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(54) **MEASURING DEVICE FOR PHYSIOLOGICAL PARAMETERS**

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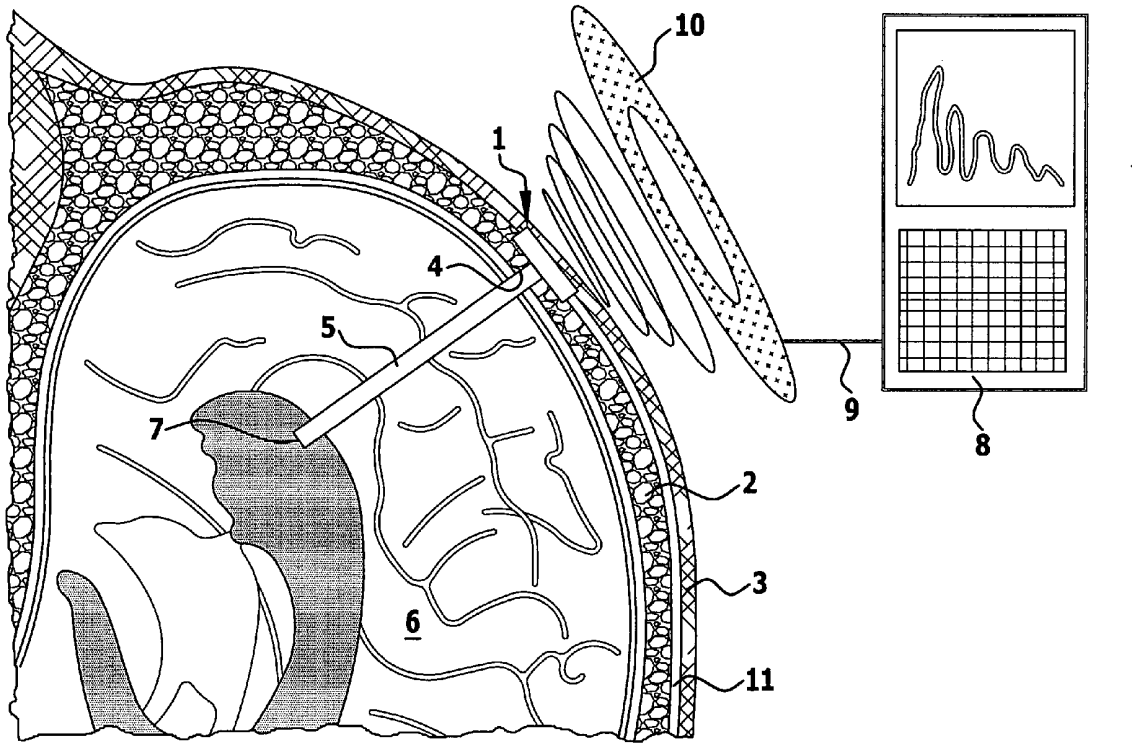
(52) **U.S. Cl.** **600/561**

(57) **ABSTRACT**

In a measuring device for physiological parameters with an implantable fluid chamber accommodating brain fluid, with a sensor device communicating with the brain fluid in the fluid chamber via a membrane and comprising a sensor for one or more physiological parameters, electronic components and a telemetry device for wireless transmission of signals of the sensor, in order to improve the manufacture and handling, it is proposed that the fluid chamber comprise at least two housing parts which are adapted to be fitted together in a sealed manner, thereby forming a closed interior, and which allow access to the interior when not fitted together, and that the sensor device be arranged in a measurement chamber closed on all sides, which is configured as a component that is adapted for independent handling and is insertable in a defined position in the interior of the fluid chamber.



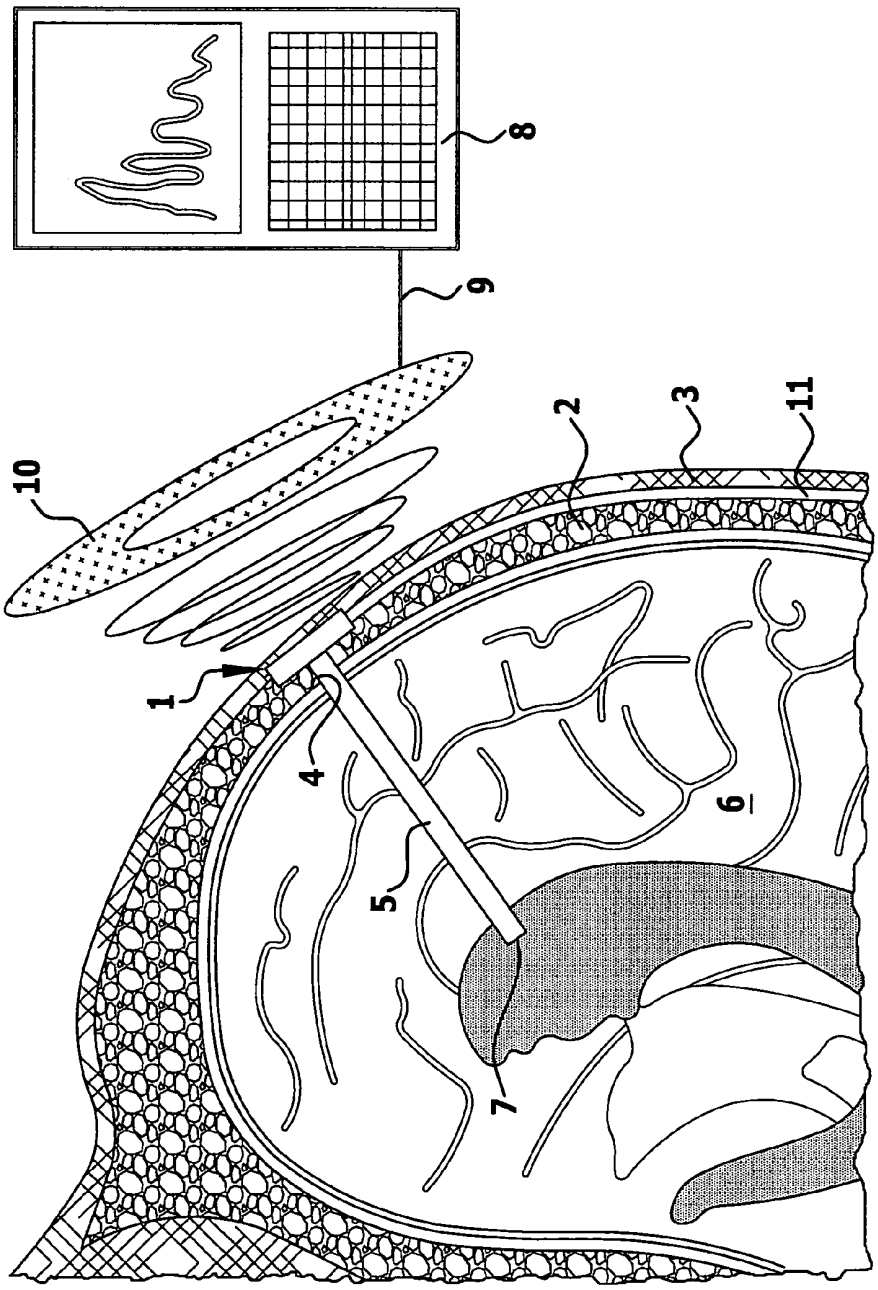


FIG.1

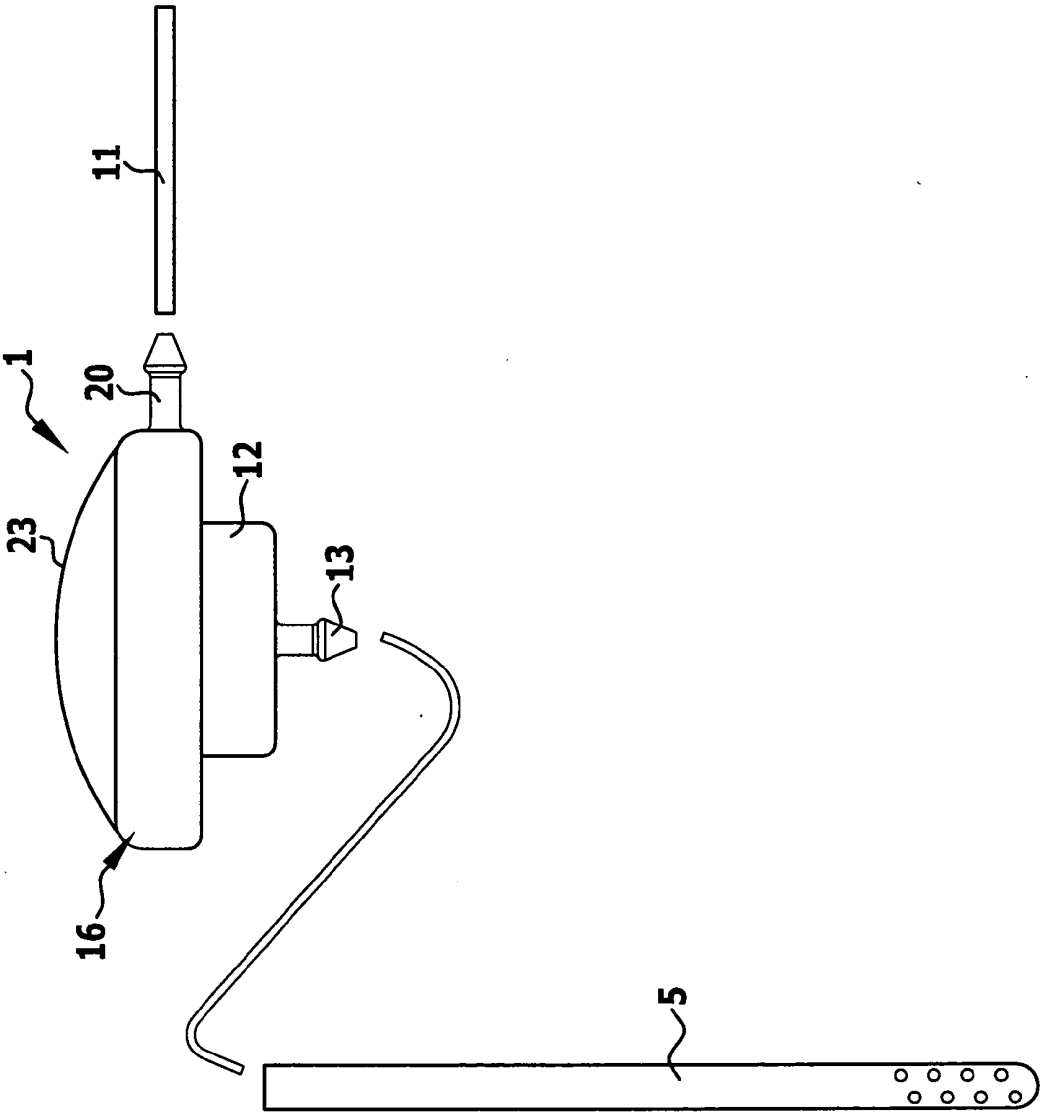


FIG.2

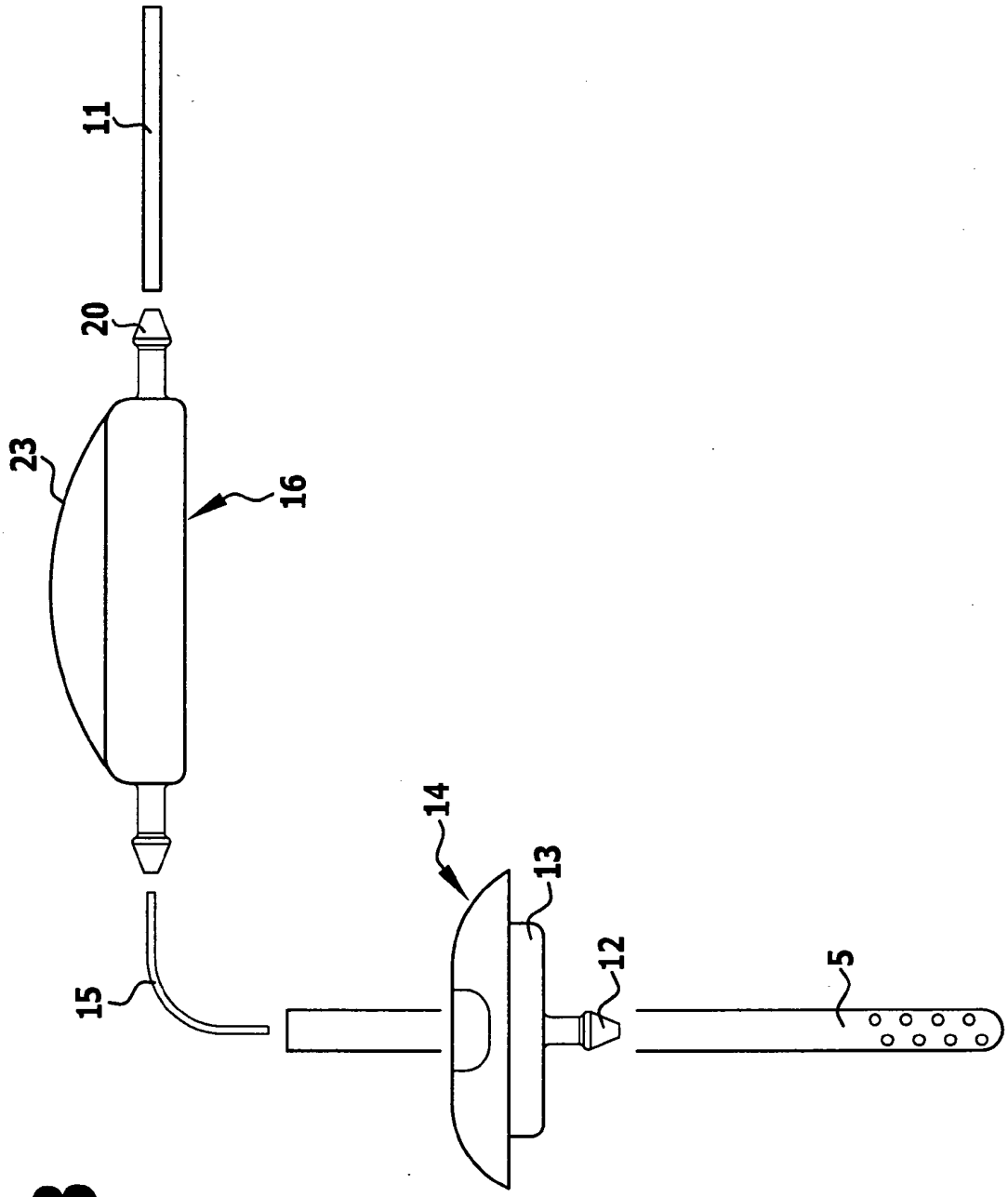


FIG.3

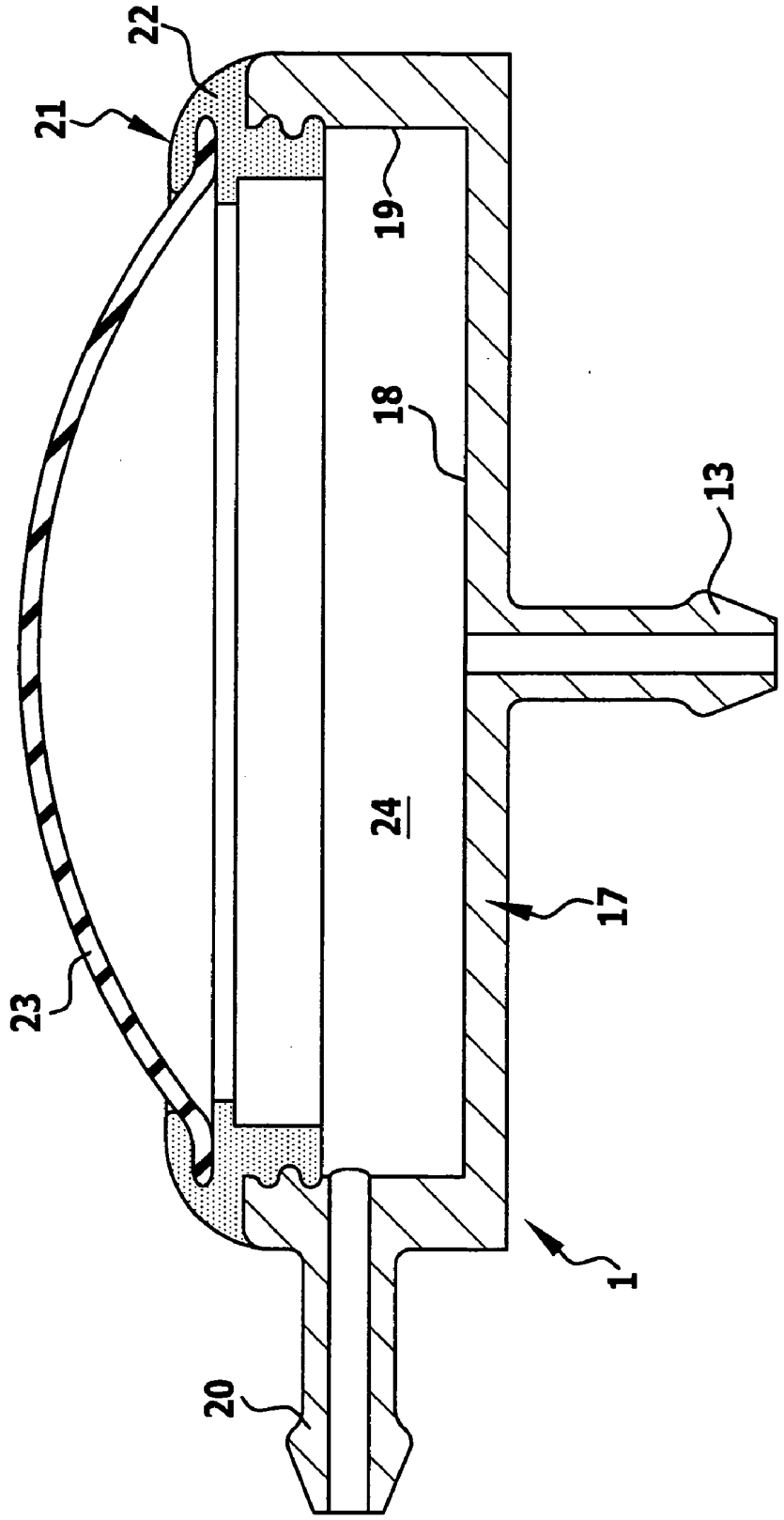


FIG.4

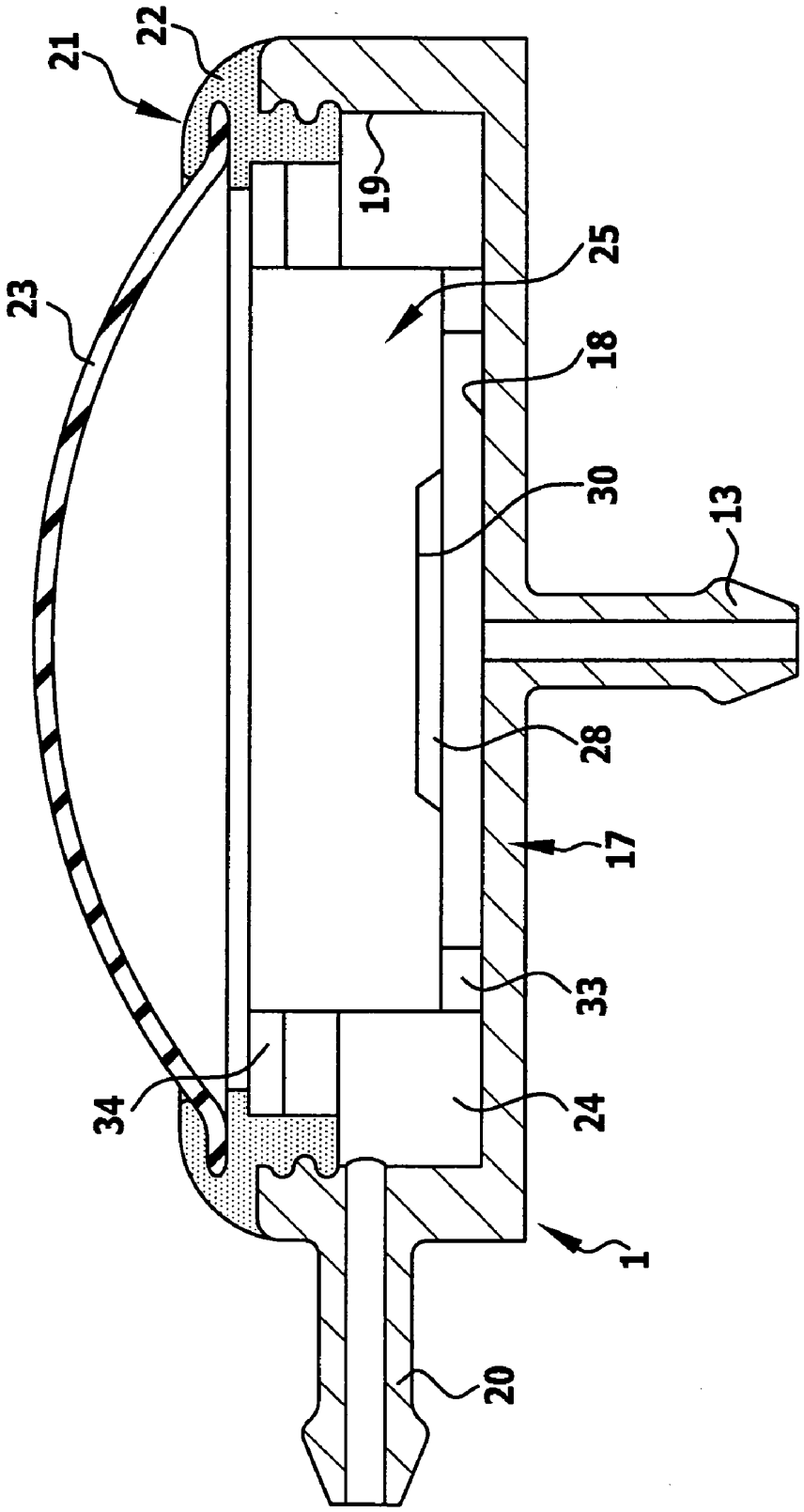


FIG.5

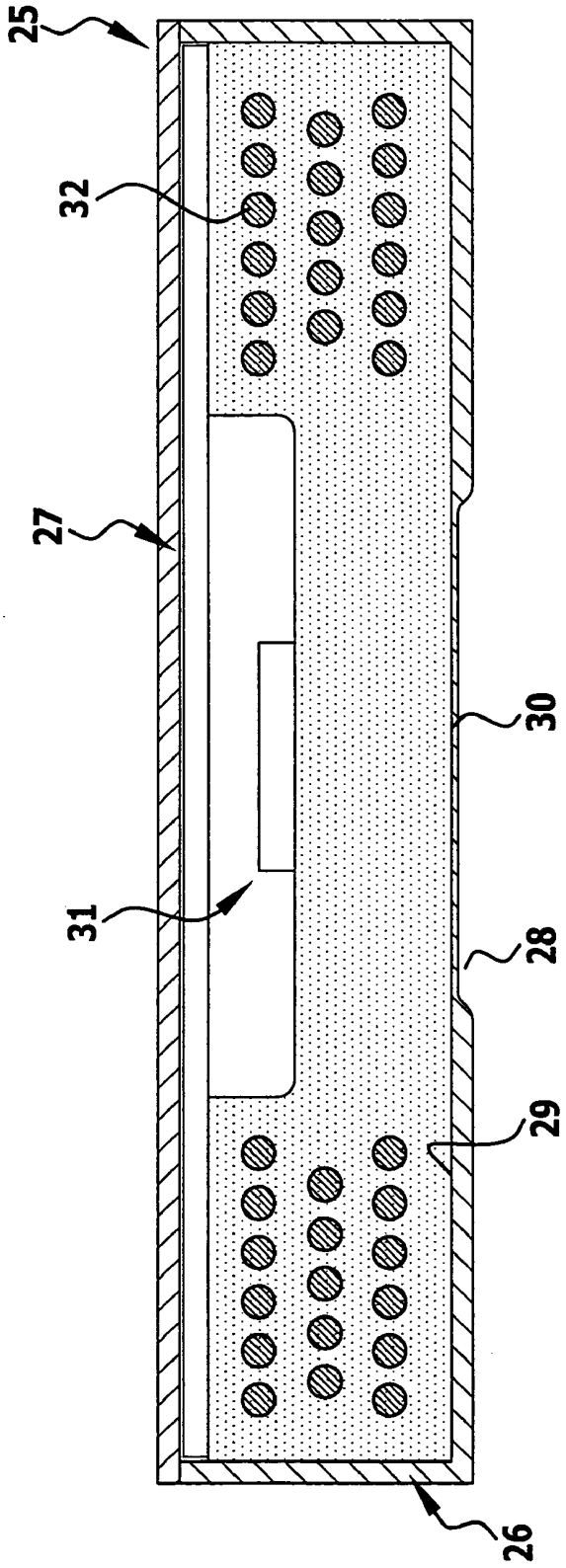


FIG.6

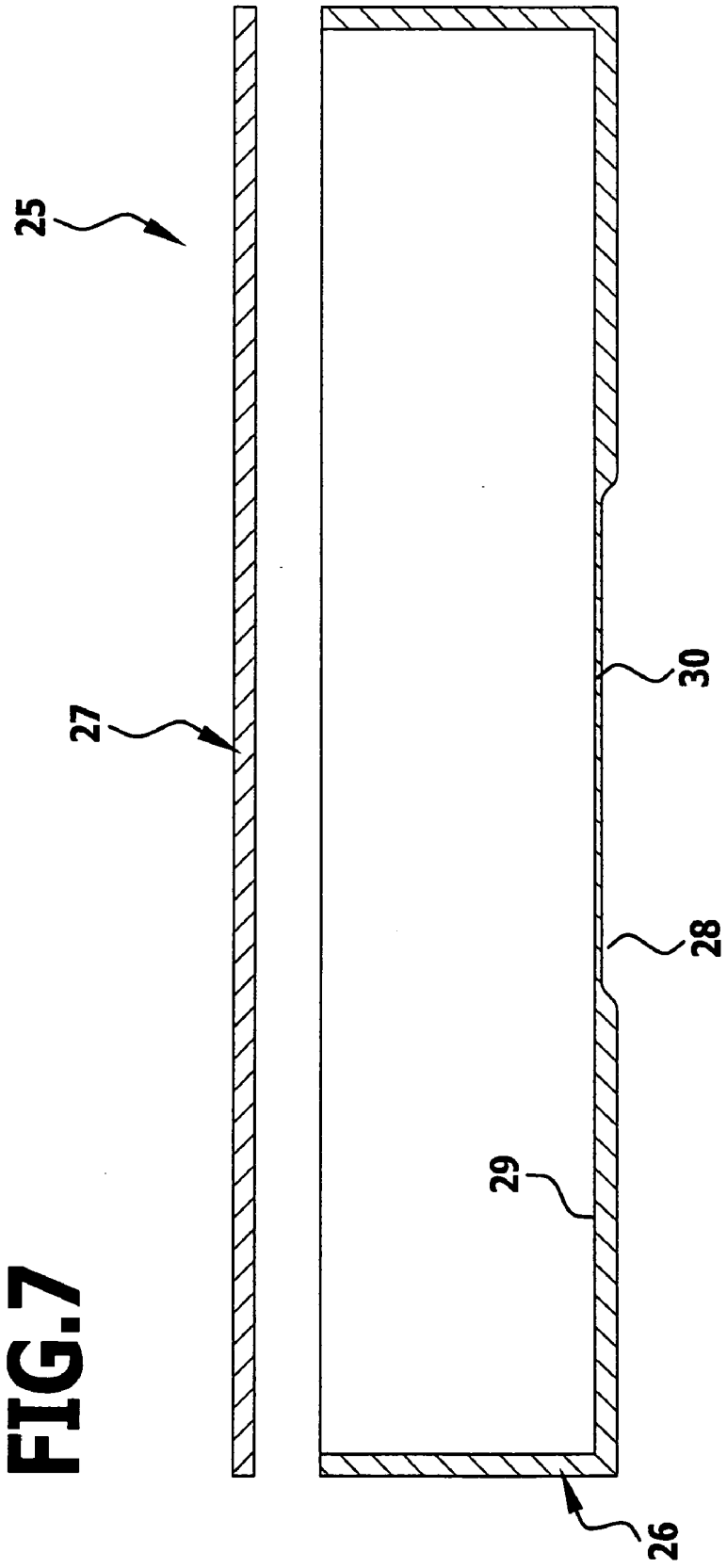
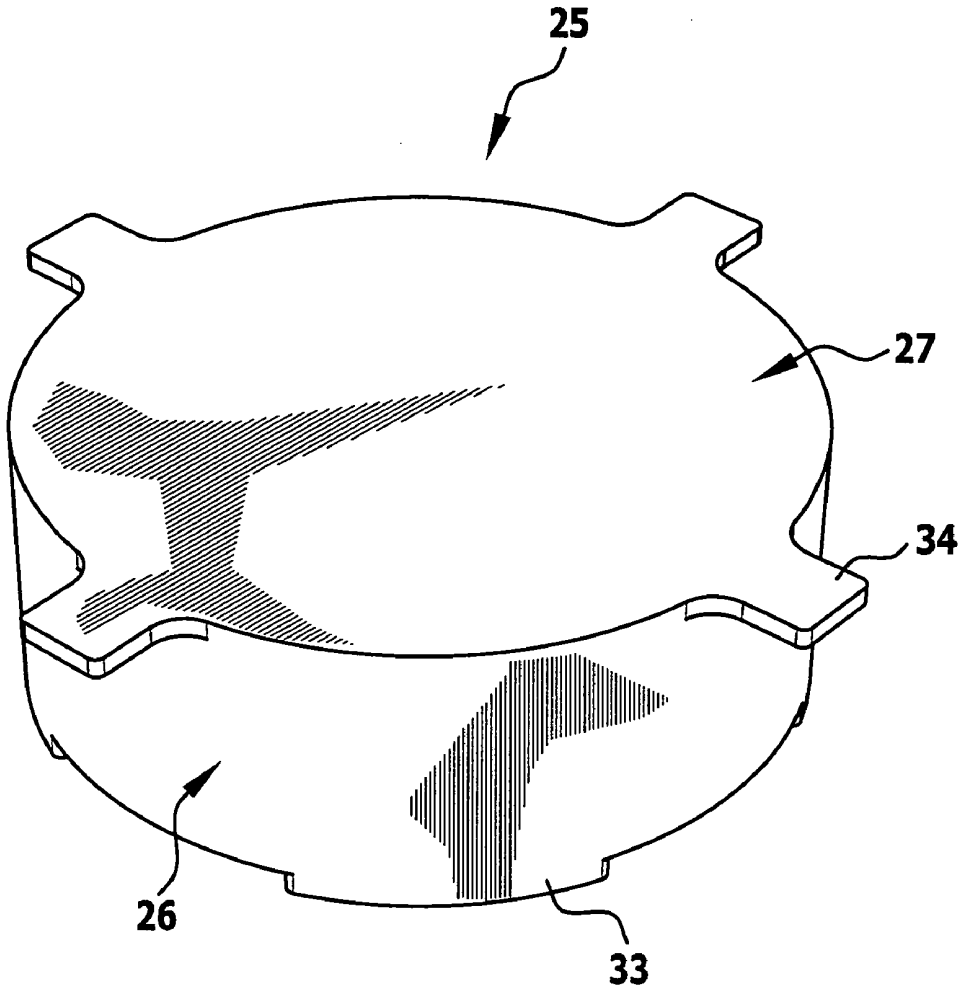


FIG.7

FIG.8



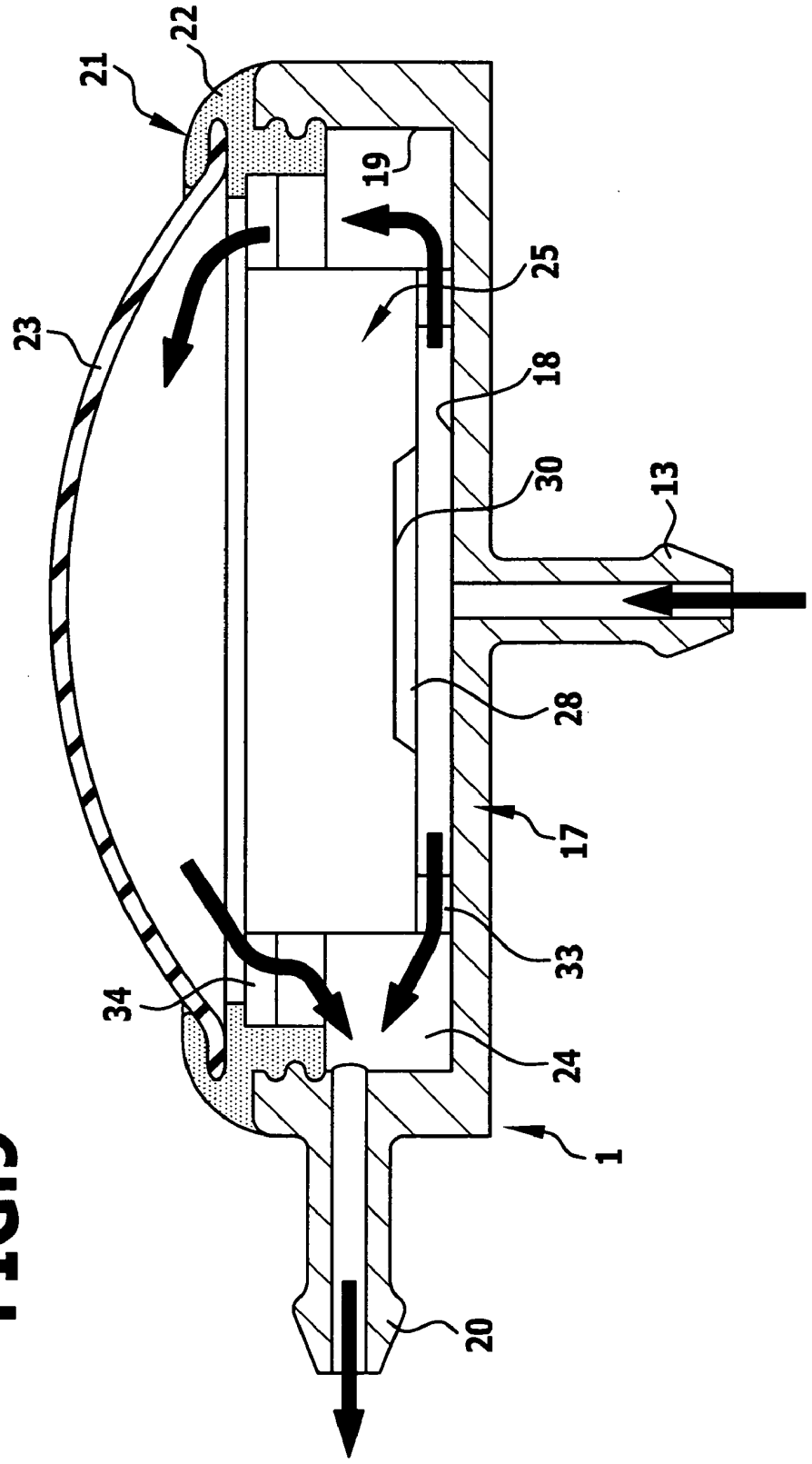


FIG.9

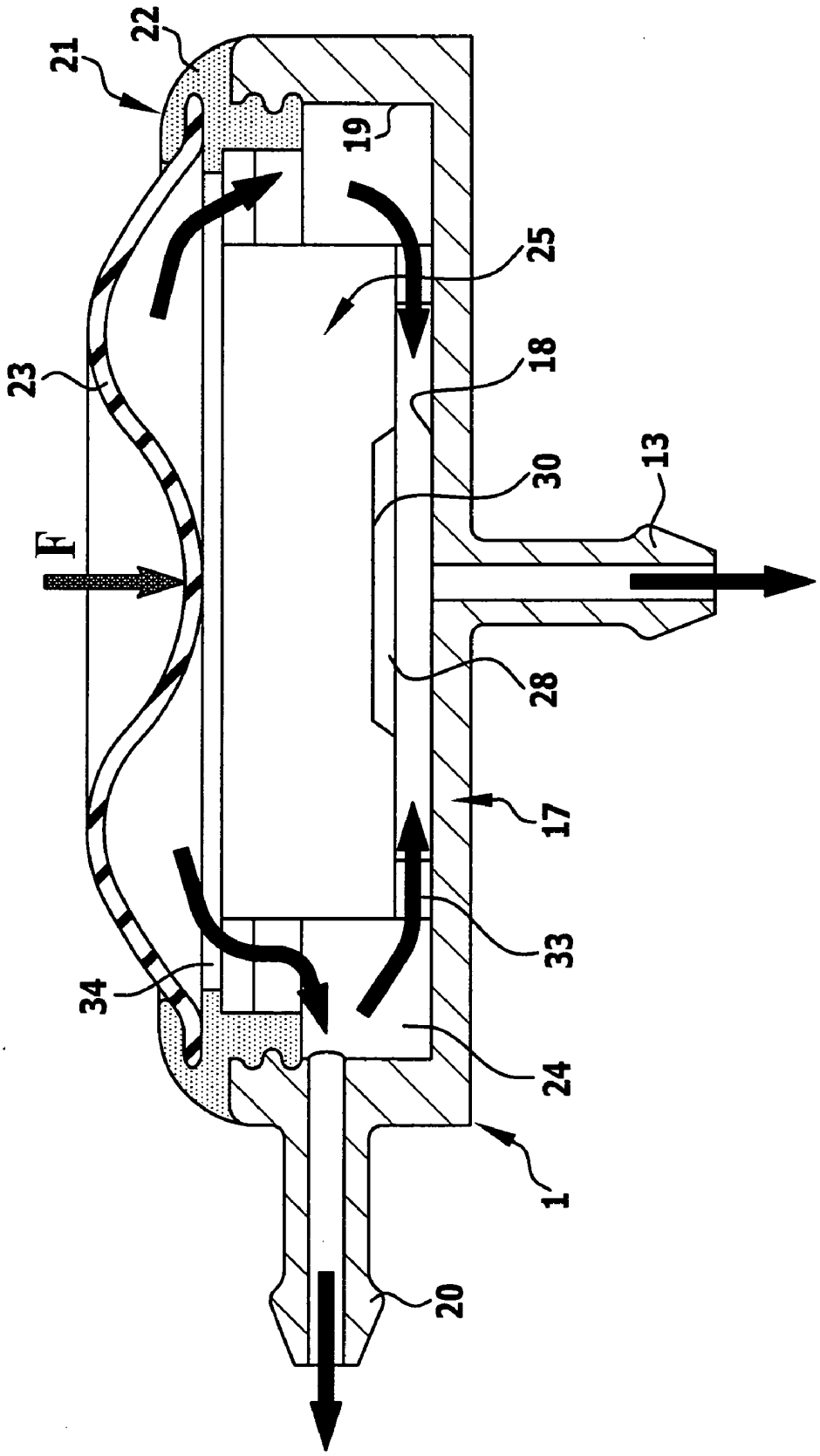


FIG.10

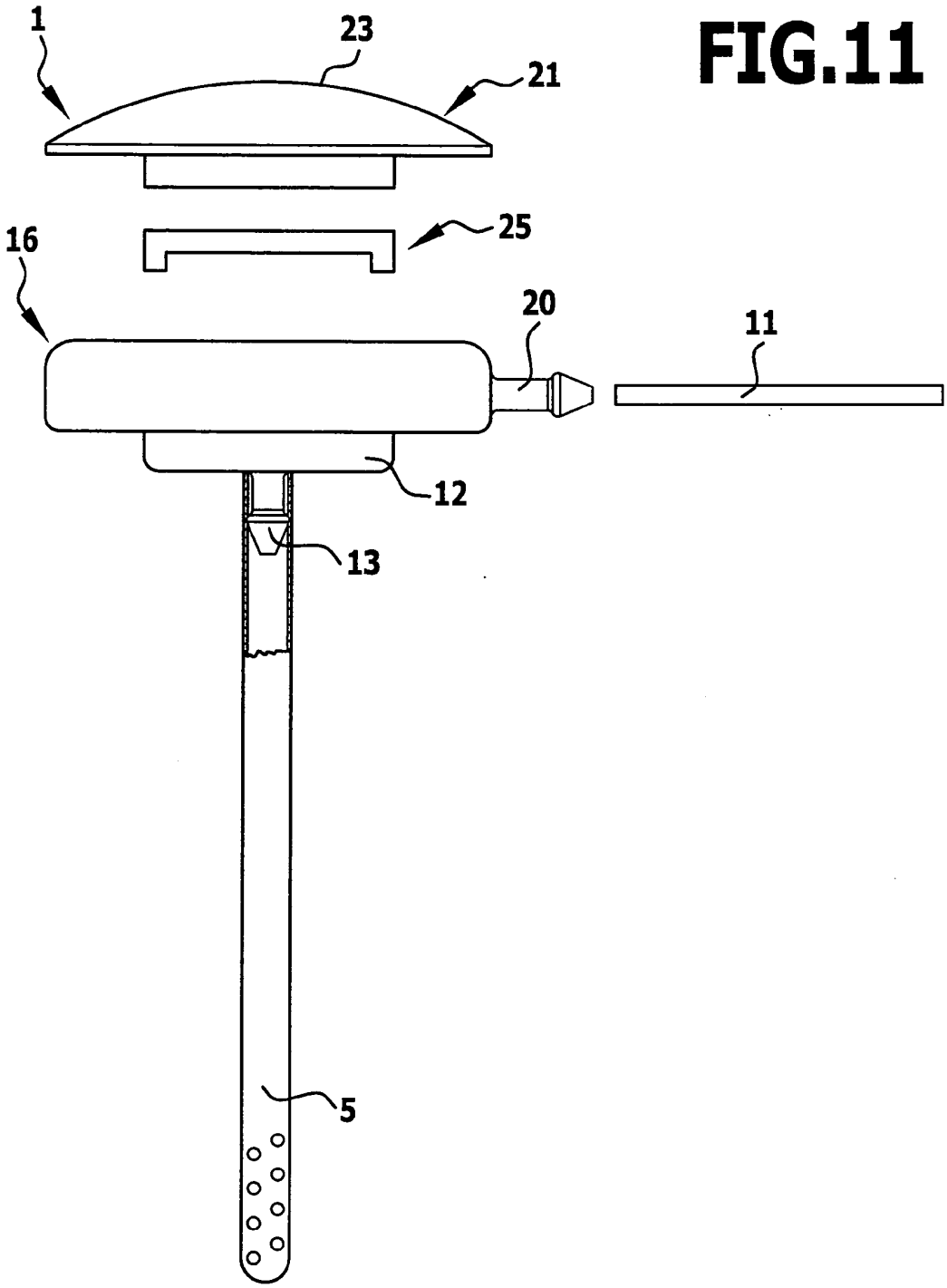


FIG.11

MEASURING DEVICE FOR PHYSIOLOGICAL PARAMETERS

[0001] This application is a continuation of international application number PCT/EP2008/000039 filed on Jan. 5, 2008.

[0002] The present disclosure relates to the subject matter disclosed in international application number PCT/EP2008/000039 of Jan. 5, 2008 and German application number 10 2007 008 642.5 of Feb. 22, 2007, which are incorporated herein by reference in their entirety and for all purposes.

BACKGROUND OF THE INVENTION

[0003] The invention relates to a measuring device for physiological parameters with an implantable fluid chamber accommodating brain fluid, with a sensor device communicating with the brain fluid in the fluid chamber via a membrane and comprising a sensor for one or more physiological parameters, electronic components and a telemetry device for wireless transmission of signals of the sensor.

[0004] Such a measuring device is described, for example, in WO 2006/117123 A1. Such measuring devices are usually implanted outside the cranial bone and underneath the scalp, in some cases directly over a drill hole in the cranial vault, in other cases next to such a drill hole through which brain fluid can enter the fluid chamber from the interior of the cranium. In the previously known measuring device, the fluid chamber is configured as a double chamber which is divided by an intermediate wall into two compartments, one of the compartments accommodating the sensor device, and the brain fluid flowing through the other compartment. Arranged in the intermediate wall between the compartments is a membrane through which the pressure of the brain fluid is transferred to a pressure senor of the sensor device.

[0005] Such an assembly must be prefabricated in its entirety and must be hermetically sealed. Therefore, in the event of a failure, only a complete exchange is possible. Moreover, the manufacture is complex.

[0006] The object of the invention is to so construct a generic measuring device that the manufacture is simplified and that, if necessary, repair work can be carried out without having to exchange the entire measuring device.

SUMMARY OF THE INVENTION

[0007] This object is accomplished, in accordance with the invention, in a measuring device of the kind described at the outset in that the fluid chamber comprises at least two housing parts which are adapted to be fitted together in a sealed manner, thereby forming a closed interior, and which allow access to the interior when not fitted together, and in that the sensor device is arranged in a measurement chamber closed on all sides, which is configured as a component that is adapted for independent handling and is insertable in a defined position in the interior of the fluid chamber.

[0008] Owing to the construction of the measurement chamber as a component that can be handled independently, it can be inserted into the open interior of the fluid chamber and is then held in a defined position in it. By joining the at least two housing parts of the fluid chamber, the fluid chamber can then be sealed tightly towards the outside, but it can also be opened again, if necessary, so that the measurement chamber can be taken out and, if necessary, exchanged, without exchange of the fluid chamber being required. The fluid chamber may even remain in its implanted position in the event of a failure of the sensor device and can continue to be used after insertion of a new measurement chamber.

[0009] Therefore, the surgeon also has the possibility of not inserting the measurement chamber until the operation is in progress, when the difficult implantation of the fluid chamber has been completed. This facilitates the operation and is easy on the sensitive sensor device during the operation.

[0010] It is expedient for the interior to be connected via at least one inlet to a probe via which brain fluid can flow from a measuring point of the brain into the interior. In addition, it may be provided that the interior has at least one outlet for brain fluid. The fluid chamber is then part of a shunt system with which brain fluid can be discharged in a manner known per se from the brain, for example, through a drainage pipe into the abdominal cavity.

[0011] In a preferred embodiment, it is provided that the fluid chamber comprises a first housing part with a bottom and adjoining side walls and a second housing part which is configured as a cover that is adapted to be placed in a sealed manner on the first housing part.

[0012] It is particularly advantageous for one region of the wall of the fluid chamber to be of flexible construction whereas the remaining regions of the wall are of rigid construction. In this way, it is possible to transfer a pressure pulse to the brain fluid in the fluid chamber by pressing in the flexible wall region. This pressure pulse can act as pumping pulse and, therefore, in the event of contamination and clogging of the flow paths, for example, bring about a cleaning. The pressure pulse may, however, also be used, for example, to generate control signals of the sensor and to thereby check whether it is functioning.

[0013] In particular, the flexible wall region can be formed by a flexible membrane, for example, a flexible membrane made of silicone.

[0014] Such a construction has the further advantage that a cannula for removal of samples of the fluid can be introduced into the interior of the fluid chamber through such a flexible membrane made of silicone or a similar material. In this way, it is possible to gain access to the brain fluid through the scalp and through the flexible membrane even when the measuring device is implanted.

[0015] In accordance with a preferred embodiment, the flexible membrane may be inserted into a sealing ring which together with the membrane forms a housing part which is adapted to be fitted together with a second housing part in order to form the fluid chamber. This sealing ring may, for example, be screwed in a sealed manner into the second housing part.

[0016] In particular, in a configuration with a flexible wall region of the fluid chamber, it is advantageous for the measurement chamber to be inserted into the fluid chamber in such a way that it is surrounded on all sides by brain fluid. The pumping possibility is thereby improved with the aid of the flexible wall region as the brain fluid also flows through the part of the interior immediately adjacent to the flexible wall region.

[0017] The measurement chamber preferably consists of metal, for example, of titanium or a titanium alloy, and it is expedient for the measurement chamber to have rigid walls. Nevertheless, the walls may be relatively thin, for example, the wall thickness lies in the order of magnitude of a few tenths of a millimeter.

[0018] The fluid chamber may also consist of a body-compatible metal, for example, of titanium or a titanium alloy. It is, however, also possible to make the fluid chamber from a sterilizable plastic material, for example, from polyetheretherketone. Use of a plastic material has the advantage that the screening effect for the telemetry device in the interior of the measurement chamber, which exists in the case of a metallic construction of the fluid chamber and which impedes transmission of the signals, is eliminated.

[0019] The following description of preferred embodiments of the invention serves as a more detailed explanation in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. **1** is a schematic sectional view through the cranium of a patient with an implanted measuring device and an external evaluating device;

[0021] FIG. **2** is a schematic side view of a measuring device with a probe insertable into the brain and with a drainage pipe for the brain fluid in a measuring device insertable over a drill hole in the cranial vault;

[0022] FIG. **3** is a view similar to FIG. **2** in a measuring device implantable next to a drill hole in the cranial vault;

[0023] FIG. **4** is a sectional view of a closed fluid chamber without the measurement chamber inserted;

[0024] FIG. **5** is a view similar to FIG. **4** with the measurement chamber inserted;

[0025] FIG. **6** is a longitudinal sectional view through a measurement chamber;

[0026] FIG. **7** is a sectional view of an empty and unclosed measurement chamber;

[0027] FIG. **8** is a perspective view of a closed measurement chamber;

[0028] FIG. **9** is a longitudinal sectional view similar to FIG. **5** of a measuring device through which brain fluid is flowing;

[0029] FIG. **10** is a view similar to FIG. **9** representing the flow of the brain fluid when a flexible wall region is pressed in; and

[0030] FIG. **11** is an exploded view of a further preferred embodiment of a measuring device.

DETAILED DESCRIPTION OF THE INVENTION

[0031] The measuring device **1** shown in the drawings is usually implanted outside the cranial bone **2** and beneath the scalp **3** over a drill hole **4** or next to such a drill hole. A probe **5** or a catheter passes through the drill hole **4** into the interior of the brain **6** and terminates at an inlet point **7**, at which brain fluid from the brain **6** can enter the probe **5**. This brain fluid is fed by the probe **5** to the measuring device **1**, so that physiological values of the brain fluid, for example, the pressure of the brain fluid and/or the temperature can be measured in the measuring device **1**.

[0032] The measured values of the physiological parameters recorded in this way in the measuring device **1** are transmitted in a wireless manner to an external evaluating device which is connected by a measurement line **9** to a coil **10**. This coil **10** can be so arranged in the proximity of the measuring device **1** that it can exchange signals with a corresponding coil of the measuring device in a wireless manner. The measuring device **1** can also be supplied with external power via these coils.

[0033] Brain fluid fed to the measuring device **1** can be discharged through a drainage pipe **11**. Such a drainage pipe terminates, for example, in the abdominal cavity of the patient. The probe **5**, the measuring device **1** and the drainage pipe **11** therefore form a shunt system with which brain fluid can be removed from the cranium.

[0034] If the measuring device **1** is placed directly over the drill hole **4**, it is then expedient for the measuring device **1** to have on its underside a projection **12** entering the drill hole **4** and an adjoining connection **13** which, for example, can be connected by a flexible line **14** to the probe **5** (FIG. **2**) or onto which the probe **5** can be directly pushed (FIG. **11**).

[0035] If, in contrast, the measuring device **1** is arranged next to a drill hole **4**, it is advantageous for a drill hole cover **14** to be provided, which also carries a projection **12** and a connection **13** on its underside, and which diverts the brain fluid parallel to the cranial bone, so that the brain fluid enters the measuring device **1** at the side through a further line **15** (FIG. **3**).

[0036] The measuring device **1** comprises a fluid chamber **16** with a can-shaped base part **17** with a flat bottom **18** and adjoining perpendicular walls **19** on the outside. This can-shaped base part **17** preferably has a circular cross section. In the embodiment shown in FIGS. **4** and **5**, the bottom **18** has a downwardly directed connection **13** for admission of the brain fluid and an outlet **20** extending horizontally out of the wall **19** for discharge of the brain fluid.

[0037] The can-shaped base part **17** is open on its upper side where it can be closed tight by a lid-shaped housing part **21**. This lid-shaped housing part **21** comprises a ring **22**, which is configured as a sealing ring and is sealingly connectable to the wall **19** of the base part **17**, for example, by being screwed in or glued in. Inserted in a sealed manner into the ring **22** is a hood-shaped flexible membrane **23**, which preferably consists of silicone, whereas the ring **22** may, for example, consist of polyetheretherketone. When fitted together, the bottom-shaped base part **17** and the lid-shaped housing part **21** form a housing-like fluid chamber with an interior **24**, which is closed except for the connection **13** and the outlet **20**. In the implanted state, the brain fluid flows through this interior **24** and fills it out completely. The flexible membrane **23** is thereby arched outwards in the manner shown in FIG. **9**.

[0038] This flexible membrane can be pushed inwards, as shown in FIG. **10**, by pressure on the membrane **23**. The brain fluid is thereby expelled from the interior **24** through both the outlet **20** and the connection **13** out of the fluid chamber **16**, i.e., a backflushing of the probe **5** takes place and an increased flushing of the drainage pipe **11**. This flushing effect may be used to clean the corresponding pipes, however, it is also possible to transmit by means of this pressure on the flexible membrane **23** a pressure pulse onto the brain fluid, which can then be registered by the measuring device **1**. It is thereby possible to check whether the measuring device is functioning.

[0039] Inserted in the interior **24** is a completely closed-off measurement chamber **25** comprising a base part **26** which is likewise can-shaped and has a circular cross section, and a cover **27** which is placed in a sealed manner on this base part **26** (FIG. **7**). This measurement chamber preferably consists of metal, in particular, of titanium or a titanium alloy. The walls are of rigid construction except for a central region **28** on the bottom **29** of the base part **26**. In this region, either a flexible membrane **30** is inserted or the bottom **29** is of such

thin construction owing to the removal of material that it forms a flexible membrane **30**.

[0040] Accommodated in the interior of the measurement chamber **25** are a sensor chip **31** and a coil **32** surrounding this. The sensor chip **31** carries at least one sensor, for example, a pressure sensor and/or a temperature sensor, in addition, electronic components for processing and digitizing the electric signals generated by the sensors and for supplying power, and also electronic components of a telemetry circuit which transmits the signals generated by the sensors via the coil **32** to the outside. These signals can then be received by the coil **10** of the external evaluating device **8**.

[0041] The interior of the measurement chamber **25** is filled with a pressure-transferring medium, for example, with air, with an oil or with a gel. It is also possible for mechanical transfer members, for example, pistons or levers to be provided between the flexible membrane **30** and the sensors on the sensor chip **31**. It is only essential that the pressure of the brain fluid be able to reach the sensors on the sensor chip **31** via the flexible membrane **30** and result in corresponding measurement signals there.

[0042] The measurement chamber **25** carries at its lower end supporting projections **33** extending over part of the circumference and projecting downwardly, and on its cover **27** centering webs **34** which protrude radially so that the measurement chamber **25** is arranged in a precisely defined position when inserted into the base part **17** of the fluid chamber **16**. The supporting projections **33** are then supported on the bottom **18** of the base part **17**, and the radial centering webs **34** either on the wall **19** of the base part **17** or after closure of the fluid chamber on the ring **22**. At any rate, it is ensured by this arrangement that the brain fluid can flow all around the measurement chamber **25**, i.e., the measurement chamber **25** is spaced all over from the bottom **18**, from the walls **19** and also from the lid-shaped housing part **21**, so that the brain fluid can flow unimpeded through these spaces.

[0043] This is particularly important when a backflushing pulse or a pressure pulse is to be transmitted to the brain fluid by means of the flexible membrane **23**, but it is also of importance that no distortions of the pressure measurement occur as a result of the brain fluid being able to flow freely through the interior **24**.

[0044] The measurement chamber **25** can be inserted into the fluid chamber **16** after the latter has been implanted. It is also readily possible to exchange the measurement chamber, should malfunctions of the measurement chamber occur or should other measurements be of interest.

1. Measuring device for physiological parameters, comprising an implantable fluid chamber accommodating brain fluid, a sensor device communicating with the brain fluid in the fluid chamber via a membrane and having a sensor for one or more physiological parameters, electronic components and a telemetry device for wireless transmission of signals of the sensor, wherein the fluid chamber comprises at least two housing parts which are adapted to be fitted together in a sealed manner, thereby forming a closed interior, and which allow access to the interior when not fitted together, and wherein the sensor device is arranged in a measurement chamber closed on all sides, which is configured as a component that is adapted for independent handling and is insertable in a defined position in the interior of the fluid chamber.

2. Measuring device in accordance with claim **1**, wherein the interior is connected via at least one inlet to a probe via which brain fluid can flow from a measuring point of the brain into the interior.

3. Measuring device in accordance with claim **1**, wherein the interior has at least one outlet for brain fluid.

4. Measuring device in accordance with claim **1**, wherein the fluid chamber comprises a first housing part with a bottom and adjoining side walls and a second housing part which is configured as a cover that is adapted to be placed in a sealed manner on the first housing part.

5. Measuring device in accordance with claim **1**, wherein one region of the wall of the fluid chamber is of flexible construction whereas the remaining regions of the wall are of rigid construction.

6. Measuring device in accordance with claim **5**, wherein the flexible wall region is formed by a flexible membrane.

7. Measuring device in accordance with claim **6**, wherein the flexible membrane consists of silicone.

8. Measuring device in accordance with claim **5**, wherein the flexible membrane is inserted into a sealing ring which together with the membrane forms a housing part which is adapted to be fitted together with a second housing part in order to form the fluid chamber.

9. Measuring device in accordance with claim **1**, wherein the measurement chamber is inserted into the fluid chamber in such a way that it is surrounded on all sides by brain fluid.

10. Measuring device in accordance with claim **9**, wherein fixing projections which are part of the fluid chamber and/or the measurement chamber are arranged between the fluid chamber and the measurement chamber for securing the measurement chamber in the fluid chamber.

11. Measuring device in accordance with claim **1**, wherein the measurement chamber consists of metal.

12. Measuring device in accordance with claim **1**, wherein the measurement chamber has rigid walls.

13. Measuring device in accordance with claim **1**, wherein the fluid chamber consists of a sterilizable plastic material.

14. Measuring device in accordance with claim **13**, wherein the fluid chamber consists of polyetheretherketone.

* * * * *

专利名称(译)	生理参数测量装置		
公开(公告)号	US20100030103A1	公开(公告)日	2010-02-04
申请号	US12/460447	申请日	2009-07-17
[标]申请(专利权)人(译)	阿拉贡外科手术公司		
申请(专利权)人(译)	AESCULAP AG		
当前申请(专利权)人(译)	AESCULAP AG		
[标]发明人	LUTZE THEODOR SCHAUER DIRK MIETHKE CHRISTOPH		
发明人	LUTZE, THEODOR SCHAUER, DIRK MIETHKE, CHRISTOPH		
IPC分类号	A61B5/00		
CPC分类号	A61B5/0008 A61B5/0031 A61B5/6865 A61B5/6864 A61B5/031		
优先权	102007008642 2007-02-22 DE		
外部链接	Espacenet USPTO		

摘要(译)

在用于生理参数的测量装置中，具有容纳脑液的可植入流体室，传感器装置经由膜与流体室中的脑液连通并且包括用于一个或多个生理参数的传感器，电子部件和用于为了改善制造和操作，传感器的信号的无线传输提出，流体室包括至少两个壳体部分，这些壳体部分适于以密封方式装配在一起，从而形成封闭的内部，并且当未安装在一起时允许进入内部，并且传感器装置布置在所有侧面都封闭的测量室中，该测量室被配置为适于独立操作的部件并且可插入在内部的限定位置中。流体室。