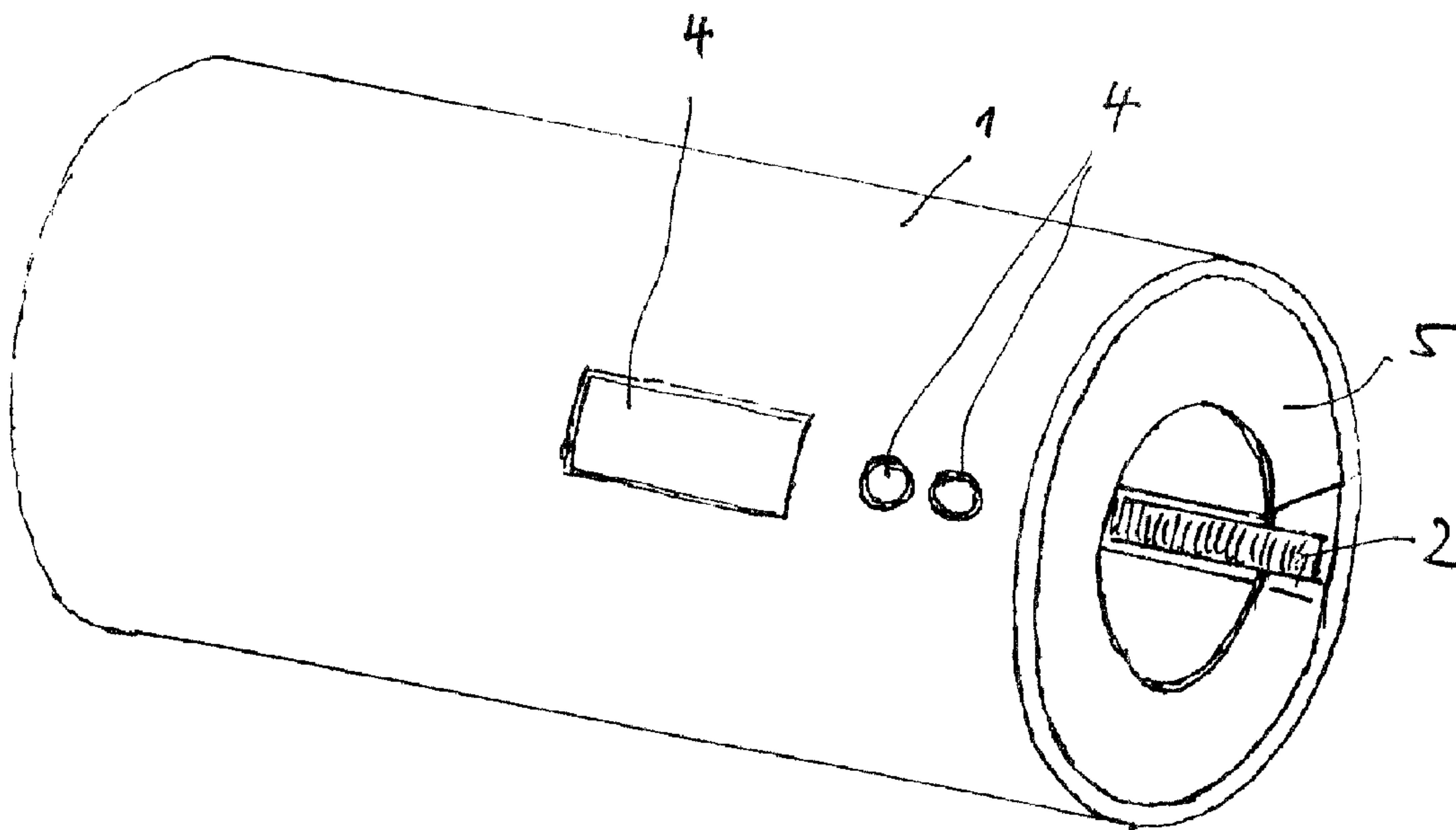




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(54) Titre : PROCÉDE POUR VERIFIER ET IDENTIFIER DES SERINGUES MEDICALES PREREMPLIES ET
 DISPOSITIF CONNEXE
 (54) Title: PROCEDURE FOR IDENTIFYING AND TESTING PREFILLED MEDICAL SYRINGES AND TEST DEVICE
 FOR PERFORMING THE PROCEDURE



(57) Abrégé/Abstract:

A procedure and a testing device designed for executing the procedure, serve to read and verify codes, in particular on medical syringes. A recording sleeve allows insertion of part of the syringe barrel that contains the code. Inside the syringe barrel there is a reading device, which is designed as a two-dimensional or linear optical scanner. In a linear embodiment, the scanner runs either axially along the retaining sleeve or radially in an annular arrangement on the inner wall of the retaining sleeve. An analytical unit with a data memory collects the information registered by the reading device and compares it with stored target values. A display unit shows the results of the analysis.

ABSTRACT

A procedure and a testing device designed for executing the procedure, serve to read and verify codes, in particular on medical syringes. A recording sleeve allows insertion of
5 part of the syringe barrel that contains the code. Inside the syringe barrel there is a reading device, which is designed as a two-dimensional or linear optical scanner. In a linear embodiment, the scanner runs either axially along the retaining sleeve or radially in an annular arrangement
10 on the inner wall of the retaining sleeve. An analytical unit with a data memory collects the information registered by the reading device and compares it with stored target values. A display unit shows the results of the analysis.

**PROCEDURE FOR IDENTIFYING AND TESTING PREFILLED MEDICAL
SYRINGES AND TEST DEVICE FOR PERFORMING THE PROCEDURE**

FIELD OF THE INVENTION

The present invention relates to a procedure for
5 identifying, testing and/or releasing prefilled medical
syringes before their use and a test device for performing
the procedure.

The invention specifically refers to a procedure for use by
patients themselves, by means of a test device in whose
10 interior is located a reading device for a code that has
been applied to the syringe. Furthermore, the invention
involves a test device for the performance of the procedure.

BACKGROUND OF THE INVENTION

Increasingly, patients are being called upon to self-
15 administer pharmaceutical products, by subcutaneous or
intramuscular injection, much as diabetics have been doing
for quite some time. While in the oral administration of
medication in the form of drops or tablets and more
particularly through the colour and shape in the case of
20 tablets especially, the patient can be confident of
relatively high safety. However, that is not always the
case with the administration of pharmaceutical substances by
syringe. Yet such patients typically require an even higher
degree of reliability, given that an injected medication
25 takes effect more rapidly.

SUMMARY OF THE INVENTION

The task addressed by the present invention is the
development of a procedure addressed so that the patient,

before administering medication by injection, can check the syringe to verify that the pharmaceutical substance it contains is correct and original.

The present invention thus provides a procedure for
5 identifying, verifying or releasing content of a medical syringe before use, by means of a test device, comprising the steps of: a) inserting the syringe axially into the test device; b) reading the pre-existing code applied radially on the syringe; c) comparing the code with target values stored
10 in a memory of the test device; and d) displaying information on the identity of the content of the medical syringes.

The present invention also provides a test device for reading and verification of a code on a medical syringe,
15 comprising: a) a recording sleeve for receiving a part of the syringe bearing the code; b) a reading apparatus inside the recording sleeve, designed as a two-dimensional or linear optical scanner; c) an analytical unit with a data storage device for comparing information from the reading
20 apparatus against stored target values; and d) a display unit for displaying a result.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is described in greater detail in conjunction with the following figures, wherein:

- 25 Fig. 1 is a perspective view of an embodiment of the test device of the present invention;
Fig. 2 is a longitudinal cross-section of the device according to Figure 1; and
Fig. 3 is an end view of the device according to Figure 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The task addressed by the present invention involves, from a procedural viewpoint, axially introducing the syringe into the test device and reading the code on the syringe, and/or
5 by rotating the syringe, after insertion into the test device, about its longitudinal axis and taking a radial reading, the coding of which transmits the information that identifies the contents of the syringe. This information is compared against stored target values and, based on a
10 positive or negative match, a display appears on the test device that signals to the user whether the syringe contents may or may not be used.

The procedure allows the patient to receive a relatively simple signal, before application of the syringe, indicating
15 whether the syringe he has selected can be applied or not. The indicator can be visual and/or acoustic, and can accommodate visual or hearing impairments that often occur in elderly patients, for example.

One embodiment of the invention can involve labelling the
20 syringe with an additional code after the first code has been read and successfully verified; this additional code would show that the syringe has already been scanned. This additional code can be so designed so that the syringe contents can be approved repeatedly by the same test device,
25 but not if previous scans were carried out using a different test device. This means the originality of the syringe cylinder can be ensured; this ensures that a syringe cylinder that has been intentionally or unintentionally refilled with a pharmaceutical substance is not re-used.

30 To this end, during the procedure an additional code can be stamped on the syringe cylinder. Nonetheless the possibility

remains that the additional coding could be performed by modifying the existing code. Thus, the application of an additional code has the advantage that the original code is retained, and a syringe can thereby be traced back to the manufacturer, including lot number and the like. If this is unnecessary in individual cases, the possibility remains to alter a code after scanning such that no further scanning is possible, so that the syringe will be classified by the test device as no longer usable.

10 In order to reliably register any additional coding on the syringe, the procedure provides for the display of a radial reading only once the code has been read twice in succession. This ensures that the syringe makes at least a full 360° rotation, so that any additional code present will
15 always be detected.

In terms of the apparatus, the invention comprises a test device for the reading and verification of codes, in particular on medical syringes, with a recording sleeve for insertion of that part of the syringe cylinder that bears
20 the code. In one embodiment, the test device is characterized by a reading apparatus that is designed as a two-dimensional or linear optical scanner for the reading of codes, located on the inside of the recording sleeve, whereby, in a linear construction, the scanner runs either
25 axially along the recording sleeve (1) or radially in a ring-shaped formation on the outside wall of the recording sleeve (1), and, further, by an analytical unit with a data recorder for the information registered by the reading device and comparison thereof with stored target values, as
30 well as a display unit to show the results of the analysis conducted.

In order to be able to use a uniform test device for the verification of various syringe types and sizes, the device optionally features in the recording sleeve, an exchangeable adapter insert that is suited to the type of syringe to be tested. Thus, by simply exchanging the adapter insert, an adjustment can be made to suit various syringes. This is particularly advantageous for the patient, who, if he is, for example, prescribed a medication in a syringe of a different size, or even a different medication, need only exchange the adapter insert.

In another advantageous refinement of the invention, the adapter insert can feature an optical image element for the reading apparatus, in order always to provide optimal image characteristics for reliable readout of codes.

There is also the possibility of fitting the adapter insert with a lighting unit for the codes.

Further, the adapter insert or the recording sleeve can be equipped with a printing unit for labelling the syringe cylinder with an additional code. This printing unit can, for example, be designed in the manner of an ink-jet printer head.

The data storage device can be designed as a fixed component of the analytical unit or as an external storage module. If the test device includes only a fixed data storage device, then this is as a rule in set correlation to a specific medication. By contrast, if the design includes an additional or an exclusively external storage module, for example in the form of a so-called memory stick, then this storage module can for example be given to the patient by the prescribing physician, or it can be included in the syringe package. Such an external storage module also

offers further possibilities. For example, the storage module can be designed in such a way that, for example, it first registers the results of a blood sugar test, then influences the insulin dose via the analytical unit.

- 5 The display unit can be designed as an especially simple, bicolour, preferably red-green, light display. Acoustic signals are also possible.

The display unit can also be designed as an alphanumeric display element, through which the patient can receive
10 additional information, for example regarding the expiry date, the prescribed dose, and the like.

Especially with regard to the expiry date it is also conceivable for the analytical unit to feature a receiving unit for a time signal transmitter, which in turn uses the
15 current date and the expiry date contained in the code to give the patient information on the usability of the medication, whether valid or expired.

The test devices represented in the drawings are intended for the reading and verification of codes, in particular
20 those on medical syringes, which are not shown in the drawings.

With reference to Fig. 1, the test device is equipped with a recording sleeve (1) into which that part of the syringe cylinder bearing the code is inserted. The code is read by
25 means of a scanning device (2) that is located on the inside of the recording sleeve (1); the device is designed as a two-dimensional scanner or, in a simpler and less costly form, as a linear optical scanner.

In Fig. 2 a linear optical scanner is shown that runs axially along the recording sleeve (1). In this arrangement, it is necessary, after inserting the syringe in the recording sleeve, to rotate the syringe about its longitudinal axis, so that the code passes the scanner at least one time completely.

Rotation of the syringe can be eliminated by use of a linear optical scanner arranged on the inner wall of the recording sleeve (1) in a radially annular arrangement, since in this case the reading process can take place while the syringe is being inserted into the recording sleeve (1).

Further, the test device includes an analytical unit (3) with a data storage device that processes the data collected by the reading apparatus (2), then compares it with target values present in the data memory.

Finally, the test device features a display unit (4) for showing the results of the analysis conducted.

In order to be able to use the test device to verify syringes of various sizes, the recording sleeve includes an exchangeable adapter insert (5) that is sized for the syringe to be tested.

As seen in Fig. 3, this adapter insert (5) includes an optical image element (6) for the reading apparatus (2), whereby an optimal image of the code is always ensured for the reading apparatus (2), even with varying syringe diameters. In addition, in the adapter insert (5) there can be an illumination device, (not shown) for the code. This device is adapted to the design of the reading apparatus (2).

Further, the adapter insert (5) or even the recording sleeve itself can include a printing apparatus (not shown) that enables labelling of the syringe cylinder with an additional code. This additional code is likewise registered by the reading apparatus and processed by the analytical unit to report whether a given syringe has already been previously read, or previously used in some other way.

The data memory can be either a fixed component of the analytical unit (3) or an external, mountable storage module. In the latter case, there is the possibility for a simple adaptation or alteration of the comparative data; in particular, this makes possible an adaptation for other administration forms or even other medications. Moreover, an external storage module can serve to transfer measured values, for example, from a blood glucose measuring device. In particular a combination is possible of both a fixed and an external data storage device.

The display (4) can, in an especially simple form, be designed preferably as a red-green light display. To the extent that more extensive information is desired, an alternative or additional alphanumeric display element can exist that can give the patient such information.

Finally, there is also the possibility, not further indicated in the figures, of providing the analytical unit with a receiving unit for a time signal transmitter, whereby the testing device additionally can check the expiry date, or even remind the patient of administration times for his medication.

Claims:

1. A procedure for identifying, verifying or releasing
content of a medical syringe before use, by means of a test
5 device, comprising the steps of:
 - a) inserting the syringe axially into the test
device;
 - b) reading the pre-existing code applied radially on
the syringe;
 - 10 c) comparing the code with target values stored in a
memory of the test device;
 - d) displaying information on the identity of the
content of the medical syringes; and
 - e) printing on the syringe an additional code.
- 15 2. Procedure according to claim 1, wherein the additional
code is stamped on the syringe cylinder.
3. Procedure according to claim 1, wherein applying the
20 additional coding comprises altering the pre-existing code.
4. Procedure according to any one of claims 1 to 3,
wherein, when there is radial reading of a code, a display
appears only after the code has been read twice in
25 succession.
5. Procedure according to any one claims 1 to 4, wherein
the medical syringe is a prefilled syringe.
- 30 6. Procedure according to any one of claims 1 to 5,
wherein the procedure is performed by a patient.

7. Procedure according to claim 1, further comprising rotating the syringe around a longitudinal axis in the test device to read the pre-existing code.

5 8. A test device for reading and verification of a code on a medical syringe, comprising:

a) a recording sleeve for receiving a part of the syringe bearing the code;

10 b) a reading apparatus inside the recording sleeve, designed as a two-dimensional or linear optical scanner;

c) an analytical unit with a data storage device for comparing information from the reading apparatus against stored target values;

d) a display unit for displaying a result; and

15 e) a printer that applies an additional coding to the syringe.

9. Test device according to claim 8, wherein the recording sleeve further comprises an exchangeable adapter insert, adapted to fit various syringes to be tested.

10. Test device according to claim 9, wherein the adapter insert features an optical imaging element for the reading apparatus.

25

11. Test device according to claim 9 or 10, wherein the adapter insert features a lighting element.

12. Test device according to any one of claims 9 to 11, wherein the data storage device is a fixed component of the analytical unit.

30

13. Test device according to any one of claims 9 to 11, wherein the data storage device is an external storage module.

5 14. Test device according to any one of claims 8 to 13, wherein the display unit is a bicolour light display.

15. Test device according to claim 14, wherein the display unit is a red-green light display.

10

16. Test device according to any one of claims 8 to 13, wherein the display unit is an alphanumeric display element.

15 17. Test device according to any one of claims 8 to 13, characterized in that the analytical unit features a receiving unit for a time signal transmitter.

20 18. Test device according to claim 8, wherein when the reading apparatus is designed as a linear optical scanner, the scanner runs axially along the recording sleeve or runs radially in a ring-shaped formation along an inner wall of the recording sleeve.

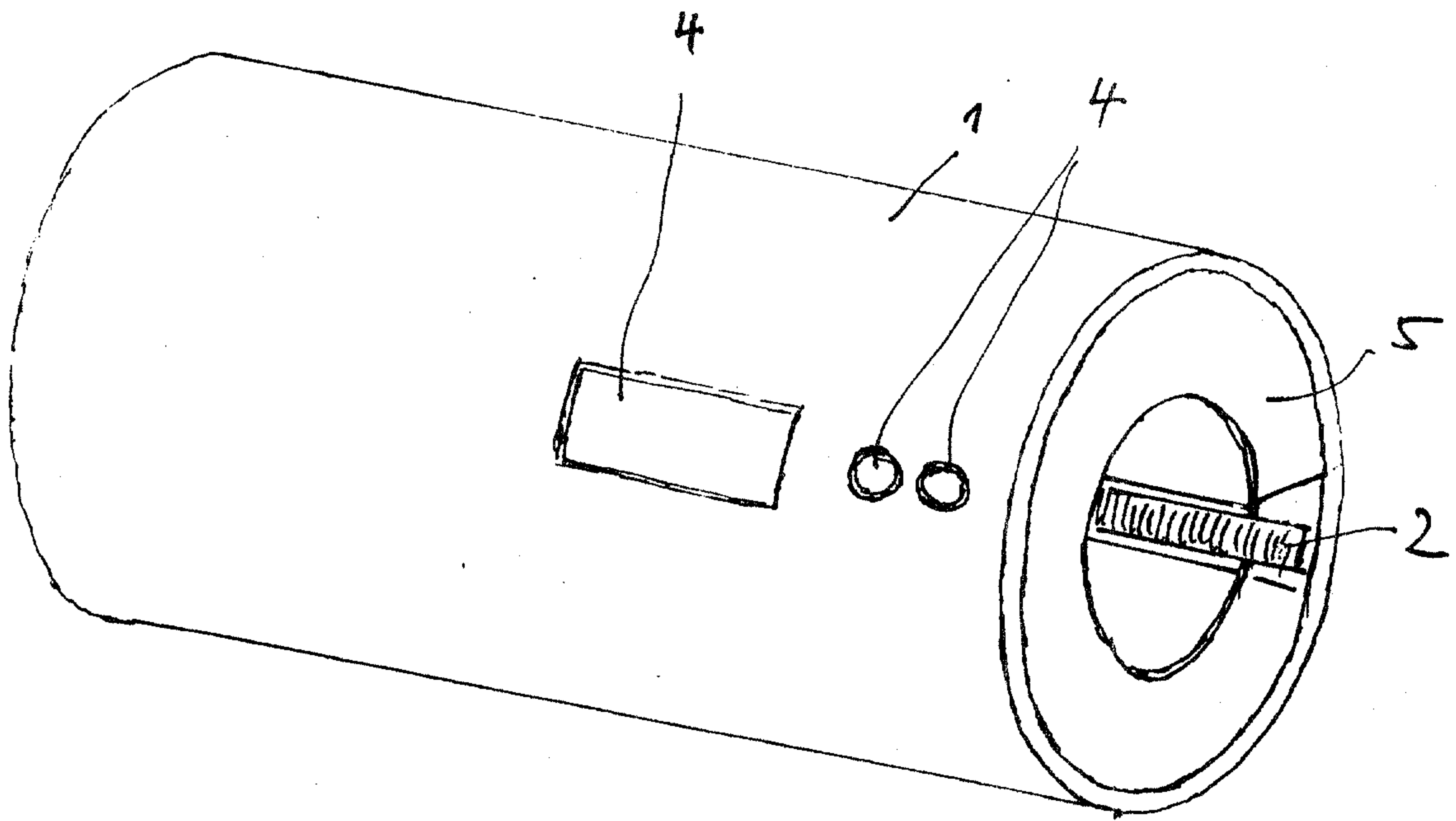


Fig. 1

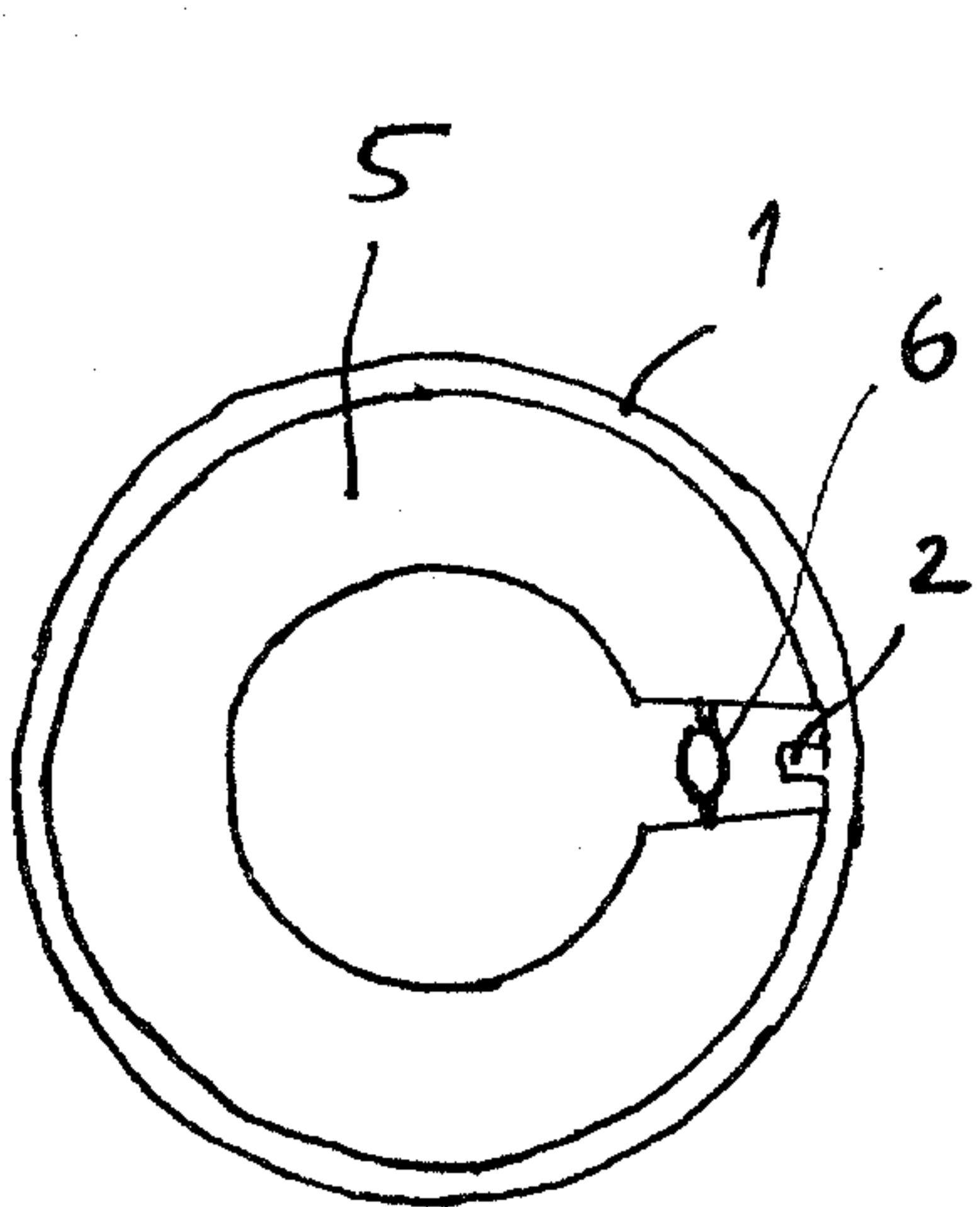


Fig. 3

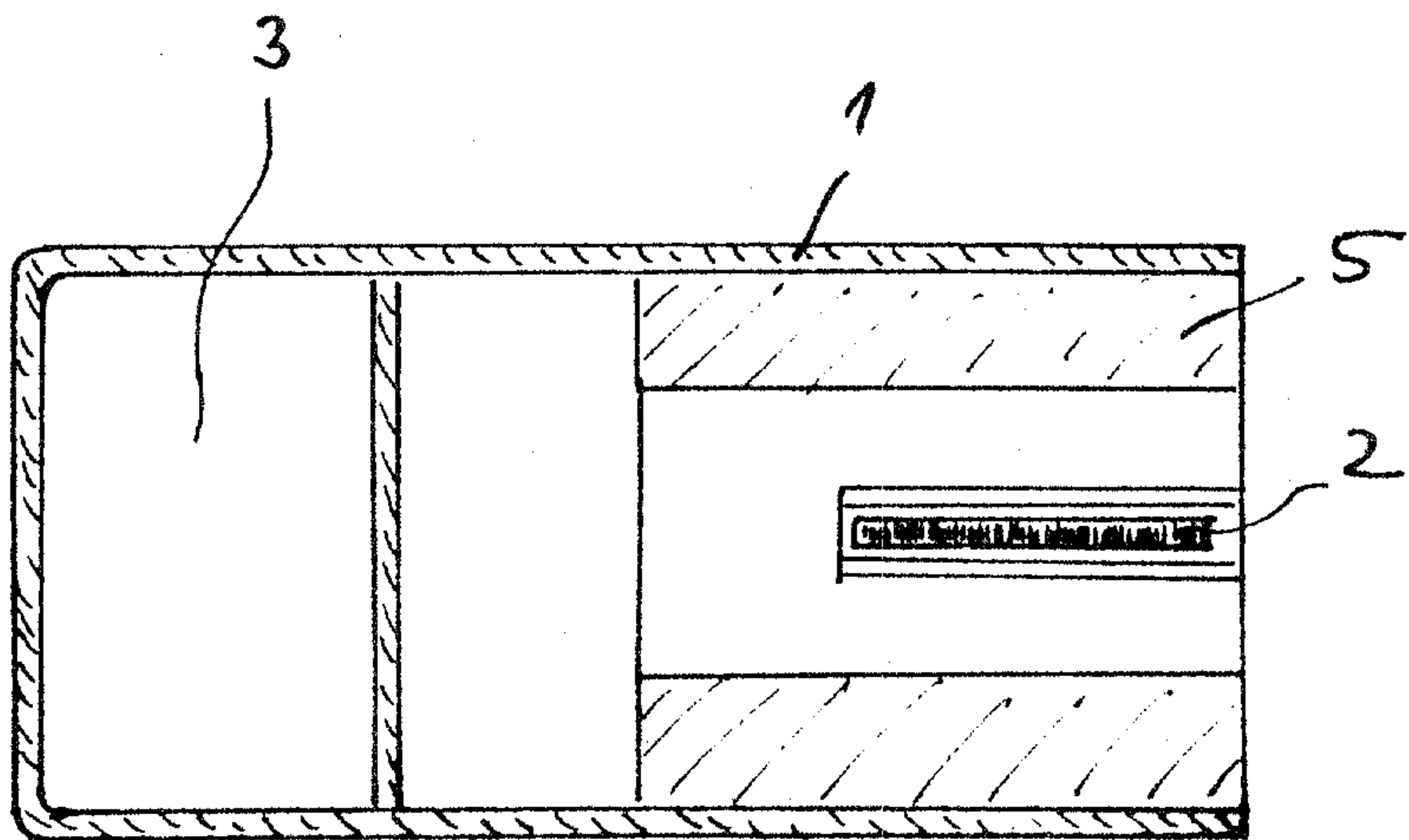


Fig. 2

