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(54) **DISPENSING SYSTEM FOR MEDICAMENT REGIME**

AUSGABESYSTEM FÜR EINEN ARZNEIMITTERTHERAPIEPLAN

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## Description

### Field of the Invention

**[0001]** 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

**[0002]** 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).

**[0003]** 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.

**[0004]** 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™/ Manrex™. 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.

**[0005]** 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.

**[0006]** 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.

**[0007]** 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.

**[0008]** Lewis (US 6,681,935) shows a tray where each compartment is connected to directly to the next. There is no frame at all in the construction shown. Bouthiette (US 2008/0023366) document is a similar arrangement to Lewis. Bouthiette (US 5,788,079) uses two trays, one as the "recessed support" of Figure 1 and the second as the "plastic sheet" (tray) of Figure 3. Pabari (GB 2,448,188) discloses a rigid holder with a series of compartments over which a rupturable sheet is placed. Pabari does not allow for the removal of individual pots. Doull (US 4,998,623) is similar in construction to Bouthiette (US 5,788,079) and suffers from the same drawbacks. It is a support system with an insertable series of compartments. Mernoe (WO 99/25307) is simply a series of blister packs. Lubow (WO2004/000520) discloses a method of applying a barcode. DE 202006007553 relates to a childproof enclosure for blister packs. In particular it relates to a blister pack that folds up into a complex wallet. This document is concerned with the problem of making access to medication childproof. Niven (WO2009/047560) describes a system having a tray with individual compartments and with an individual pot within each compartment.

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

### **Summary of the Invention**

**[0010]** In a first aspect the present invention provides a dispensing system for administration of medicaments during a medicament dosage regime as set out in Claim 1.

**[0011]** 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.

**[0012]** Desirably the system may further comprise an openable flap which allows access to the tray, and optionally wherein the openable flap is a cover for the top of the tray. The tray and openable flap (lid or cover) may be integrally formed (continuous) with one another, for example in an arrangement where a fold between the tray and flap may form a hinge. Desirably the continuous piece comprising the tray, the cover, and the hinge may

be integrally formed from a single piece of material. This may be done by any suitable technique including vacuum moulding. The cover may hold patient information and it is preferable that the cover or openable flap is transparent. The transparency of the cover permits a user to read the patient information for example where it is provided on a patient information sheet.

**[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 closures. Information identifying a time during the dosage regime at which it is intended to administer the medication in the container is provided.

**[0018]** The closure may comprise individual lids. For example individual lids may be formed from the same material as the tray, a closeable flap for the tray and any hinge connecting the flap to the tray. For example all may be made from a continuous piece of material. By providing a sheet of material and forming two parallel hinge lines thereon forming a three panel arrangement. This

may be done by any suitable technique including vacuum molding. In one arrangement, a three-panel system is formed with two folds. One panel is used to form the lids, a second panel is used to form the tray, and the third panel forms a closeable flap. Desirably, a middle panel forms the tray, and the left or right panels form either the lids or the closeable flap. It will be understood by one skilled in the art that the left and right panels may form either one of the lids or the closeable flap. The lids may be provided in a frangible array so that each lid can be broken off to mate with a corresponding compartment to form a sealed container of the invention.

**[0019]** It is also desirable that information identifying the medicaments, which should be contained within each container, is provided on each closure for example 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. A representation, suitably an image (desirably with appropriate colour) of the medication(s) may be utilised. This gives a visual reference against which the actual contents can be checked. 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.

**[0020]** The present invention may provide a dispensing system as set out in the claims 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.

**[0021]** 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.

**[0022]** 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. Desirable indicating means are provided to indicate when a tray and/or a 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

**[0023]** 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*.

**[0024]** 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.

**[0025]** It is desirable in embodiments where an openable flap is present that a securing mechanism is provided that can hold the flap in a closed position covering the tray. For example one or more protrusions and corresponding recess(es), for example blind aperture(s) may be provided where the protrusion(s) mate with the recess(es) to secure the flap to the tray. The protrusions may be on the tray and the recesses on the flap or vice versa.

**[0026]** 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.

**[0027]** 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.

**[0028]** 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.

**[0029]** 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. It will be appreciated that in the embodiments where the tray comprises an integrally formed flap (as described above) a cassette may be additionally used but it is not generally required.

**[0030]** 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.

**[0031]** 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.

**[0032]** 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.

**[0033]** 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.

**[0034]** 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 which retaining the remainder of the interconnected array. In particular the retainer may retain a frame to which the compartments are connected.

**[0035]** 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.

**[0036]** 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.

**[0037]** 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.

**[0038]** 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.

**[0039]** 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.

**[0040]** 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.

**[0041]** In a further aspect of the present invention, there is provided a dispensing system as set out in the claims for administration of medicaments during a medicament dosage regime and comprising:

10 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,  
15 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.

**[0042]** 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.

**[0043]** 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.

40 **[0044]** Optionally the cage structure comprises a grid with openings into which compartments of the tray are received.

**[0045]** 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.

**[0046]** 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. In a still further aspect of the invention, a frangible connection is formed by a plurality of break-points or tabs between each compartment and the interconnected array and breaking the plurality of break-points releases a sealed container from the array. The plurality of break-points or tabs may comprise at least 2 and often between 2 and 6 break-points, such as between 2 and 4 break-points, and desirably at least 3 break-points for example no more than 5 break-points.

**[0047]** In the embodiments where the closure comprises individual lids the closure may comprise a frangible array of individual lids, and the frangible array of lids and the tray are formed from a continuous piece of material. The frangible lids desirably have weaker frangible connections than those connecting the compartments to the frame of the tray. It is further desirable that the frangible lids are marginally bigger than a mouth, for example a lip of the compartments to ensure that the lids seal the compartments. In one aspect of the invention, the lids push fit into the compartments for mating thereof. For example a lid may have a male portion that engagingly mates with the mouth of the compartment.

**[0048]** In the embodiments where the tray comprises an integrally formed flap (as described above), the invention may further comprise a plurality of support legs or struts (which are not compartments) to provide standing support for the tray when resting on a surface and also to provide support when a user is removing a compartment from the tray. The struts are generally located at each corner of the tray and may take any shape or form.

**[0049]** 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.

**[0050]** 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.

**[0051]** 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.

**[0052]** A method of filling a medicament dispensing system with medicaments comprises 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.

**[0053]** It is desirable that the method further provides patient identification information.

**[0054]** In the method 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.

**[0055]** The method desirably provides patient identification information on each closure.

**[0056]** In a desired aspect of the method, 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.

**[0057]** In a further desired aspect of the method, information identifying the medicaments which should be contained within each container is provided on each closure, for example, using barcodes.

**[0058]** 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.

**[0059]** 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.

**[0060]** 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 the case where closure comprises individual frangible lids, pushing off or popping off the lid may open the containers. In both instances, the terms "medicine pot(s)" and "container" can be used interchangeably.

**[0061]** 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.

**[0062]** 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.

**[0063]** 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.

**[0064]** 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.

**[0065]** It will be appreciated that in embodiments where the tray is integrally formed with a flap that the patient information, such as a sheet, typically a card may be carried on the flap. For example the flap may have slits therein arranged to engage and hold the patient information.

**[0066]** 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 sep-

arate 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**

**[0067]** 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:

**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.

**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.

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

**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).

**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).

**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.

**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 illus-

trating a tab for indicating the time of the day of the dosage.

**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.

**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.

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

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

**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.

**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.

**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.

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

**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.

**Figure 17A** illustrates a top view of the dispensing system of the present invention with an openable flap or cover in an open position; **Figure 17B** illustrates a top (plan) view of the dispensing system of

Figure 17A in a closed position with a patient information sheet attached; and **Figure 17C** illustrates an underneath plan view of the tray thereof showing medicaments in the compartments.

**Figure 18A** illustrates an openable flap for the tray of the present invention in the process of being lowered to cover the interconnected array of sealed compartments; **Figure 18B** illustrates a hinge for the openable flap; **Figure 18C** illustrates the indicating means of the tray of the present invention, which also acts a securing mechanism to capture the openable flap in a closed position over the tray; and **Figure 18D** illustrates the tray and openable flap in a closed position.

**Figures 19A to 19C** are respectively an enlarged perspective view of a frangible compartment of the tray of the dispensing system of the present invention showing (**Figure 19A**) the frangible connection of the compartment to the interconnected array, (**Figure 19B**) a frangible line of the patient information seal on the compartment, and (**Figure 19C**) a frangible sealed container removed with the patient information seal intact. **Figure 19D** illustrates removal of a single sealed compartment from the interconnected array of compartments.

**Figure 20A** is a perspective view of a patient identity card for fitting to a openable flap of a tray of the dispensing system of the present invention; **Figure 20B** is a perspective view of a medicament (tablet) information sheet for a tray of the dispensing system; **Figure 20C** is a perspective view of a closure for a tray of individually labelled adhesive closures which include patient identification information; and **Figure 20D** is a side view of six stacked trays of the dispensing system of the present invention.

#### Detailed Description of the Drawings

[0068] 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.

[0069] 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.

[0070] 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**.

**[0071]** 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.

**[0072]** 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.

**[0073]** 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.

**[0074]** 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

**[0075]** **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.

**[0076]** 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.

**[0077]** **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**.

**[0078]** 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.

**[0079]** 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 closure 12 may comprise individual lids. The lids may be formed from the same (continuous piece of) material as the tray 2. This may be done by any suitable technique including vacuum moulding. In one arrangement, a three-panel system is formed with two folds. One panel forms the lids, a second panel forms the tray of compartments 4, and the third panel forms a cover for a patient information sheet 30 and/or a medicament information sheet 105. Desirably, the middle panel forms the tray 2, and the left and right panels form the lids and cover for the patient information sheet and/or the medicament information sheet. It will be understood by one skilled in the art that the left and right panels may form either one of the lids and cover for the patient information sheet and/or the medicament information sheet. Each panel is pivotably connected to the next. Alternatively the closure with its individual lids can be pivotably attached to the tray, for example as a separate hinged sheet which is optionally intermediate a flap 121 (see below) and the tray. Alternatively it may be carried by the flap 121.

**[0080]** The patient information 38 comprises the patient's 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**.

**[0081]** 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.

**[0082]** 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**.

**[0083]** 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.

**[0084]** 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).

**[0085]** 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.

**[0086]** 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.

**[0087]** 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.

[0088] As described above, the closure may comprise individual lids formed from a continuous piece of material as the tray. This may be done by any suitable technique including vacuum moulding. In one arrangement, a three-panel system is formed with two folds. One panel forms the lids, a second panel forms the tray of compartments, and the third panel forms a cover for a patient information sheet and/or a medicament information sheet. Desirably, the middle panel forms the tray, and the left and right panels form the lids and cover for the patient information sheet and/or the medicament information sheet. It will be understood by one skilled in the art that the left and right panels may form either one of the lids and cover for the patient information sheet and/or the medicament information sheet. It is desirable that the lids have patient information provided thereon. When such a closure is folded over the compartments (by pivotal movement), each lid seals their corresponding compartment.

[0089] 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.

[0090] 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.

[0091] 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.

[0092] 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.

[0093] 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.

[0094] 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**).

**[0095]** **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.

**[0096]** **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.

**[0097]** 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.

**[0098]** **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 suitable 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 in-

vention.

**[0099]** As illustrated in **Figure 14**, there is a 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.

**[0100]** **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.

**[0101]** **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.

**[0102]** **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.

[0103] 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.

[0104] 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.

[0105] 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.

[0106] Figure 17 shows a top and perspective view of the tray 2 of a further embodiment of the present invention. The tray 2 comprises a single piece, with a hinge or fold 100 connecting an openable flap 121 and the interconnected array 3. That is, the flap 121 is continuous with the tray 2. The openable flap 121 comprises a plurality of slots 103 on the internal surface 104 of the flap 121 into which a medicament information sheet 105 and/or a patient information sheet 30 may be inserted (see Figure 17B). In particular the slots 103 are arranged to hold the corners of the inserted sheet. A plurality of female receptacles in the form of depressions or blind holes 106 is provided on the flap 121 to matingly engage with indicating means which in this instance are in the form of male protrusions 107. Protrusions 107 also function as alignment indicators to indicate when the closure 12 is correctly aligned with the tray 2. When the flap 121 is pivoted about hinge 100 then the flap 121 forms a cover for the tray 2 and is held closed by the securing arrangement formed by engagement of the protrusions 107 in holes 106. The advantages of having a holder in the form

of a cassette are thus integrated into this embodiment and while a cassette may be employed there is no real advantage in doing so. The flap 121 is desirably transparent to allow a user or medical personnel to examine the tray 2 through the flap 121. The flap 121 further comprises a lip 110 (see Figure 18A) on which patient information may also be adhered. The flap 121 is moved in the direction of arrow R (Figure 18A) to cover the tray 2, as shown in Figure 17B and 17C. This movement can also be used to seal the compartments 4 for example by having the flap 121 carry the closure 12. When the flap 121 is closed, the patient information sheet 30 is clearly visible for the user to make reference thereto. The closure 12 is also visible through the closed flap 121 as illustrated in Figure 17B.

[0107] Figure 17B and 17C show the flap 121 in a closed position over the tray 2. The transparent nature of the flap 121 allows the user to examine the patient information sheet 30 and the information provided on the closure 12 without opening the flap 121 (Figure 17B). Furthermore, the transparent nature of the compartments 4 allows the user to examine the medicaments 5 placed in the compartments 4, even when the closure 12 is adhered to the tray 2 (see for example the underside view illustrated in Figure 17C).

[0108] The protrusions 107 may be of a particular shape and size. One function of the protrusions 107 of the present embodiment, and as per the previous embodiments, is to ensure that the closure 12 is placed correctly on the dispensing system 1. This negates the possibility of incorrectly applying the closure 12 which in an extreme misalignment could result in dispensing the incorrect medication at the requisite time. The mechanism prevents the closure 12 from being placed over the compartments 4 incorrectly. The protrusions 107 may be positioned at any point on sides 130,131, and 132 of the tray and in any number of combinations. It will be apparent to one skilled in the art that the protrusions 107 can take any suitable form or shape. For example protrusions 107 at the sides 130,131, and 132 as illustrated in Figure 17A can be placed at either or a combination of the left and right corners thereof.

[0109] Figure 18A is a side-view of the dispensing system 1 of the present invention. The tray 2 further comprises a plurality of support legs or struts 120 (which are not compartments) to provide standing support for the tray 2 when resting on a surface and also to provide support when a user is removing a compartment 4 from the tray 2. The struts 120 are generally located at each corner of the tray 2 (see Figure 18A, 18D, and 18E).

[0110] As explained above, the tray 2 is a continuous piece where the flap 121 and tray 2 are connected by the hinge 100. The hinge 100 is merely a fold in the one-piece system 1. Figure 18B shows a side view of the hinge 100. It will be appreciated that the hinge 100 between tray 2 and flap 121 comprises a fold 108 in within which an additional hinge point 109 is provided. The hinge point 109 is effectively a hinge pivot point about

which parts of the fold 108 can pivot. The hinge point 109 is a weakened point in the dispensing system of the present invention which makes for a less resilient hinge joint. For example such a weakened hinge joint may allow the cover 121 to fall backwards when opened, providing access to the sealed containers 19.

[0111] Figure 18C provides more detail of the protrusions 107 mated with the receptacle 106. As can be seen from the Figures and in particular Figure 18C each can be provided as a depression with one nesting within the other when mated. The protrusions 107 and receptacles 106 of the embodiment being discussed can also act as indicating means 11 as discussed above for example in relation to Figures 1 to 16. **Figure 18D** shows the dispensing system 1 in a closed position, with the protrusions 107 engaged with the receptacles 106, maintaining the flap 121 in a closed position. The supporting struts 120 are clearly visible at the tray corners.

[0112] **Figures 19A to Figure 19D** shows a perspective view of a single compartment 4 of the tray 2, where medicaments in the form of tablets 5 are placed into the compartment 4 according to the prescribed dosage regime as indicated by arrow G. As explained previously, 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 for example **Figure 17C**). The sidewalls 24 and a lip 26 form the perimeter of open mouth or (top) opening 13. The lip 26 forms part of the frame 27 of the interconnected array 3. It is connected to the array 3 by the frangible tabs (or break points) 8. These are arranged in a spaced part configuration about the periphery of the compartment 4. In particular the frangible tabs 8 are 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 tabs 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 of the tray 2. **Figure 19A** shows medication in the compartment 4, having being dispensed manually or by appropriate dispensing equipment by a pharmacist. As explained previously, **Figure 19B** shows a closure 12 of the type illustrated in **Figure 6** and **Figure 20B** applied to the tray. The closure 12 is placed over the opening 13 in the direction of arrows H. The closure 12 in the current embodiment is a single sheet having an adhesive underside 17 and a topside 18 with patient information 38 provided thereon (see **Figure 6** and **20C**). 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. As above, the closure may comprise individual lids.

[0113] The compartments 4 having medicaments 5 therein and the closure 12 applied thereon form sealed

containers 19, as indicated in **Figure 19B**. 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 19C**. The compartment 4 in **Figure 19B** now forms a sealed container 19 as the compartment contains medicaments 5 and sealed with closure 12.

[0114] **Figure 19C** is a perspective view of a sealed container 19 removed from the tray 2 of the present invention, while **Figure 19D** shows a side view of the tray 2 with one sealed container 19 being removed. The sealed container 19 is removed from the tray 2 by applying manual pressure in the direction of arrow J (**Figure 19C** and **19D**) to disengage the frangible tab 8 from the frame 27. When the sealed container 19 is removed from the tray 2, the patient information details 38 remain attached to the container 19 and the container 19 remains sealed as shown in **Figure 19C**. The patient information details 38 can be readily peeled back due to a tab 125 positioned below the level of the lip 26 of the compartment 4, allowing easy access to the seal having the patient information details 38. 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.

[0115] **Figure 20A-C** respectively illustrate a patient identity card 30, a medicament information sheet 105, and a closure 12 for a tray of individually labelled adhesive closures which include patient identification information, respectively. **Figure 20D** is a side view of six stacked trays 2 of the dispensing system 1 of the present invention.

[0116] 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.

[0117] 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 (1) for administration of medicaments (5) during a medicament dosage regime and comprising:

(i) a tray (2) comprising:

a frame (27);

an interconnected array (3) of compartments (4), 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 (11) in the frame;

(ii) a closure (12) for the compartments wherein the closure comprises a sheet which includes an individual closure (9) for each of the compartments, the closure arranged so that the closure and the compartments form a series of sealed containers (19) 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 further wherein each sealed container comprises information identifying a time during the dosage regime at which it is intended to administer the medication in the container and the sealed containers are arranged sequentially according to times of administration.

2. A system according to Claim 1, further comprising an openable flap (21) which allows access to the tray, and optionally wherein the openable flap is a cover (21) for a top of the tray.
3. A system according to Claim 2, wherein the openable flap (21) is integrally formed with the tray (2).
4. A system according to any one of Claims 2 or 3, wherein a fold between the flap (21) and the tray (2) forms a hinge (100).
5. A system according to Claim 4, wherein the tray (2), the flap (21) and the hinge (100) are integrally formed from a single piece of material and optionally wherein the flap holds patient information.
6. A system according to any one of the preceding claims wherein each closed container (19) comprises patient identification information
7. A system according to any one of the preceding claims wherein the compartments (4) are constructed of a substantially transparent material which allows visual inspection of medicament (5) contained therein and optionally wherein the compartments are constructed so as to avoid any substantive magnification or reduction of the perceived size of the medicament contained therein.

8. A system according to Claim 1 wherein an account for the number of medicaments (5) which should be contained within each container (19) is provided on each closure (9) and optionally wherein patient information is provided in the form of a barcode on each closure.
9. A system according to any preceding claim further comprising indicating means (107) which indicate to a user that a closure (9) for the compartments has been incorrectly positioned on the tray (2) and optionally wherein the indicating means comprise one or more protrusions (107) which interfere with incorrect positioning of the closure and further optionally wherein the indicating means comprise one or more alignment protrusions (107) which assist with correct positioning of the closure.
10. A system according to any one of Claims 2 to 9 wherein a securing mechanism (106;107) is provided for the openable flap (21) that can hold the flap in a closed position covering the tray (2).
11. A system according to Claim 1 wherein a frangible connection (8) is formed between each compartment (4) and the interconnected array (3) by at least one breakable tab (8), and breaking of the tab releases a sealed container (19) from the array; or wherein a frangible connection is formed between each compartment (4) and the interconnected array (3) by at least one perforated member and breaking along the perforations releases a sealed container from the array; or wherein the interconnected array comprises a series of rows (6) each row being frangibly connected to the next.
12. A system according to Claim 11 wherein a plurality of break-points are formed between each compartment (4) and the interconnected array (3) and breaking the plurality of break-points releases a sealed container (19) from the array.
13. A system according to any one of the preceding claims, wherein the closure (12) comprises a frangible array of individual lids, and the frangible array of lids and the tray (2) are formed from a continuous piece of material.

#### Patentansprüche

1. Abgabesystem (1) zur Verabreichung von Medikamenten (5) während eines Medikamenten-Dosierungsschemas, welches Folgendes aufweist:
  - (i) eine Schale (2), welche Folgendes aufweist:

- einen Rahmen (27)  
eine Verbundanordnung (3) von Abteilungen bzw. Fächern (4), wobei jedes Fach so bemessen ist, dass es darin eine Vielzahl von Medikamenten aufnehmen kann; wobei der Rahmen als ein Verbundglied wirkt, um die Fächer in einer Verbundanordnung in Position zu halten; und wobei, wenn jedes Fach aus dem Rahmen entfernt wird, eine Öffnung (11) in dem Rahmen zurückbleibt;
- (ii) einen Verschluss (12) für die Fächer, wobei der Verschluss eine Platte umfasst, welche für jedes der Fächer einen individuellen Verschluss bzw. Einzelverschluss (9) aufweist, wobei der Verschluss so angeordnet ist, dass der Verschluss und die Fächer eine Reihe von verschlossenen Behältern (19) für die Aufnahme von Medikamenten bilden;
- wobei die Fächer und der Verschluss hierfür so angeordnet sind, dass jeder verschlossene Behälter von der Verbundanordnung zerbrechlich bzw. leicht abbrechbar ist, so dass ein verschlossener Behälter von der Anordnung entfernt werden kann, wobei ferner jeder verschlossene Behälter Information aufweist, die einen Zeitpunkt während des Dosierungsschemas bestimmt, zu dem das Arzneimittel in dem Behälter verabreicht werden soll, und wobei die verschlossenen Behälter entsprechend der Zeiten der Verabreichung aufeinander folgend bzw. sequentiell angeordnet sind.
2. System nach Anspruch 1, welches ferner eine zu öffnende Klappe (21) aufweist, die den Zugriff zu der Schale ermöglicht, und wobei die zu öffnende Klappe optional eine Abdeckung bzw. ein Deckel (21) für eine Oberseite der Schale ist.
  3. System nach Anspruch 2, wobei die zu öffnende Klappe (21) integral mit der Schale (2) ausgebildet ist.
  4. System nach einem der Ansprüche 2 oder 3, wobei ein Falzkerbe zwischen der Klappe (21) und der Schale (2) eine Anlenkung (100) bildet.
  5. System nach Anspruch 4, wobei die Schale (2), die Klappe (21) und die Anlenkung (100) integral aus einem einzigen Materialstück gebildet sind und, wobei die Klappe optional eine Patienteninformation trägt.
  6. System nach einem der vorhergehenden Ansprüche, wobei jeder geschlossene Behälter (19) Patientenidentifikationsinformation enthält.
  7. System nach einem der vorhergehenden Ansprüche, wobei die Fächer (4) aus einem im Wesentlichen durchsichtigen Material hergestellt sind, welches eine visuelle Inspektion des darin enthaltenen Medikaments (5) ermöglicht und wobei die Fächer optional so hergestellt sind, dass sie eine wesentliche Vergrößerung oder Verkleinerung der wahrgenommenen Größe des darin enthaltenen Medikaments vermeiden.
  8. System nach Anspruch 1, wobei eine Aufstellung über die Anzahl von Medikamenten (5), die in jedem Behälter (19) enthalten sein sollten, auf jedem Verschluss (9) vorgesehen ist, und wobei die Patienteninformation optional in der Form eines Strichcodes auf jedem Verschluss vorgesehen ist.
  9. System nach irgendeinem vorhergehenden Anspruch, das ferner Anzeigemittel (107) aufweist, welche einem Benutzer zeigen, dass ein Verschluss (9) für die Fächer fehlerhaft in der Schale (2) positioniert worden ist, und wobei die Anzeigemittel optional einen oder mehrere Vorsprünge (107) aufweisen, die sich bei fehlerhafter Positionierung des Verschlusses behindern und ferner wobei die Anzeigemittel optional ein oder mehrere Ausrichtungsvorsprünge (107) aufweisen, die bei der korrekten Positionierung des Verschlusses helfen.
  10. System nach einem der Ansprüche 2 bis 9, wobei ein Befestigungsmechanismus (106; 107) für die zu öffnende Klappe (21) vorgesehen ist, der die Klappe in einer geschlossenen Position, die die Schale abdeckt, halten kann.
  11. System nach Anspruch 1, wobei eine leicht abbrechende bzw. Sollbruch-Verbindung (8) zwischen jedem Fach (4) und der Verbundanordnung (3) durch zumindest eine abbrechbare Lasche (8) gebildet ist, und wobei das Abbrechen der Lasche einen geschlossenen Behälter (19) aus der Anordnung freigibt; oder wobei eine Sollbruch-Verbindung zwischen jedem Fach (4) und der Verbundanordnung (3) durch mindestens ein perforiertes Glied gebildet ist, und wobei das Abbrechen entlang der Perforationen einen verschlossenen Behälter aus der Anordnung freigibt; oder wobei die Verbundanordnung eine Serie von Reihen (6) aufweist, wobei jede Reihe leicht abbrechend bzw. sollbruchmäßig mit der nächsten verbunden ist.
  12. System nach Anspruch 11, wobei eine Vielzahl von Bruchstellen zwischen jedem Fach (4) und der Verbundanordnung (3) ausgebildet ist und das Zerbrechen der Vielzahl von Bruchstellen einen verschlos-

senen Behälter (19) aus der Anordnung freigibt.

13. System nach einem der vorhergehenden Ansprüche, wobei der Verschluss (12) eine leicht abbrechende Anordnung individueller Deckel aufweist und die leicht abbrechende Anordnung von Deckeln und die Schale (2) aus einem zusammenhängenden Materialstück gebildet sind.

## Revendications

1. Système de distribution (1) pour l'administration de médicaments (5) pendant un régime de dosage de médicaments et comprenant :

(i) un plateau (2) comprenant :

un châssis (27) ;  
un réseau interconnecté (3) de compartiments (4), chacun des compartiments étant dimensionné pour accueillir une pluralité de médicaments ; dans lequel le châssis sert d'élément d'interconnexion pour maintenir les compartiments en position dans un réseau interconnecté ; et dans lequel lorsque chaque compartiment est retiré du châssis, il laisse une ouverture (11) dans le châssis ;

(ii) une fermeture (12) pour les compartiments, la fermeture comprenant une feuille qui comprend une fermeture individuelle (9) pour chacun des compartiments, la fermeture étant agencée de telle sorte que la fermeture et les compartiments forment une série de conteneurs hermétiques (19) pour contenir des médicaments ;

les compartiments et la fermeture étant agencés à cet effet de telle sorte que chaque conteneur hermétique est cassable pour se séparer du réseau interconnecté afin qu'un conteneur hermétique puisse être retiré du plateau, et en outre chaque conteneur hermétique contient des identifications identifiant le moment, dans le régime de dosage, où il faut administrer le médicament se trouvant dans le conteneur, et les conteneurs hermétiques sont disposés séquentiellement conformément à leur calendrier d'administration.

2. Système selon la revendication 1, comprenant en outre un volet ouvrable (21) qui permet un accès au plateau, et optionnellement dans lequel le volet ouvrable est un couvercle (21) pour former une partie supérieure du plateau.
3. Système selon la revendication 2, dans lequel le volet ouvrable (21) est formé d'une seule pièce avec

le plateau (2).

4. Système selon la revendication 2 ou 3, dans lequel un pli entre le volet (21) et le plateau (2) forme une charnière (100).

5. Système selon la revendication 4, dans lequel le plateau (2), le volet (21) et la charnière (100) sont formés à partir d'une seule pièce de matériau et optionnellement dans lequel le volet contient des informations sur le patient.

6. Système selon l'une quelconque des revendications précédentes, dans lequel chaque conteneur fermé (19) comprend des informations d'identification de patient.

7. Système selon l'une quelconque des revendications précédentes, dans lequel les compartiments (4) sont construits en un matériau sensiblement transparent qui permet une inspection visuelle des médicaments (5) contenus à l'intérieur, et optionnellement dans lequel les compartiments sont construits de façon à éviter un grossissement ou une réduction de la taille perçue du médicament contenu à l'intérieur.

8. Système selon la revendication 1, dans lequel un compte du nombre de médicaments (5) qui doivent se trouver dans chaque conteneur (19) est prévu sur chaque fermeture (9), et optionnellement dans lequel des informations sur le patient sont prévues sous forme d'un code à barres sur chaque fermeture.

9. Système selon l'une quelconque des revendications précédentes, comprenant en outre des moyens d'indication (107) qui indiquent à un utilisateur qu'une fermeture (9) pour les compartiments a été positionnée de façon incorrecte sur le plateau (2), et optionnellement dans lequel les moyens d'indication comprennent une ou plusieurs protubérances (107) qui interfèrent avec un positionnement non correct de la fermeture, et optionnellement en outre dans lequel les moyens d'indication comprennent une ou plusieurs protubérances d'alignement (107) qui aident à obtenir un positionnement correct de la fermeture.

10. Système selon l'une quelconque des revendications 2 à 9, dans lequel il est prévu un mécanisme de fixation (106 ; 107) du volet ouvrable (21) qui peut maintenir le volet dans une position fermée recouvrant le plateau (2).

11. Système selon la revendication 1, dans lequel une connexion cassable (8) est formée entre chaque compartiment (4) et le réseau interconnecté (3) par

au moins un onglet cassable (8), et le fait de casser l'onglet libère un conteneur hermétique (19) du plateau ; ou dans lequel une connexion cassable est formée entre chaque compartiment (4) et le réseau interconnecté (3) par au moins un élément perforé et le fait de casser suivant les perforations libère un conteneur hermétique du plateau ; ou dans lequel le réseau interconnecté comprend une série de rangées (6), chaque rangée étant connectée de façon cassable à la suivante.

12. Système selon la revendication 11, dans lequel une pluralité de points de rupture est formée entre chaque compartiment (4) et le réseau interconnecté (3), et la rupture de la pluralité de points de rupture libère un conteneur hermétique (19) du réseau.
13. Système selon l'une quelconque des revendications précédentes, dans lequel la fermeture (12) comprend un réseau cassable de couvercles individuels, et le réseau cassable de couvercles et le plateau (2) sont formés à partir d'une pièce continue de matériau.

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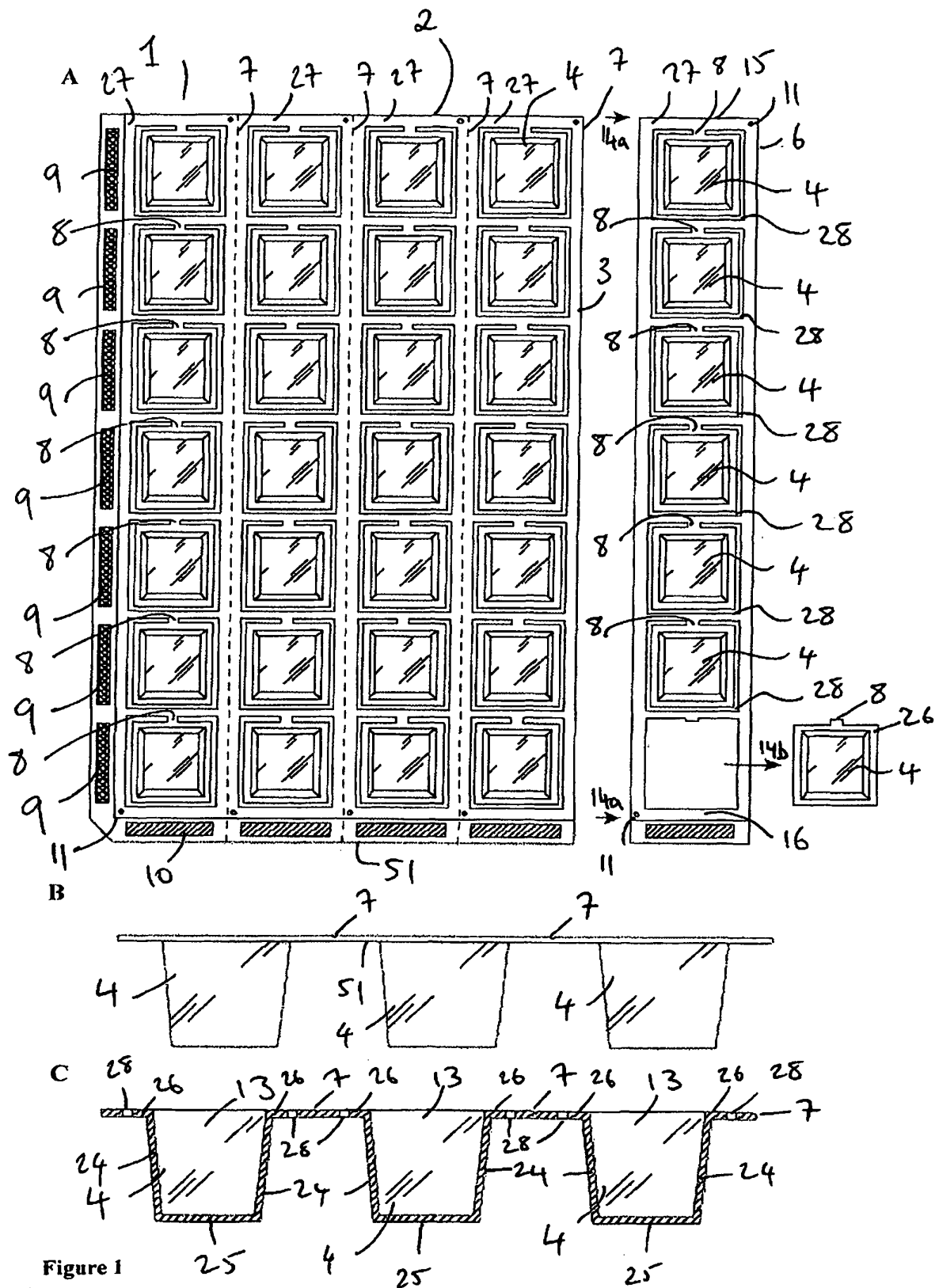
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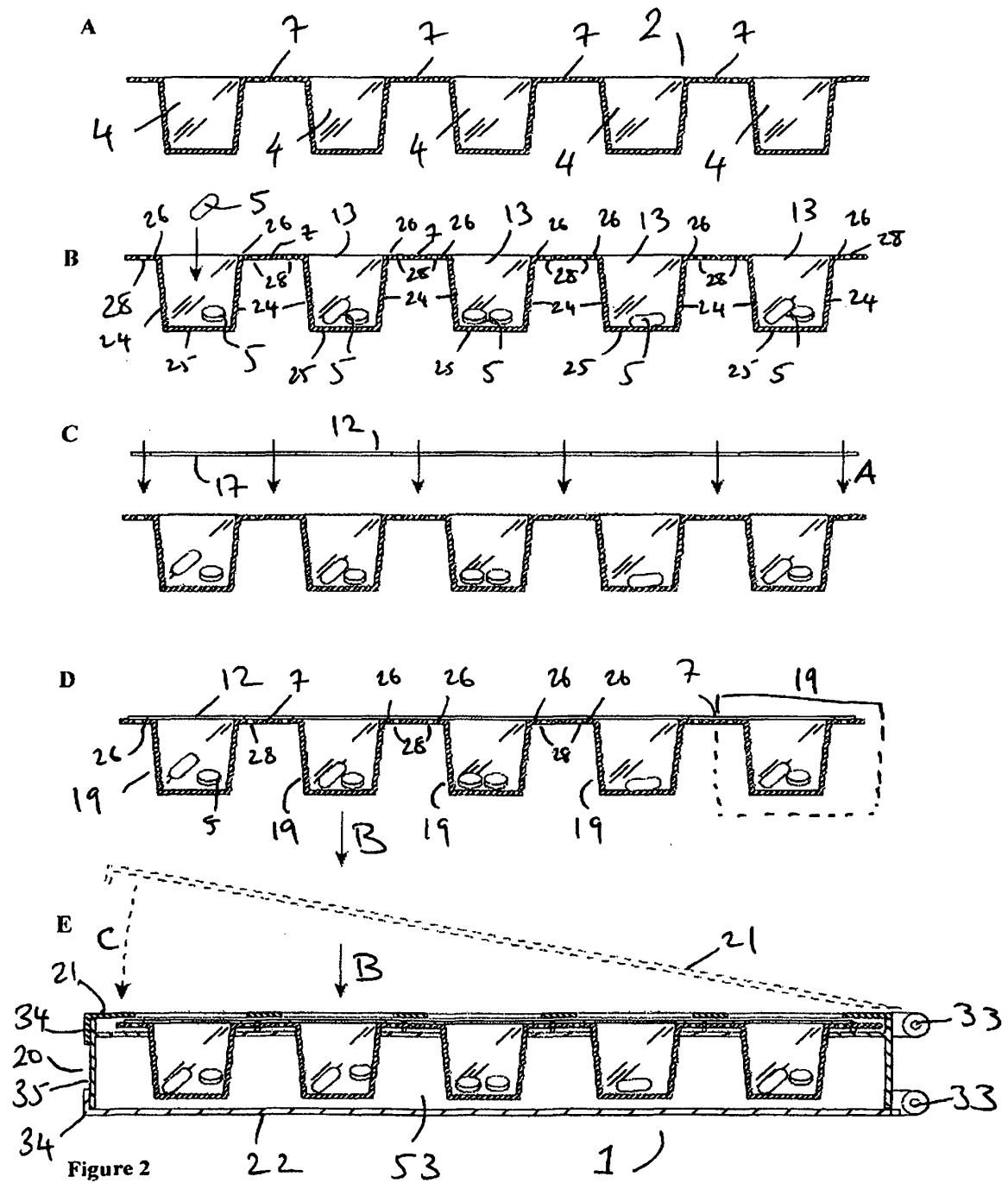
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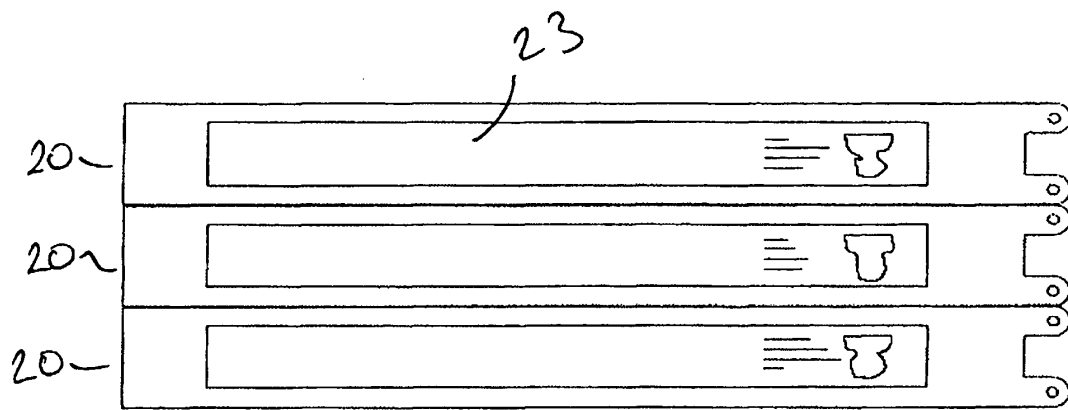


Figure 3

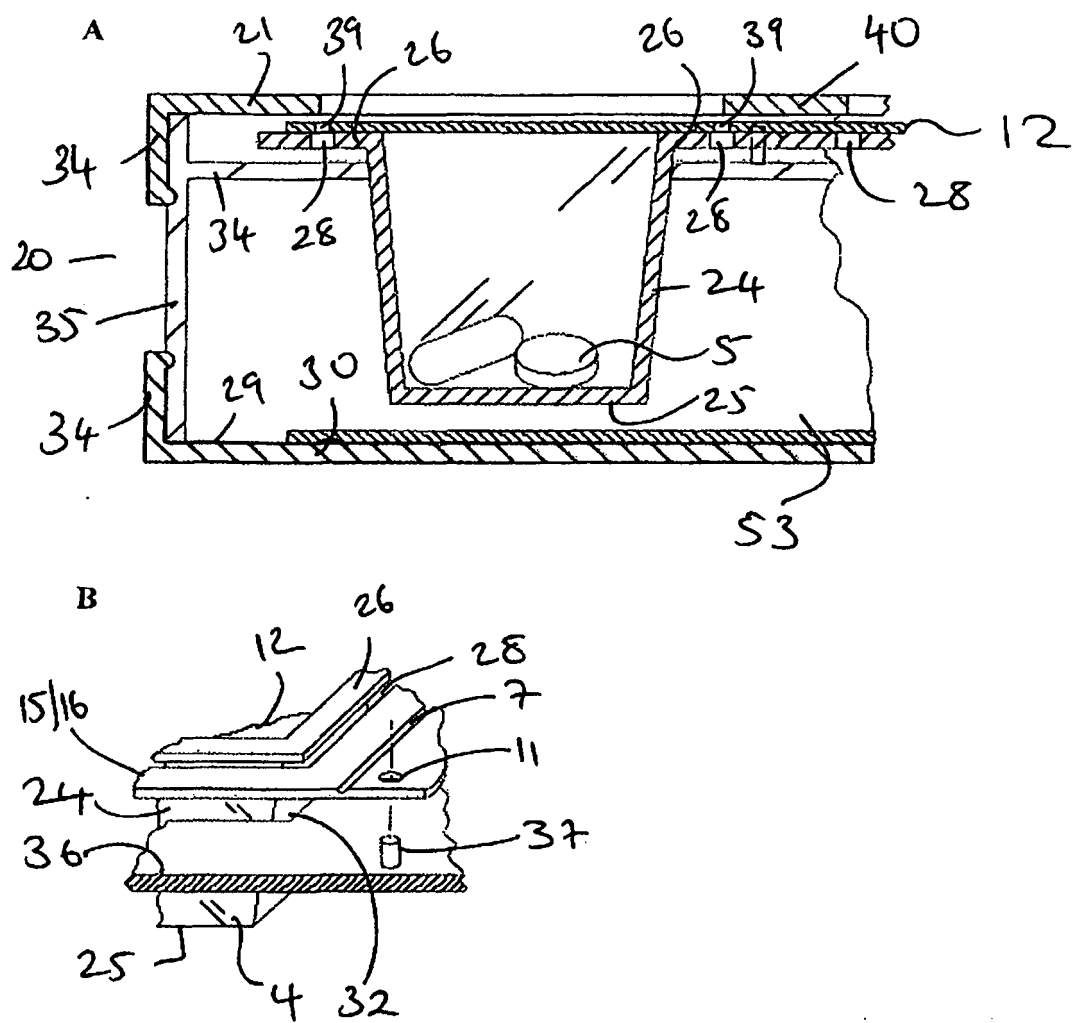


Figure 4

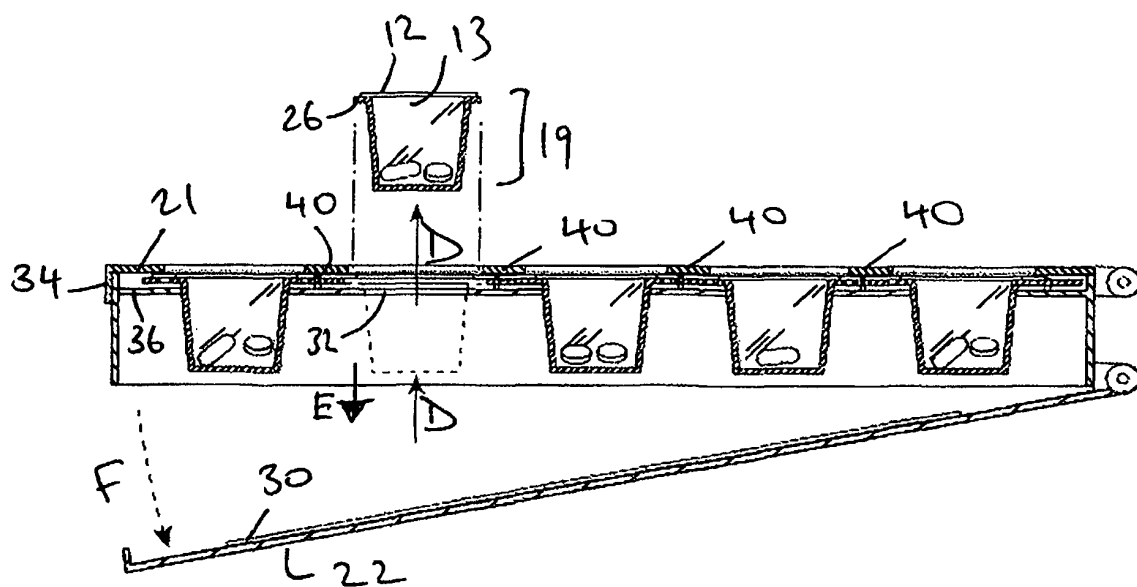
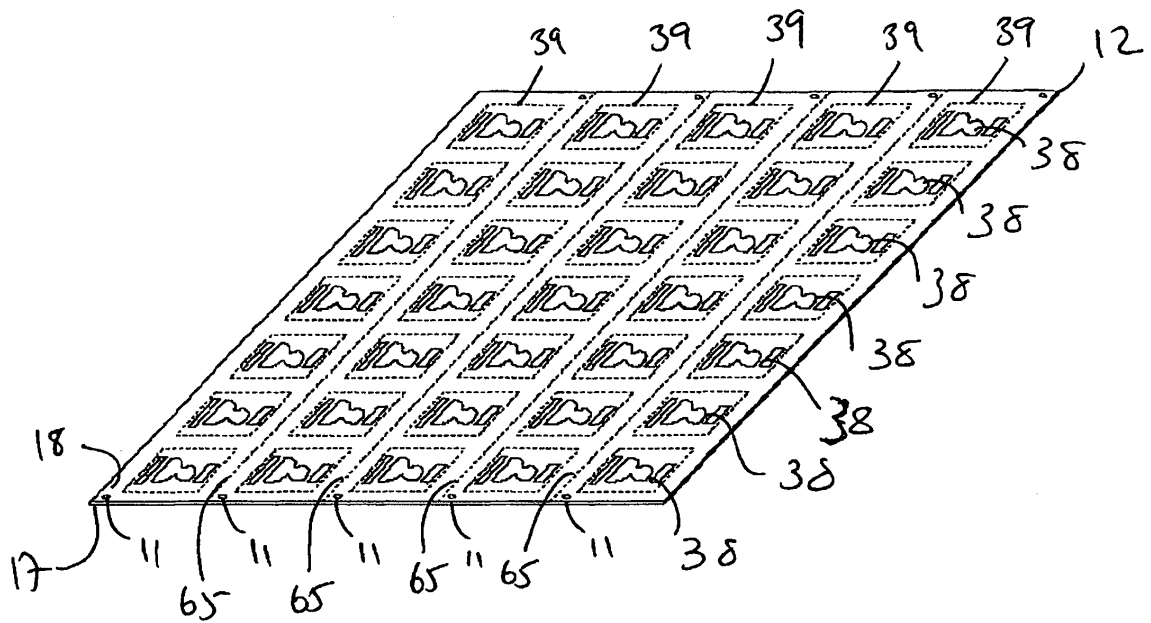


Figure 5



**Figure 6**

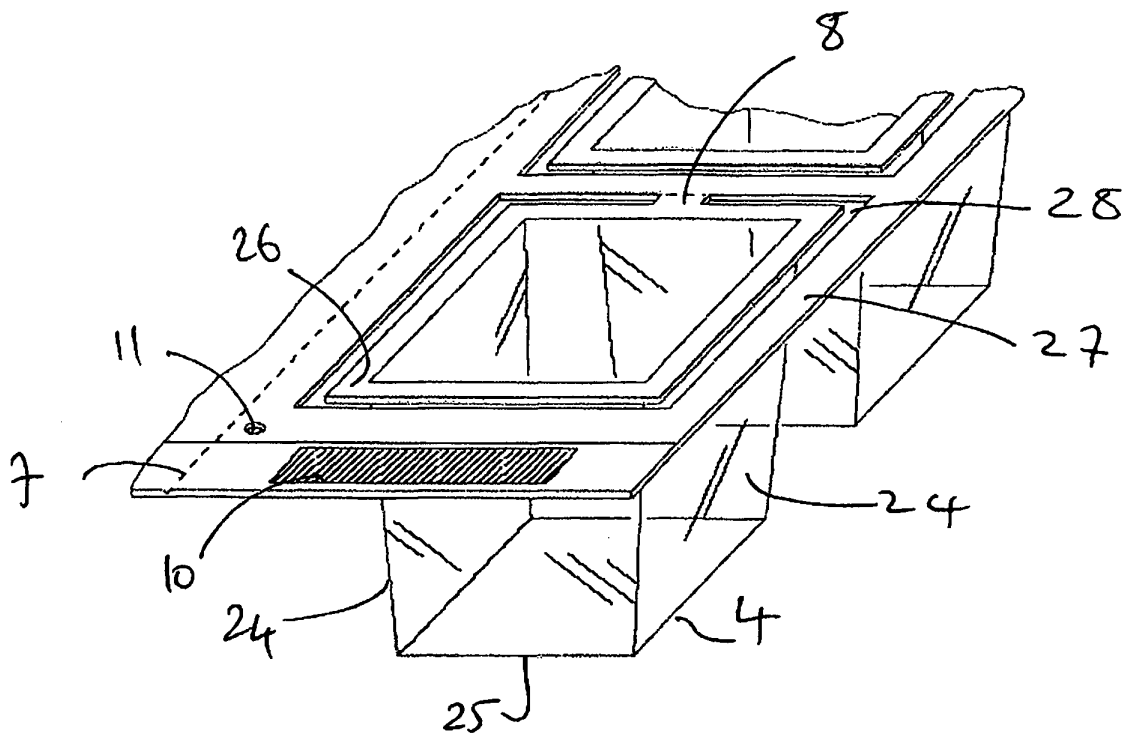


Figure 7

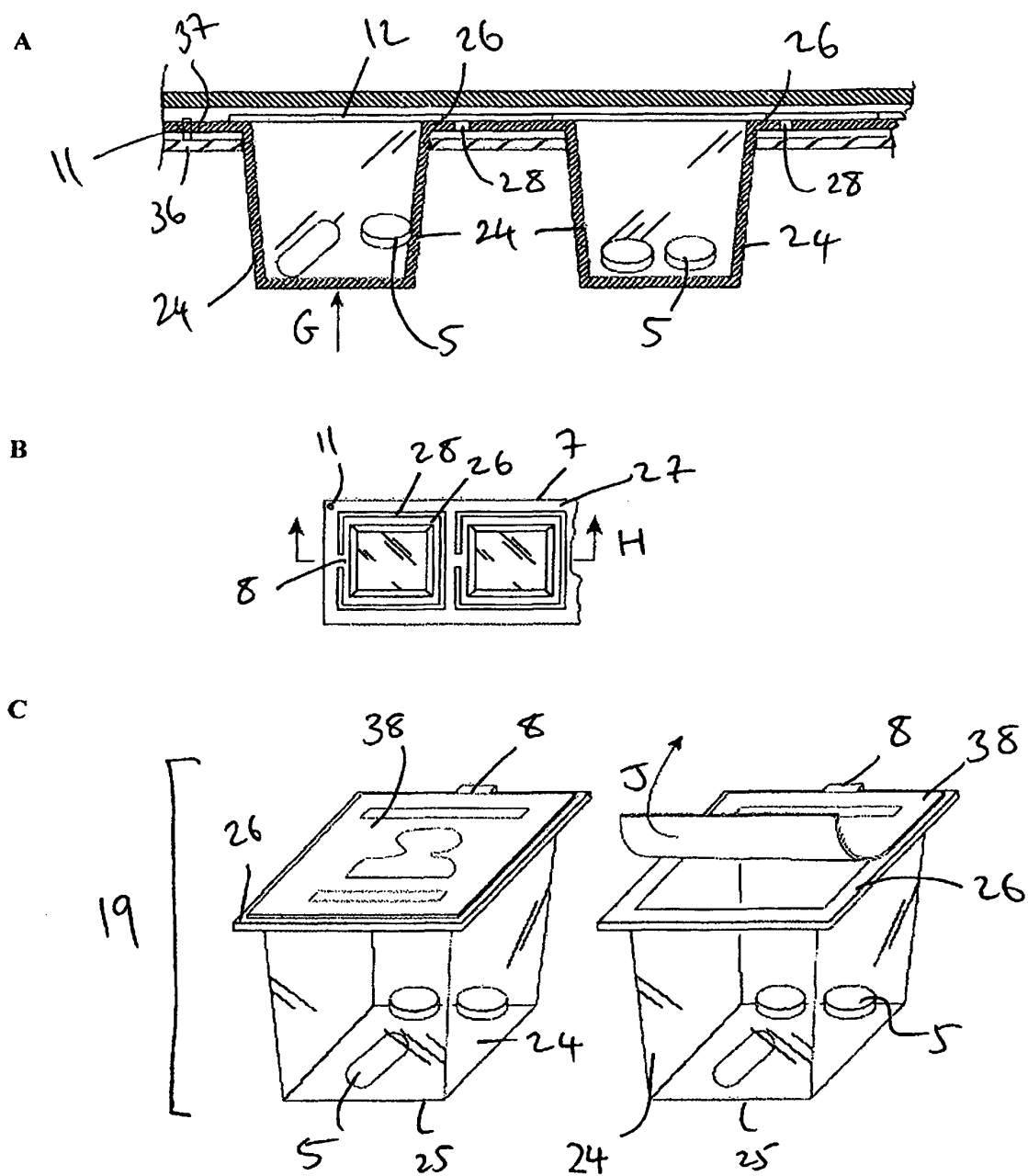


Figure 8

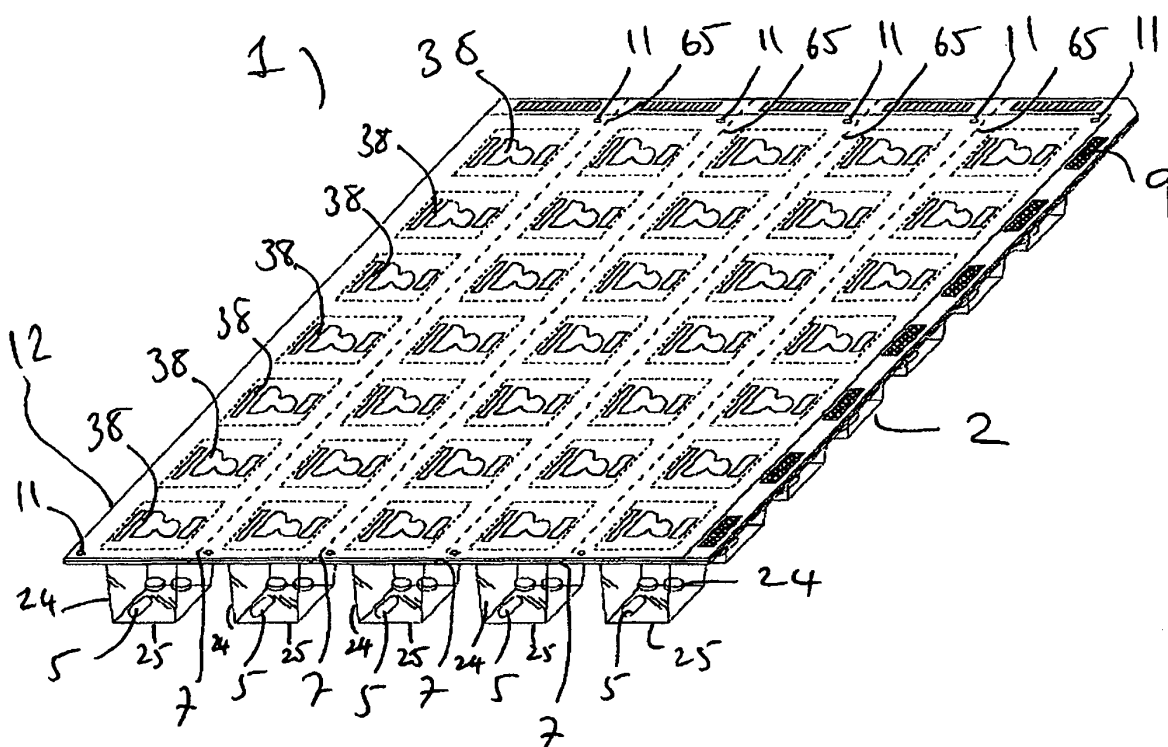


Figure 9

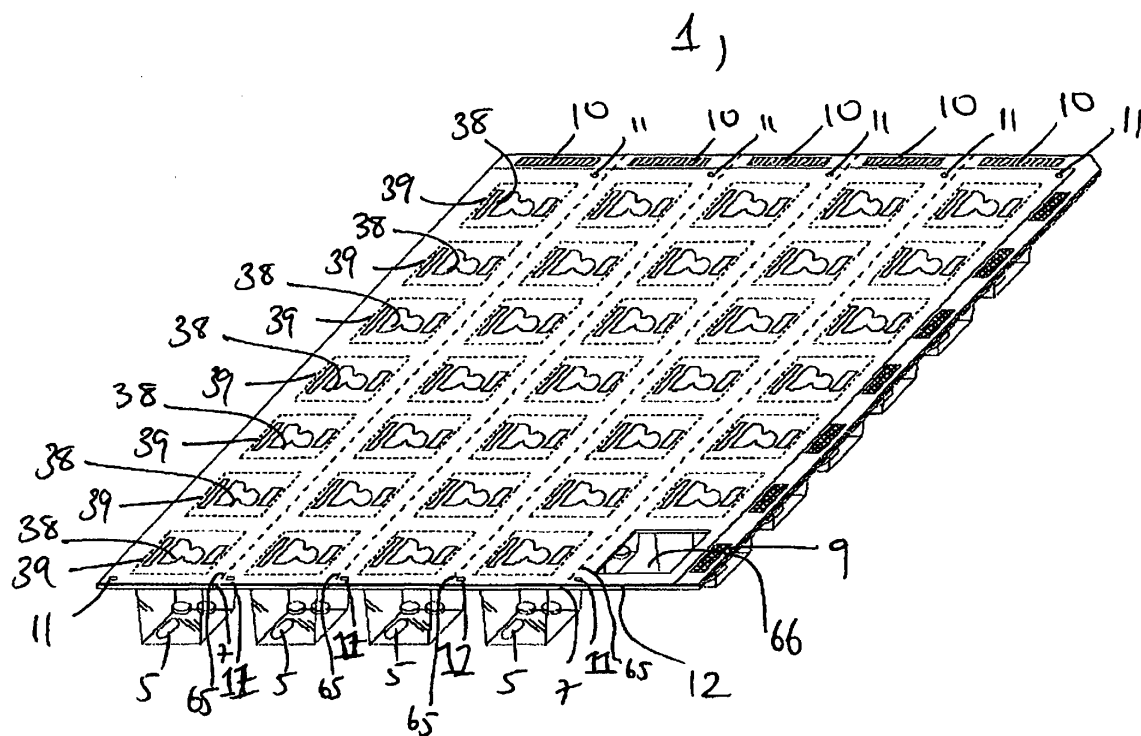
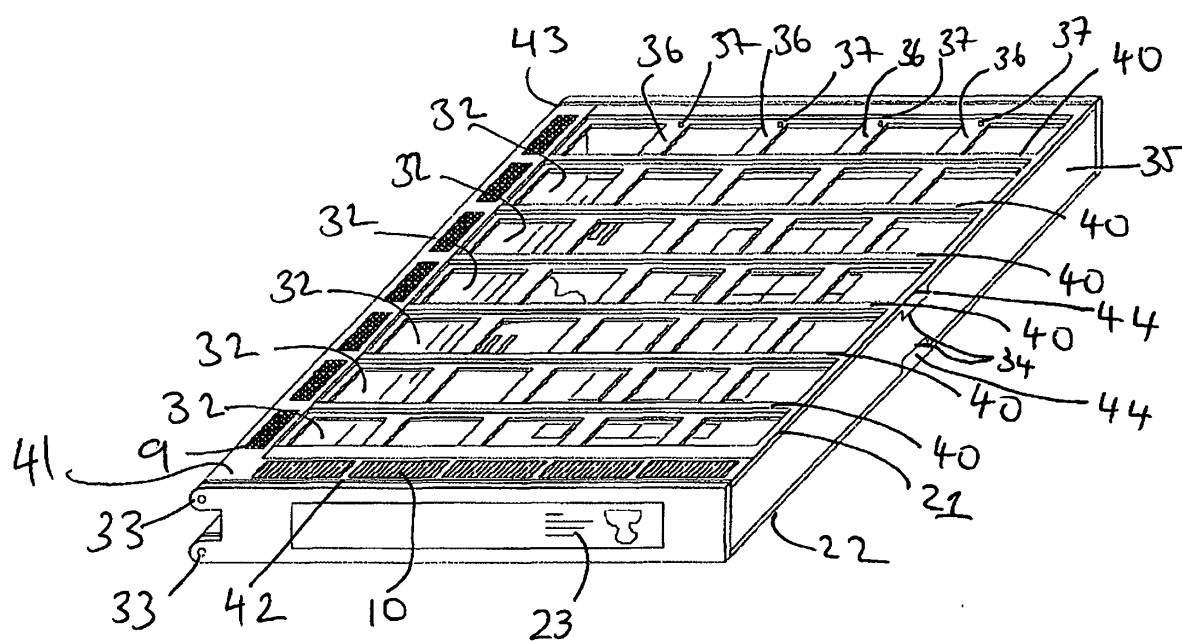


Figure 10



**Figure 11**

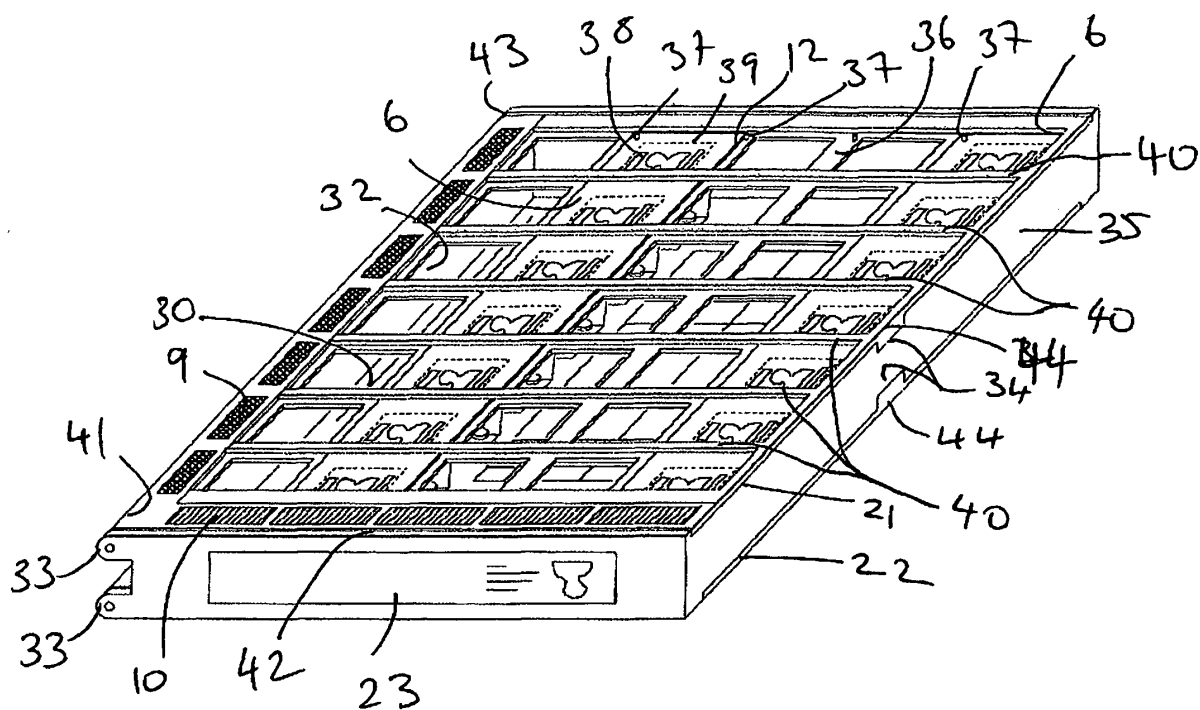
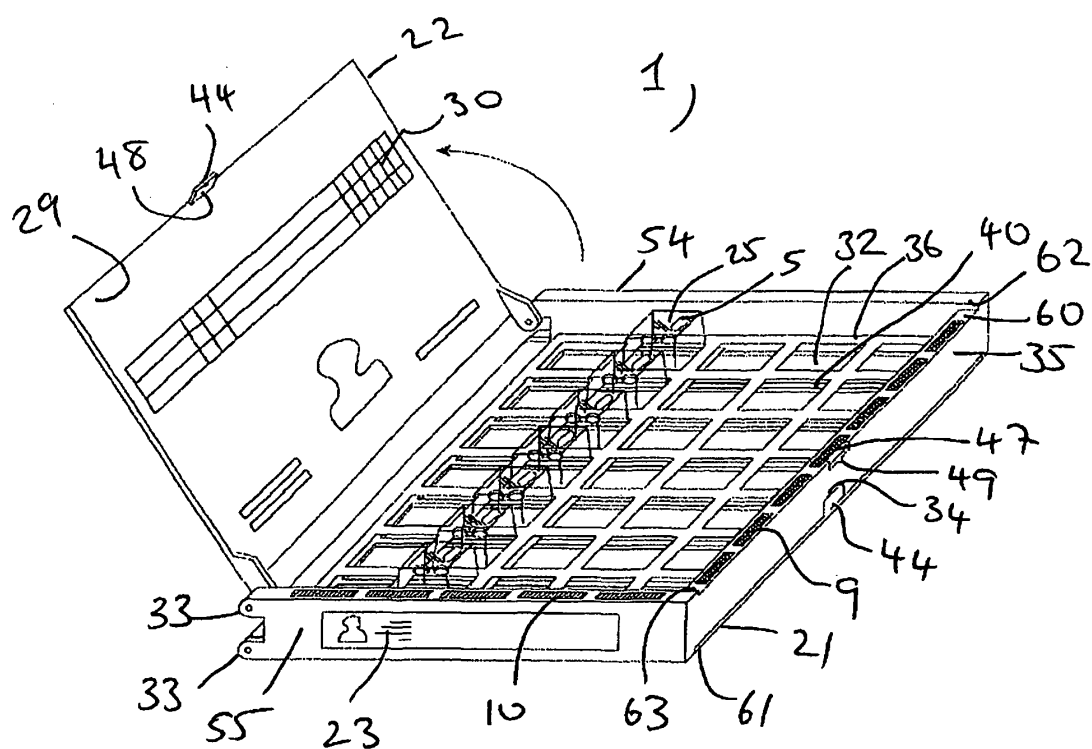


Figure 12



**Figure 13**

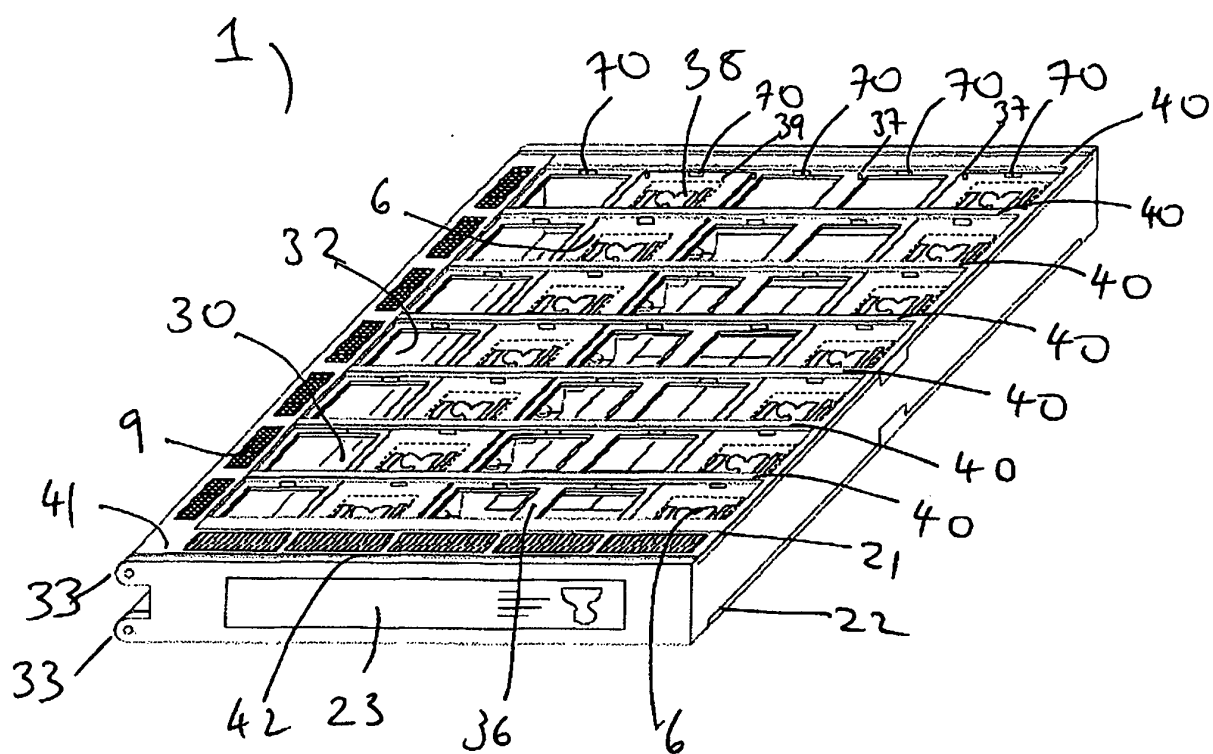
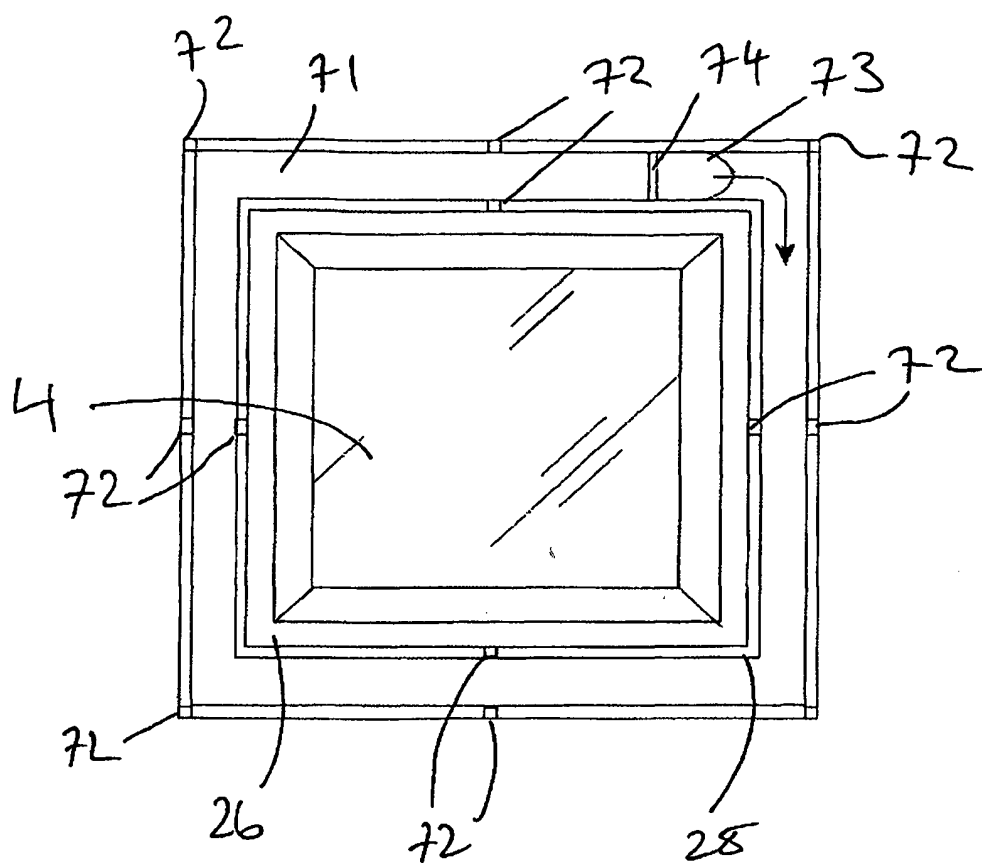


Figure 14



**Figure 15**

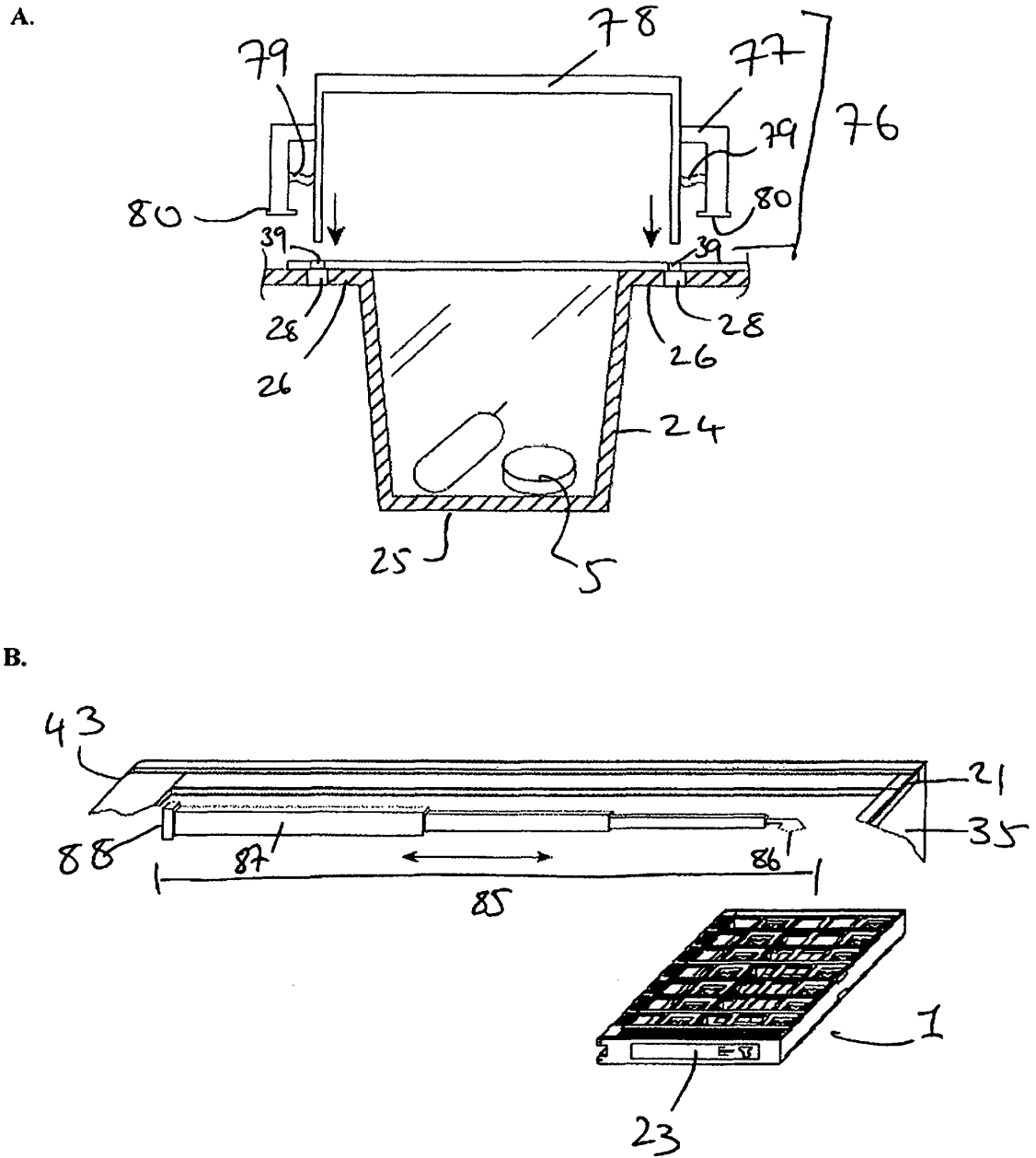


Figure 16

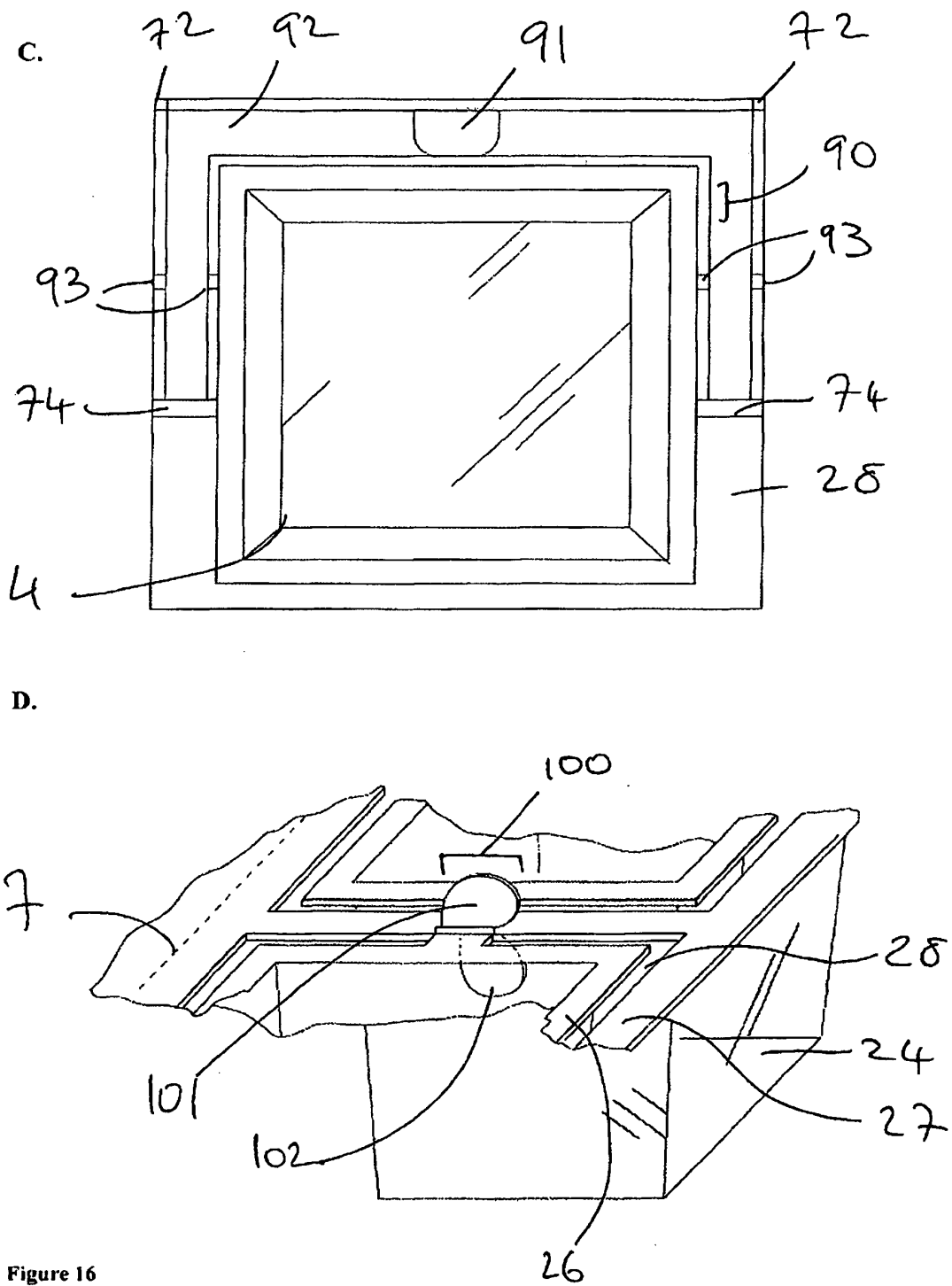


Figure 16

Figure 17

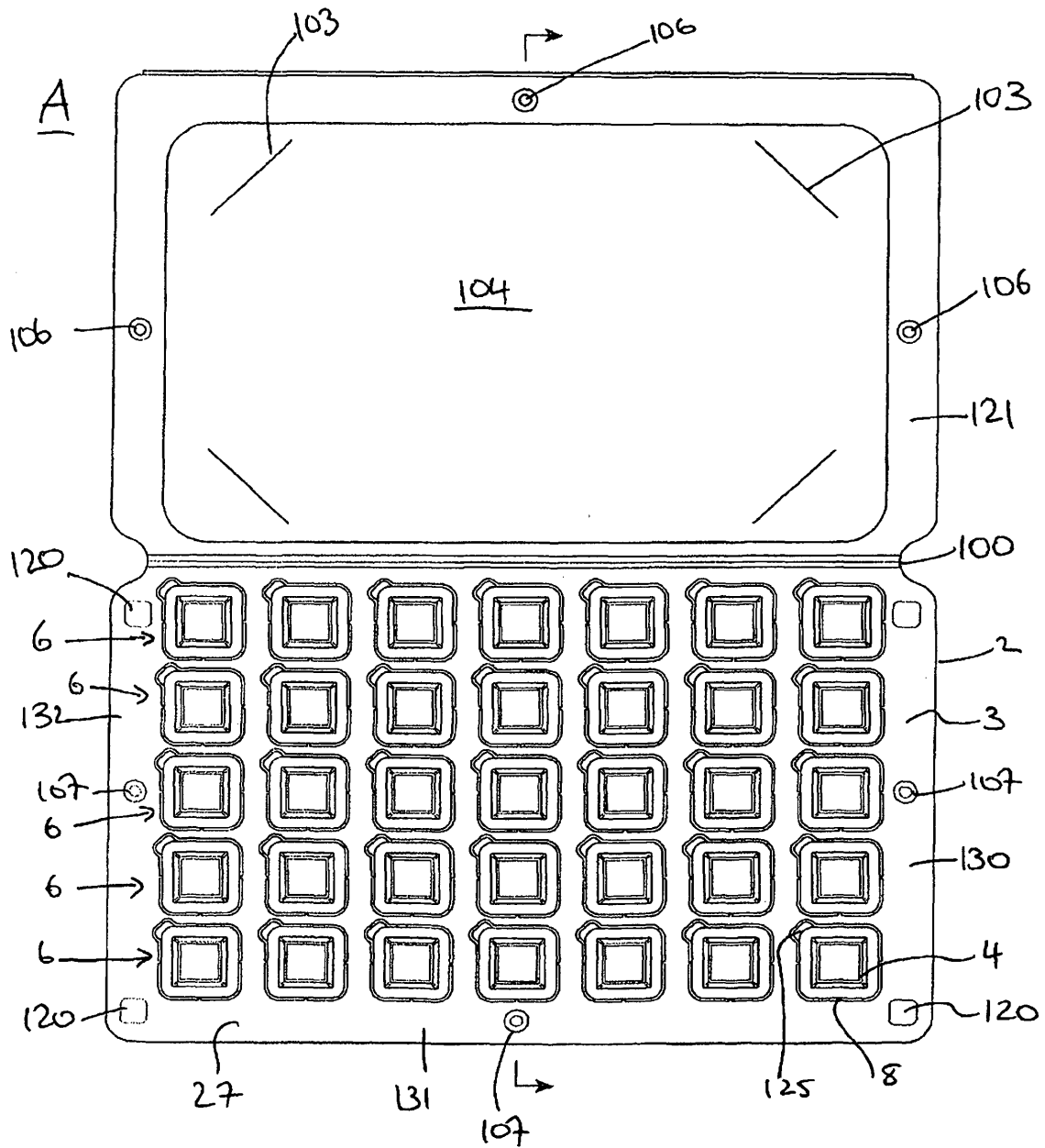


Figure 17 cont.

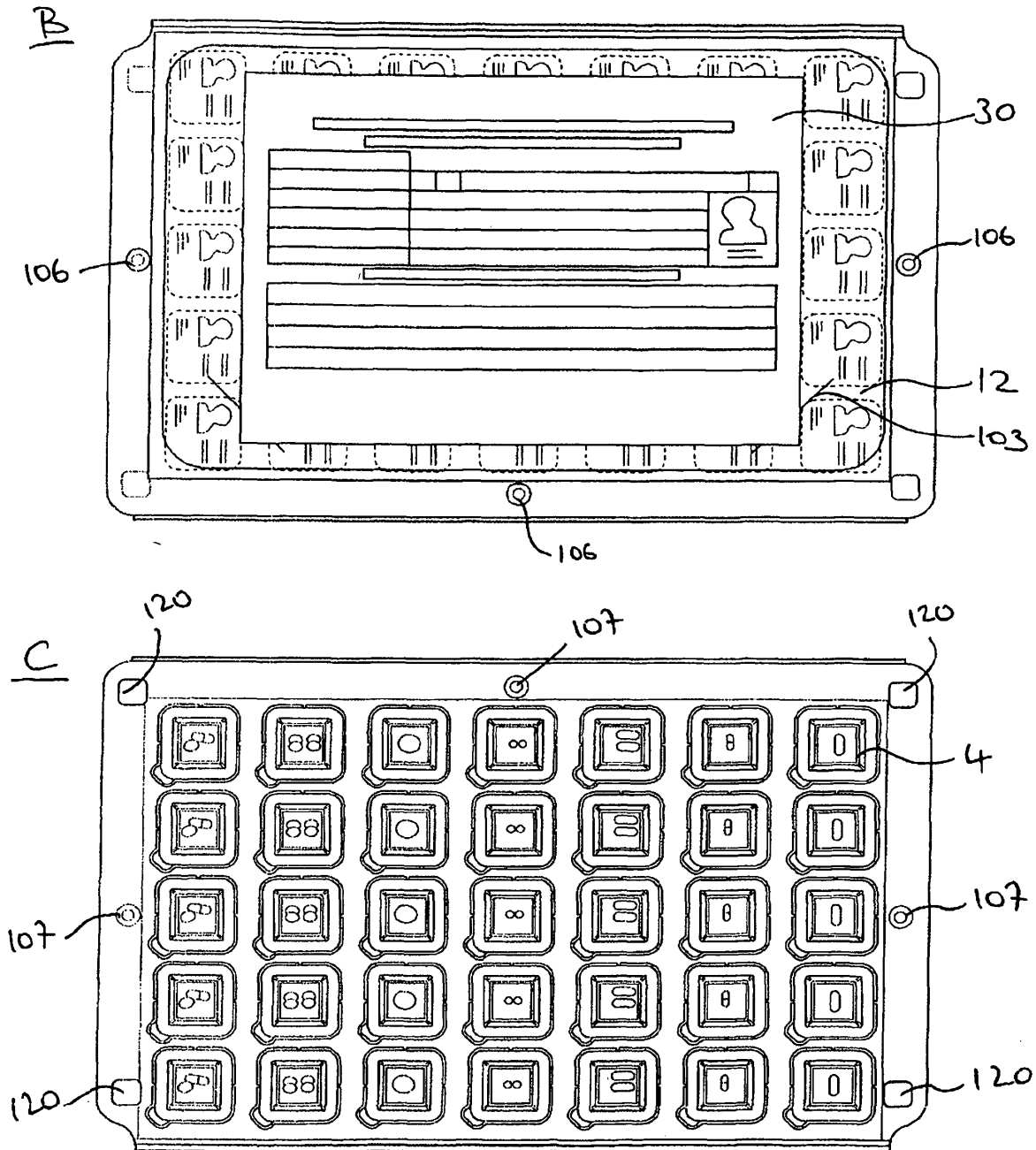


Figure 18

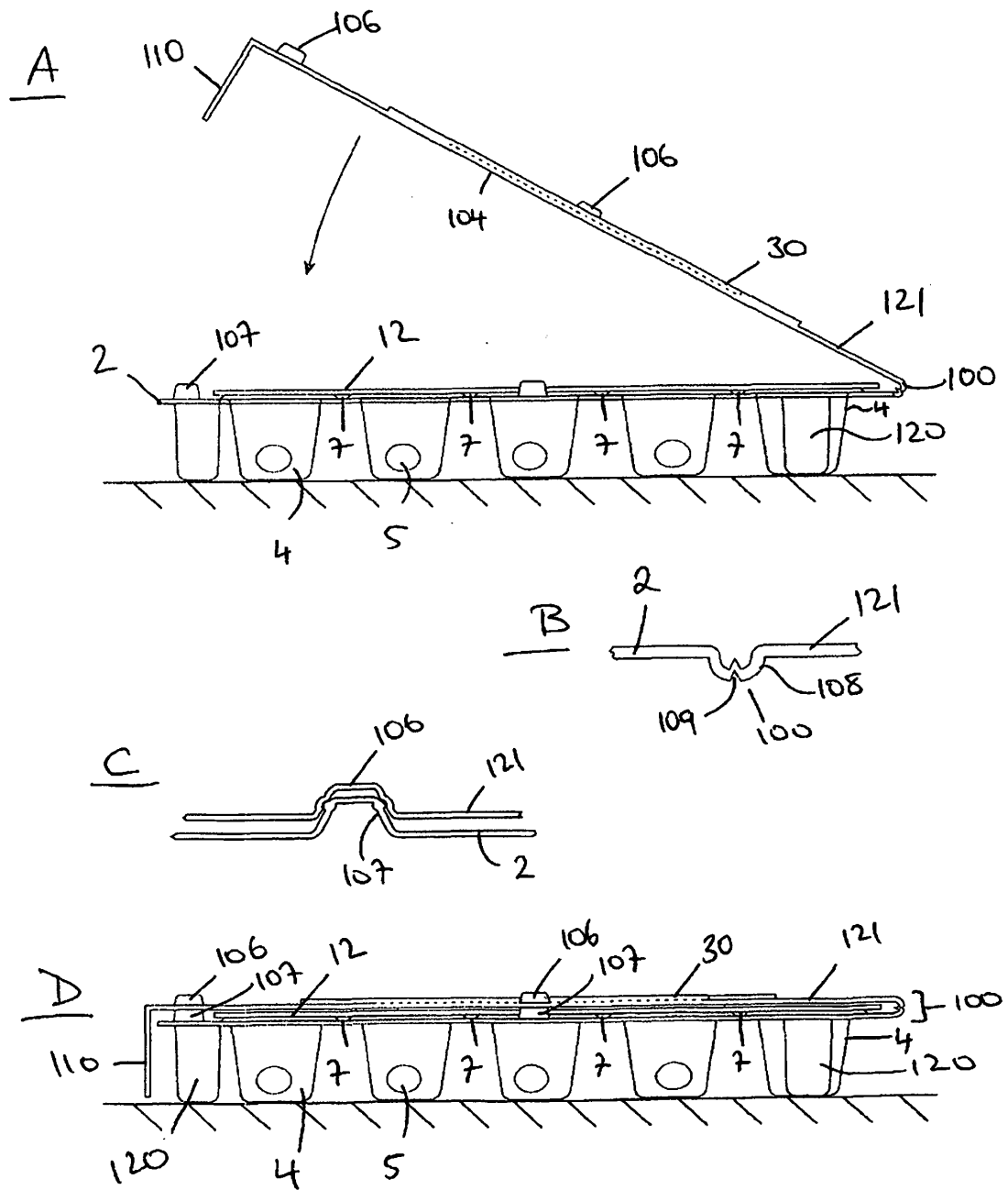


Figure 19

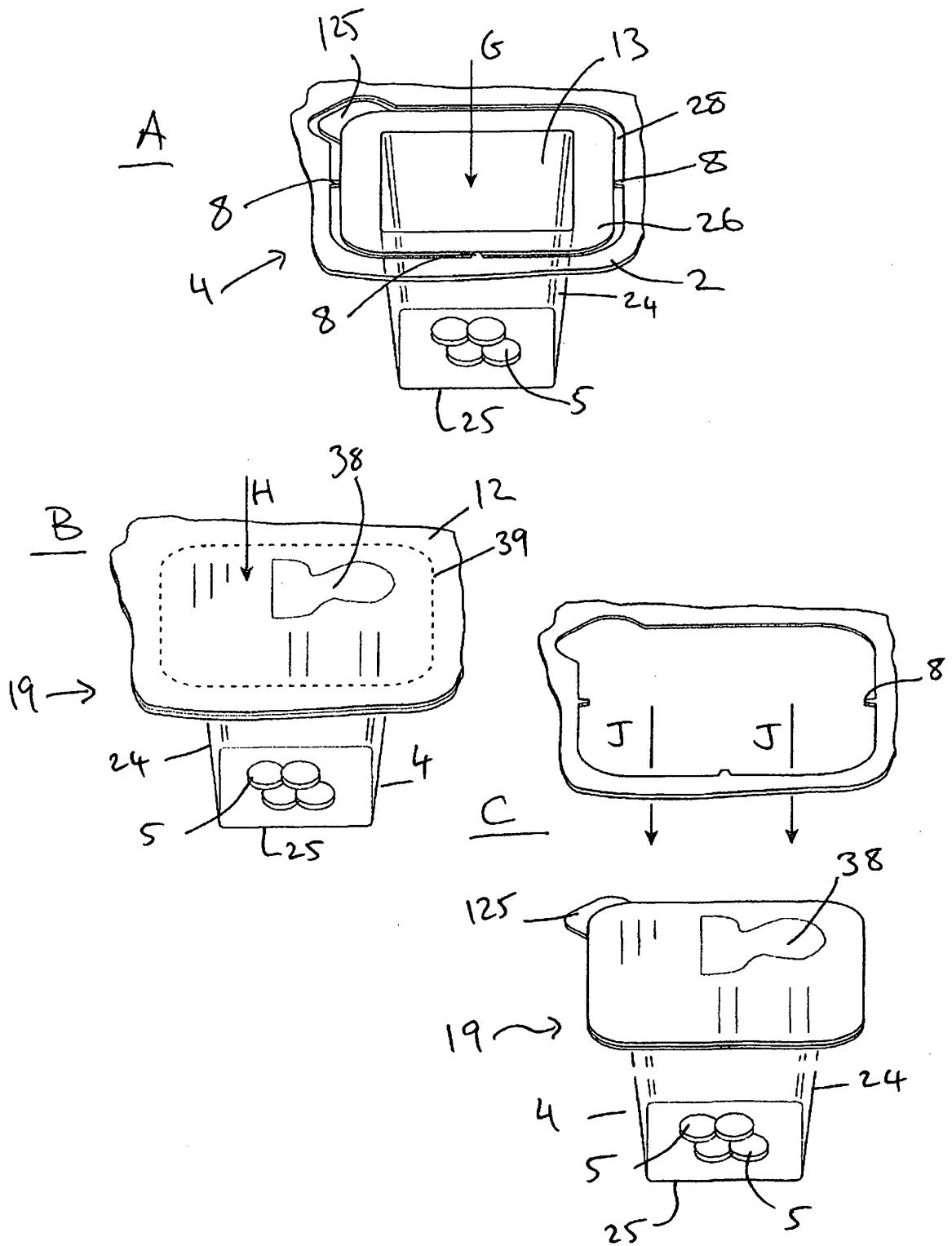


Figure 19 cont.

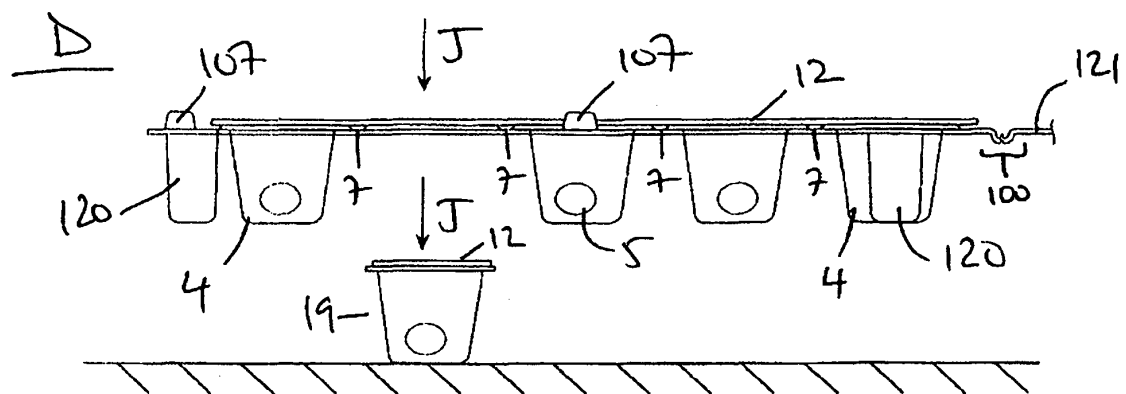
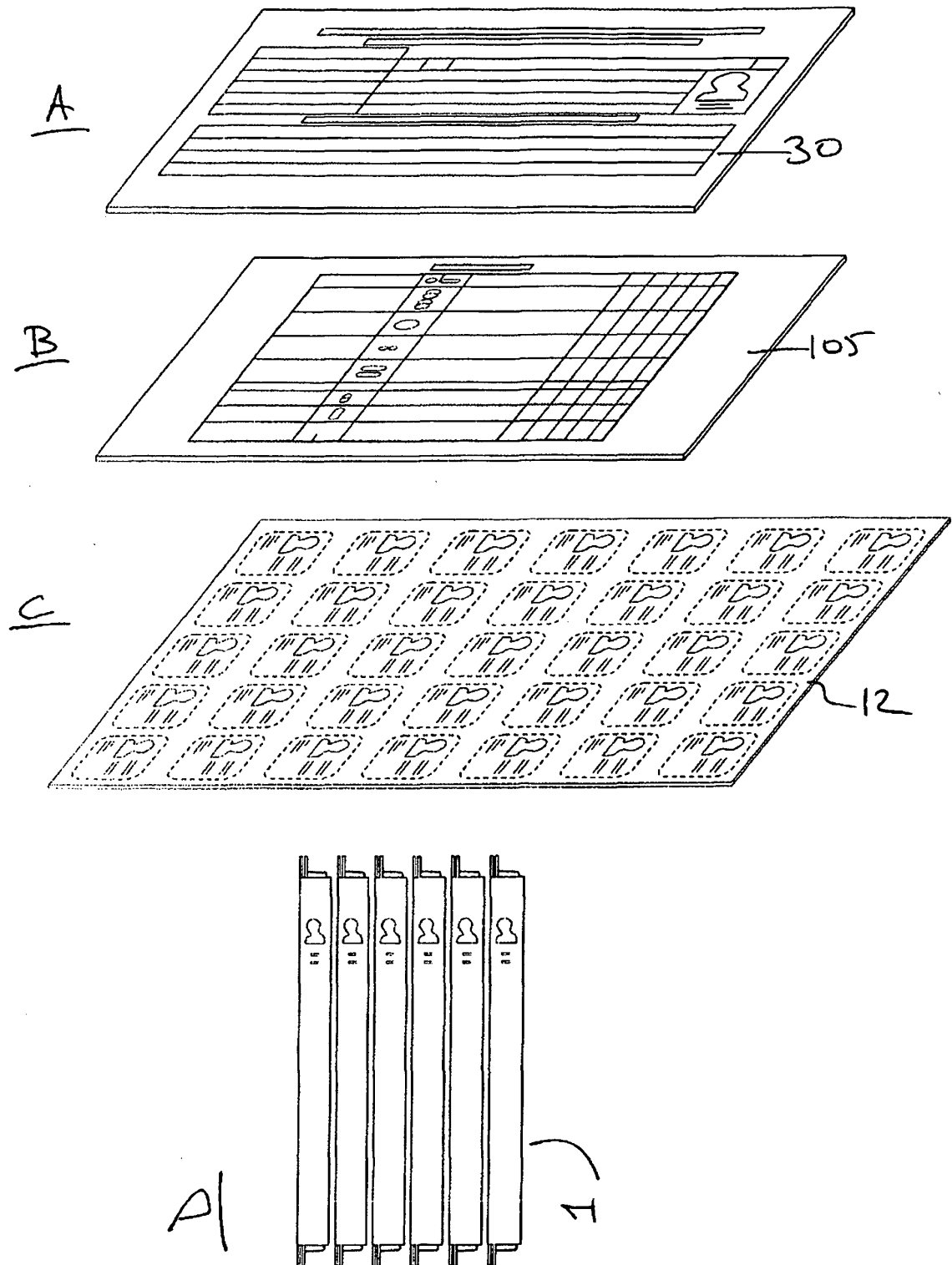


Figure 20



**REFERENCES CITED IN THE DESCRIPTION**

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