(19) DANMARK

(10) DK/EP 3011735 T3

(12) Oversættelse af europæisk patentskrift

Patent- og Varemærkestyrelsen

(51) Int.Cl.: *H 04 N 7/18 (2006.01)*

(45) Oversættelsen bekendtgjort den: **2017-06-12**

(80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2017-03-01**

(86) Europæisk ansøgning nr.: **14733248.0**

(86) Europæisk indleveringsdag: **2014-06-04**

(87) Den europæiske ansøgnings publiceringsdag: **2016-04-27**

(86) International ansøgning nr.: **FR2014051320**

(87) Internationalt publikationsnr.: **WO2014202859**

(30) Prioritet: **2013-06-20 FR 1355817** **2013-10-02 FR 1359545**

(84) Designerede stater: **AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR**

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(54) Benævnelse: **BILLEDOPTAGELSESFREMGANGSMÅDE OG -INDRETNING TIL SIKRET FREMBRINGELSE AF MEDICINSKE PRÆPARATER, TILHØRENDE BÆRER TIL POSITIONERING AF OBJEKTER**

(56) Fremdragne publikationer:
WO-A1-2009/073950
WO-A2-02/25568
US-A- 4 855 821
US-A- 6 011 876
US-A1- 2009 154 764

DESCRIPTION

TECHNICAL FIELD

[0001] The invention relates to a method for the secure, namely controlled and assisted, production of drug preparations and to an imaging system adapted to implement such a method.

[0002] The scope of the invention relates to the secure production of drug preparations enabling a release monitoring of such preparations. Such release monitoring is necessary since drug preparations are executed according to complex protocols, from reaction mixtures between components, with each component having a concentration adapted to a customized treatment for a given patient.

[0003] Any error on the nature of a component or the amount thereof may entail serious consequences for the patient whom the preparation is administered to, especially when a toxic active substance is involved, such as cytotoxic preparations used in cancer treatments.

[0004] In practice, operators can work several hours running, for example in hospitals preparation units, which substantially increases the risk of error on the composition or amounts of the components. Securing the preparations usually results from a double visual checking: checking of the key steps of each preparation and report in writing on an appropriate tracking medium, usually called a "Production Sheet".

[0005] In order to guarantee the quality of the drug preparations, AFSSAPS (French Agency for Safety of Health Products) published "Good Manufacturing Practices" which are a reference text for pharmacists. "Good Manufacturing Practices" specify the three obligations that must be complied with when implementing the raw materials used in drug preparations:

- the method for measuring the amounts of raw materials is selected according to the nature thereof and the quantity to be measured;

- the volume measurement or the weighing of raw materials quantities are saved;

- the raw materials are permanently identifiable during the above operations.

[0006] During the preparation, the nature of each raw material used as well as the weight or volume thereof are thus independently checked either by automatic saving means, or by a second person qualified under the terms of the Public Health Code and checking is noted in the preparation batch file. To meet the "Good Manufacturing Practices" and for the patient's safety, a double-checking of the nature and quantity of the compositions used in each preparation is thus recommended.

STATE OF THE ART

[0007] A device for monitoring and recording the times required for the dissolution and/or the

disintegration of drug tablets in a container is known from patent US 4,855,821. The camera lens is mounted on a side of the container. In this document, the monitoring and recording do not make it possible to check, in real-time, the nature of the compositions of the tablets or the volume thereof.

[0008] The patent document EP 1,867,998 provides a recognition of laboratory equipment from a RFID radio frequency identification tag (the initials of Radio Frequency Identification Device in English terminology) associated with a tag reader positioned on the instrument mounting and connected to a positioning stop. This solution is intended for the location and identification of laboratory equipment but it does not make it possible to check the nature, the volume or the weight of laboratory equipment.

DESCRIPTION OF THE INVENTION

[0009] The invention aims at remedying the problems mentioned above by dematerializing the production sheet using a graphic interface combined with video comparative analysis so as to cause the possible triggering of an appropriate warning with a monitoring in real time and an *a posteriori* control of the preparation.

[0010] More specifically, the present invention relates to a method for the secure production of drug preparations in compliance with a prescription on a predetermined site. The method consists in monitoring

the preparation at least in real time using a dynamic graphic interface using at least a so-called processing video stream making it possible to view the products on the preparation site with a display of information relating to the prescription once detected by a digital processing for identifying the components of the preparation and by comparing data of the steps of the preparation and stored data of the step of the prescription, in triggering a warning in case of a detected non-compliance between the data of the steps of the preparation and the prescription, and in validating the preparation in case of compliance between the steps data.

[0011] Said information relating to the prescription is preferably selected from a list of available vials according to the prescription and a list of vials used with the evolution of the volume of component taken from each of these. A display of the evolution of the volume injected into a delivery packaging and/or the missing volume and a warning display are also provided, with such information being optionally accompanied by a manual interaction to sample, inject a specific volume or to add a vial.

[0012] In advantageous embodiments:

- one of the so-called processing video streams is focused on object analysis data for a validation of steps, specifically of key steps of the preparation, and a so-called scene second video stream is focused on an overall view of the actions executed and the location of objects on the site;

- the detection extends to an automatic identification of the syringes by processing the first video streams using shape and character recognition;

- the processing stream consists of a double parallel stream, with each stream being adjusted for detecting objects in substantially different size ranges;

- an increment of the injected volumes and consequently of the remaining volume, of the number of injections, of the number of vials and of the leftovers is also automated from the graphic interface;

- the real-time warning is triggered if the vials and/or the volumes of the component detected prior to an injection do not comply with the prescription according to a stored protocol, with the warning being cancelled and the preparation being able to go on only if the compliance with the prescription is validated according to also displayed guidelines, with the progress of the preparation being then updated;

- the progress of the preparation is monitored in real time according to the data of the protocol of the identified prescription;

- the release of the preparation is validated by a confirmation that a stored patient's identification tag matches the patient's tag present on the delivery packaging;

- as the steps of the preparation are indexed, the steps detected as incorrect are identified by comparison with the step of the prescriptions, and the

subsequent validation of the steps detected as incorrect, especially key steps of the preparation, make it possible to go on with the preparation;

- an *a posteriori* checking carried out by a subsequent viewing of the video images is associated to each preparation with a synchronous browsing through at least two video streams, a processing stream focused on validation objects of the steps of the preparation and a so-called scene video stream focused on an overall viewing of the actions executed on the preparation site, in conjunction with the indexing of the analyzed steps, more particularly the key steps;

- a browsing through the history of the stored preparations is controlled by a search engine built in the digital control unit.

[0013] The invention also relates to a secure imaging system for drug preparations on a predetermined site comprising a dynamic graphic interface comprising at least one viewing and recording so-called processing camera having a focal length adjusted for the detection of objects liable to contain components and connected to a digital unit managing the video signals from the processing camera. Said unit has means for establishing a comparison between the stored data of the preparation in progress using the first images corresponding to the video signals and steps of the preparation of the prescriptions stored in a prescription memory and means for selecting a prescription in accordance with such comparison. Information on the selected prescription is displayed

with the images transmitted by the digital management unit on display means. Besides, warning means are able to be activated in the event that at least one step of the indexed preparation does not comply with the corresponding step of the selected prescription.

[0014] In preferred embodiments:

- the indexing means is adapted to index special steps specific to each prescription, so-called key steps, through the integration of information relating to each key step, in order to provide a synchronous indexation of the video streams upon the *a posteriori* checking, with the warning means being triggered in the event of non-compliance with at least one step of the preparation, especially a critical step;

- the dynamic graphic interface comprises at least another recording and viewing so-called scene camera having a focal length adjusted for the global detection of the site, with the processing camera and the scene camera having synchronized streams;

- the processing camera is composed of two cameras placed side by side having a focal length adjusted for the detection of objects in additional dimensions ranges;

- the processing camera is positioned at a mounting for positioning the products and preparation objects;

- the scene camera is positioned at a higher level so as to enable an overall view of the site;

- the mounting has a structure configuration adapted to the shape of the objects, which favors a stable and reproducible depositing of the objects, in particular the vials and the syringes, and includes a backlighting device for accurately reading syringe gradations.

The invention also relates to a device for filming a plurality of objects such as a vial and a syringe, for the secure production of drug preparations.

According to the invention, the device comprises:

- at least a pair of filming devices positioned opposite one another,

- a reflective element for each one of the filming devices,

with the two reflective elements of the same pair of devices being positioned between said devices along the axis defined by the two devices and each one being oriented so as to reflect images of a drug preparation production area towards the matching device.

The device may have one and/or the other of the following characteristics:

- the two areas covered by the two devices of the same pair of devices are identical, and the devices have different zoom lens making it possible to focus on objects with different sizes which are present in the drug preparation production area,

- the two reflective elements consist of flat surfaces associated together by a common edge,

- the two flat surfaces are formed by two adjacent faces of a prism with a triangular cross-section,

- the device comprises an elongate base at both ends of which the filming devices of a same pair are attached, with the associated reflective elements being attached to the base,

- the device comprises means for attaching to a mounting for positioning the objects involved in the production of a drug preparation

- the device comprises means for attaching to a production chamber of a drug preparation.

The invention also relates to a mounting for positioning objects comprising at least one syringe and one vial of a fluid to be taken with the syringe, comprising a flat base for supporting the objects, a screen standing at the back of the base and a syringe holder mounted to translate with respect to the base between a disengaged position independent of the base and an engaged position in the base.

The positioning mounting may have one and/or the other of the following characteristics:

- the syringe holder is mounted to translate through a slide connection with the base in a recess formed from the upper face of the base

- the upper surfaces of the base and of the syringe holder are co-planar and comprise matching reliefs for accommodating a vial, which form a relief for accommodating the bottom of a vial, such as a

recess or a rib, when the syringe holder is in its engaged position

- the syringe holder comprises a rack for retaining the wings of a syringe and a longitudinal block for supporting the body of the syringe

- when the syringe holder is in its engaged position, the recess for accommodating the bottom of a vial is positioned between the rack retaining the wings of a syringe and the block for supporting the body of the syringe, when the latter is in its engaged position.

The invention also relates to a system for filming a plurality of objects for the production of a drug preparation comprising a filming device as defined above, a mounting for positioning objects as described above, and a chamber for producing drug preparations, with the mounting for positioning objects being positioned inside the chamber, and the filming device outside thereof against a transparent window of the chamber, and at a position such that images of the mounting for positioning objects, can reach the filming devices of the system.

In this system, the filming device and the mounting for positioning objects preferably comprise additional attaching means placed opposite each other on either side of the transparent window.

DESCRIPTION OF THE FIGURES

[0015] Other data, characteristics and advantages of the present invention will become apparent from the following non restrictive description, with reference to the appended figures which represent, respectively:

- Figure 1 is a perspective view of a drug preparations site equipped with an example of the secure imaging system for such preparations;

- Figure 2 is a view of the real-time display of the invention incorporating an image provided by a processing camera, and

- Figure 3 is a view of the display of an *a posteriori* control of a drug preparation obtained using a processing camera and a scene camera

- Figure 4 is a front perspective view of a system for filming syringes and vials of various sizes, including a preparation chamber, a mounting for syringes and vials, inside the chamber, and a filming device outside the chamber,

- Figure 5 is a perspective top view of the system of Figure 4,

- Figure 6 is an exploded view of the device of Figure 4,

- Figure 7 is an exploded view of the mounting for syringes and vials of Figure 4, showing a syringe holder in the disengaged position with respect to a support base,

- Figure 8 is a perspective view of the right side of the mounting supporting a syringe,

- Figure 9 is a perspective view of the left side of the mounting without a syringe.

DETAILED DESCRIPTION

[0016] Reference is made to the perspective view of Figure 1 showing a portable hood 1 incorporating a drug preparation site 10. The site 10 is equipped with an imaging system 20 for the secure production of such preparations. This system includes a so-called processing camera 21. The focal length of the camera 21 is adjusted to focus on containers and drug administration tools, here 22 a vial, a drip pouch 30 containing a saline solution, and a syringe 23. In the example the vial 22 contains cisplatin to be diluted in the drip pouch 30. For this purpose, a sample is taken by the operator from the cisplatin vial 22 using the syringe 23 and then injected into the drip pouch 30. The operation is repeated until the desired dilution of the active ingredient in the pouch is obtained to prepare, in the example, a polychemotherapy component.

[0017] Advantageously, the bottom 11 of the hood 1 has a structure configuration adapted to the shapes of the objects, which favors a stable and reproducible deposition of the vials and syringes, and includes a backlighting device 12 facilitating the reading of the syringes gradations 23.

[0018] The processing camera 21 is positioned at the bottom of the hood 11, slightly above the workbench 3 whereon the portable hood 1 is placed, i.e.

substantially, facing the operator's stomach (not shown), in the example.

[0019] The processing camera 21 is connected to a digital management unit, a laptop computer 25 in the example. The computer 25 mainly comprises a processor and memories (not shown) which process the video signals Sv1 from the processing camera 21 to provide images to a display screen 24 and record same.

[0020] The display screen 24 then makes it possible to view information corresponding to the preparation in progress from the video stream FV_1 provided by the processing camera 21.

[0021] Another recording and viewing so-called scene camera 27, has a focal length adjusted for an overall detection of the site 10. The lens of the scene camera 27 is advantageously positioned at the upper level 13 of the hood 1 so as to enable an overall view of the site 10 by transmitting a video stream FV_2 to the display screen 24.

[0022] The processing 21 and scene 27 cameras provide video signals Sv_1, Sv_2 synchronized by the computer processor 25 so as to form a dynamic graphic interface for real-time and *a posteriori* controls.

[0023] The processing camera 21 is advantageously composed of two cameras placed side by side 21a, 21b, the focal length of which is adjusted to detect objects - vials and syringes in general - in additional size ranges of less than 3cm and ranging from 3 to 10cm in this example.

[0024] An example of real-time display on the screen 24 is shown in Figure 2. The display includes here an image 34 from the video stream from the processing camera 21b focused on the cisplatin vial 22. The video stream of the processing cameras 21a and 21b are analyzed by a shape and character recognition tool, built in the computer processor 25 (see Figure 1).

[0025] The analysis enables the automatic identification of the objects used, i.e. a vial 22 and a syringe 23, by processing the first video streams using the recognition tool. The detection of product volumes contained in the syringes and the vials enables a non-destructive control of the active substance used in the preparation.

[0026] The delivery of the preparation is validated by a match between the patient's identification tag stored in the information insert E1 and the patient's identification tag on the syringe.

[0027] All data printed on the vial 22 tag 22a, in particular the concentration in active substance are thus identified by said recognition tool. Such data is stored in the computer 25. During the preparation, analysis data relative to the vial and syringe content are displayed on the screen 24 and saved for validating each step of the preparation: amount of liquid in the syringe 23 and the liquid level in the vial 22 (see below).

[0028] The computer processor 25 searches a memory, wherein a set of prescriptions is stored, with

the prescription corresponding to the preparation in progress. For this purpose, the stored prescriptions are indexed by steps using a digital indexing tool. The key steps - i.e. the specific steps that are specific to each prescription - have a particular indexation, for example EC1, EC2,…

[0029] The processor compares the stored data of the preparation in progress provided by the first recorded images 34 - name of the components, amounts poured into the syringes, etc. - and steps of the stored prescriptions. As soon as a key step of such prescription is recognized, the prescription corresponding to the preparation in progress is then identified and displayed through the steps thereof in an insert E2. Information is selected based on the prescription detected from a list of available vials and a list of vials used which has been stored in the computer according to data supplied by the laboratory management center.

[0030] A warning display 26 is integrated in the insert E2 as well as the possibility of a manual interaction to sample or inject a given volume, or add a vial.

[0031] In addition, the progress of the preparation is displayed based on data of the stored protocol corresponding to the identified prescription: information relative to the management of the volume contained in the vial 22 and the evolution of the injected/missing/prescribed component volumes in the syringe 23 are displayed respectively in the inserts E4

and E5. Such management information is initiated by an increment of the injected volumes and consequently the remaining volume, the number of injections, the number of vials and the remaining quantities. This increment is automated from the graphic interface of the synchronized video streams from the cameras 21 and 27. Such management makes it possible to significantly reduce the errors due to handling operations.

[0032] The warning display 26 is activated in real time as soon as the vial and/or the component volumes detected prior to the injection in one step do not comply with the stored protocol of the identified prescription. The steps detected as errors are identified by comparison with the steps of the prescription. Non-compliance of a key step triggers a search for errors in the identification of the prescription which has been selected.

[0033] The display then provides guidelines in the insert E4 and the warning is cancelled and the preparation goes on only if the compliance between the steps of the preparation and those of the protocol of said prescription is validated. The progress of the preparation is then updated in real time until the final validation indicated in the insert E2. The preparation is thus secured by an almost instantaneous reactivity and the reproducibility of the preparations is optimized.

[0034] The validation of the steps detected as incorrect, especially the key steps of the preparation

makes it possible to carry on with the preparation up to the completion thereof.

[0035] Referring to Figure 3, the *a posteriori* checking of the cisplatin-based preparation is displayed on the screen 24. The stored tags of the preparation and of the patient are displayed in an insert E6 (patient's name, active molecule and injection date). Recorded images of the processing 34' and scene 35 video streams respectively from the processing camera 21 and the scene camera 27 are also displayed. The scene video stream is focused on an overall viewing of the actions executed and of the location of the objects on the site 10, here the vial 22 and the syringe 23.

[0036] The *a posteriori* checking is executed through a subsequent viewing of the video recordings from a synchronous browsing between the processing and scene video streams, in conjunction with the indexing of the steps of the preparation, of the key steps in this example.

[0037] Thus, the steps of preparation P1 to P26, the indexing of the key steps "I", as well as the time of their implementation are displayed in the insert E7. In the example, the step P4, i.e. the step of presentation of the vial P4 is not validated. This is a key step the correction of which is saved as necessary for the final validation. This situation is explained by displaying a particular insert E8. Other key steps of the vial presentation (P13, P14) and syringe presentation (P5, P22) are indexed.

[0038] Additionally, the previous preparations are stored and browsing through a history of such preparations, controlled by an integrated search engine, makes it possible to display comparisons with the preparation in progress.

[0039] The invention is not limited to the embodiments described and shown. The preparation can thus be in a stationary hood or any environment adapted to install the imaging system.

[0040] Besides, the number of cameras is not limited to two or three but adapted to the types of preparation desired. Similarly, the management of the steps of the preparation can be adapted to the various prescriptions.

[0041] In addition, a final report is prepared on the conditions of production of the preparation from the recordings, with highlighting of errors and problems.

[0042] Referring to Figures 4 to 9, an exemplary filming system implementing the method for the secure production of drug preparations is described.

[0043] This system is positioned on either side of a transparent window 40 of a chamber used for the secure production of a drug preparation, and comprises a filming device 41 positioned outside the chamber against the transparent wall 40, and a mounting for positioning objects 42 positioned inside the chamber opposite the filming device.

[0044] More specifically, as best seen in Figure 6, the filming device 41 comprises two processing cameras 43, 44 positioned at both ends of an elongated, rectangular base 46, a reflective element 47, 48 for each filming device 43, 44, positioned at mid-length of the base 46.

[0045] The two reflective elements 47, 48 are oriented along the axis defined by the two cameras, so as to reflect images of the syringe and vials support 42 towards the corresponding camera.

[0046] More specifically, the two reflective elements are formed by two adjacent rectangular faces of a totally reflecting prism with a triangular cross-section 49, with the prism being mounted on the base through one of its triangular bases.

[0047] The two cameras 43, 44 have different focal lengths to focus on objects of various dimensions placed on the syringes and vials mounting. For example, the right camera can be devoted to the focusing on small-sized vials and syringes with a 12mm lens, the left one on large vials and syringes with a 8mm lens.

[0048] For the filming device to have small dimensions, both cameras will also have small dimensions, for instance 47x29x29mm (LxWxH). One example of cameras suitable for such use is reference DFK23F445 by Imaging source®.

[0049] The elongate base 46 is attached inside a box 51 comprising a front flat and substantially

rectangular face 52, with two shorter sides slightly rounded, and provided with a substantially rectangular viewing central window 53 and a rear elongated shell 54 wherein the base is firmly attached by its rear longitudinal edge, with the prism 49 being placed in the window opening 53 when the front face 52 of the box closes the shell 54, so that the images of the syringes and vials mounting can reach both cameras 47, 48 through the prism.

[0050] The front face 52 may be attached to the shell 54 by means of screws passing through holes 56 provided for this purpose at the four corners of the front face and screwed into a corresponding sleeve 57 provided for this purpose on the inner wall of the rear shell 54.

[0051] The rear shell 54 also comprises two lugs 58 extending vertically from its lower side edge 59, with such lugs being provided with a circular central recess for accommodating a matching magnetic means (a metallic or magnetized chip, not shown) intended for holding the syringes and vials 42 mounting which is provided with additional magnetized means against the glass wall 40 and the front face 52 of the box.

[0052] The shell 54 further comprises two rigid side plates 61 attached to the external face of its back wall and protruding from both sides of its ends, with these two plates 61 carrying two suction cups 62 facing forward in order to be attached to the glass window of the chamber.

[0053] Moreover, according to Figure 7, the syringes and vials mounting 42 comprises a mounting flat base 66, an inclined screen 67 standing behind the base to form a white background and a syringe holder 68 mounted to translate relative to the base 66 between a disengaged position independent of the base 66 (shown in Figure 7) and an engaged position in the base 66 (shown in Figure 4).

[0054] More specifically, the syringe holder 68 comprises a rectangular plate 69, at one end of which a block 71 protrudes, which has a substantially rectangular shape but the upper wall of which is a longitudinal recess 72 (the upper wall is made of converging inclined surfaces joining at a common edge, thus defining a "M"-shaped cross-section) to be used as a mounting for the body of a syringe, and to laterally hold such syringe body by the inclined faces.

[0055] At the other end, the plate 69 of the syringe holder 68 comprises a rack 73 retaining the wings 74 of a syringe 75. Such rack 73 is formed by two parallel walls, separated from each other by a distance sufficient to accommodate the wings 74 of a syringe 75 (see Figure 8), and have the shape of a "M", like the block 71, to support and laterally hold the syringe part near the wings 74.

[0056] According to Figure 9, an additional rack 76 is provided for the small-sized syringes mounting, between the block 71 and the main rack 73, closer to the block 71, and in the form of a "M"-shaped single

wall 76 and the groove of which is at the same level as that of the block 71.

[0057] As shown in Figure 7, the plate 69 of the syringe holder 68 comprises two thinner side edges 77 adapted to slide in grooves formed on the side edges of a recess accommodating the plate provided in the base 66 so as to slidingly engage the syringe mounting in the base up to an engaged position (Figure 4).

[0058] In this engaged position, the syringe mounting 68 and the base 66 together define a relief for accommodating the bottom of a vial 78.

[0059] Specifically, the upper surfaces of the base 66 and the plate 69 of the syringe mounting 68 are coplanar when the syringe holder is in its engaged position and comprise complementary recesses 78 for accommodating half disc-shaped vials and which form a circular recess for accommodating the bottom of a vial when the syringe holder is in its engaged position, with the recess being then positioned between the retaining rack 73 and the support block 71. Of course, another relief, such as a circular rib, may provide the same function.

[0060] The base 66 carries the magnetic means 81 matching those 58 provided on the filming device. More specifically, such magnetic means (a magnetic or metal chip, depending on the one used for the magnetic means of the filming device) are accommodated between two pins 82 vertically projecting from the edge of the base 66 opposite the screen 67, and having a flat front wall

which can be pressed against the inner face of the glass wall at the level of the matching lugs 58 on the filming device.

[0061] The system as described above makes it possible to implement the method for the secure production of drug preparations, even when syringes and vials of different sizes are used, thanks to the plurality of filming devices having different lens used and to the reflective elements enabling such devices to collect images of the same area: the syringes and vials mounting.

[0062] This object is further achieved with the smallest possible overall dimensions due to the use of a central prism for both filming devices.

Patentkrav

1. Fremgangsmåde til sikret frembringelse af et medicinsk præparat, der overholder en recept på et bestemt sted (10), **kendetegnet ved, at** den består i at følge præparatet mindst i realtid med en dynamisk grafisk grænseflade (21, 27), der anvender mindst en videostrøm (FV1, FV2), en såkaldt behandlingsstrøm, der muliggør visualisering af produkterne (22, 23, 30) på fremstillingsstedet (10) med en visning af oplysninger (24) vedrørende recepten, så snart den er detekteret gennem en digital behandling til identificering af præparatets bestanddele og gennem en sammenligning mellem dataene for fremstillingstrinnene og dataene for de lagrede recepttrin (E2, E4, E5), at udløse en advarsel (26) i tilfælde af manglende overensstemmelse mellem dataene for fremstillingstrinnene og den detekterede recept og at godkende præparatet (E2) i tilfælde af overensstemmelse mellem trindataene.

2. Fremgangsmåde til sikret frembringelse ifølge krav 1, hvor oplysningerne vedrørende recepten fortrinsvis er udvalgt blandt en liste over flasker, der er til rådighed afhængigt af recepten, og en liste over flasker, der anvendes med udviklingen i volumen af udtaget bestanddel i hver af dem, idet der ligeledes er tilvejebragt en visning af udviklingen i injiceret volumen i en indgivelsesemballage og/eller i manglende volumen (E5) og en advarselsvisning (26).

3. Fremgangsmåde til sikret frembringelse ifølge et hvilket som helst af kravene 1 eller 2, hvor en af videostrømmene (FV1), en såkaldt behandlingsstrøm, fokuseres på objektanalysedata (E4, E5) med henblik på en godkendelse af trin (E2), især nøgletrin i fremstillingen, og en anden videostrøm (FV2), en såkaldt scenestrøm, er fokuseret på en samlet visualisering af de igangsatte handlinger og lokaliseringen af objekterne på stedet (10).

4. Fremgangsmåde til sikret frembringelse ifølge et hvilket som helst af de foregående krav, hvor detekteringen omfatter en automatisk identificering af sprøjterne (23) gennem en behandling af de første videostrømme (FV1) ved hjælp af form- og karaktergenkendelse.

5. Fremgangsmåde til sikret frembringelse ifølge et hvilket som helst af de foregående krav, hvor behandlingsstrømmen (FV1) består af en dobbelt parallel strøm, idet hver strøm er justeret til detektering af objekter (22, 23, 30) inden for i det væsentlige forskellige dimensionsområder.

6. Indretning til billedoptagelse af en flerhed af objekter, såsom en flaske og en sprøjte, med henblik på sikret frembringelse af medicinske præparater, omfattende:

- mindst et par billedoptageapparater (43, 44), der er anbragt over for hinanden,
- et reflekterende element (47, 48) for hvert af billedoptageapparaterne, dannet af to tilstødende flader af en prisme med trekantet tværsnit, der er indsat mellem apparaterne langs den akse, der er defineret af de to apparater, og hver orienteret således, at den i retning mod det tilsvarende apparat reflekterer billeder af en samme zone til frembringelse af et medicinsk præparat, idet de to apparater (43, 44) har objektiver med forskellige brændvidder, som gør det muligt at indstille skarpt på objekter af forskellig størrelse, der befinder sig i zonen til frembringelse af det medicinske præparat,
- midler til fastgørelse (58) til en bærer til positionering af objekter, der er involveret i frembringelsen af et medicinsk præparat,
- midler til fastgørelse til et indelukke til frembringelse af et medicinsk præparat.

7. System til sikret billeddannelse af medicinske præparater på et bestemt sted (10), som er egnet til at udføre fremgangsmåden ifølge et hvilket som helst af de foregående krav, **kendetegnet ved, at** det omfatter en dynamisk grafisk grænseflade, der omfatter mindst et visualiserings- og optagelseskamera, et såkaldt behandlingskamera, (21 ; 21 a, 21 b) som har en brændvidde, der er indstillet på detektering af objekter, der kan indeholde bestanddele, og er forbundet med en enhed til digital styring af (25) de videosignaler (SV1), som kommer fra behandlingskameraet (21 ; 21 a, 21 b), **ved, at** enheden (25) har midler til sammenligning mellem lagrede data for den igangværende fremstilling ud fra de første billeder (34) svarende til disse videosignaler (SV1) og for trinnene med fremstilling af recepter, der er lagret i en recepthukommelse, og midler til udvælgelse af en recept afhængigt af denne sammenligning, **ved, at** oplysninger om den udvalgte recept vises sammen

med de af enheden til digital styring overførte billeder på visningsmidler (24), og **ved, at** advarselsmidler (26) er egnede til at blive aktiveret i tilfælde af manglende overensstemmelse af mindst et indekseret fremstillingstrin med det tilsvarende trin i den udvalgte recept.

8. System til sikret billeddannelse ifølge det foregående krav, hvor indekseringsmidlerne er egnede til at indeksere trin, der er specifikke for hver recept, såkaldte nøgletrin, gennem en særlig indeksering (EC1, EC2, ...), og advarselsmidlerne (26) udløses i tilfælde af manglende overensstemmelse med mindst et fremstillingstrin, især et kritisk trin.

9. System til sikret billeddannelse ifølge et hvilket som helst af kravene 7 eller 8, hvor den dynamiske grafiske grænseflade omfatter mindst et andet optagelses- og visualiseringskamera, et såkaldt scenekamera (27), som har en brændvidde, der er indstillet til en samlet detektering af stedet (10), idet behandlingskameraet (21 ; 21a, 21b) og scenekameraet (27) har synkroniserede strømme.

10. System til sikret billeddannelse ifølge et hvilket som helst af kravene 7 til 9, omfattende en indretning til billedoptagelse ifølge krav 6, en bærer til positionering af objekter og et indelukke til frembringelse af medicinske præparater, idet bæreren til positionering af objekter (42) er anbragt inde i indelukket og indretningen til billedoptagelse (41) uden for dette mod et transparent vindue (40) af indelukket og i en sådan position, at billeder af bæreren til positionering af objekter når frem til indretningens billedoptageapparater.

11. System ifølge krav 10, hvor bæreren til positionering af objekter indbefatter mindst en sprøjte og en flaske med en fluid, der skal udtages med sprøjten, omfattende en plan base (66) til støtte af objekterne, en skærm (67) opsat bag ved basen og en sprøjteholder (68), der er translationsmonteret over for basen mellem en frigjort position uafhængig af basen og en position i indgreb forbundet med basen.

12. System ifølge krav 11, hvor sprøjteholderen er translationsmonteret gennem en glideforbindelse med basen.

13. System ifølge krav 12, hvor de øvre overflader af basen og sprøjteholderen er koplanare og omfatter komplementære fremspring (78) til modtagelse af en flaske, som, når sprøjteholderen er i sin position i indgreb, danner et fremspring til modtagelse af bunden af en flaske, såsom en fordybning eller en ribbe.

14. System ifølge et af kravene 11 til 13, hvor bærerens sprøjteholder omfatter en fastholdelsesstøtte (73) af vingedelene af en sprøjte og en langsgående blok (71) til anlæg af sprøjtens legeme.

15. System ifølge krav 14, hvor, når sprøjteholderen er i sin position i indgreb, modtagelsesfordybningen (78) til bunden af en flaske er anbragt mellem støtten (73) til fastholdelse af vingedelene af en sprøjte og anlægsblokken (71) til sprøjtens legeme.

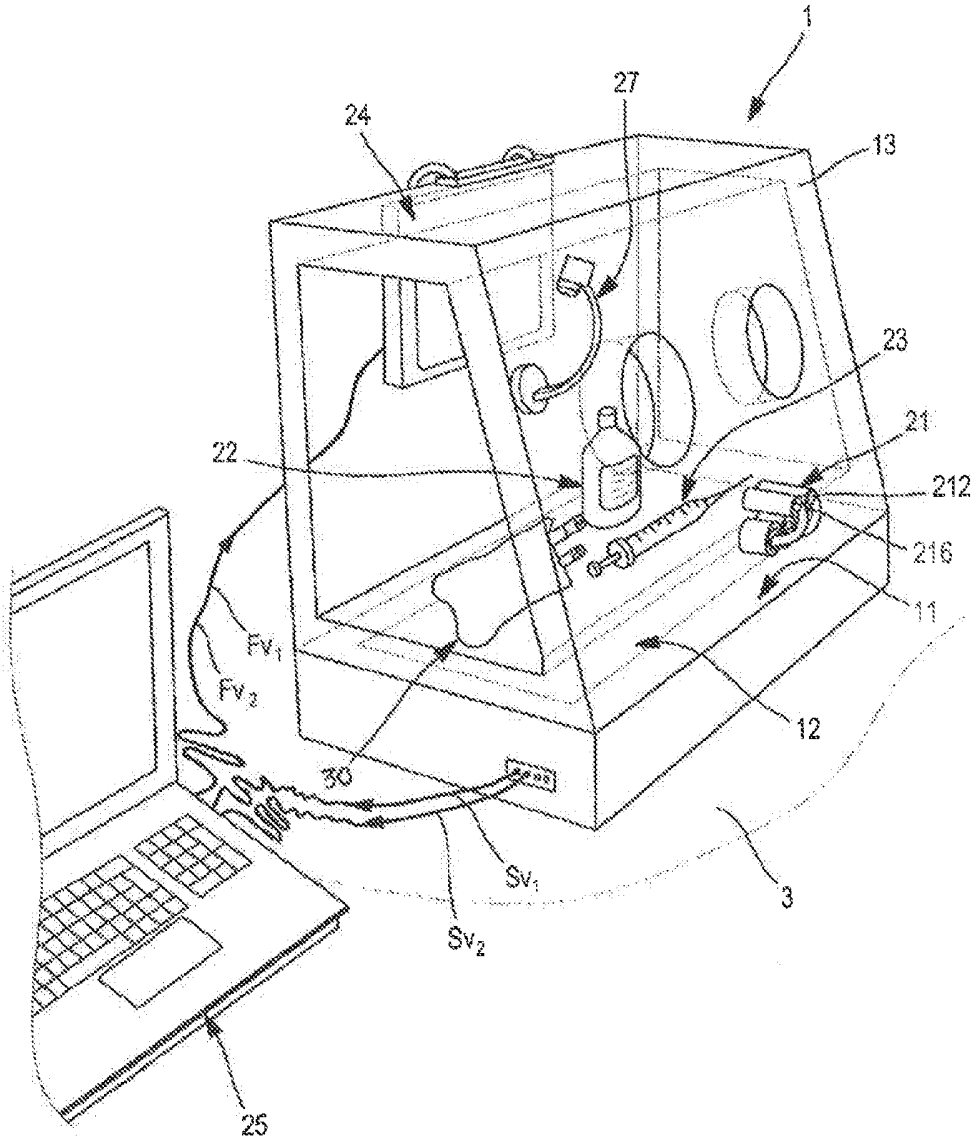

FIG. 1

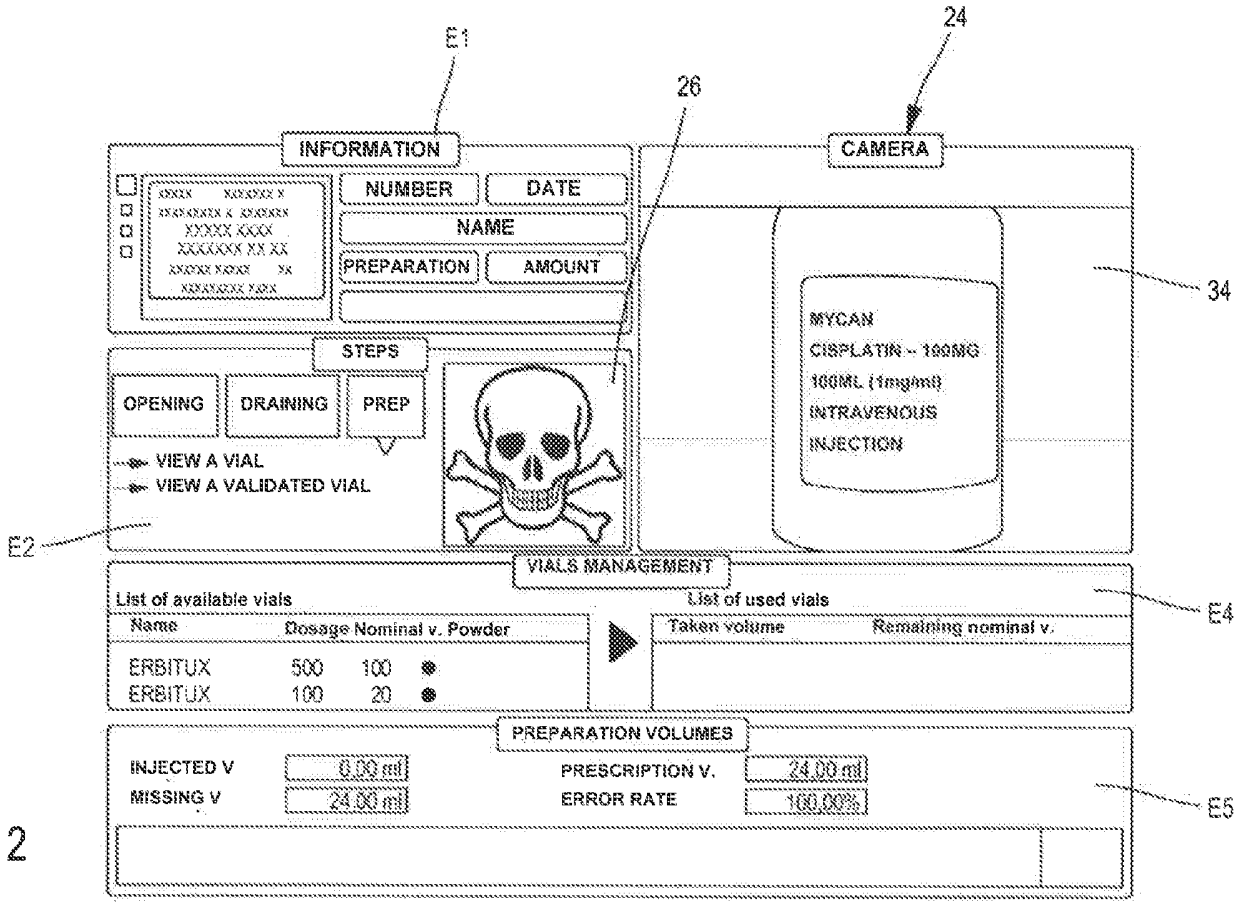
E1
24
26
INFORMATION
CAMERA
NUMBER
DATE
NAME
PREPARATION
AMOUNT
34
MYCAN
CISPLATIN – 100MG
100ML (1mg/ml)
INTRAVENOUS
INJECTION
STEPS
OPENING
DRAINING
PREP
VIEW A VIAL
VIEW A VALIDATED VIAL
E2
VIALS MANAGEMENT
List of available vials
List of used vials
E4
Name
Dosage Nominal v.
Powder
Taken volume
Remaining nominal v.
ERBITUX 500 100
ERBITUX 100 20
PREPARATION VOLUMES
INJECTED V
0,00 ml
PRESCRIPTION V.
24,00 ml
MISSING V
24,00 ml
ERROR RATE
100,00%
E5

FIG. 2

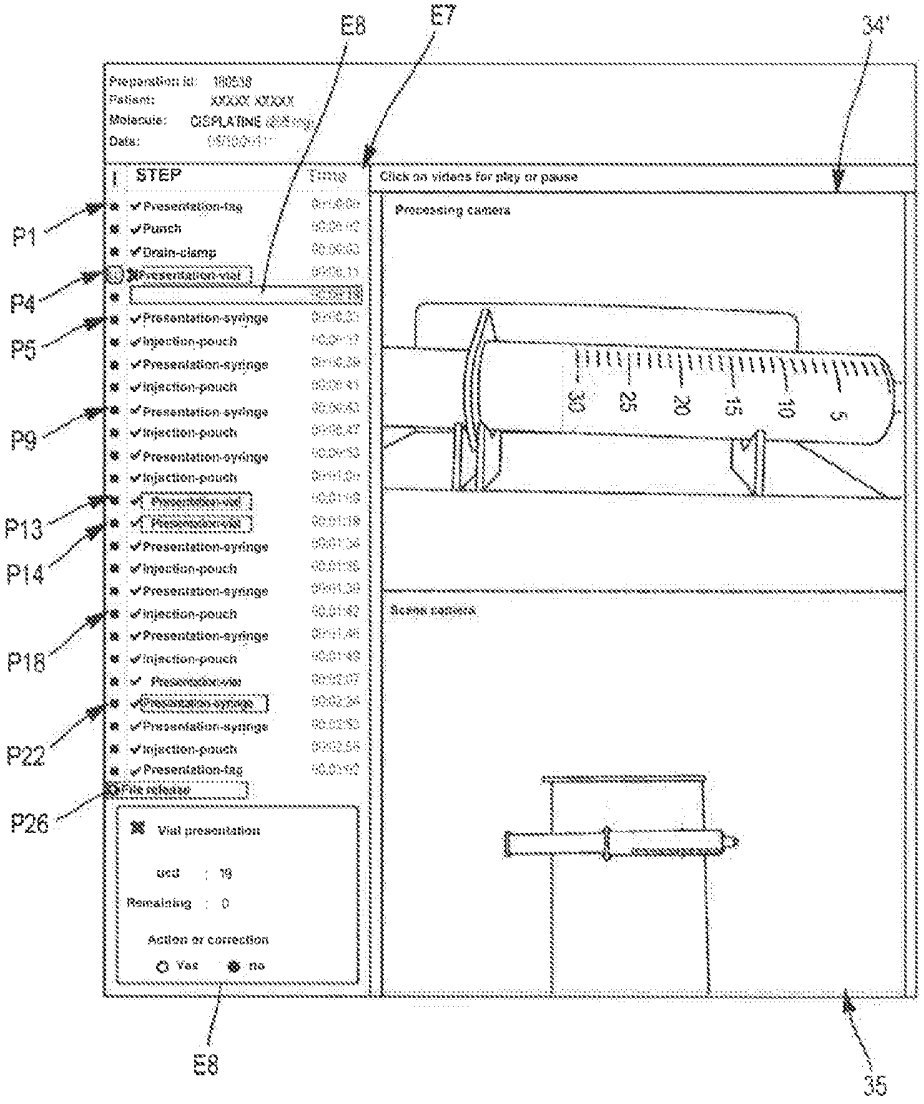
E8
E7
34'
P1
P4
P5
P9
P13
P14
P18
P22
P26
STEP
Timing
Click on videos for play or pause
Processing camera
Screw camera
Vial presentation
Used : 19
Remaining : 0
Action or correction
Yes
no
E8
35

FIG. 3

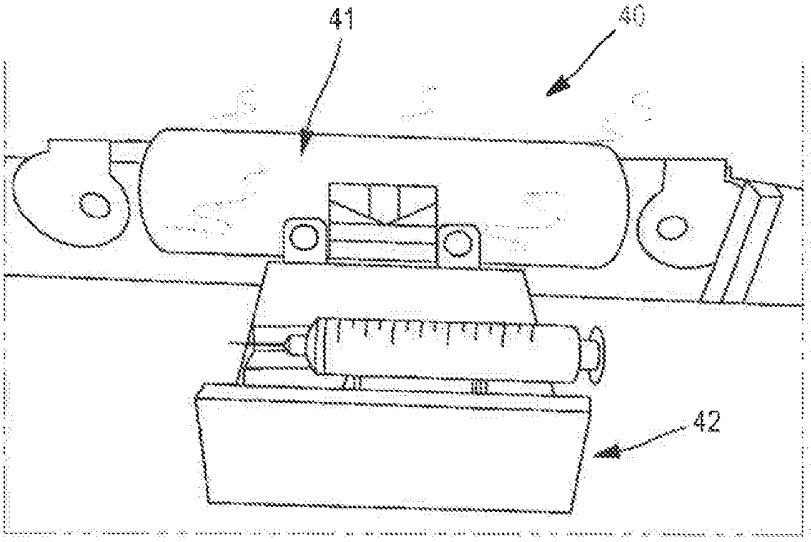

FIG. 4

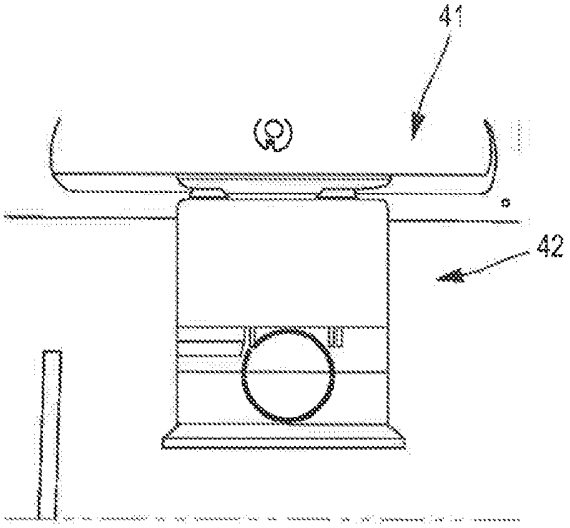

FIG. 5

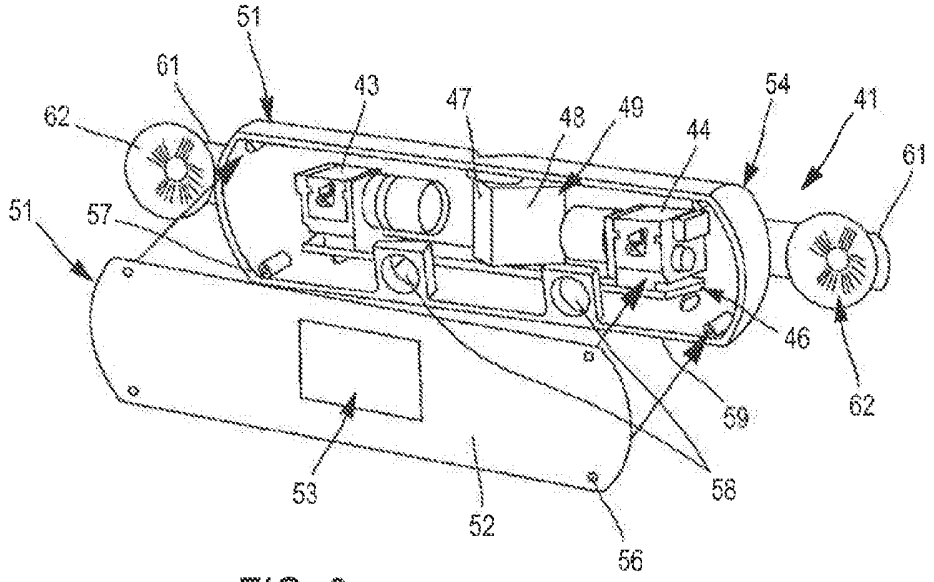
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FIG. 6

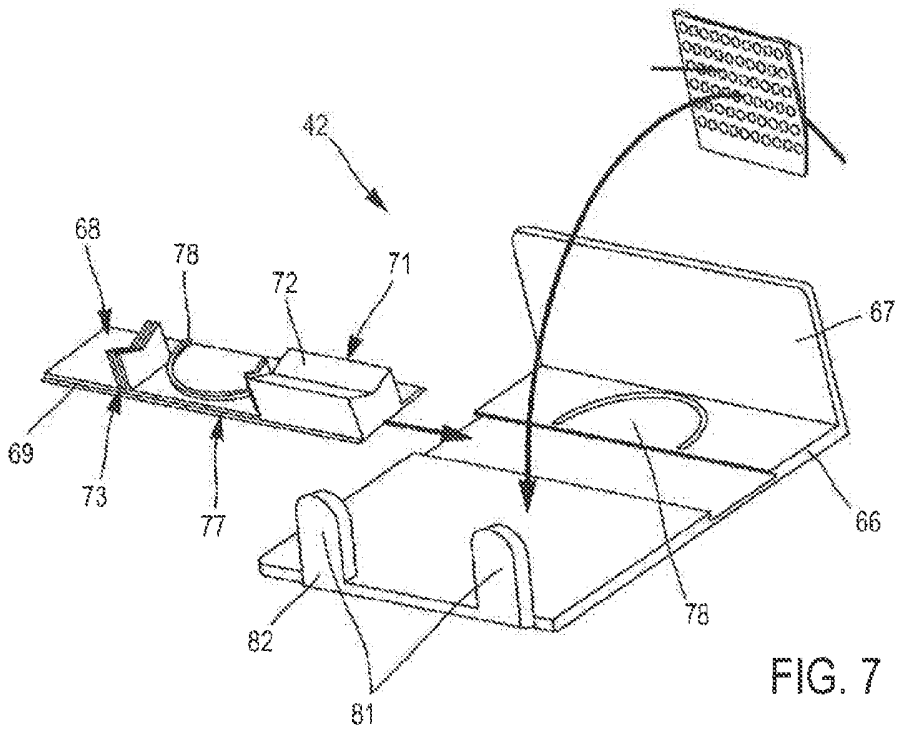
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FIG. 7

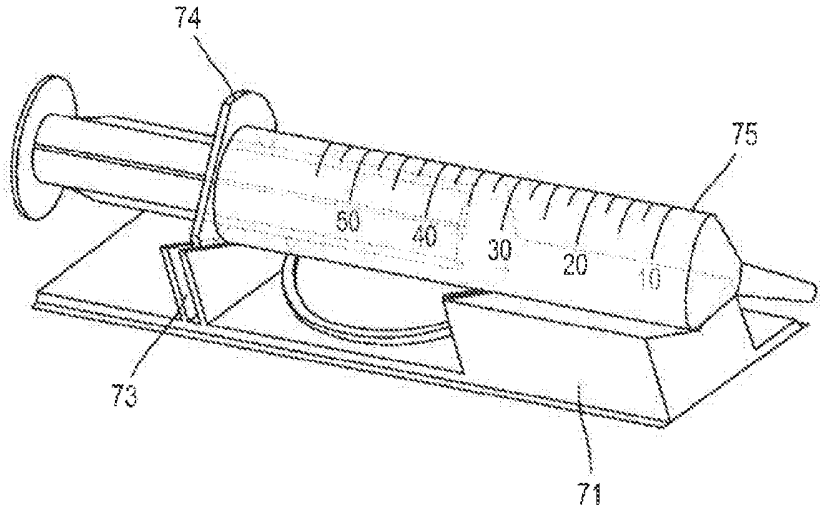

FIG. 8

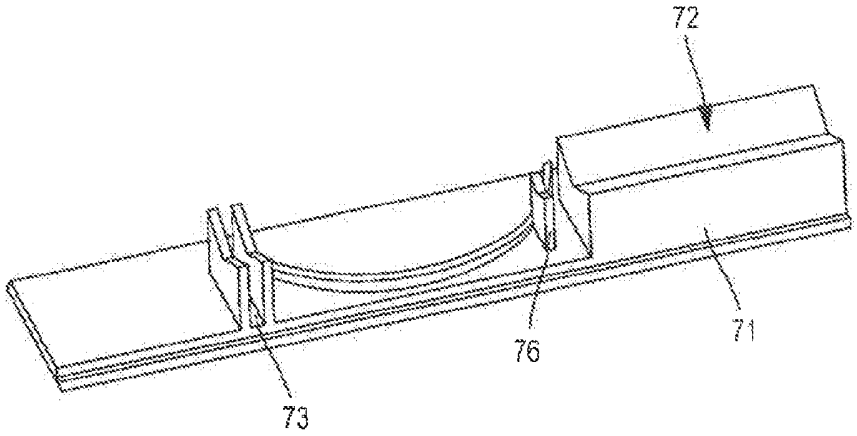

FIG. 9