(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 September 2014 (25.09.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/149013 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/TR2014/000081

(22) International Filing Date:
20 March 2014 (20.03.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2013/03468 22 March 2013 (22.03.2013) TR

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

WO 2014/149013 A2

(54) **Title**: AN INFUSION SET THAT OPERATES WITH AN INFUSION PUMP, WHICH RESTRAINS THE FLOW OF AIR FROM THE SERUM SET TO THE PATIENT AND PREVENTS SAID AIR TO MIX WITH AMBIENT AIR

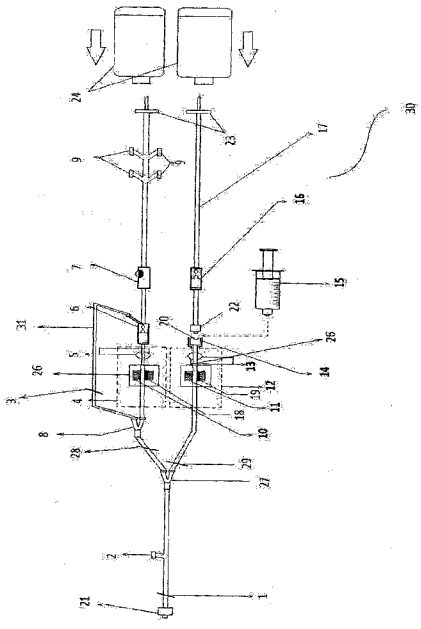

Figure 1

(57) **Abstract**: The invention is related to a system wherein the flow of air is sensed by means of the infusion pump 1st channel air sensor (5) and/or the infusion pump 2nd channel air sensor (13) located on the infusion pump (25), following the passage of air, clamp 3 (28) on the infusion set (30) is closed and the usually closed clamp 2 (3) is opened; the command to fill the infusion set (30) or to operate it is given to the infusion pump (25) and following this the infusion set (30) traps the air inside the drip cup 1 (6); wherein fluid can be transferred with a method, using an injector (15) without the need to use a different infusion pump (25) and infusion set (30).

DESCRIPTION

AN INFUSION SET THAT OPERATES WITH AN INFUSION PUMP, WHICH RESTRAINS THE FLOW OF AIR FROM THE SERUM SET TO THE PATIENT AND PREVENTS SAID AIR TO MIX WITH AMBIENT AIR

Technical Field

The present invention is related to automatically restraining air bubbles which have been formed within medicines, and fluids that are to be transferred via the IV set to patients, inside the set.

The invention is related to an infusion set that prevents air bubbles to be transferred to the patient, that also prevents the confined air to mix with ambient air; that eliminates the toxic effect of medicines which can be harmful to everyone within the environment when it aerifies; and that enables to transfer the medicine or serum within the same injector and the set to the patient.

Prior Art

In the known state of the art, when air is formed inside the infusion set, the health personnel takes out the set from the patient and the liquid inside the set is poured out until the air bubbles are eliminated.

In a similar known state of the art, when air is formed inside the infusion set, the air bubbles formed inside the set are discharged using filters that allow the discharging of air bubbles formed inside the set.

In another known state of the art device, it is possible to grab air and discharge it using manual apparatus that can trap small amounts of air.

Moreover a different type of device is required in order to transfer the serum or the medicine to the patient that is to be transferred with an injector. These devices are perfusion devices that enable the fluid inside the injectors only to be transferred to the patient.

In the known state of the art, if air is formed inside the set during the transfer of medicines or chemotherapy serums applied to especially oncology patients, the devices transferring the medicine using the serum set, detect the air that is formed and the medicine flow to the patient is stopped. However the user needs to somehow discharge the air formed inside the serum set. In the case that the air bubbles that have been formed are not discharged, the air will reach the patient and unwanted conditions such as a seizure or eve death can occur if the air is transferred to the patient. However a different device and different set is required for medicines or serums that need to be transferred to the patient via an injector.

In such cases hospital staff takes the serum set out of the patient and pour out the fluid inside the set until the air bubbles are discharged and then shall again connect the IV set to the patient to continue the transfer process. However the medicine that is discharged while getting rid of the air bubbles is wasted and medicines that are generally used for chemotherapy patients that may be toxic to everyone in the environment when they are aerified can also be risky for human health.

It must be known especially that, in the known state of the art, the medicines and serums used for chemotherapy patients can be harmful to human health when they are aerified. Moreover when these medicines are aerified hospital staff and patients also face serious health problems.

In the known state of the art, personnel and a new device needs to be used when using medicines or serums that needs to be transferred to the patient via an injector. Although the same device can be used whilst transferring medicine or serum, it is soon realized that such a process can only be carried out using small injectors.

In another prior art technique, it is known that a part on a set can retain a small amount of air. In such a case, as air can be retained in small amounts only, when the amount of air bubbles increase, the serum again needs to be discharged in order to discharge the excess

amount of air inside and again toxic chemicals that are harmful to everyone around, will be distributed into the environment. When using injectors, most of the time the amount of the fluid that an injector can comprise is insufficient.

Moreover in the known state of the art, even if a small amount of air is retained, the hospital staff will need to discharge this air manually. This will lead to loss of time, could lead to personal errors and may endanger the health of the patient. When usage with an injector is required, as small volume injectors are insufficient a new injector set and device will need to be used.

In the prior art, the infusion pump sets, can be used in nearly all departments of the hospitals. As some of the medicines sent to these departments may be very expensive and as they can be sent to only a few number of patients, the discharging of the medicine/fluid together with the air bubbles will lead to both financial losses and the patient will not be receiving the necessary amount needed for his/her treatment.

Moreover in the known state of the art, the patient's comfort rate is decreased highly when an old set needs to be taken out of his/her arm and new set needs to be inserted. When the process is carried out using an injector, as the injector is not sufficient when a new one is used, the additional injector takes up space.

Moreover in the prior art, it should also be taken into consideration that the hospital staff needs to take the old set from the patent and insert a new set to the arm of the patient in order to discharge the air bubbles formed inside the serum sets that operate with an infusion pump and this increases the risk of infection, which is one of the most crucial problems in hospitals.

In the prior art, as the device operating with an injection is inserted into the patient, and then a new set is inserted into the patient, the intervention of the health specialist is regularly needed.

In the prior art, the hospital staff needs to check on the patient, to see the status of air formed inside the infusion pump set, then said staff needs to take out the set from the patient and has to wait until the air bubbles are completely discharges; thereby this creates loss of time and the usage of unnecessary manpower.

Especially when the usage field such as health is taken into consideration where human life is at stake, it can easily be perceived that loss of time is a crucial problem. Moreover as another device operating with an injector is inserted to the arm of the patient by the hospital staff this means that there will be extra work as more than one device needs to be checked by the health personnel.

Moreover in the prior art, in order to discharge a small amount of air formed inside the infusion pump serum set, a high amount of fluid needs to be discharged also.

In addition, in the prior art, in order to discharge the air inside the infusion pump serum set, the health staff needs to use a new glove each time he/she carries out this process. The usage of a new pair of gloves with each new process also leads to extra costs.

Moreover in the known state of the art, as the health personnel needs to intervene frequently in order to discharge the air formed inside the serum set, and they have to take out the serum set out of the arm of the patient and then insert it back in, the risk of contagious diseases increases. Moreover the health personnel need to open a new set for the liquid inside the injector that the health personnel are going to transfer to the patient; thereby this again increases costs.

In the prior art, the air inside the infusion pump serum set that is used to transfer medicines needs to be discharged, or said set is frequently taken out of the arm of the patient; wherein the medicine inside said sets that may be used for chemotherapy treatment of oncology patients can be risky when said medicine aerifies and is distributed into ambient air, causing sufficient risk to be very harmful to those within the vicinity.

In addition, according to the prior art, oncology patient and patients in intensive care can be transferred with a plurality of liquid medication. The lesser number of sets or devices used shall lead to lesser amount of workforce and this in turn will ensure that infection risks are minimized. Moreover saving could be achieved.

As a result due to the disadvantages mentioned above, and as the present solutions are not sufficient to overcome all problems, an obligation to improve a new set, in order to solve the problems caused by the sets within the prior art, to ensure that the usage of the sets, called infusion sets that are used to transfer serum or medicines to patients are made easier, has emerged.

Brief description of the Invention

The present invention is related to an infusion set that meets the requirements mentioned above, that eliminates all disadvantages, that provides additional advantages, that prevents the aerifying of the medicines and serum within the infusion sets and that prevents the discharging out of said system.

The foremost aim of the invention is to retain the high amounts of air that is formed inside the infusion pump serum set automatically and to ensure that said air is not discharged into the external environment, and to transfer the necessary fluid medicines at the same time but independent from each other to the patient via injectors without the necessity to use a different set or a different device.

The aim of the present invention is to completely prevent the aerification of medicines and serums that may be toxic to people, especially to medical personnel, patients and patient's relatives; who inhale said medicines in the case of aerification of said medicines that are being transferred to patients using an infusion pump serum set

Moreover another similar aim is to ensure that instead of using a different device to transfer the fluids with an injector, a single set and single device is used.

Another similar aim of the invention is to automatically prevent the transfer of air bubbles that have been formed within the infusion pump serum set to the patient and to be able to

trap said air in high amounts inside the set. The aim is to ensure that the air does not reach the patient at all and is not released into the environment either.

Moreover another similar aim is to be able to transfer the fluids that are to be transferred with an injection to the patient in different speeds without the necessity to use a different device.

Another aim of the invention to provide an infusion pump serum set application wherein medicine loss is prevented by eliminating the need to discharge the small amount of medicine which is expensive, together with the air that is formed inside the set.

Moreover another aim is to prevent the usage of extra sets or devices by transferring the medicine or serum; that needs to be transferred to the patient, which operates with an additional injector, by using a single set and device.

Another aim of the invention is to prevent the loss of medicine that is discharged together with the air that is formed inside the medicine or serums in low amounts that are being transferred to patients, because in such a case the loss of medicine also results in the treatment of the patient to be incomplete as the patient has received a lesser amount of medicine or serum because an amount of said medicine or serum has been discharged together with the air that was formed within the set. By using the infusion pump serum set, loss of medicine is prevented; thereby the treatment of the patient is also completed.

Another aim of the invention is to eliminate the set from air bubbles that have been formed within the set and as result to prevent the transferring of air bubbles to the patient. Moreover when a single set and device is used, the controlling of the device-set by the medical staff is made easier.

In addition another aim of the invention is to prevent unnecessary medicine and serum loss. Medicine or serum may not be sent via an injector depending on the preference of the user and a second serum bag can be connected from the same second section and the process can be continued.

Yet another aim of the invention is to eliminate the need to take out the set from the patient and to re-insert a set by the medical personnel. Moreover as the medical personnel can transfer the fluid within the injector to the patient from a single set, without using a new set, this also minimizes the risk of infection.

Another similar aim of the invention, is to ensure a financial gain by not using the additional materials that need to be used when the medical personnel has to take the set out of the patient and insert a new set.

Another aim of the invention is for the set to eliminate the air inside the set automatically. This also brings about the fact that the usage of a new device or set operating with an injector is not used. This situation will minimize the manpower used by the medical staff and will minimize the loss of time.

A similar aim of the invention is to eliminate the discomfort felt by the patients and the extra pain caused to the patient when the set is detached from the patient in order to discharge the air inside said set.

The structural and characteristic features of the invention together with all its advantages shall be understood better by the usage of the figures attached and which shall be referenced and by means of the following detailed disclosure and for this reason any kind of evaluation regarding the invention should be made by taking into consideration the following figures and detailed description.

Description of the Figures

Figure 1: Is the general illustrative drawing of the infusion set subject to the invention

Figure 2: Is the drawing that shows the part that shall enable to better understand the invention; said part being connected to the infusion pump of the infusion set subject to the invention.

Figure 3: Is the discharge serum line that provides the recirculation, the drip cup and the infusion pump set subject to the invention.

Figure 4: Is the section that connects the injector to the set during usage with an injector, illustrated in order to better explain the invention.

Figure 5: Is the detailed drawing of the piston mechanism at the channels where the infusion set, subject to the invention is mounted.

Figure 6: Is the work steps that summarize the operation of the set, subject to the invention.

The drawings must be scaled and the details which are not significant to clarify the present invention may not have been shown in the figures. Besides this, it should be noted that the parts which may substantially have the same functions or which may be substantially the same have been given the same reference numbers.

Description of the part references

1. Clamp 1
2. Y valve
3. Clamp 2
4. Infusion pump 1st channel
5. Infusion pump 1st channel air sensor

6. Drip cup 1
7. Roller clamp
8. Y Connector
9. Y Valve inlet
10. First channel piston mechanism
11. Second channel piston mechanism
12. Infusion pump 2nd channel
13. Infusion pump 2nd channel air sensor
14. Valve inlet slot
15. Injector
16. Drip cup 2
17. Additional set
18. First channel piston bearing
19. Second channel piston bearing
20. Valve inlet
21. Check valve patient inlet
22. Valve inlet connection apparatus
23. Serum IV bag inlet
24. Serum, IV bag
25. Infusion pump
26. Pumping mechanism
27. Y connector

28. Clamp 3

29. Clamp 4

30. Infusion set

31. Discharge serum hose

Description of the steps of the invention

101. The infusion set (30) is attached to serum, IV bag (24)

102. The drip cup (6) is filled with fluid until half full

103. The infusion pump (25) is adjusted to the desired speed and is started

104. If air is formed inside the set during the transferring of medicine or serum to the patient, the infusion pump (25) will stop the transfer and shall give an alarm.

105. The medical personnel will close clamp 3 (28) and will open clamp 2 (3).

106. The infusion pump (25) will be sent the command to be filled or to start the process and the air inside set is directed to the drip cup (6) by means of the discharge serum hose (31) as soon as the device is actuated.

107. The air inside the set is eliminated and clamp 3 (28) shall be opened and clamp 2 (3) shall then be closed.

108. The infusion pump (25) will continue to function normally.

109. For fluids that are transferred using an injector (15), an injector (15) will be attached to the valve inlet slot (14) of the valve inlet (20) section located in the 2nd channel (12) of the infusion pump.

110. The additional set (17) which is a valve inlet connection apparatus (22) can be attached from the point mentioned above and a new serum, IV bag (24) can be attached thereto.

111. By this means fluid transfer can also be carried out using an injector (15) via the single infusion pump (25).

Detailed description of the Invention

In this section the serum set operating with an infusion pump, subject to the invention shall be described further in order for those interested to better understand the invention, and the descriptions herein should not be assumed to be limiting to the infusion set which prevents the air inside the set to be transferred to the patient and which is also suitable to be used with an injector.

Moreover some elements and process steps that have been prepared in order to ensure that the invention is better understood have been used in different ways in order to provide the meaning unity within sentences. The elements or process steps that have been used with different expressions actually refer to the same numbered related element or process steps.

The invention is related to an infusion set (30) that operates with an infusion pump, provided to overcome the above mentioned problems of the known state of the art suitable to be used with an injector and at the same time which prevents the air in the serum set to be transferred to the patient or to aerify.

The infusion set (30) ensures that high amounts of air are trapped inside the infusion set (30) by ensuring that the fluid circulates between the drip cup 1 (6) and the air within the set is transferred into the drip cup 1 (6).

The infusion set (30) is used to transfer fluid to the patient; however when air is formed inside the set, the infusion pump (25) stops pumping and gives an alarm signal, and following this the clamp 3 (28) is closed by the user and the flow to the patient is cut off; then clamp 2 (3) is opened and the air found inside the discharge serum hose (31) is discharged into the drip cup 1 (6).

The infusion pump (25) of the infusion set (30) subject to the invention shall discharge the air inside the set into the drip cup 1 (6) and while doing this as clamp 3 (28) is closed, air will not be transferred to the patient and as clamp 2 (3) is opened, the air inside the infusion set (30) will continuously be discharged into the drip cup 1 (6) and the fluid inside the drip cup 1 (6) shall be carried to the set.

After the infusion pump (25) of the infusion set (30) subject to the invention senses air, the user shall close clamp 3 (28) and open clamp 2 (3) and give the device the command to fill; whereupon the air inside the set will be discharged into the air cup 1 (6) and the fluid located inside the drip cup 1 (6) shall be returned back into the infusion set (30). This cycle can be repeated several times.

After the infusion set (30) does not contain any more air, the user shall close clamp 2 (3) and open clamp 3 (28); following this the infusion pump (25) will continue to operate where it left off at the normal operation settings and the set which does not contain any air and the infusion set (30) which has discharged all the air will then be able to continue to transfer medicine-serum to the patient.

<u>The operation principles of the infusion set suitable to be used with an injector and which prevents aerification and prevents the transfer to the patient of the air found inside the serum set operating with an infusion pump (25) subject to the invention can be found below:</u>

The infusion set (30) which operates with an infusion pump (25) subject to the invention which prevents the air inside the serum set to be transferred to the patient, or for the air to be discharged into the environment and which is suitable to be used with an injector (15) comprises a serum medicine bag inlet (23) located at the end part of the infusion set (30); wherein said serum medicine bag inlet (23) allows the medicine to enter into the IV bag (24). By means of the connectors that can be attached to the serum IV bag (24) the serum-medicine will start to enter the set. The fluid that starts to fill the infusion set (30) arrives at

the drip cup 1 (6) located under the set. The user will tighten the drip cup 1 (6), and ensure that it is half filled with fluid. By this means the drip cup 1 (6) is half filled with fluid.

By means of the roller clamp (7) found on the infusion set (30), the user can use the roller clamp (7) to adjust the flow of the fluid found inside the infusion set (30) to the patient at certain speeds without the need to use a device.

An air sensor (5) is located at the section where the infusion pump of the infusion set (30) is attached to the 1st channel (4) of the infusion pump. This infusion pump first channel air sensor (5) determines the air bubbles that could be formed within the infusion set (30) and the infusion pump (25) stops operating. Generally all infusion pump devices operate with the same principle (Figure 2).

As the infusion set (30) first channel is located between the piston mechanism (10) and the piston bearing (18) the snake like movement the piston carried out will ensure that the fluid within the infusion set (30) is moved downwards. Many devices in the world transfer the fluid by this method to the patient (Figure 5).

Thereby the fluid inside the infusion set (30) fills up the whole of the infusion set (30) and is connected to the patient via the check valve patient inlet (21).

The air bubbles that could be formed inside the infusion set (30) in time, starts travelling towards the patient from the medicine bag inlet (23) where the infusion set (30) serum, medicine bag (24) is attached to.

In the case that air is formed inside the infusion set (30) when the infusion pumps (25) are operating, said air is sensed by the infusion pump first channel air sensor (5) and infusion pump 2nd channel air sensor (13) and the pumps stop working and cut off the flow of fluid

and give a signal. After the infusion pump (25) subject to the invention, connected to the infusion set (30) that operates with said infusion pump (25) suitable to be used with an injector, and which prevents the transfer of air inside the serum set to the patient and the mixing of said air into the environment, gives an alarm signal, a warning on the screen of the device can be seen, said warning will show that air is present inside the set; following this the user shall close clamp 3 (28) located on the set and shall open clamp 2 (3) which is usually closed when the device is operating under normal conditions. The user shall give the command to eliminate air from the infusion pump (25) of the infusion set (30) or shall give the command to fill the infusion set (this may change according to the device) and the infusion pump (25) will start to function. As the clamp 3 (28) inside the infusion set (30) is closed and clamp 2 (3) is open, the fluid will not travel to the patient but will travel into the drip cup 1 (6) and the air together with the fluid from the infusion set (30) will be discharged into the drip cup 1 (6). The fluid inside the drip cup 1 (6) enters the infusion set (30) again and the air will be left inside the drip cup 1 (6). The air received inside the drip cup 1 (6) enters the section of air cavity of the drip cup 1 (6) and this area traps high amounts of air. The formation of the storable air amount inside the infusion set (30) is equivalent to amounts which are actually technically not possible. By this means the air formed inside the infusion set (30) is not delivered to the patient or distributed into ambient air.

This procedure can be repeated several times.

The valve inlet (20) which enables the fluid at the other end of the infusion set (30) to be transferred; is attached to the valve inlet slot (14) found on the infusion pump (25). (Has been shown in detail in Figure 3). When transfer is not being carried out from the injector (15) section of the infusion set, the clamp 4 (29) on the infusion set (30) needs to be at a closed position for safety purposes.

The pumping mechanism (26) (Figure 5) of the infusion pump (25) ensures that the fluid inside the injector (15) is retracted and said fluid inside the injector (15) is transferred to the patient without the need for a different device to be used.

The fluid inside the injector (15) then passes from the Y connection (27) section, and comes together with the fluid arriving from the other channel, two different fluids at different speeds via a single infusion set (30) is transferred to the patient over the infusion pump (25) one by one without the need to use two different infusion pumps (25).

CLAIMS

1. Infusion set (30) suitable to be used with an injector, comprising at least two infusion pump channels, further comprising at least a drip cup 1 (6) for the infusion set 1st channel (4) and/or at least a drip cup 2 (16) for the infusion pump 2nd channel, which operates with an infusion pump (25), and prevents the air inside the serum set to be transferred to the patient or to be distributed to the environment; **characterized with** the following:

- A **discharge serum hose (31)** which is located from the end of the Y connector (8) found at the outlet section of the infusion pump (25) , and which reaches the drip cup 1 (6) and is used to discharge the air bubbles that may be formed, and which provides circulation of the fluid between the drip cup 1 (6) and again the drip cup 1 (6)

- A **clamp 3 (28)** that is used to cut the flow of fluid/air in order to prevent air bubbles, sensed by the air sensor at any channel of the infusion pump (25) connected to the infusion set (30), to be transferred to the patient

- A **clamp 2 (3),** that cuts the flow that needs to be opened during the discharging of air bubbles, which actually stays at a closed position all the time on the discharge serum hose (31)

- A **Y connector (8)** located at the outlet section of the discharge serum hose (31) and used in order to discharge the air bubble that may have been formed.

2. Infusion set (30) according to claim 1, characterized in that; it comprises a valve inlet (20) used for the infusion pump 2nd channel (12) and for the injector (15) to transfer medicine or serum with the same infusion pump (25).

3. Infusion set (30) according to claim 1 and 2, characterized in that it comprises a valve inlet connection apparatus (22) which enables the insertion of the valve inlet (20) into the infusion pump (25).

4. Infusion set (30) according to claim 1 characterized in that the clamp 2 (3) cuts the flow.

5. Infusion set (30) according to claim 1 characterized in that the clamp 3 (28) cuts the flow

6. An infusion set (30) application and operation method which operates with an infusion pump, suitable to be used with an injector, wherein said set prevents the air inside the serum set to be transferred to the patient and to be distributed into ambient air; **characterized in that** it comprises the following steps:

- The air bubble passing through the infusion set (30) hose is sensed by the infusion 1st channel air sensor (5) and/or by the infusion pump 2nd channel air sensor (13),
- The infusion pump (25) stops working
- Clamp 2 (3) which is usually at an open position is closed and clamp 3 (28) which is usually at a closed position is opened,
- The air bubble which has passed through the infusion pump (25) is transferred into the drip cup 1 (6) by means of the discharge serum hose (31) when clamp 2 (3) located on the discharge serum hose (31) is opened,
- The air formed inside the infusion set (30) infusion pump (25) is circulated between the infusion pump (25) and the drip cup 1 (6) and the air is trapped inside the drip cup 1 (6),
- The air bubble which is discharged out of the system is transferred into the drip cup 1 (6),
- The fluid inside the drip cup 1(6) exchanges placed with the air, by means of the density difference of the fluid found inside the drip cup 1 (6).

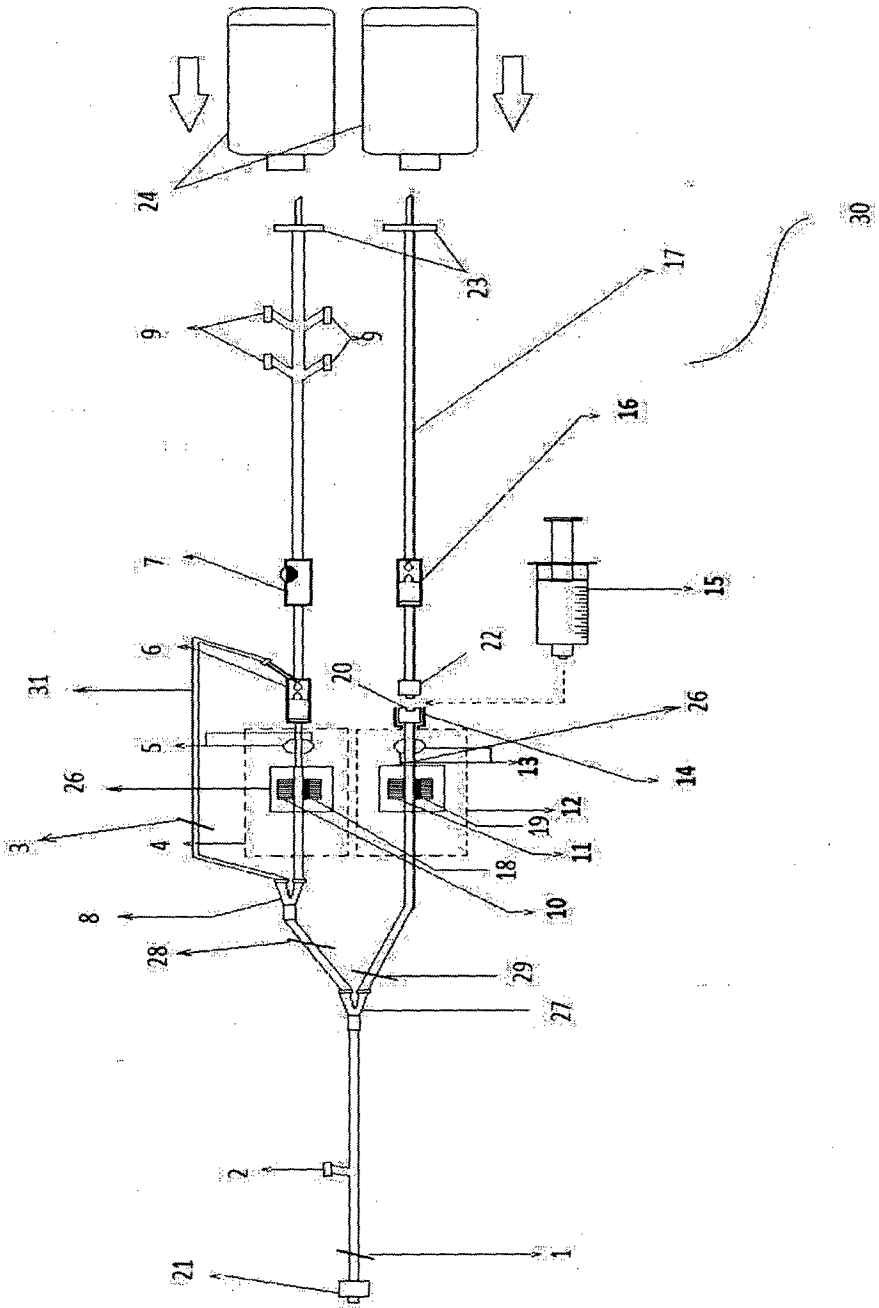
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Figure 1

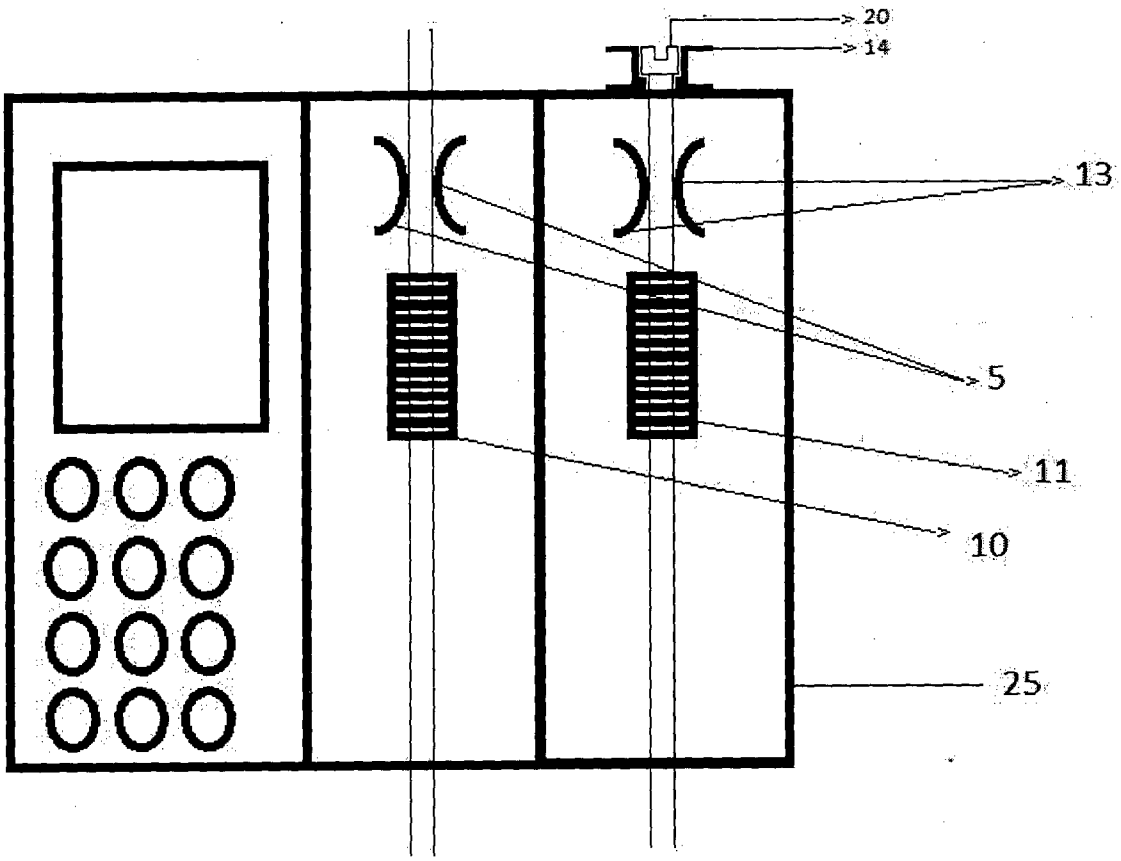

Figure 2

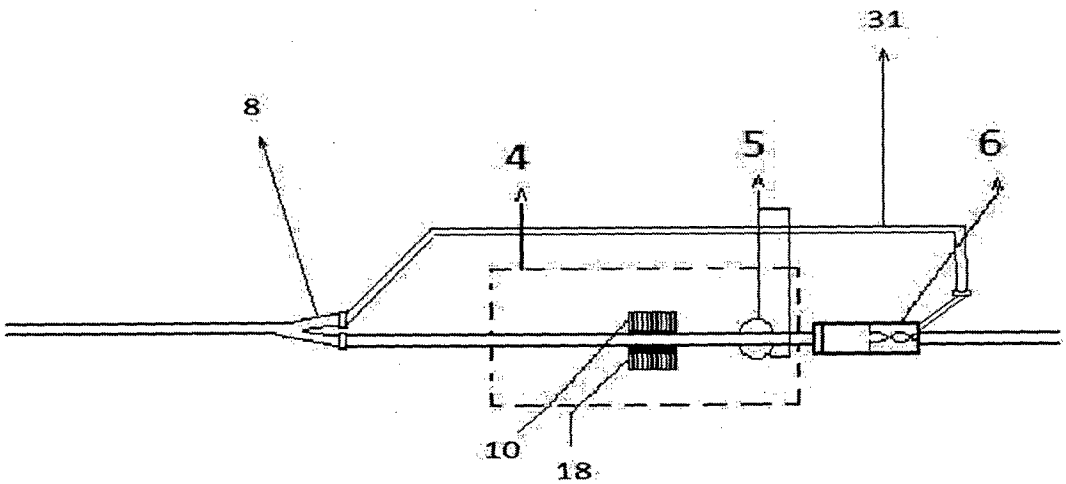

Figure 3

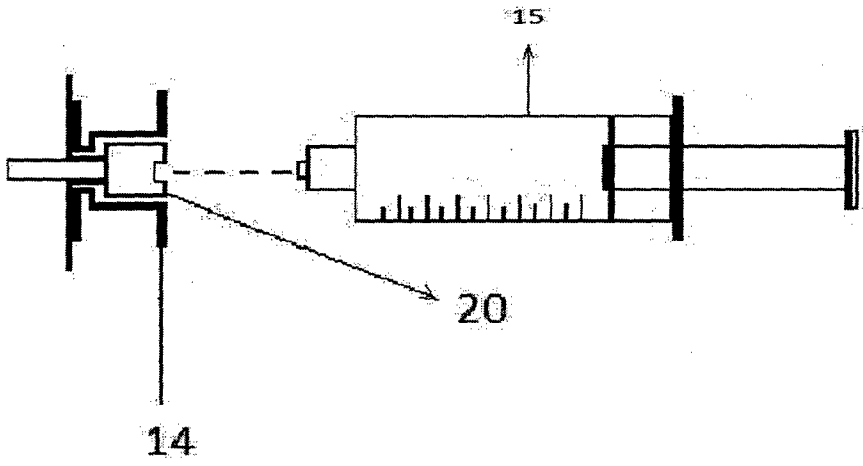

Figure 4

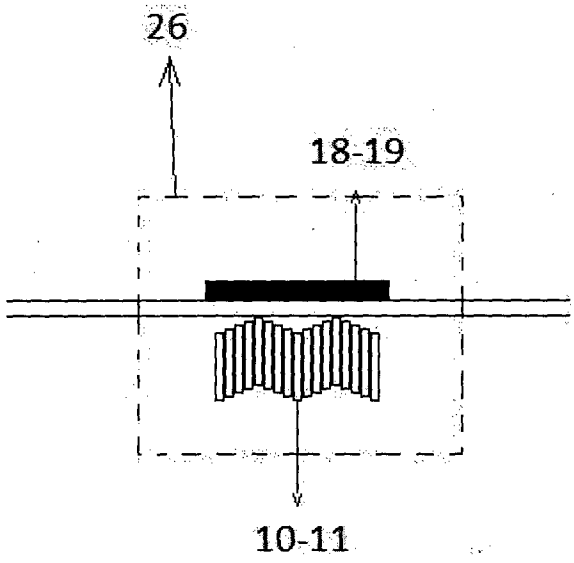

Figure 5

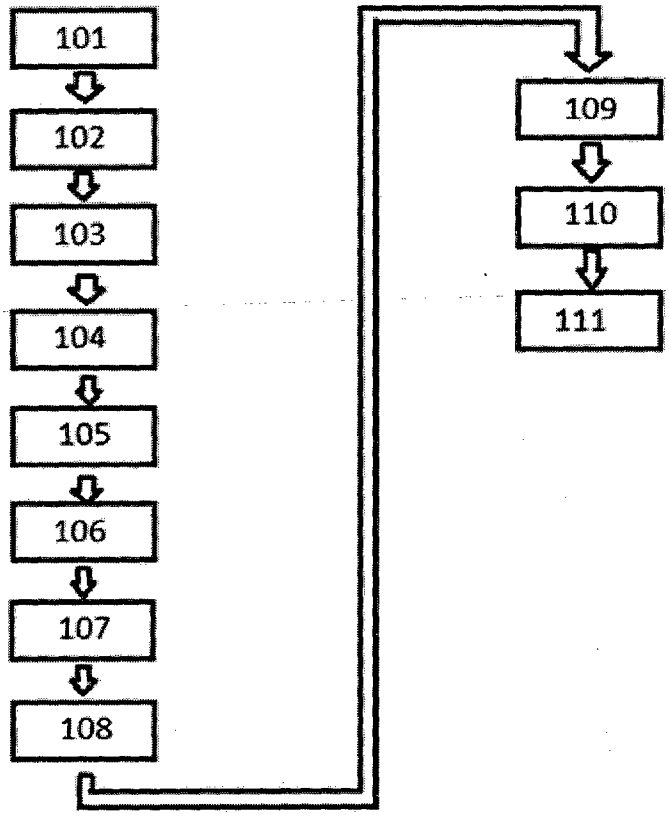

Figure 6