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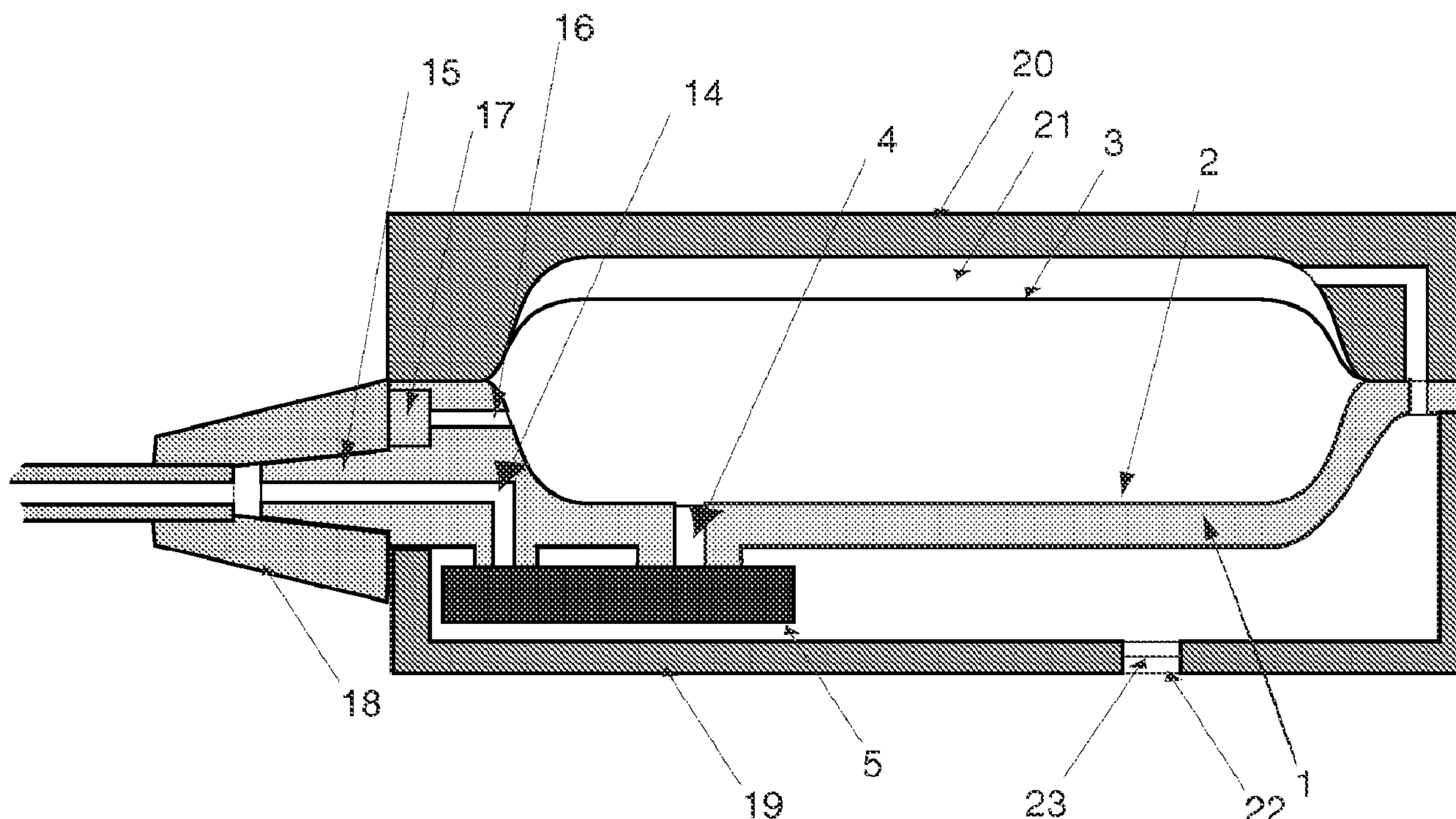
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(54) Title: MEDICAL LIQUID INJECTION DEVICE



(57) Abrégé/Abstract:

Medical liquid injection device comprising the following distinct elements : a container (1), an outlet channel (14) and a pumping unit (5); said container (1) comprising a rigid wall on which said pumping unit (5) is rigidly fixed; said rigid wall furthermore including a passage (4) which forms a direct fluid connection between said pumping unit (5) and said container (1); said outlet channel (14) being directly connected to said pumping unit (5) in such a way that a fluid initially kept in said container (1) may first flow through said pumping unit (5) and then reach said outlet channel (14), said medical liquid injection device furthermore comprising an inlet (16), distinct from said outlet channel (14), and disposable elements.

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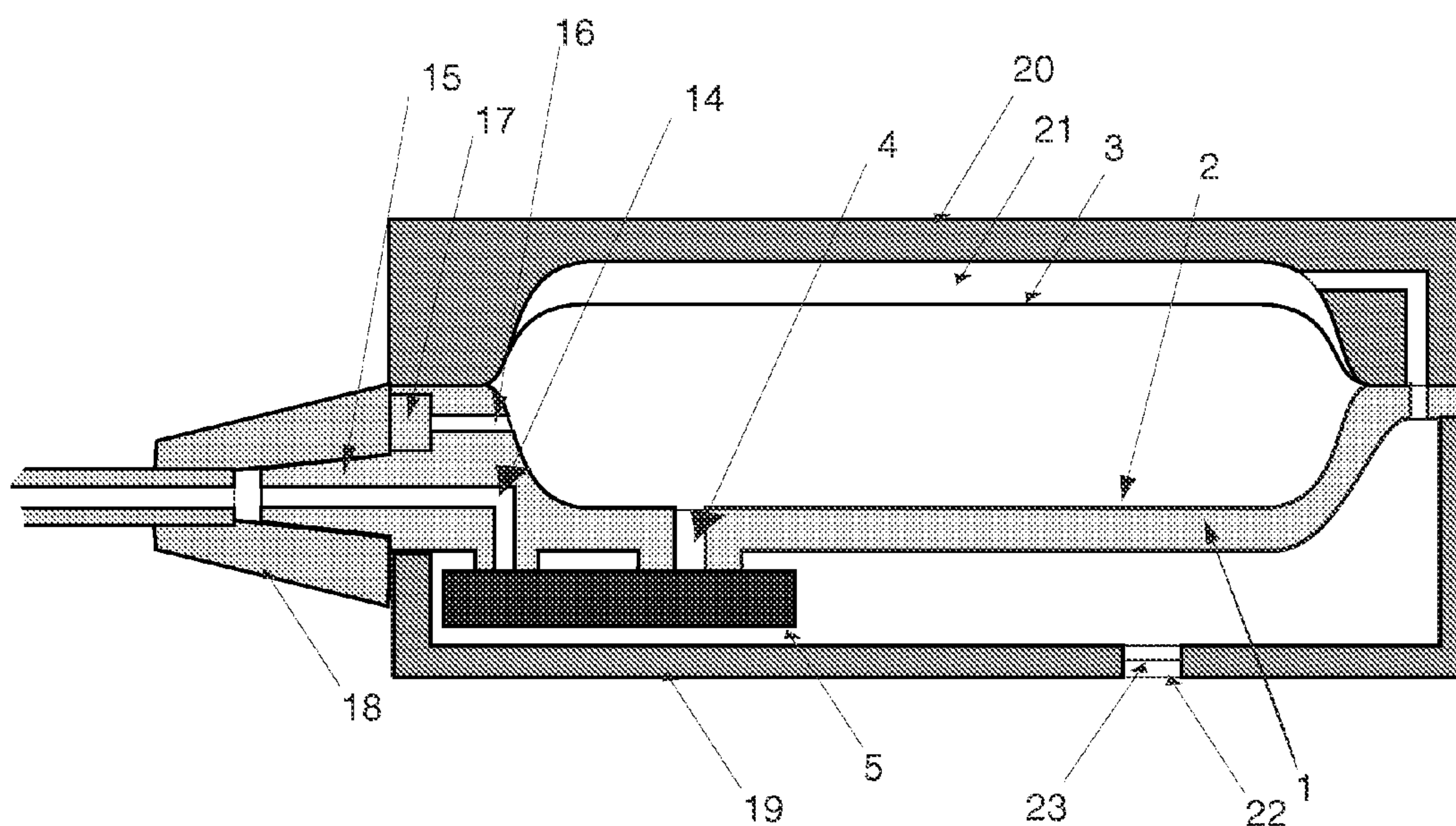
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(54) Title: MEDICAL LIQUID INJECTION DEVICE



(57) Abstract: Medical liquid injection device comprising the following distinct elements : a container (1), an outlet channel (14) and a pumping unit (5); said container (1) comprising a rigid wall on which said pumping unit (5) is rigidly fixed; said rigid wall furthermore including a passage (4) which forms a direct fluid connection between said pumping unit (5) and said container (1); said outlet channel (14) being directly connected to said pumping unit (5) in such a way that a fluid initially kept in said container (1) may first flow through said pumping unit (5) and then reach said outlet channel (14), said medical liquid injection device furthermore comprising an inlet (16), distinct from said outlet channel (14), and disposable elements.

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Medical liquid injection deviceField of invention

The present invention relates to medical containers for liquid substances, e.g. insulin, which are adapted to be fixed to an injection device, such as a pump,
10 which administers the liquid substance to a patient over an extended period.

State of the art

Administering a liquid medical substance, e.g. insulin, to a patient is usually made with a syringe pump. See for instance WO 2004/084976 or US 2003/055323.

15 The liquid is contained in a syringe which is has to be pre-filled before the treatment.

When the syringe is empty, a new pre-filled syringe is used.

A new pre-filled syringe may also be needed if the first syringe is partially empty, for instance when the patient wishes to have a completely full container before
20 starting an activity or before traveling.

General description of the invention

One objective of the invention is to reduce the number of containers used during a
25 treatment.

Another objective of the invention is to provide an easy and comfortable way to administer a liquid medical substance over a long period.

Those objectives are achieved with the medical injection device according to the
30 invention which includes at least the following distinct elements : a container, an outlet channel and a pumping unit; said container comprising a rigid wall on which said pumping unit is rigidly fixed; said rigid wall furthermore including a passage which forms a direct fluid connection between said pumping unit and said container; said outlet channel being directly connected to said pumping unit
35 in such a way that a fluid initially kept in said container may first flow through said pumping unit and then reach said outlet channel, said medical liquid injection device furthermore comprising an inlet, distinct from said outlet channel, which is

5 adapted to act as refilling means. In addition, the medical injection device according to the invention comprises disposable parts.

The present invention offers in particular the following advantages :

- 10
- Avoid a waste of containers, only one is used,
 - Easy and comfortable way to administer medical liquid without interruption,
 - Possible to have a container of a relative small size.

The device according to the invention may advantageously be used as a drug
15 infusion pump. In contrast to the state-of-the-art devices, i.e. syringe drives, the pumping unit according to the invention offers a permanent occlusion between the container and the patient line, thus preventing a contamination of the container from the patient. Because the container content has to remain sterile, it can be considered to refill it several times, up to the specified lifetime of the drug in such
20 a sterile type of reservoir. After this lifetime the container and all others parts that are wetted by the drug are preferably discarded. Several other parts of the device, notably the driving electronics and user interface can be used permanently.

The pumping unit according to the invention preferably consists of a permanent part and a disposable part. The disposable part contains, as mentioned above, all
25 the elements that are wetted by the drug, i.e. the container, the pumping unit, the inlet, and the connection port for the infusion line. The parts can be connected and disconnected repeatedly. In particular the permanent part can be reused with several disposable parts.

30

Detailed description of the invention

An embodiment of the invention is discussed below in a more detailed way together with the following figures :

35 Figure 1 is a cross-section view of a medical liquid injection device.
Figure 2 is an enlarged view of the pumping unit illustrated in figure 1.

5 Figure 3 is a perspective upper view of the device of figure 1, with a flexible membrane but without the bottom and the upper protective shells.

Figure 4 is represents the same object than the object of figure 3 but without the flexible membrane.

10

Figure 5 is a perspective bottom view of the device of figure 1.

The medical liquid injection device illustrated on the figures, and more precisely its disposable part, is mainly built around one piece forming an hard shell **1**. This
15 hard shell **1** serves as structural base and fluidic interconnect between the functional elements in the disposable, and as functional element as well. It is a shell like structure presenting two major surfaces, one having a concave surface and forming thereby a cavity **2**. A flexible film **3** is attached all around the periphery of this cavity **2**, closing it off. They are thus forming a closed cavity,
20 whose volume is variable because of the flexibility of the film **3**. The film **3** is thermoformed to conform to the shape of the cavity **2** when it collapses into the cavity **2** such that the remaining volume is negligible.

A first passage **4** is crossing the hard shell from the cavity **2** to the opposite side, on which is mounted a microfluidic pumping unit **5**. The microfluidic pumping unit
25 **5** has an inlet **6** and an outlet port **7** on one of the two principal faces.

The fluidic connection between the pumping unit **5** and the hard shell **1** is made by aligning the first passage **4** of the hard shell **1** and the inlet port **6** of the pumping unit **5**. Tightness is easily achieved with elastomeric O-rings between the two surfaces.

30 The microfluidic pumping unit **5** is a fabricated using micromachining techniques. It is a positive displacement pump. It features a pumping chamber **8** with an elastic membrane **9** that is cyclically compressed and decompressed by the movement of the membrane **9**. Fluid flow is directed by a passive inlet **10** and a passive outlet check valve **11** connected to the pumping chamber. The pumping
35 unit **5** also features a pressure sensor **12** monitoring the pressure inside the fluid path. Electrical lines and contacts link this sensor **12** and the actuator driving the

5 movement of the membrane to the permanent part that contains the necessary circuits.

An outlet channel **14** in the hard shell **1** links the outlet port **7** of the pumping unit **5** to a Luer type connector **15** for the infusion line.

10 A third channel **16**, acting as an inlet, is crossing the hard shell **1**, leading into the cavity **2** and is closed off by a septum **17** on the outside, that allows to fill and refill the container using e.g. a needle and syringe. The septum **17** is located next to the connector for the infusion line. The mating connector **18** on the infusion line is shaped in such a fashion that it covers the refilling septum while connected. This is done to prevent the users from refilling the reservoir while somebody is
15 connected to the device.

The elements described form the principal functional structure of the disposable and are called the fluidic block.

The fluidic block is housed between two rigid shells **19**, **20**, mainly for mechanical protection. In particular the flexible film **3** must be protected from mechanical
20 forces to prevent pressurizing the drug in the container. In case of excessive pressure in the container the two passive check valves in the pump might be forced open and dangerous amounts of drug could be injected into the patient. The pressure in the volume **21** between the flexible film **3** and the rigid outer shell **20** is equilibrated through a vent **22**. Water ingress into this volume is prevented
25 through the use of a hydrophobic filter membrane **23**. If this vent becomes blocked dangerous overpressure on the flexible membrane **3** may occur. To prevent opening of the check valves an anti-free-flow check valve is used in the pumping unit. As shown in the drawing this valve features three ports: a fluidic inlet port **24** connected to the pumping chamber **8**, a fluidic outlet port **7** leading
30 out of the unit and a reference port **25**. This reference port **25** is communicating with the air pressure inside the housing. The valve features an elastic membrane **26** to which the valve body **27** is attached that blocks the outlet port **7**. On the inside the membrane **9** is exposed to the pressure of the inlet port **6**. On the outside the membrane **9** is exposed to the pressure of the reference port **25**. The
35 outlet port's pressure is only present on a negligibly small surface and has thus little influence on the valves behaviour. The valve is designed in such a fashion

- 5 that the fluid path opens up, only if the inlet port pressure exceeds the reference port pressure by a predefined amount. If the pressure inside the housing increases, the pressure on both inlet and reference port increase likewise and the valve does thus not open.

10

It should be underlined that the present invention is not limited to the embodiment discussed above. Any other configuration included in the claimed subject-matter is forming part of the invention.

5

Claims

1. Medical liquid injection device comprising the following distinct elements : a container (1), an outlet channel (14) and a pumping unit (5); said container (1) comprising a rigid wall on which said pumping unit (5) is rigidly fixed; said rigid wall furthermore including a passage (4) which forms a direct fluid connection between said pumping unit (5) and said container (1); said outlet channel (14) being directly connected to said pumping unit (5) in such a way that a fluid initially kept in said container (1) may first flow through said pumping unit (5) and then reach said outlet channel (14), said medical liquid injection device furthermore comprising an inlet (16), distinct from said outlet channel (14), and disposable elements.
2. Medical liquid injection device according to claim wherein said inlet (16) is adapted to act as refilling means.
3. Medical liquid injection device according to claim 1 or 2 furthermore comprising a connector (15) and an infusion line that can be connected and disconnected from said outlet channel (14).
4. Medical liquid injection device according to claim 3 wherein said inlet (16) is in close vicinity to the outlet channel (14) and the connector of the infusion line is formed such that it blocks the access to the inlet (16) while connected.
5. Medical liquid injection device according to anyone of the previous claims furthermore comprising non-disposable elements.
6. Medical liquid injection device according to anyone of the previous claims characterized by the fact that it is designed to have a pre-determined usage period which is not longer than the labeled life time of use of a drug present in said container.

5

7. Medical liquid injection device according to claim 6 comprising usage preventing means which are adapted to prevent the usage of the device after said pre-determined usage period.

10

8. Medical liquid injection device according to claim 5 wherein the non-disposable elements comprise electronic control parts.

15

9. Medical liquid injection device according to claim 8 wherein said electronic control parts are adapted to prevent usage of the device after a pre-determined period.

20

10. Medical liquid injection device according to claim 9 wherein said electronic control parts are adapted to recognize the identity of the disposable parts in order to prevent reuse after said pre-determined period.

25

11. Medical liquid injection device according to claim 9 or 10 wherein said electronic control parts are adapted to determine if said disposable parts have been used previously.

12. Medical liquid injection device according to anyone of the previous claims wherein said container has a variable volume.

30

13. Medical liquid injection device according to the previous claim wherein said container comprises a movable wall, for instance a flexible wall.

35

14. Medical liquid injection device according to claim 12 or 13 comprising a control element that prevents injection into a user when the container is pressurized.

- 5 15. Medical liquid injection device according to claim 14 wherein said control
element is a three ports valve connected to said pumping unit, to said
outlet and communicating with said container.
- 10 16. Medical liquid injection device according to claim 15 wherein said three
ports valve is adapted to open only when the pressure on the port
connected on the pumping unit is higher than the pressure in or around the
container.
- 15 17. Medical liquid injection device according to anyone of the previous claims
furthermore comprising a pressure sensor.
- 20 18. Medical liquid injection device according to claim 17 wherein said pressure
sensor is adapted to measure the liquid pressure inside said container.
- 20 19. Medical liquid injection device according to claim 18 comprising display
means which are adapted to communicate the container filling level to user,
said filling level being obtained from said pressure sensor.
- 25 20. Medical liquid injection device according to claim 18 or 19 comprising first
alarm means to alert a user in case of excessive filling, said first alarm
means being connected to said pressure sensor.
- 30 21. Medical liquid injection device according to anyone of claims 18 to 20
comprising second alarm means for detecting potentially dangerous states
of reservoir pressure, said second alarm means being connected to said
pressure sensor.
- 35 22. Medical liquid injection device according to anyone of claims 18 to 21
comprising third alarm means for detecting when the container is empty,
said third alarm means being connected to said pressure sensor.

- 5 23. Medical liquid injection device according to anyone of claims 12 to 22
 wherein said container is fabricated as a rigid shell having a concave
 surface forming a cavity and a flexible membrane covering the cavity.
- 10 24. Medical liquid injection device according to claim 23 wherein said rigid shell
 comprises a channel that connects the interior of said container with the
 external environment.
25. Medical liquid injection device according to claim 23 wherein said rigid shell
 comprises several channels.
- 15 26. Medical liquid injection device according to claim 23 wherein said flexible
 membrane is formed to conform to the cavity to allow the container to be
 emptied without substantial under pressure.
- 20 27. Medical liquid injection device according to claim 23 comprising an inlet
 wherein said inlet and said outlet are disposed in said rigid shell.
28. Medical liquid injection device according to claim 23 wherein said flexible
 membrane is covered with a concave cover shell.
- 25 29. Medical liquid injection device according to claim 28 wherein said concave
 cover shell is rigid and thereby limits the container filling volume.
30. Medical liquid injection device according to anyone of claims 23 to 29
30 wherein the shape of the cavity in the covering shell is the mirror image of
 the cavity in the container such that the membrane also conforms to the
 cover shell in the full state.
31. Medical liquid injection device according to claim 28 adapted in a way so
35 that the volume between the flexible membrane and the cover shell is
 ventilated for pressure equilibration when the container volume varies.

5 32. Medical liquid injection device according to claim 28 wherein the cover shell
is reinforced to protect said flexible membrane from mechanical pressures.

10 33. Medical liquid injection device according to claim 32 wherein said flexible
membrane contains a weak zone that breaks in case of dangerous over
pressures.

15 34. Medical liquid injection device according to claim 29 comprising limiting
means situated between said flexible membrane and said cover shell for
reducing the filling volume.

20 35. Medical liquid injection device according to claim 34 wherein the position of
said limiting means is adjustable in order to vary the volume reduction.

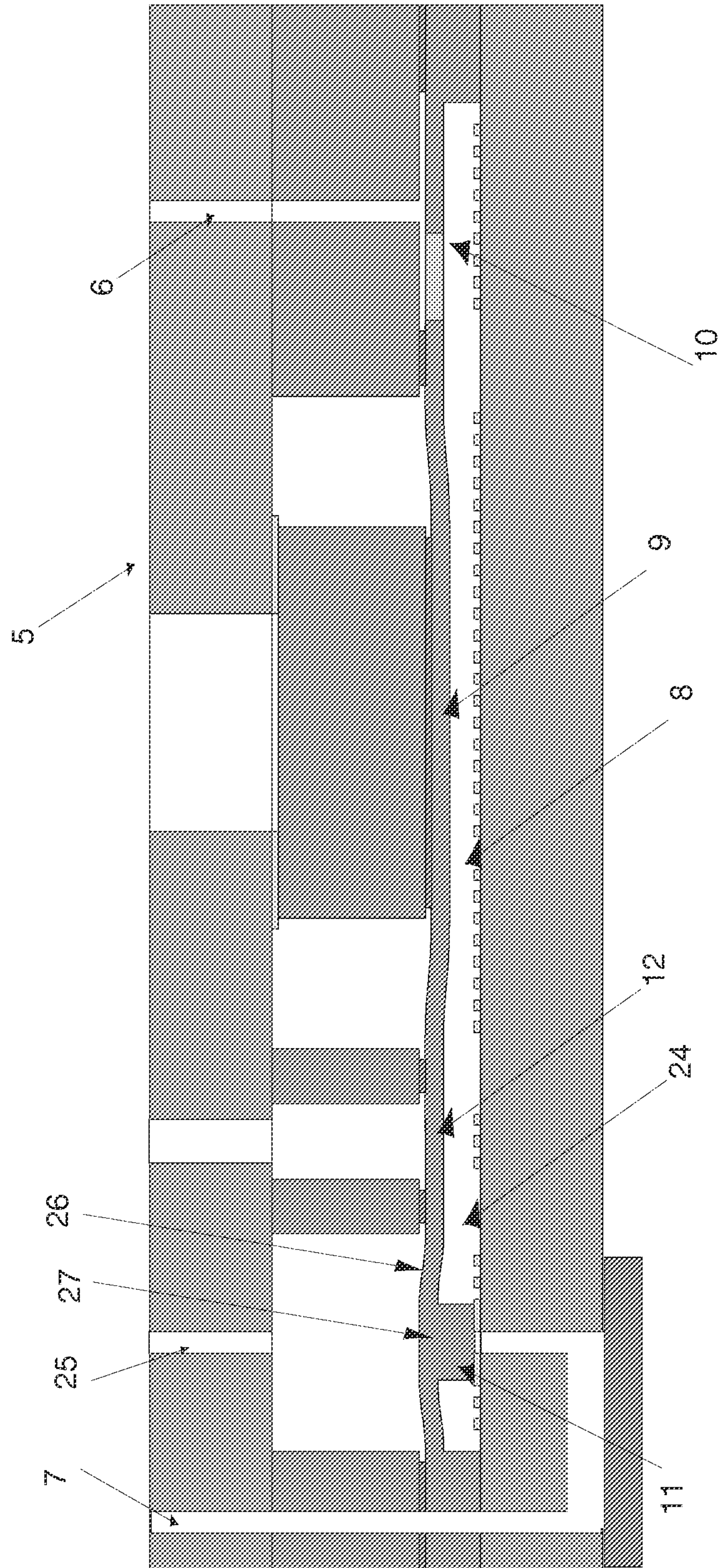


Fig. 1

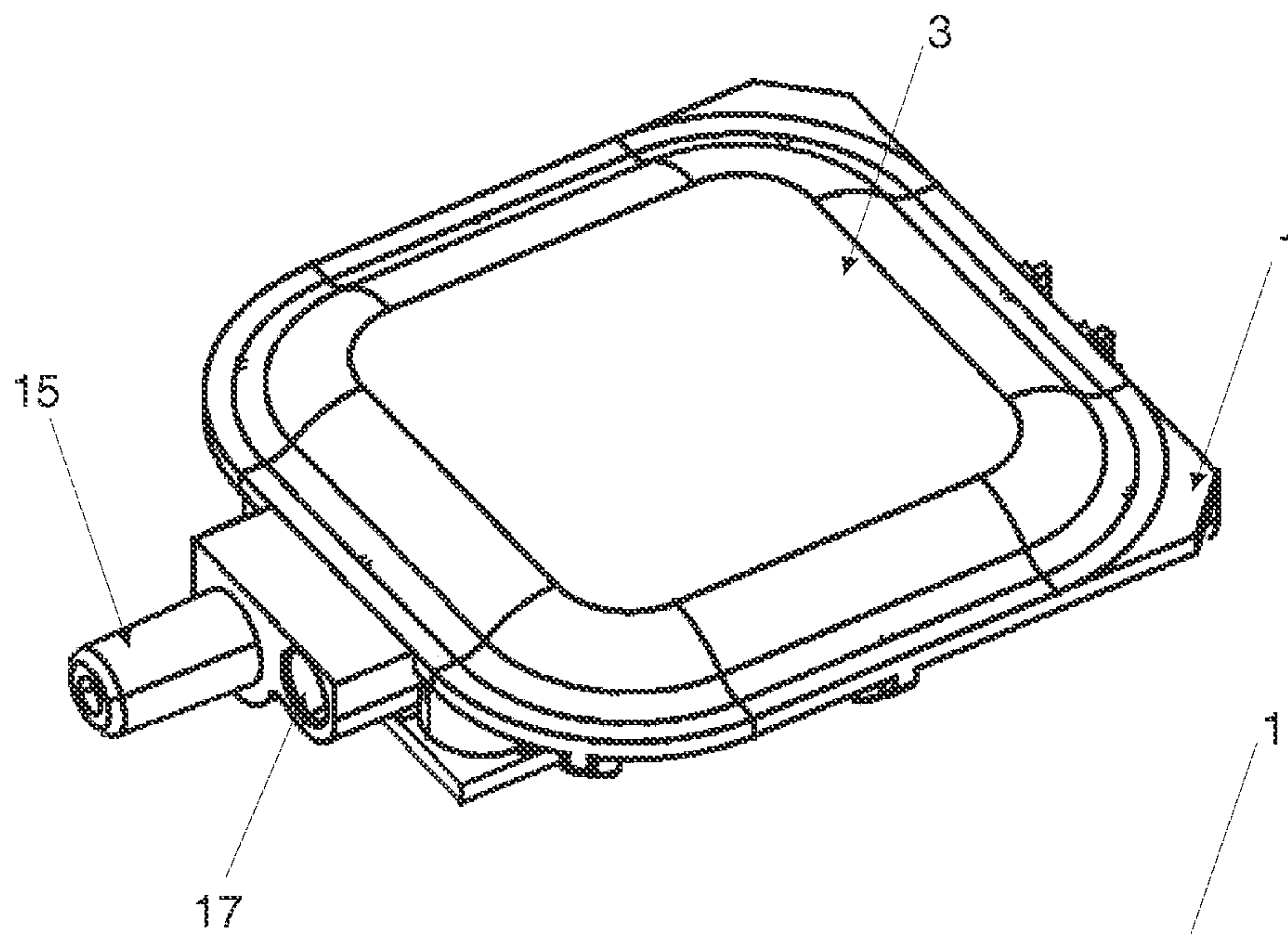


Fig. 3

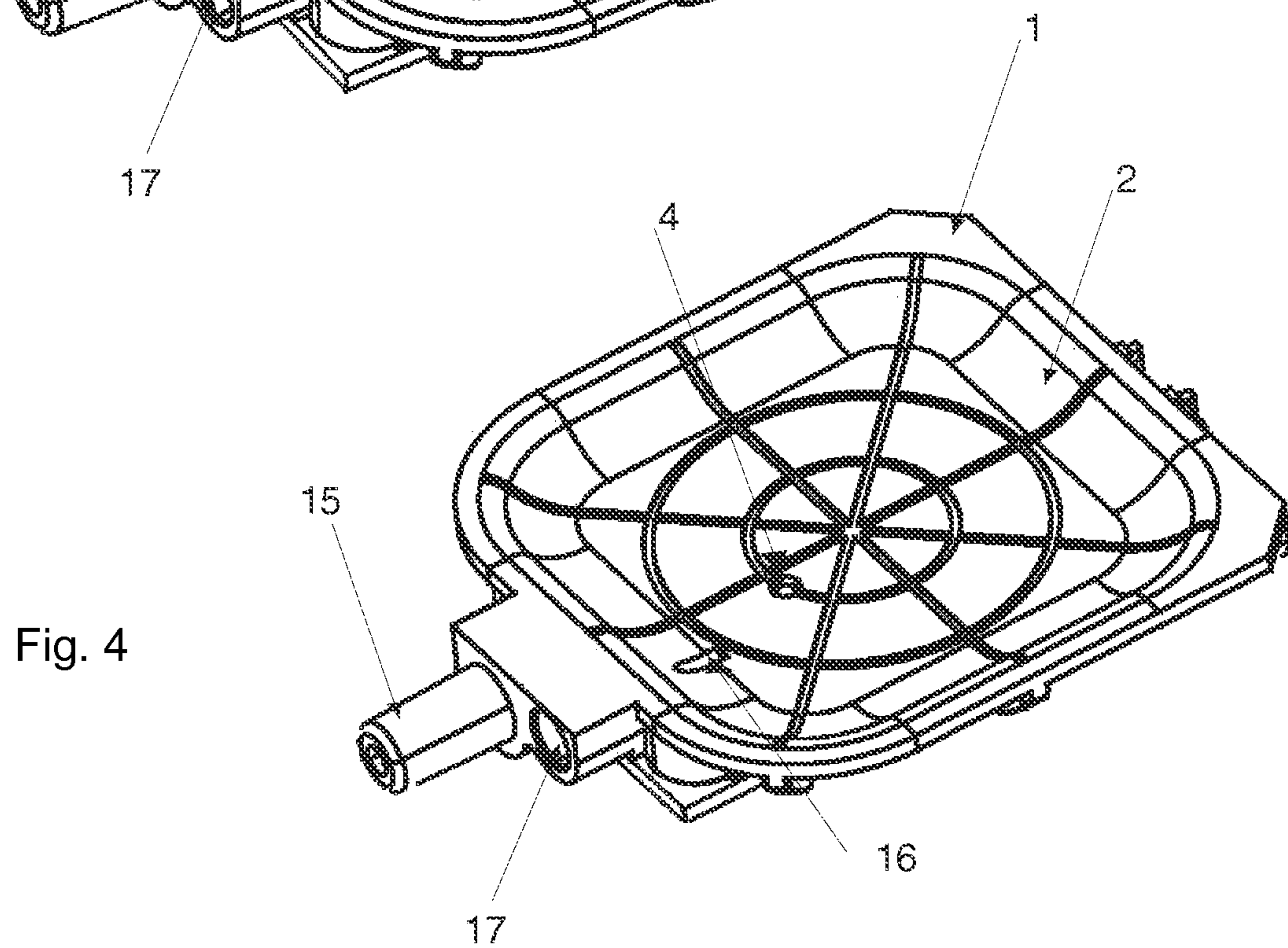


Fig. 4

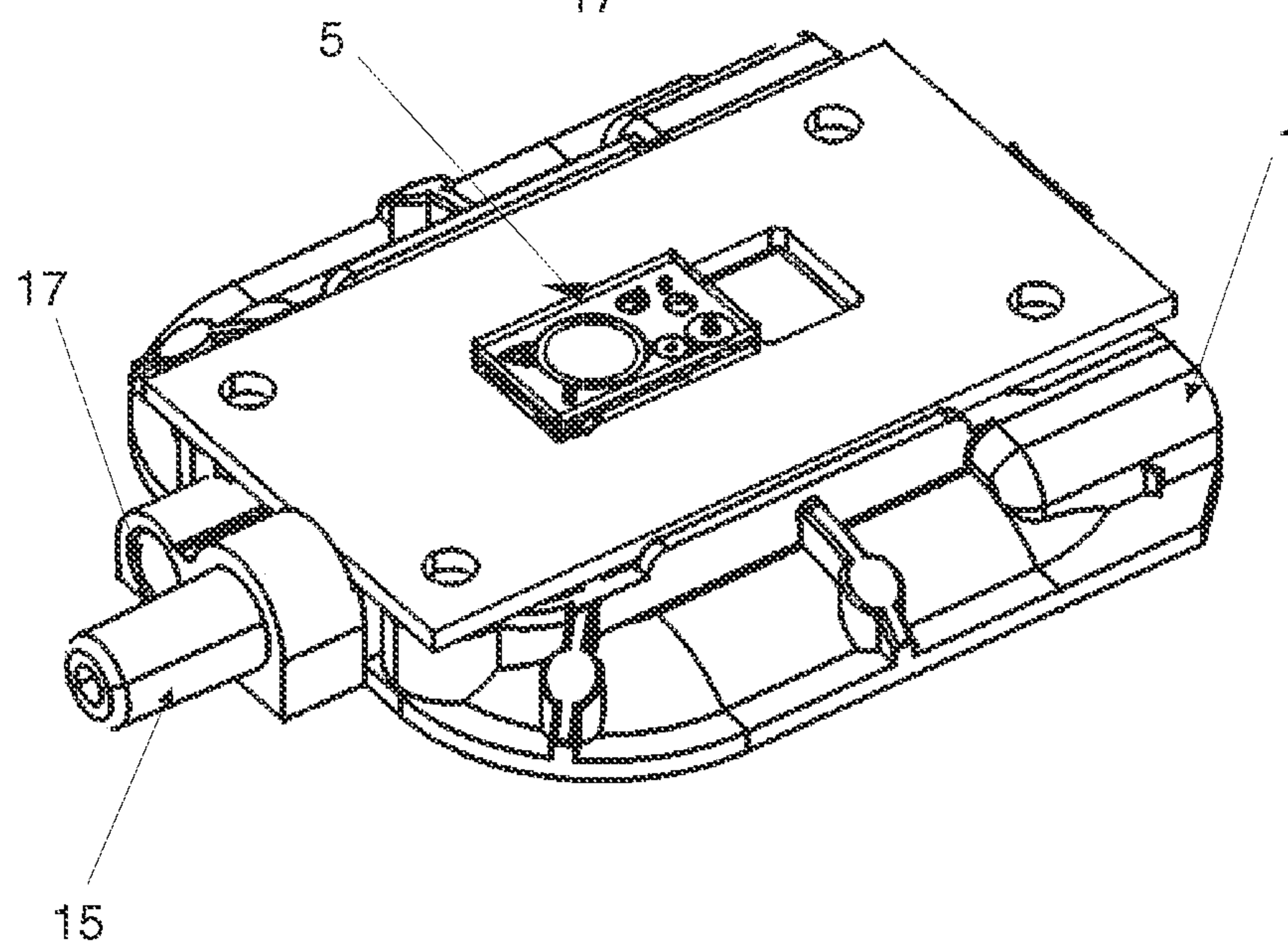


Fig. 5

