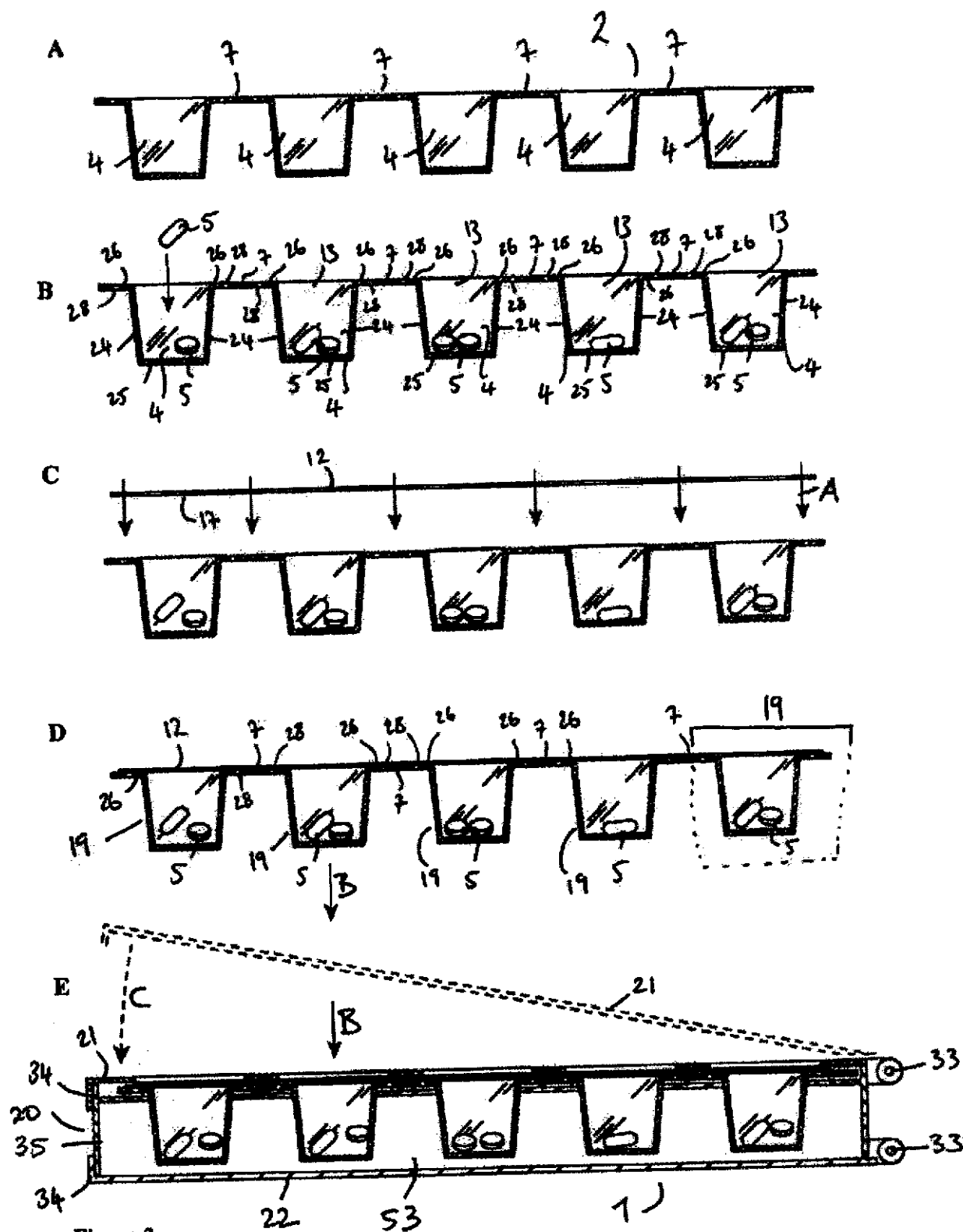


Figure 1

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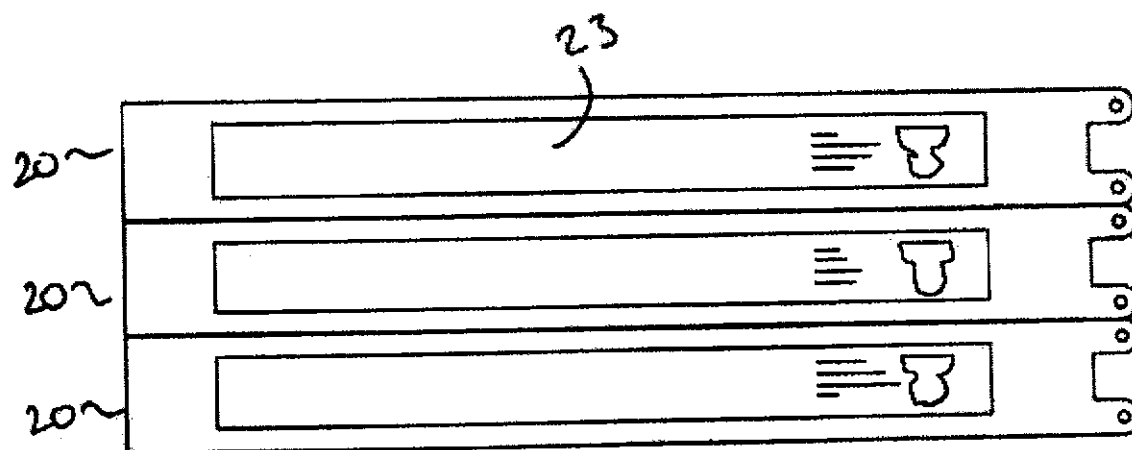


Figure 3

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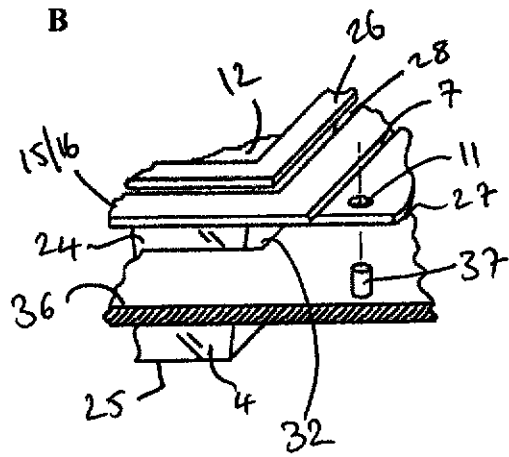
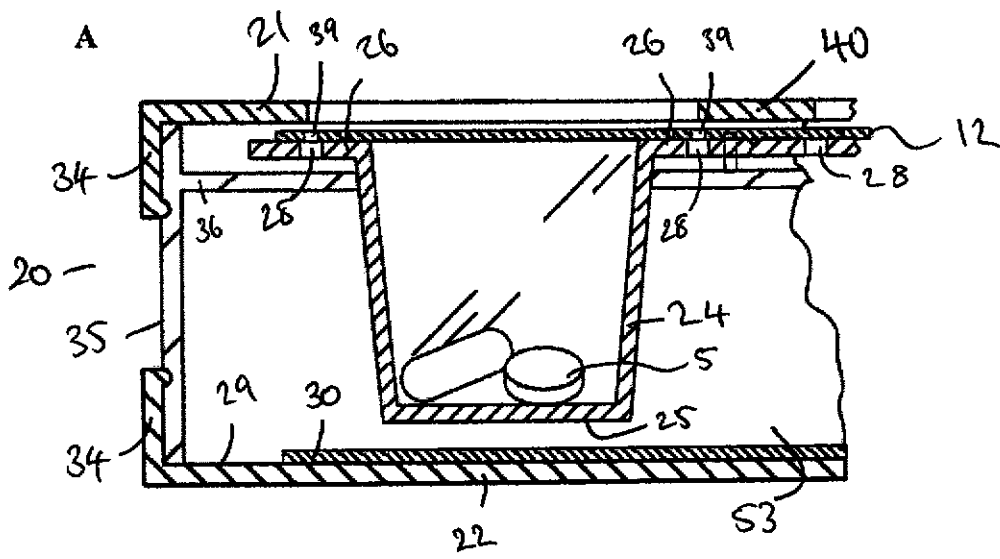


Figure 4

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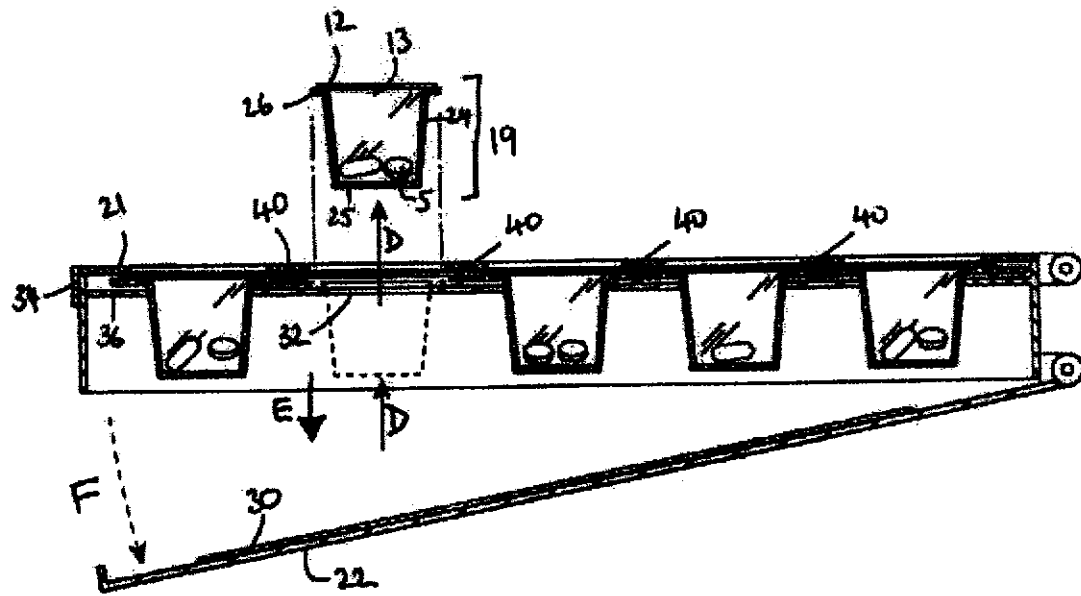


Figure 5

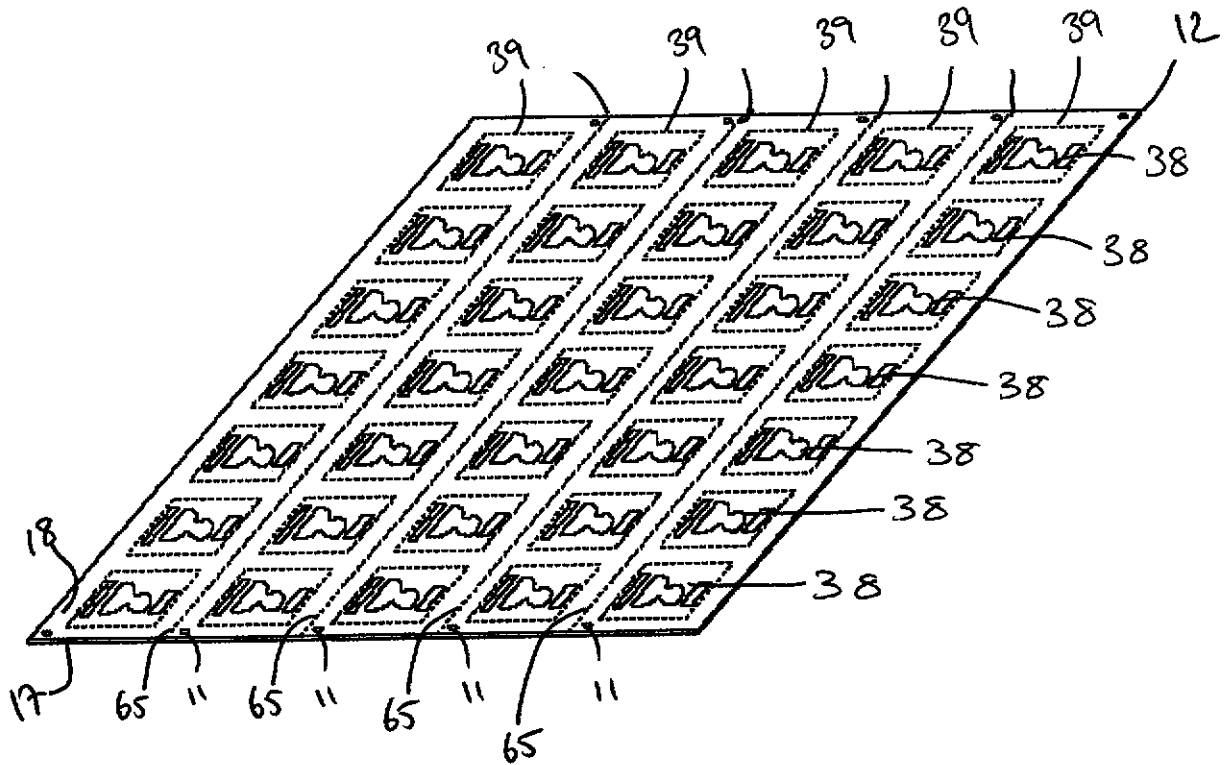


Figure 6

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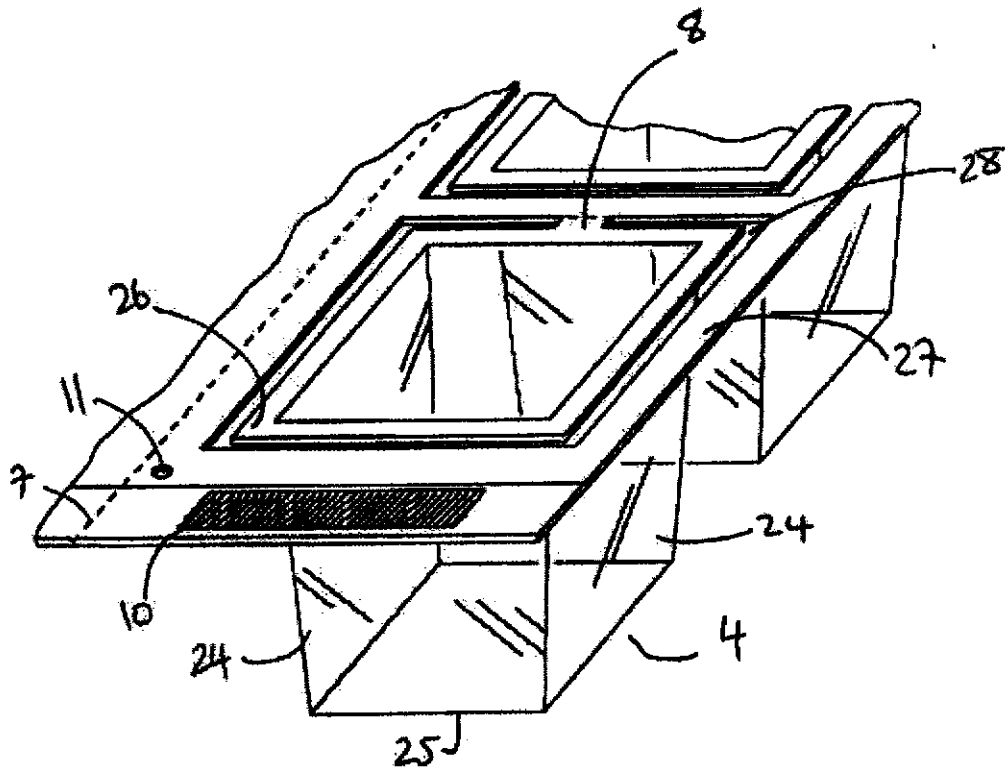


Figure 7

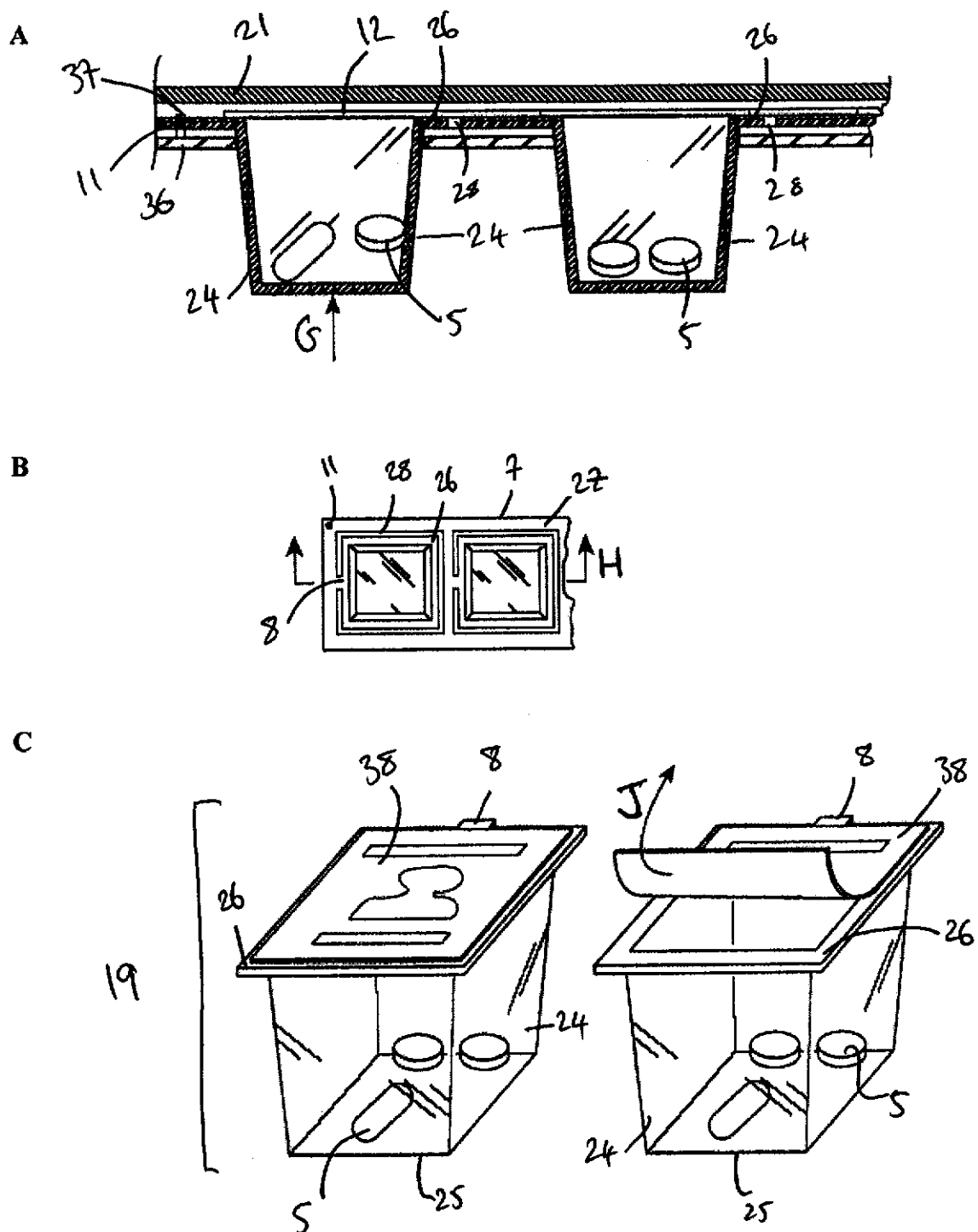


Figure 8

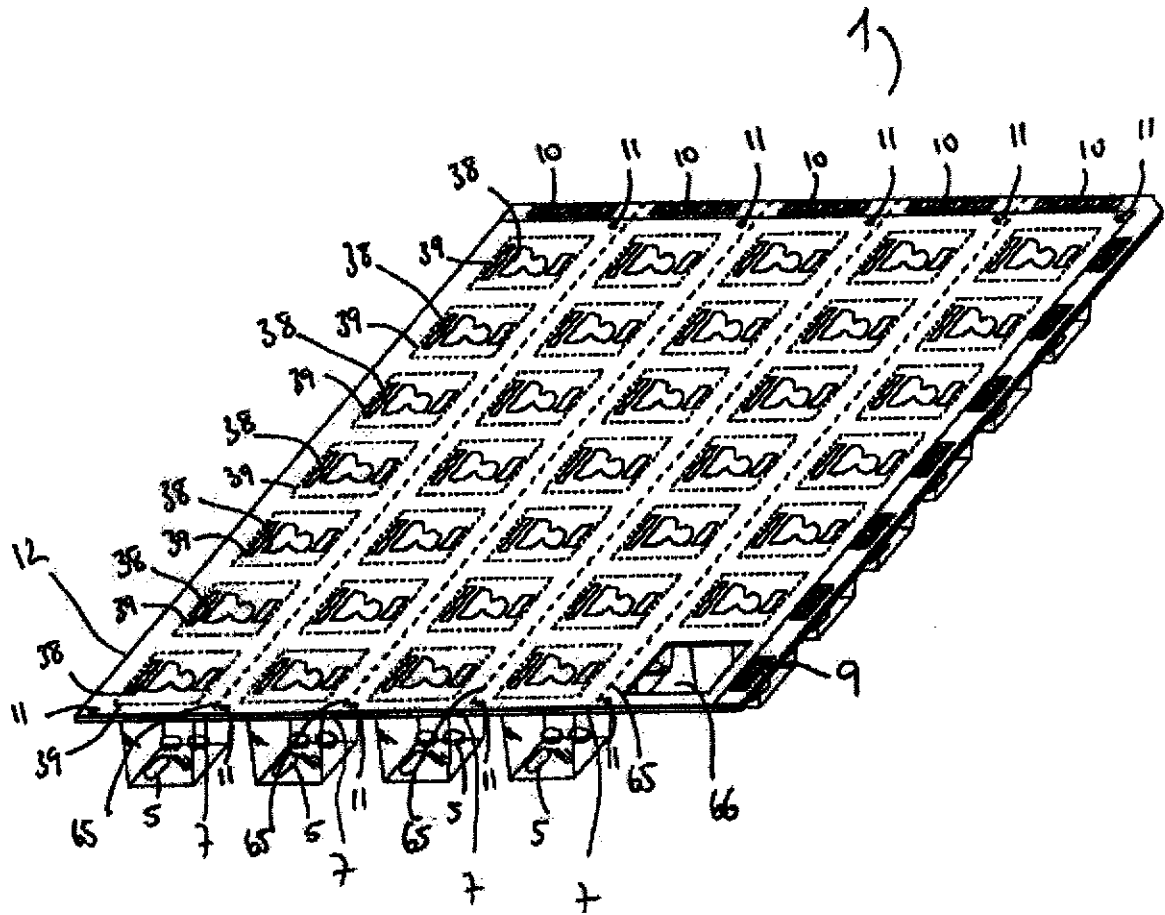


Figure 10

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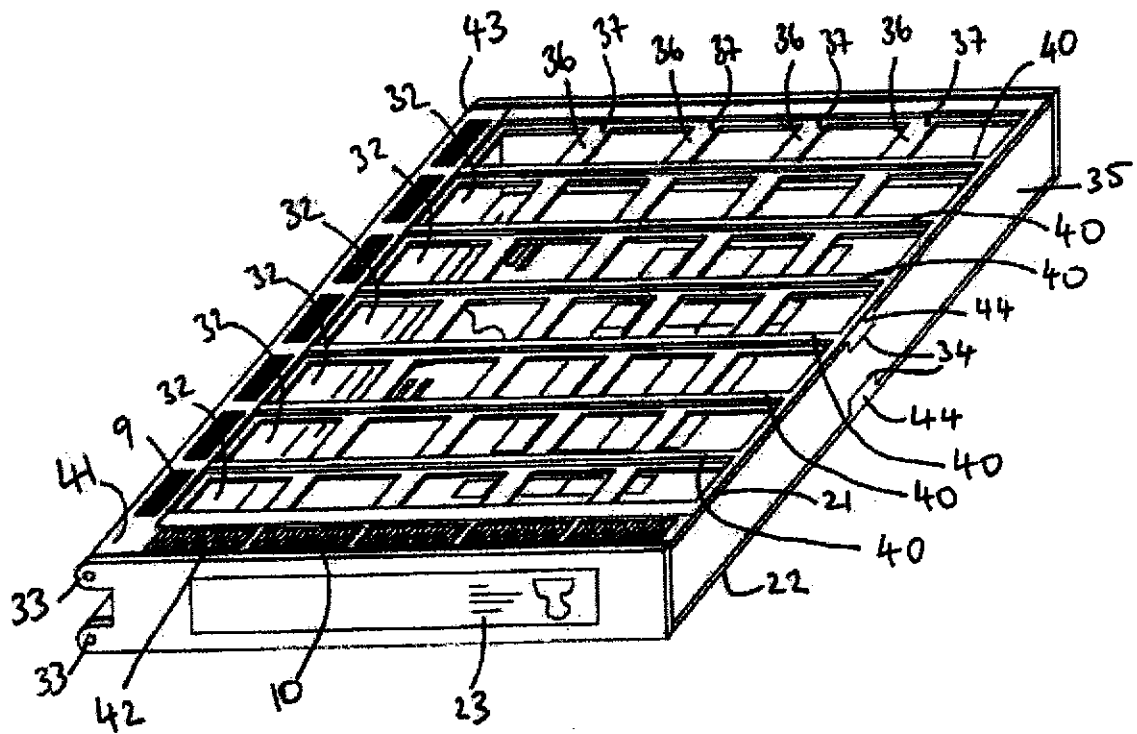


Figure 11

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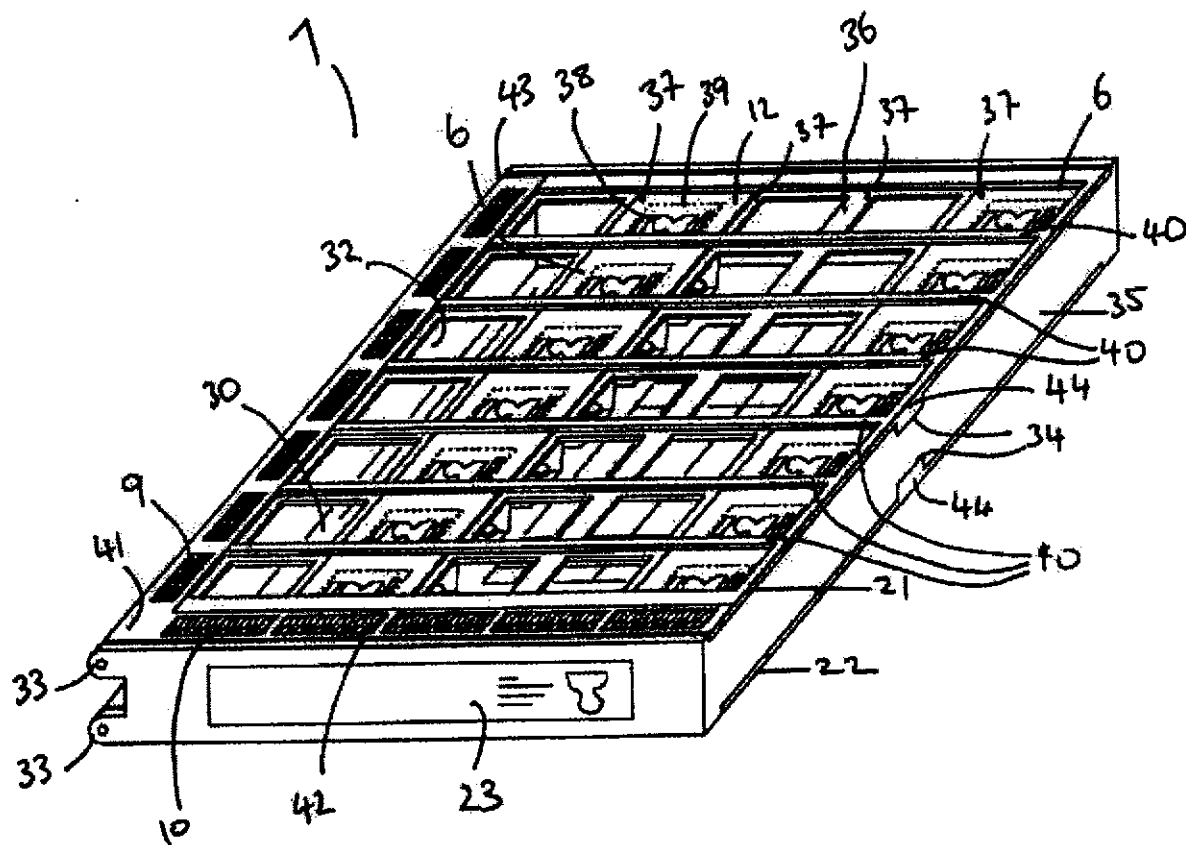


Figure 12

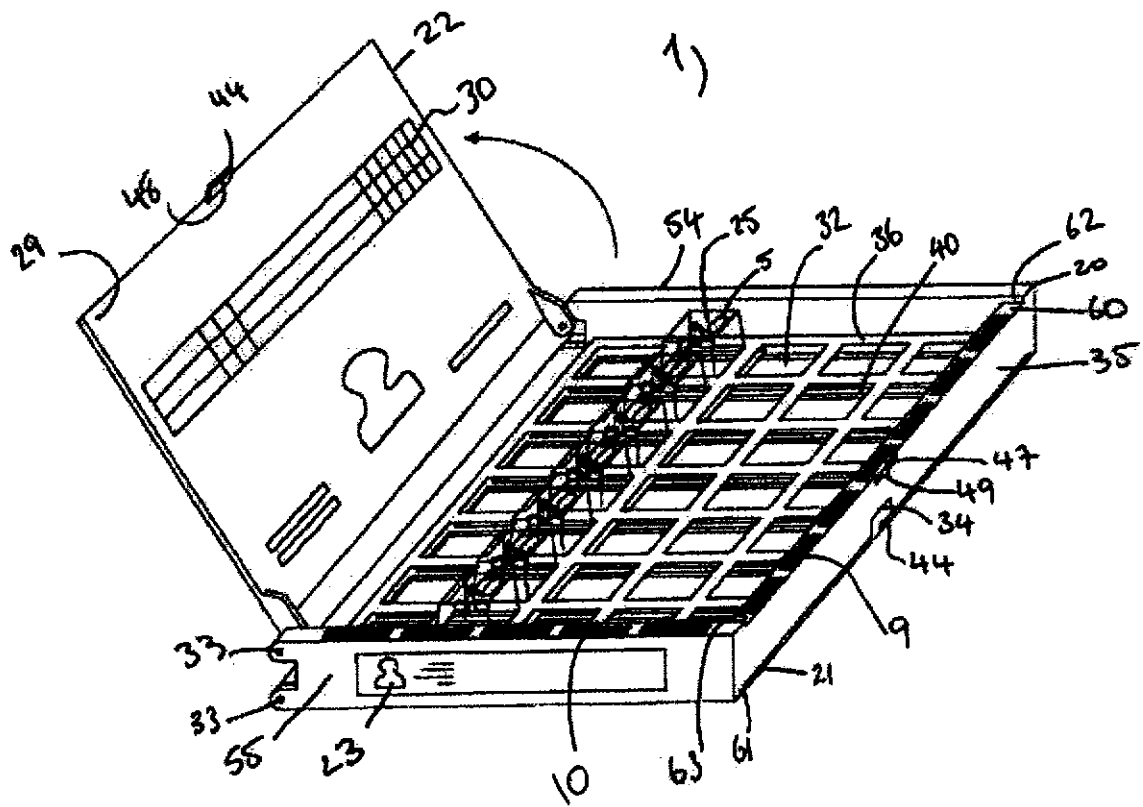
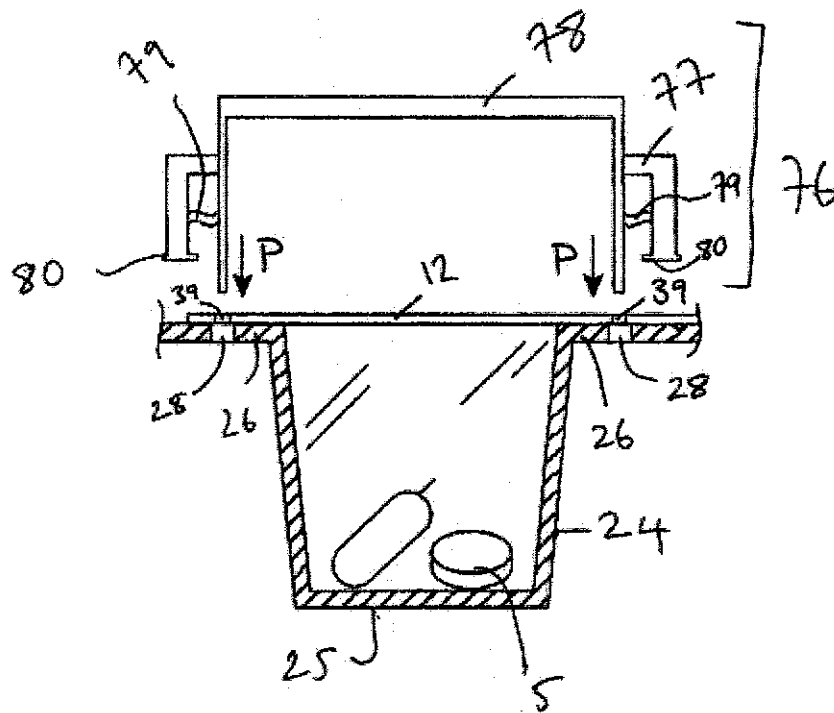


Figure 13

A.



B.

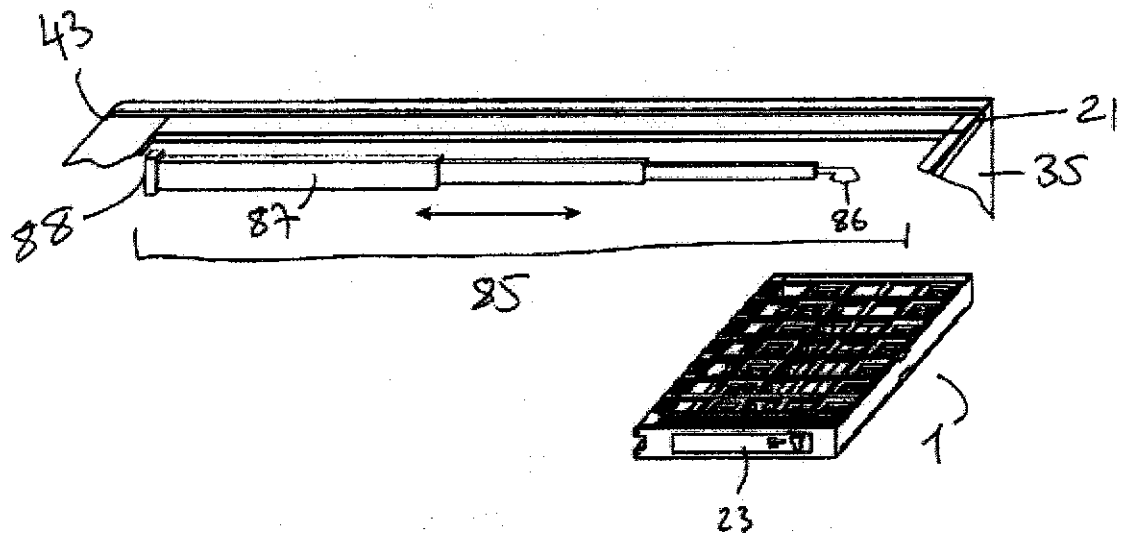
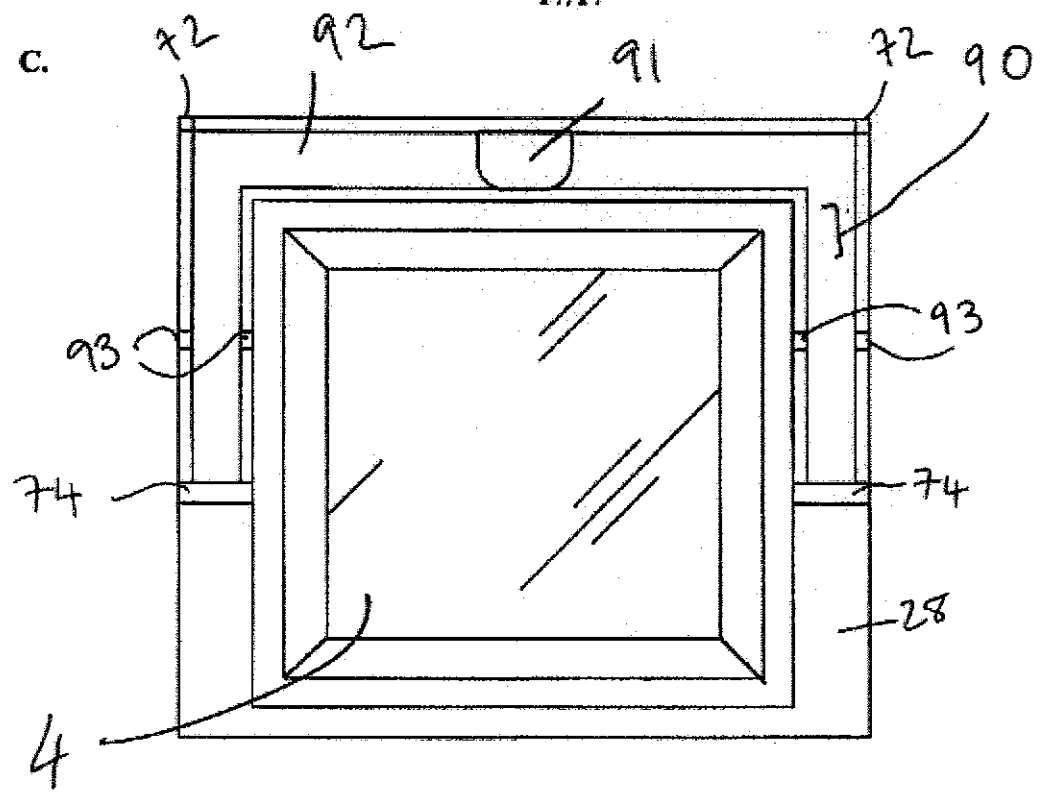


Figure 16

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D.

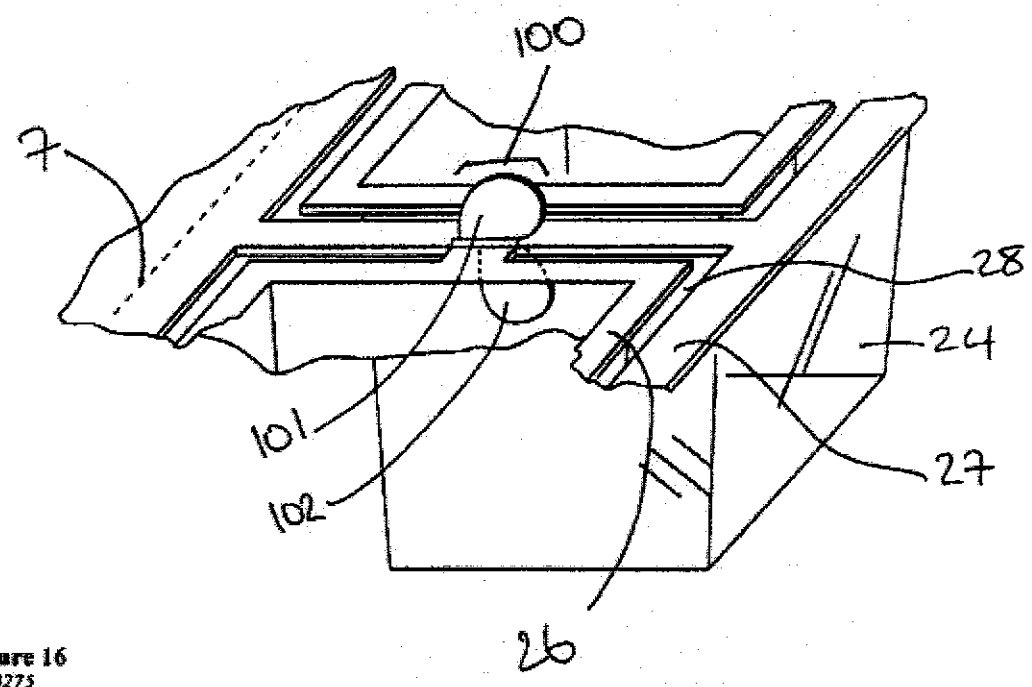


Figure 16
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