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An agency of Industry Canada

CA 2611921 C 2011/05/10

(11)(21) 2 611 921

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(86) Date de dépôt PCT/PCT Filing Date: 2006/06/13
(87) Date publication PCT/PCT Publication Date: 2006/12/28
(45) Date de délivrance/Issue Date: 2011/05/10
(85) Entrée phase nationale/National Entry: 2007/12/12
(86) N° demande PCT/PCT Application No.: EP 2006/063145
(87) N° publication PCT/PCT Publication No.: 2006/136512
(30) Priorité/Priority: 2005/06/22 (EP05013452.7)

(51) Cl.Int./Int.Cl. *G01N 33/50* (2006.01), *G01N 21/55* (2006.01), *G02B 1/04* (2006.01)

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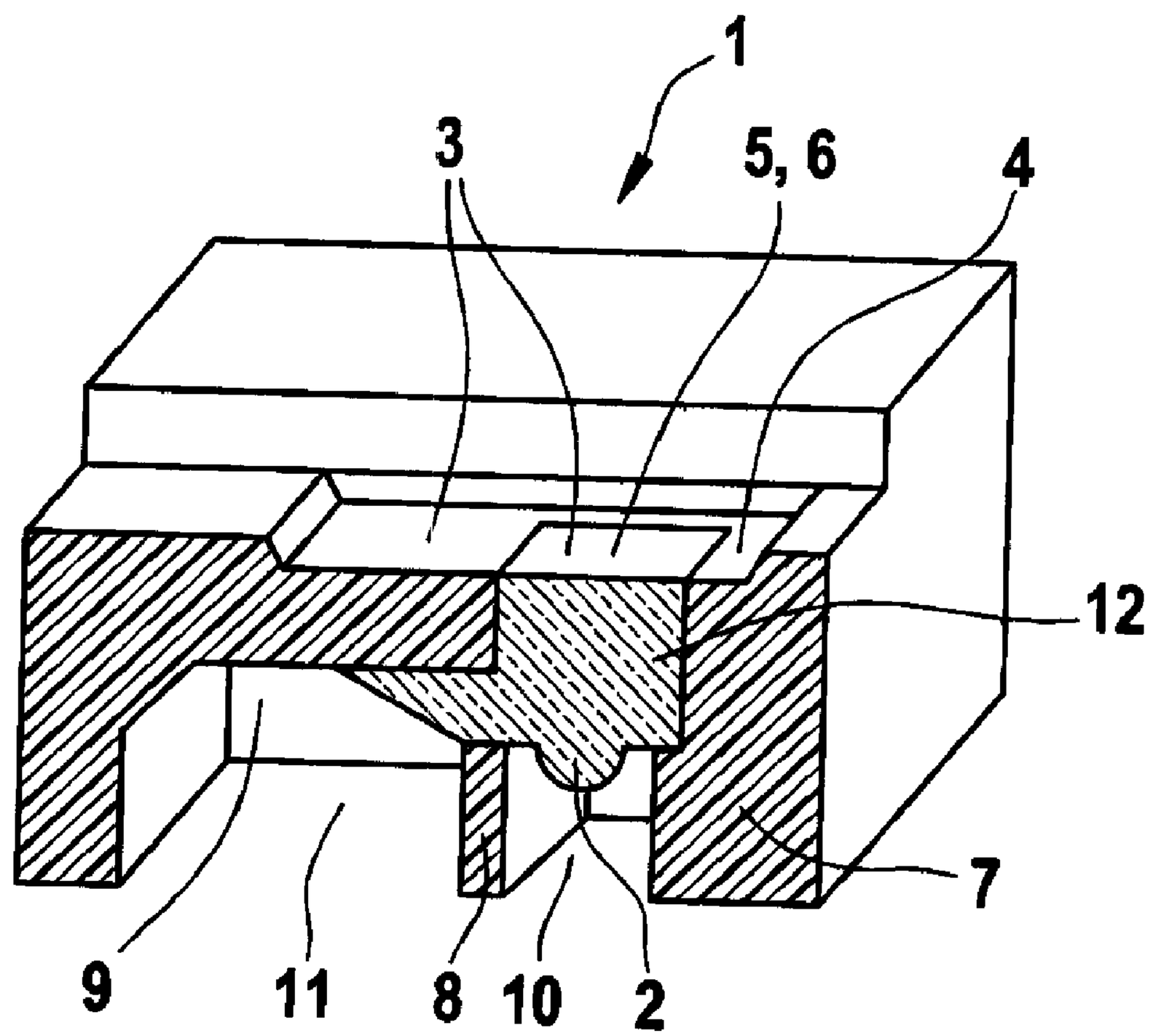
(54) Titre : SYSTEME D'ANALYSE DESTINE A L'ANALYSE D'UN ECHANTILLON SUR UN ELEMENT D'ESSAI ANALYTIQUE

(54) Title: ANALYSIS SYSTEM FOR ANALYSING A SAMPLE ON AN ANALYTICAL TEST ELEMENT



(57) Abrégé/Abstract:
The invention relates to an analysis system for analysing a sample on an analytical test element comprising a measuring module for carrying out measurements on the sample on the analytical test element and an optical module, which comprises a lens and a

CA 2611921 C 2011/05/10

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(57) Abrégé(suite)/Abstract(continued):
diaphragm, by which the light can be focused. In this case, the lens and the diaphragm of the optical module are combined as one piece in a multi-component injection-molded part.

Abstract

The invention relates to an analysis system for analysing a sample on an analytical test element comprising a measuring module for carrying out measurements on the sample on the analytical test element and an optical module, which comprises a lens and a diaphragm, by which the light can be focused. In this case, the lens and the diaphragm of the optical module are combined as one piece in a multi-component injection-molded part.

Analysis system for analyzing a sample on an analytical test element

The present invention relates to an analysis system for analyzing a sample on an analytical test element with an optical module comprising a lens and a diaphragm.

For the analysis of samples, for example body fluids such as blood or urine, use is often made of analysis systems in which the samples to be analyzed are located on a test element and possibly react in a test area with one or more reagents on the test element before they are analyzed. The optical, in particular photometric, and electrochemical evaluation of test elements are the most commonly used methods for rapidly determining the concentration of analytes in samples. Analysis systems with test elements for sample analysis are generally used in the field of analytics, environmental analytics and in particular in the field of medical diagnostics. In particular in the field of blood glucose diagnostics using capillary blood, test elements which are photometrically or electrochemically evaluated are of great value.

There are various forms of test elements. Essentially square, small plates, also referred to as slides, in the middle of which there is a multilayered test area, are known for example. Diagnostic test elements of a strip-shaped form are referred to as test strips. Test elements are extensively described in the prior art, for example in the documents DE-A 19 753 847, EP-A 0 821 233, EP-A 0 831 234 or WO 97/02487. The present invention relates to test elements of any form, in particular to test elements in the form of strips.

For the analytical examination of a sample on a test element, the prior art discloses test element analysis systems which contain a test element holder for positioning the test element in a measuring position and a measuring and evaluation device for carrying out a measurement and determining an analysis result resulting from this.

WO 00/19185 A1 relates to a device for the photometric evaluation of test elements, comprising

- an illuminating unit with at least a first and a second light source,

- a holder for receiving a test element with a detection zone in such a way that the detection zone is positioned with respect to the illuminating unit,

- a detection unit with at least one detector, which detects light reflected by the detection zone or transmitted through the detection zone,

- a control unit, which activates the two light sources and records the signal generated by the detection unit as a detection signal, and

- an evaluation unit, which evaluates the detection signals in order to determine the analyte concentration contained in the sample.

EP 0 618 443 A1 relates to a test strip analysis system comprising an evaluation device with a test strip holder and suitable test strips. The strip holder serves the purpose of positioning the test strip in a defined position with respect to a measuring unit. It has a test strip support and a guide for the test strip.

WO 01/48461 A1 concerns a test element analysis system for the analytical examination of a sample. The analysis system comprises test elements with a supporting film and a test area which is attached to a flat side of the supporting film and, to carry out the analysis, is brought into contact with the sample in such a way that liquid sample constituents penetrate into the test area, the test area containing a reagent system which, when it reacts with constituents of the sample, leads to an optically measurable change in a detection zone that is characteristic of the analysis and is on the side of the test area facing the supporting film. Furthermore, the analysis system comprises an evaluation device with a test element holder for positioning a test element in a measuring position and a measuring device for measuring the optically measurable change in the detection zone, the measuring device having a light transmitter for illuminating the detection zone with primary light and a detector for detecting the secondary light thereby diffusely reflected by the detection zone.

Many such known analysis systems have at least one optical module, which may comprise, inter alia, a lens and a diaphragm, by which the light can be focused. These optical modules are produced in the prior art from a number of individual parts, which are put together and connected to one another for example by means of ultrasonic welding, hot caulking or adhesive bonding. When doing so, the lens and the diaphragm aperture must be spatially positioned exactly in relation to one another in a way corresponding to the path of rays of the light. The joining

together of the parts is only possible with great effort on account of their tolerances and small size. Furthermore, many individual parts result in a great overall tolerance of the optical module.

The object of the present invention is therefore to avoid the disadvantages of the prior art. In particular, the effort and the costs of assembling the analysis system are to be reduced.

This object is achieved according to the invention by an analysis system for analyzing a sample on an analytical test element, comprising

- a measuring module for carrying out measurements on the sample on the analytical test element and

- an optical module, which comprises a lens and a diaphragm, by which the light can be focused,

- the lens and the diaphragm of the optical module being combined as one piece in a multi-component injection-molded part.

The analysis system according to the invention contains, inter alia, a measuring module for carrying out measurements on a sample on an analytical test element.

The sample is, for example, a body fluid, in particular blood or interstitial fluid. The examination of blood samples or of interstitial fluid makes it possible in clinical diagnostics to provide early and reliable detection of pathological conditions and to carry out targeted and substantiated monitoring of physical states. Medical diagnostics always relies on the obtainment of a sample of blood or interstitial fluid from the individual to be examined.

To obtain the sample, the skin may be perforated, for example at the finger tip or the ear lobe of the person to be examined, with the aid of a sterile, sharp lancet, in order in this way to obtain a small amount of blood or interstitial fluid for the analysis. In particular, this method is suitable for the analysis of a sample that is carried out directly after the sample is obtained.

In particular in the area of so-called "home monitoring", that is to say where medically untrained people carrying out simple analyses of their own blood or interstitial fluid, and where in particular diabetics need to obtain blood regularly

several times a day to monitor blood glucose concentration, lancets and associated equipment (known as lancing devices) are offered, making it possible to obtain samples reproducibly and with as little pain as possible.

To carry out the measurements, the sample is applied to an analytical test element, which contains reagents (for example in a test area). When the reagents contact the sample, a reaction of the analyte contained in the sample with the reagents leads to a physically measurable change in the test element, which correlates with the concentration of the analyte.

The measuring module of the analysis system according to the invention serves for measuring this change. The measured values obtained in the measurements of the measuring module serve for determining the concentration of the analyte in the sample.

In the case of photometric analysis systems, the test elements contain a reagent system, the reaction of which with the analyte leads to a photometrically detectable change (a change in color). The reagents are in this case usually located in a test area of the test element, the color of which changes in dependence on the concentration. This change in color can be determined quantitatively by reflection photometry with the aid of a measuring module.

Electrochemical test elements contain an electrochemical reagent system, the reaction of which with the analyte influences the electric voltage between two poles of the test element and/or of the current intensity flowing between two poles of a test element with a defined voltage. In this case, the voltage or current intensity is therefore the physically measurable variable that is determined by a corresponding measuring module, which is integrated in the analysis system and designed as a voltage or current measuring device, and a change of which that correlates with the concentration of the light is converted into the analysis data (concentration of the analyte).

For the purposes of the present invention, an optical module is a subassembly which contains, inter alia, at least a lens and a diaphragm. Light can be focused by the lens and the diaphragm. In this context, a lens refers to an optical component known to a person skilled in the art as an optical lens. In this context, a diaphragm refers to an optical component which comprises an opaque diaphragm body and a light-transmitting diaphragm aperture. The diaphragm prevents light from

spreading in certain spatial directions. It serves for delimiting the cross section of beams and for reducing stray light.

In the analysis system according to the invention, the lens and the diaphragm of the optical module are combined as one piece in a multi-component injection-molded part. Injection molding is a process known in the prior art in which a plasticized material (injection molding compound) (in particular a thermoplastic or thermoset) is injected into a forming tool (injection mold) at high pressure and transformed there under the effect of pressure into the solid state. The injection-molded part can then be removed from the injection mold. Multi-component injection molding is likewise a process known in the prior art. In particular, so-called sandwich molding is suitable for producing the multi-component injection-molded part for the analysis device according to the invention. In this case, two or more materials are injected one after the other into an injection mold, whereby they are joined together with a material bond at their interfaces. The geometry of the cavity present in the injection mold is changed between the two injections.

In the prior art, for example, a number of lenses are produced as a one-piece multi-component injection-molded part, as described for example in DE 102 61 974 A1, US 2004/0120053 A1 or DE 44 31 744 A1.

In the case of the analysis system according to the invention, the one-piece combination of the lens and the diaphragm of the optical module in the multi-component injection-molded part provides many advantages. It is no longer necessary for the lens and the diaphragm to be joined together after their production, dispensing with a working step in the production of the analysis system according to the invention. One of the consequences is that costs are saved. The handling of the multi-component injection-molded part is easier than that of the individual lens and the individual diaphragm. A reproducibly exact unit of lens and diaphragm can also be mass-produced. There are no tolerances between the lens and the diaphragm. Therefore, exact positioning of the diaphragm in relation to the lens is ensured.

In the case of the analysis system according to the invention, not only the lens and the diaphragm but also further lenses and/or further diaphragms and/or further component parts of the optical module may be combined in the injection-molded part of the optical module. If appropriate, the entire optical module is a multi-component injection-molded part.

According to a preferred embodiment of the present invention, two diaphragms and one or two lenses are combined in the multi-component injection-molded part. The multi-component injection-molded part is preferably a two-component injection-molded part, in particular a two-component injection-molded part with a first, translucent plastic component and a second, opaque plastic component. The translucent plastic component is translucent with preference for light in a wavelength range from 200 to 1700 nm, with particular preference in a wavelength range from 600 to 950 nm, the opaque plastic component preferably being largely non-transmitting for light in this wavelength range. The lens integrated in the multi-component injection-molded part preferably consists of the translucent plastic. For this purpose, a region of the multi-component injection-molded part is formed from the translucent plastic in such a way that it assumes the function of an optical lens. An opaque plastic may be used, for example, for regions of the multi-component injection-molded part that assume the function of a diaphragm body. The translucent plastic component may, for example, contain at least one plastic selected from the group comprising acrylonitrile-butadiene-styrene polymers (ABS), methyl methacrylate-butadiene-styrene copolymers (MABS), polycarbonate (PC), polycarbonate blends (PCB), polysulfone (PSU) and polyether sulfone (PES). The opaque plastic component preferably contains at least one plastic selected from the group comprising acrylonitrile-butadiene-styrene polymers (ABS), polycarbonate blends (PCB) and polyether sulfone (PES).

According to a preferred embodiment of the present invention, the diaphragm comprises a diaphragm body of an opaque plastic and a diaphragm aperture, the diaphragm aperture being filled with the translucent plastic. The diaphragm aperture is therefore closed by a protective window of the translucent plastic, which prevents contaminants from passing through the diaphragm aperture. It is particularly preferred in this respect for the lens and the diaphragm aperture filled with the translucent plastic to be combined in a contiguous region. They are in this case made of the translucent plastic and are combined in the multi-component injection-molded part. This simplifies the injection-molding process and the optical module and ensures a fixedly defined positioning of the diaphragm aperture (or of the window) in relation to the lens.

The diaphragm in the optical module of the analysis system according to the invention may, however, also comprise a diaphragm body of an opaque plastic and a diaphragm aperture, the diaphragm aperture being a clearance in the diaphragm body. The clearance is in this case not filled with material. As a result, less light

is absorbed as it passes through the diaphragm aperture than if the diaphragm aperture is filled with a material.

According to a preferred embodiment of the present invention, the measuring module contains the optical module, the optical module serving for carrying out optical measurements on the sample on the analytical test element. It is in this case in particular a measuring module that is intended for photometric measurements on the sample (for example a human or animal body fluid) and is designed for determining the concentration of an analyte (for example glucose) in the sample.

Currently in use in the prior art, for example in the AKKU CHEK®-Compakt analysis system from Roche Diagnostics, Germany, is a measuring module which contains an optical module, the optical module being made up of two plastic parts, one of which contains a diaphragm with a plastic window as the diaphragm aperture and the other of which contains a lens. The parts are of a small size (14.5 times 7.5 times 21 mm and 0.7 times 4 times 60 mm, respectively). The task of the measuring module in this prior-art analysis system is to position a test element for carrying out measurements and, with the aid of the optical module, to direct rays of light to determine blood sugar values optically. The two plastic parts of the optical module in the case of this analysis system are connected to one another by means of ultrasonic welding. High costs are incurred by the joining together of the two parts. The small overall size of the parts makes handling very complicated. The welding requires an additional operation, which is carried out with great effort. Additional tolerances as a result of two parts cannot be avoided. The position of the diaphragm is also determined here by its production tolerances.

In the analysis system according to the invention, the measuring module contains an optical module in which at least one lens and at least one diaphragm are combined as one piece in a multi-component injection-molded part. It is particularly preferred for the entire optical module contained in the measuring module to be a two-component injection-molded part, in which at least one lens and at least one diaphragm are contained. A great advantage of this is that the complete optical module can be injection-molded in one operation. For this purpose, the optical path of rays may have to be recalculated and the optical components contained in the optical module may have to be differently designed.

The measuring module in the analysis system according to the invention preferably comprises a light source, a detector and a test element holder, which are arranged

in such a way that light from the light source can pass through a translucent region of the multi-component injection-molded part to a test element arranged in the test element holder and be reflected by the test element through the translucent region to the detector. The light source is, for example, a light-emitting diode (LED). The detector is, for example, a photodiode. The test element holder serves for receiving a test element, in particular during the carrying out of the measurements with the optical module. It is designed for guiding during the manual or automatic placement of the test element into the measuring module and for the exact positioning of the test element during the measurements. During the measurements, the test element is positioned in the test element holder in such a way that the light from the light source is directed via the translucent region of the multi-component injection molded part onto a test area on the test element, containing the sample and reagents. Depending on the concentration of the analyte in the sample, a proportion of the light hitting the test element is reflected at it in such a way that it passes through the translucent region of the multi-component injection-molded part to the detector.

According to another embodiment of the present invention, the measuring module comprises a light source, a detector and a test element holder, which are arranged in such a way that light from a light source can pass through a translucent region of the multi-component injection-molded part to a test element arranged in the test element holder and be transmitted by this to the detector.

According to a further preferred embodiment of the present invention, the analysis system contains a reading module for reading optically coded data, the reading module containing the optical module or a further optical module.

In the prior art, there are known analysis systems that contain a storage container (magazine) with a multiplicity of test elements. In these systems, a test element is transported, for example, by a slide or pushrod from the magazine to the site of the measurement in the measuring module and, after carrying out the measurement, is automatically ejected from the analysis system or re-magazined in the magazine. For example, DE 199 02 601 A1 discloses a device for removing an analytical consumable, in particular a test element, from a storage container that has one or more chambers which contain the consumables. The chambers respectively have a removal opening for removing a consumable and a push-in opening, opposite the removal opening, for inserting a pushrod for transporting the consumable. The removal opening and the push-in opening are closed with a film to store the

consumable. The device comprises a pushrod, which can be made to move by means of a drive unit for the removal of a consumable.

In the AKKU CHEK®-Compakt analysis system from Roche Diagnostics, Germany, there is contained, for example, a reading module (with a barcode reader), which can read a barcode on the outer surface of a test element magazine in the form of a drum that is placed into the analysis system. The barcode contains, for example, information on the test elements contained in the magazine that are relevant for the evaluation of the data measured by the measuring module and are taken into consideration in the evaluation. In the prior art, the reading module contains two individual plastic injection-molded parts and a printed circuit board, which are joined together during the production of the reading module. The one injection-molded part contains a diaphragm and the other contains a lens arrangement. The printed circuit board and the two injection-molded parts are connected to one another in a complicated adhesive-bonding operation. The joining together is only possible in this case with great effort, for one reason on account of the tolerances of the injection-molded parts. The handling is problematic because of the small size of the parts. The many individual parts result in a great overall tolerance of the optical module.

In a preferred embodiment of the present invention, the two injection-molded parts are combined as one piece in a multi-component injection-molded part. Consequently, the diaphragm and the lens arrangement can be produced positionally exactly in relation to one another and the disadvantages mentioned can be avoided.

No adhesive-bonding operation is necessary between the diaphragm and the optical module. Reproducibly exact parts are also obtained in mass production. The handling of the three-component injection-molded part is easier than the handling of the two individual parts. There are no tolerances between the optical module and the diaphragm. The construction is less expensive, so that a cost saving is achieved.

The printed circuit board of the reading module can be subsequently attached to the multi-component injection-molded part. The printed circuit board carries, for example, a detector (for example a photodiode) and a light source (for example an LED).

According to a preferred embodiment of the present invention, the reading module comprises a light source, a detector and a magazine holder, which are arranged in such a way that light from the light source can pass through a translucent region of the multi-component injection-molded part to a test element magazine held in the magazine holder and be reflected by the test element magazine through the translucent region to the detector.

The printed circuit board, which preferably carries the detector and the light source, is preferably positioned, with the aid of pins engaging in recesses, in relation to the multi-component injection-molded part and then connected to the latter, for example by adhesive bonding, ultrasonic welding or hot caulking. In this case, the multi-component injection-molded part has recesses and/or pins and the printed circuit board has matching pins and/or recesses.

The invention also relates to a method for producing an analysis system for analyzing a sample on an analytical test element, the analysis system containing a measuring module and an optical module, the optical module comprising a lens and a diaphragm, characterized by the following steps:

- multi-component injection molding of a one-piece multi-component injection-molded part, in which the lens and the diaphragm are combined, and

- positioning and mounting of the multi-component injection-molded part in the analysis system.

The invention is explained in more detail below on the basis of the drawing, in which:

Figure 1 shows a section through an optical module which is contained in a measuring module of an analysis system from the prior art,

Figure 2 shows a section through an optical module which is contained in a measuring module of an analysis system according to the invention,

Figure 3 shows a section through a measuring module of an analysis system according to the invention with a test element,

Figure 4 shows the path of rays in the measuring module according to Figure 3,

Figure 5 schematically shows a comparison of component parts of a reading module in an analysis system from the prior art and in an analysis system according to the invention,

Figure 6 schematically shows a reading module in an analysis system according to the invention,

Figure 7 shows the path of rays in the reading module from Figure 6,

Figure 8 shows the printed circuit board and multi-component injection-molded part of an analysis system according to the invention and

Figure 9 shows various ways of attaching the printed circuit board to the multi-component injection-molded part.

Figure 1 shows a section through an optical module which is contained in a measuring module of an analysis system from the prior art.

The optical module 1 comprises a lens 2 and a diaphragm 3, which contains a diaphragm body 4 and a diaphragm aperture 5. The diaphragm aperture 5 is filled by a translucent window 6. The lens 2 and the diaphragm 3 are individual components, which are adhesively bonded to an optical module base body 7. The mount 8 of the lens 2 serves as a further diaphragm. In the optical module base body 7 there is a large cavity 9 and a small cavity 10. Rays of light from a light source (not represented) can pass from the small cavity 10 through the lens 2, through the large cavity 9 and through the translucent window 6, closing the diaphragm opening 5, to a test element (not represented), which is located above the diaphragm 3 in a test element holder 15. Light reflected by the test element can then pass back through the window 6 into the large cavity 9 and from there through an opening 11 to a detector (not represented). This optical module comprising many individual parts that are adhesively bonded to one another has the already mentioned disadvantages of the prior art.

Figure 2 shows a section through an optical module, which is contained in a measuring module of an analysis system according to the invention.

The optical module 1 is in this case a two-component injection-molded part, which combines the diaphragm 3 (including the diaphragm body 4 and the window 6

serving as the diaphragm aperture 5), the lens 2 and the optical module base body 7 as one piece. The optical module base body 7, the diaphragm body 4 and the mount 8 of the lens 2 are in this case injection-molded from an opaque plastic. The lens 2 and the window 6 in the diaphragm aperture 5 are combined in a continuous region 12 of a translucent plastic in the two-component injection-molded part.

Figure 3 shows a section through a measuring module of an analysis system according to the invention with a test element.

Contained in the measuring module 13 are an optical module 1 according to Figure 2 and a printed circuit board 14. The optical module 1 comprises the optical module base body 7, the lens 2, the diaphragm 3, the mount 8 of the lens 2, the cavities 9, 10 and a test element holder 15. The optical module 1 is configured as a two-component injection-molded part with a first, translucent plastic component (region 12) and a second, opaque plastic component. In the test element holder 15 there is a strip-shaped analytical test element 16, the test area 17 of which, in which a sample to be analyzed is located, is arranged above the window 6.

On the printed circuit board 14 there are a detector 18 and a light source 19, which protrude into the large cavity 9 and into the small cavity 10, respectively. The printed circuit board 14 is, for example, adhesively fixed to the two-component injection-molded part.

Figure 4 shows the path of rays in the measuring module according to Figure 3.

A light source 19 emits light for the photometric analysis of a sample on the test area 17 of the test element 16, which is focused onto the test element 16 by the continuous translucent region 12. In dependence on its optical properties (for example its coloration), on the test area 17 part of the light is reflected and returns through the region 12 into the large cavity 9 to the detector 18, from the signal of which the concentration of an analyte in the sample can be determined (for example in an evaluation module (not represented) of the analysis system according to the invention).

Figure 5 schematically shows a comparison of component parts of a reading module in an analysis device from the prior art and in an analysis system according to the invention.

In the prior art (Figure 5a), a reading module comprises a printed circuit board 20, a diaphragm 21 and a lens arrangement 22 with at least one lens, these being produced as three separate components and subsequently joined together.

According to the present invention (Figure 5b), in the reading module, the lens arrangement 22 and the diaphragm 21 are combined as a one-piece multi-component injection-molded part 23. The multi-component injection-molded part is joined together with the printed circuit board 20.

Figure 6 schematically shows a reading module in an analysis system according to the invention.

The reading module 24 contains, inter alia, an optical module 25 and a printed circuit board 20. In the optical module 25, a first lens 26 (shown in section), a second lens 27 and a diaphragm 21 are combined to form a one-piece two-component injection-molded part. The lenses 26, 27 are injection-molded from a first, translucent component (translucent region 38) and the diaphragm 21 is injection-molded from a second, opaque component. The printed circuit board 20 is connected to the optical module, for example by means of an adhesive bond. It carries a light source 28 and a detector (not represented), which protrude into cavities 29 of the optical module 25. The printed circuit board is, for example, attached to an analysis system board 30.

Also represented in Figure 6 is a test element magazine 31 in the form of a drum, which serves for storing a multiplicity of test elements. On its circumferential surface 32, the magazine 31 has a barcode 33, which the reading module 24 can read. The magazine 31 is located in a magazine holder in the reading module 24, whereby it is positioned in relation to the optical module 25 for reading the barcode 33.

Figure 7 shows the path of rays in the reading module from Figure 6.

For better clearness, the analysis system board 30, the printed circuit board 20 and the optical module 25 are represented separately. The path of rays 37 is indicated by arrows. Light from a light source 28 propagates through the first cavity 34, the diaphragm 21 and the translucent region 38, including the first lens 26, to the barcode 33, is reflected by it and reaches the detector 36 through the translucent region 38 with the second lens 27, the diaphragm 21 and the second cavity 35.

Figure 8 demonstrates how the printed circuit board and the multi-component injection-molded part can be connected to one another in an analysis system according to the invention.

For this purpose, the printed circuit board 20 has two pins 39, which can engage in openings provided for them (bore 40 and oblong hole 41) in the multi-component injection-molded part 23. In this case, the light source 28 and the detector 36 are positioned in such a way that they are aligned exactly within the cavities 34, 35. Then, the two parts 20, 23 are joined together by a joining process known to a person skilled in the art. The multi-component injection-molded part 23 is, for example, the optical module of a reading module.

Figure 9 shows various ways a) to c) of attaching the printed circuit board.

In variant a), the printed circuit board 20 has two pins 39, which are arranged offset in relation to one another. Variant b) corresponds to the variant shown in Figure 8, with two pins 39 that lie on a central line and engage in a bore 40 and a milled oblong hole 41. In variant c), the two pins 39 lie on a common lateral line and on a line taken as an extension of the light source 28 and of the detector 36, respectively.

List of designations

1	optical module
2	lens
3	diaphragm
4	diaphragm body
5	diaphragm aperture
6	translucent window
7	optical module base body
8	mount of the lens
9	large cavity
10	small cavity
11	opening
12	continuous region
13	measuring module
14	printed circuit board
15	test element holder
16	test element
17	test area
18	detector
19	light source
20	printed circuit board
21	diaphragm
22	lens arrangement
23	multi-component injection-molded part
24	reading module
25	optical module
26	first lens
27	second lens
28	light source
29	cavities
30	analysis system board
31	test element magazine
32	circumferential surface
33	barcode
34	first cavity
35	second cavity
36	detector
37	path of rays
38	translucent region
39	pins
40	bore
41	oblong hole

Patent claims

1. An analysis system for analyzing a sample on an analytical test element (16), comprising:
a measuring module (13) for carrying out measurements on the sample on the analytical test element (16) and
an optical module (1, 25), which comprises a lens (2, 26, 27) and a diaphragm (3, 21), by which the light can be focused,
wherein the lens (2, 26, 27) and the diaphragm (3, 21) of the optical module (1, 25) are combined as one piece in a multi-component injection-molded part (23).

2. The analysis system as claimed in claim 1, wherein the multi-component injection-molded part (23) is a two-component injection-molded part with a first, translucent plastic component and a second, opaque plastic component.

3. The analysis system as claimed in any one of claims 1 and 2, wherein the diaphragm (3, 21) comprises a diaphragm body (4) of an opaque plastic and a diaphragm aperture (5), the diaphragm aperture (5) being filled with a translucent plastic.

4. The analysis system as claimed in claim 3, wherein the lens (2, 26, 27) consists of the translucent plastic.

5. The analysis system as claimed in claim 4, wherein the lens (2, 26, 27) and the diaphragm aperture (5) filled with the translucent plastic are combined in a continuous region (12) of the translucent plastic in the multi-component injection-molded part (23).

6. The analysis system as claimed in any one of claims 1 and 2, wherein the diaphragm (3, 21) comprises a diaphragm body (4) of an opaque plastic and a diaphragm aperture (5), the diaphragm aperture (5) being a clearance in the diaphragm body (4).

7. The analysis system as claimed in any one of claims 1 to 6, wherein the measuring module (13) contains the optical module (7), the optical module (7) serving for carrying out optical measurements on the sample on the analytical test element (16).

8. The analysis system as claimed in claim 7, wherein the measuring module (13) comprises a light source (19), a detector (18) and a test element holder (15), which are arranged in such

a way that light from the light source (19) can pass through a translucent region (12) of the multi-component injection-molded part (23) to a test element (16) arranged in the test element holder (15) and be reflected by the test element (16) through the translucent region (12) to the detector (18).

9. The analysis system as claimed in any one of claims 1 to 8, wherein a reading module (24) for reading optically coded data, the reading module (24) containing the optical module or a further optical module (25).

10. The analysis system as claimed in claim 9, wherein the reading module (24) also comprises a light source (28), a detector (36) and a magazine holder, which are arranged in such a way that light from the light source (28) can pass through a translucent region (38) of the multi-component injection-molded part (23) to a test element magazine (31) held in the magazine holder and be reflected by the test element magazine (31) through the translucent region (38) to the detector (36).

11. The analysis system as claimed in claim 10, wherein the light source (28) and the detector (36) are arranged on a printed circuit board (20), which is connected to the optical module (35).

12. A method for producing an analysis system for analyzing a sample on an analytical test element, the analysis system containing a measuring module and an optical module, the optical module comprising a lens and a diaphragm, the method comprising the following steps:

multi-component injection molding of the lens and the diaphragm in a one-piece multi-component injection-molded part and

positioning and mounting of the multi-component injection-molded part in the analysis system.

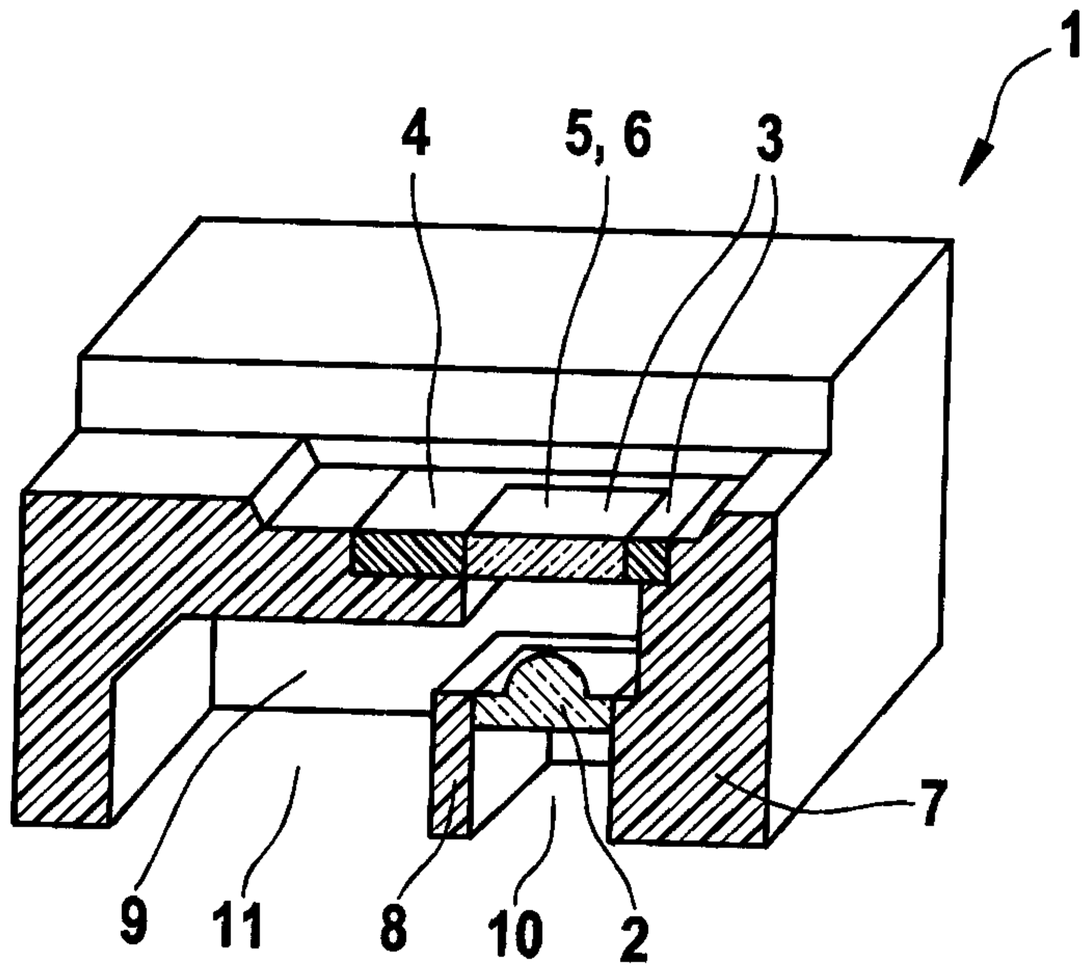


Fig. 1
(PRIOR ART)

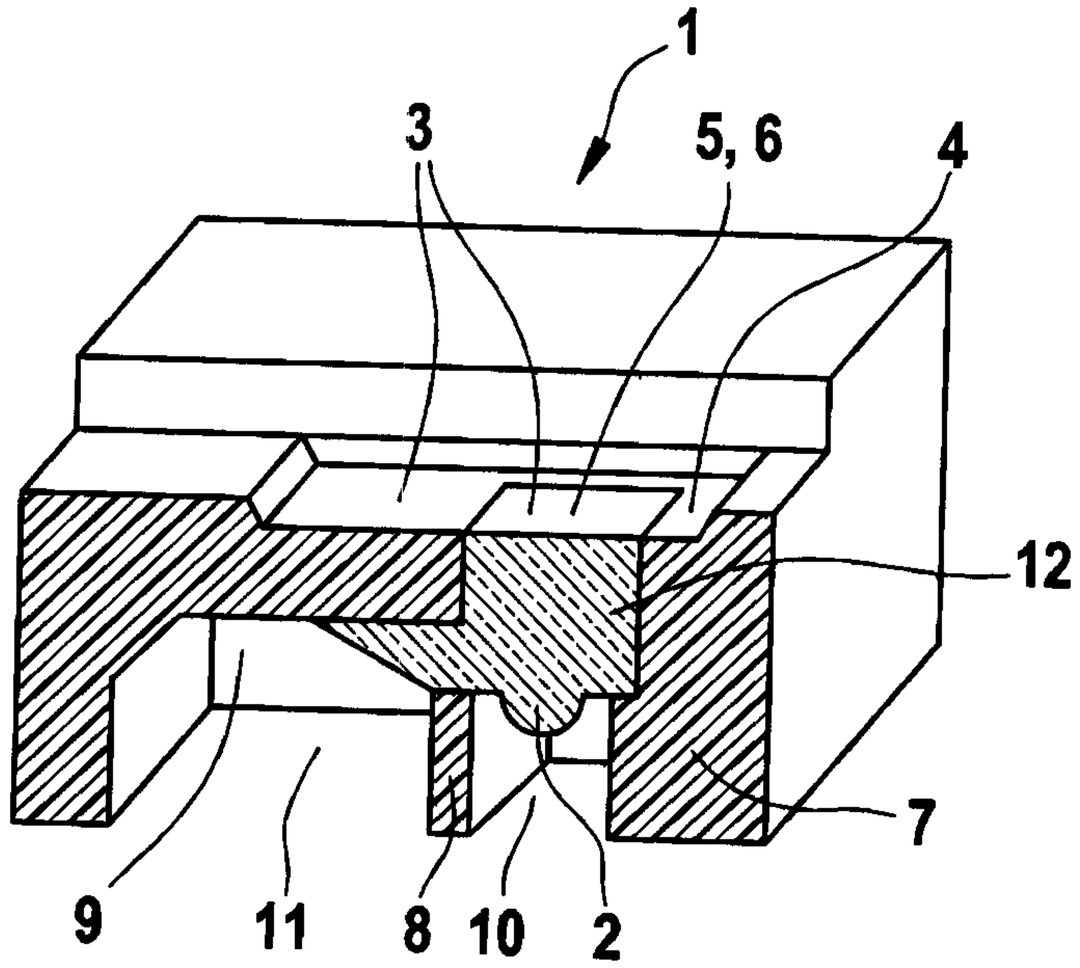


Fig. 2

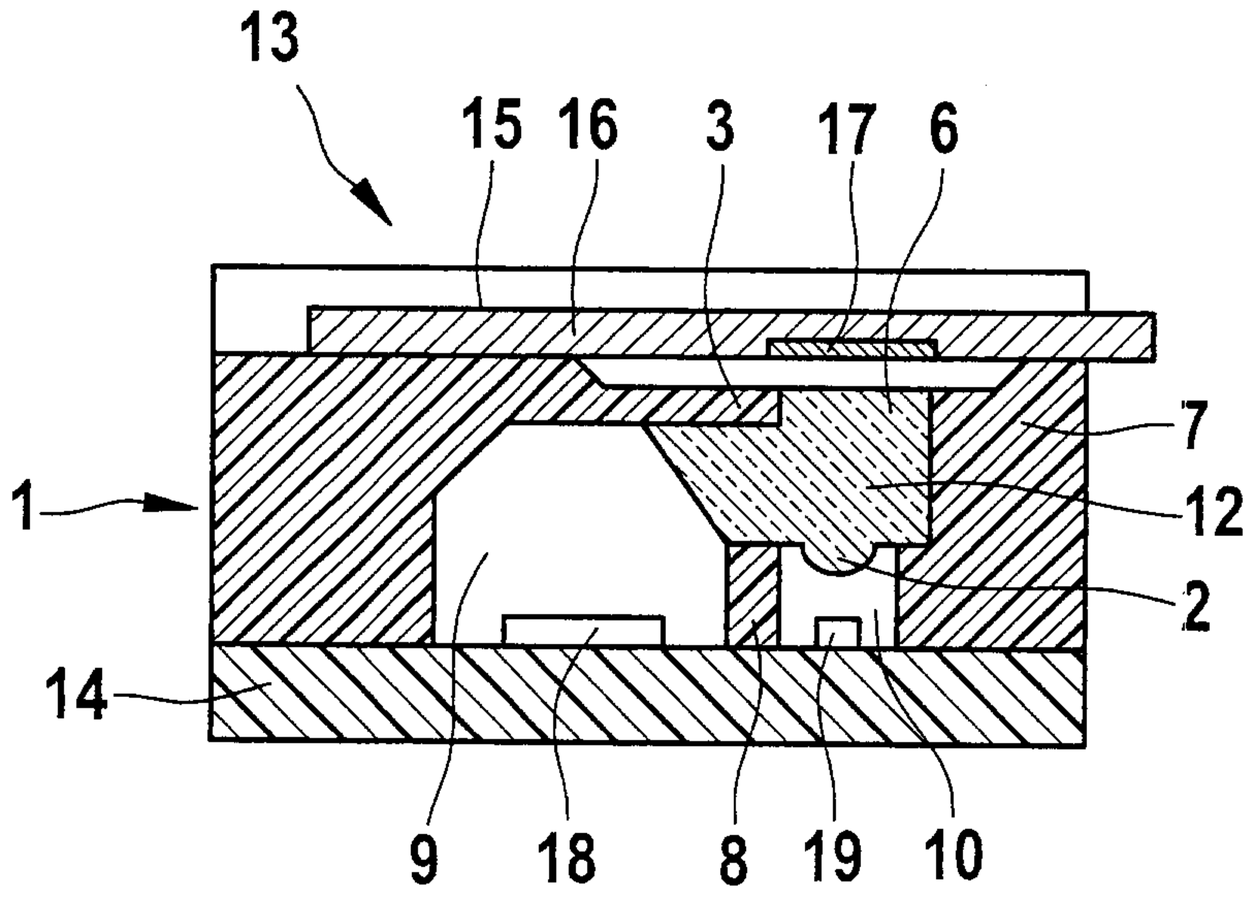


Fig. 3

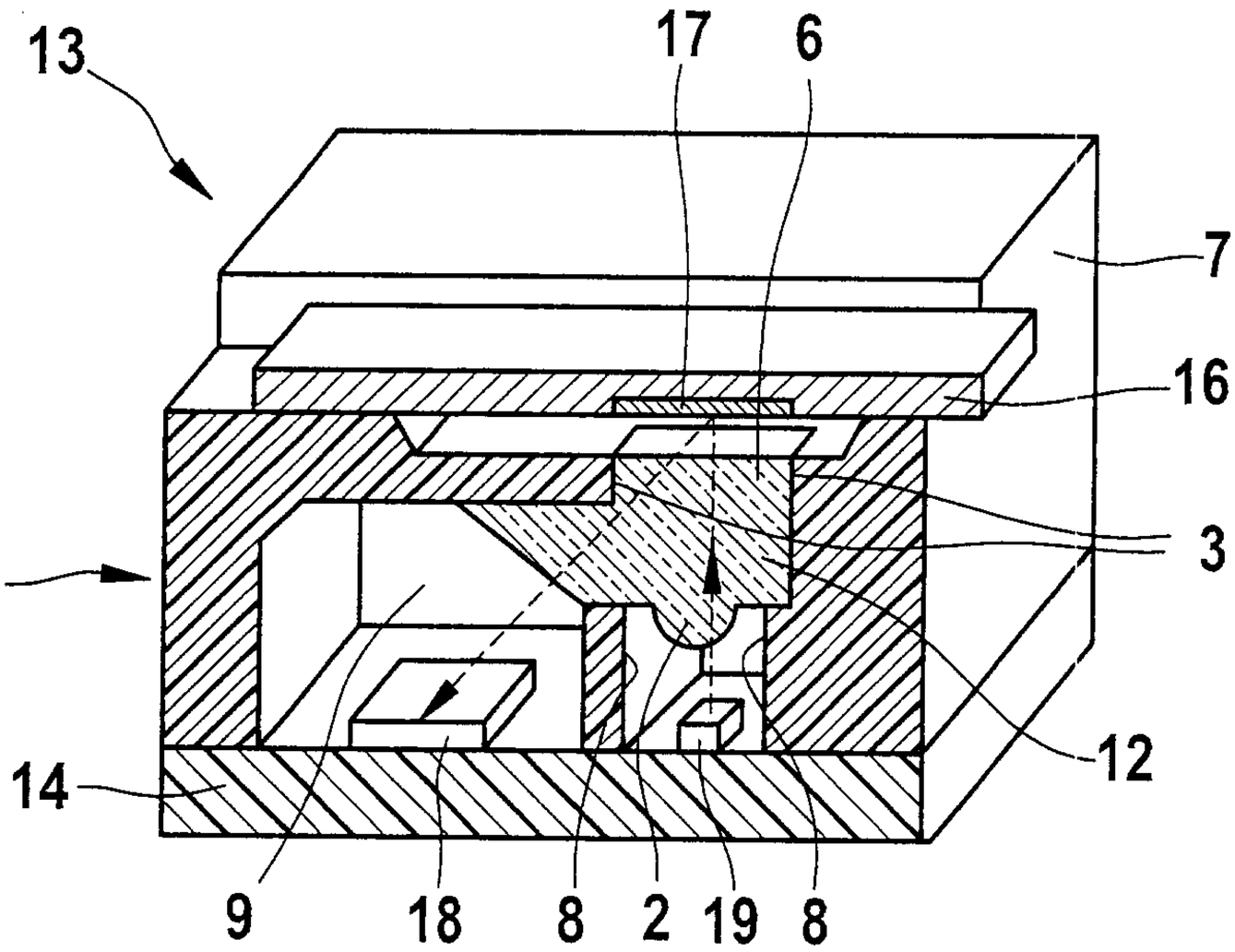


Fig. 4

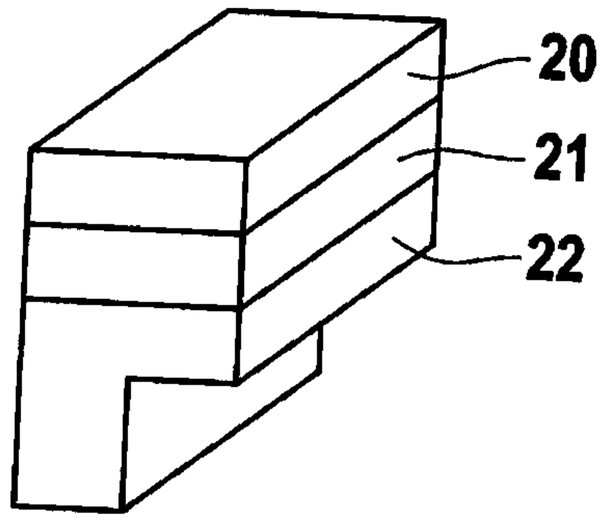


Fig. 5a
(PRIOR ART)

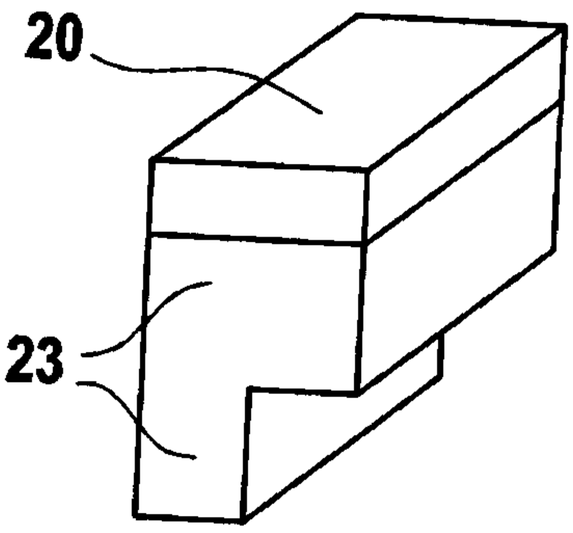


Fig. 5b

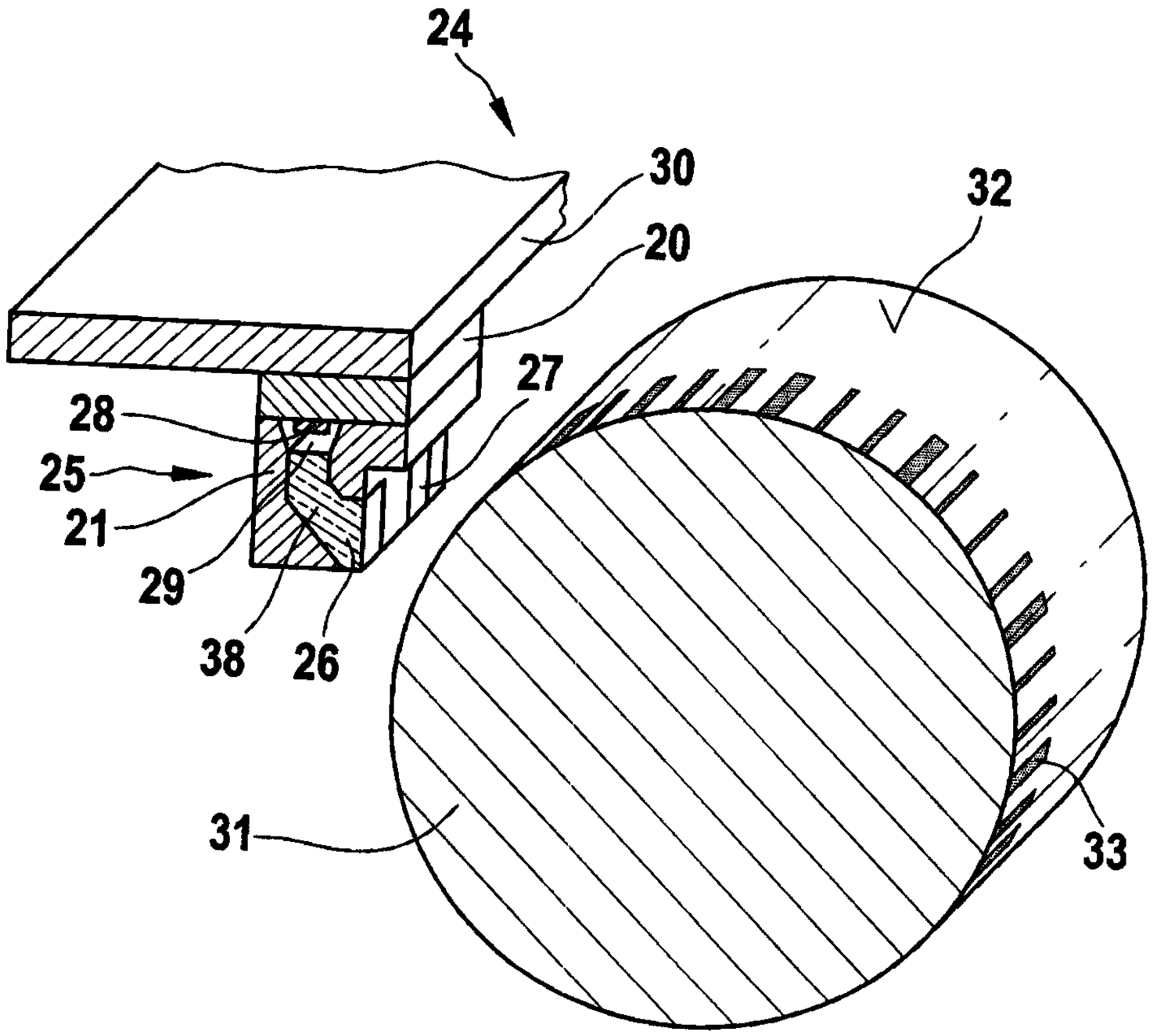


Fig. 6

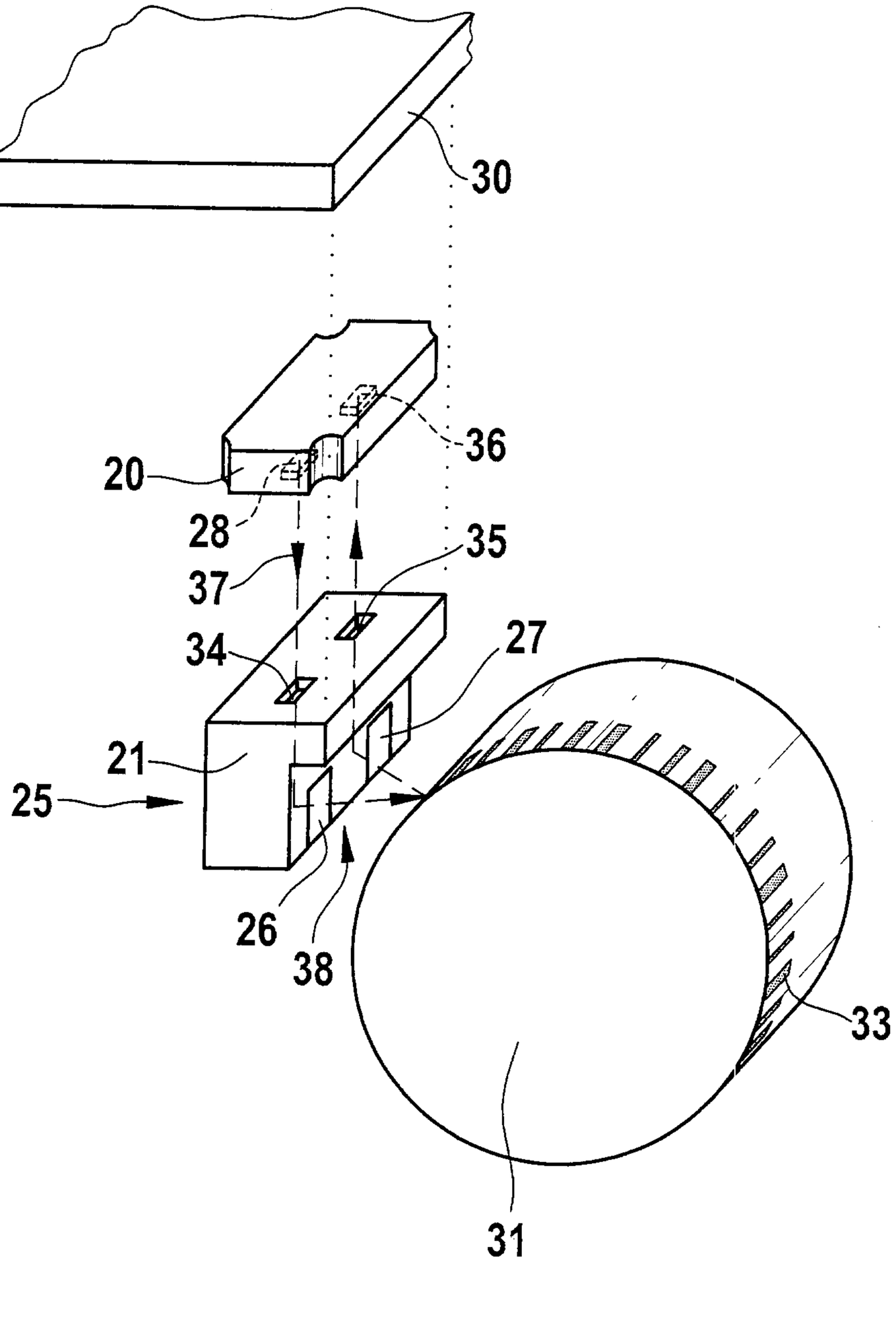


Fig. 7

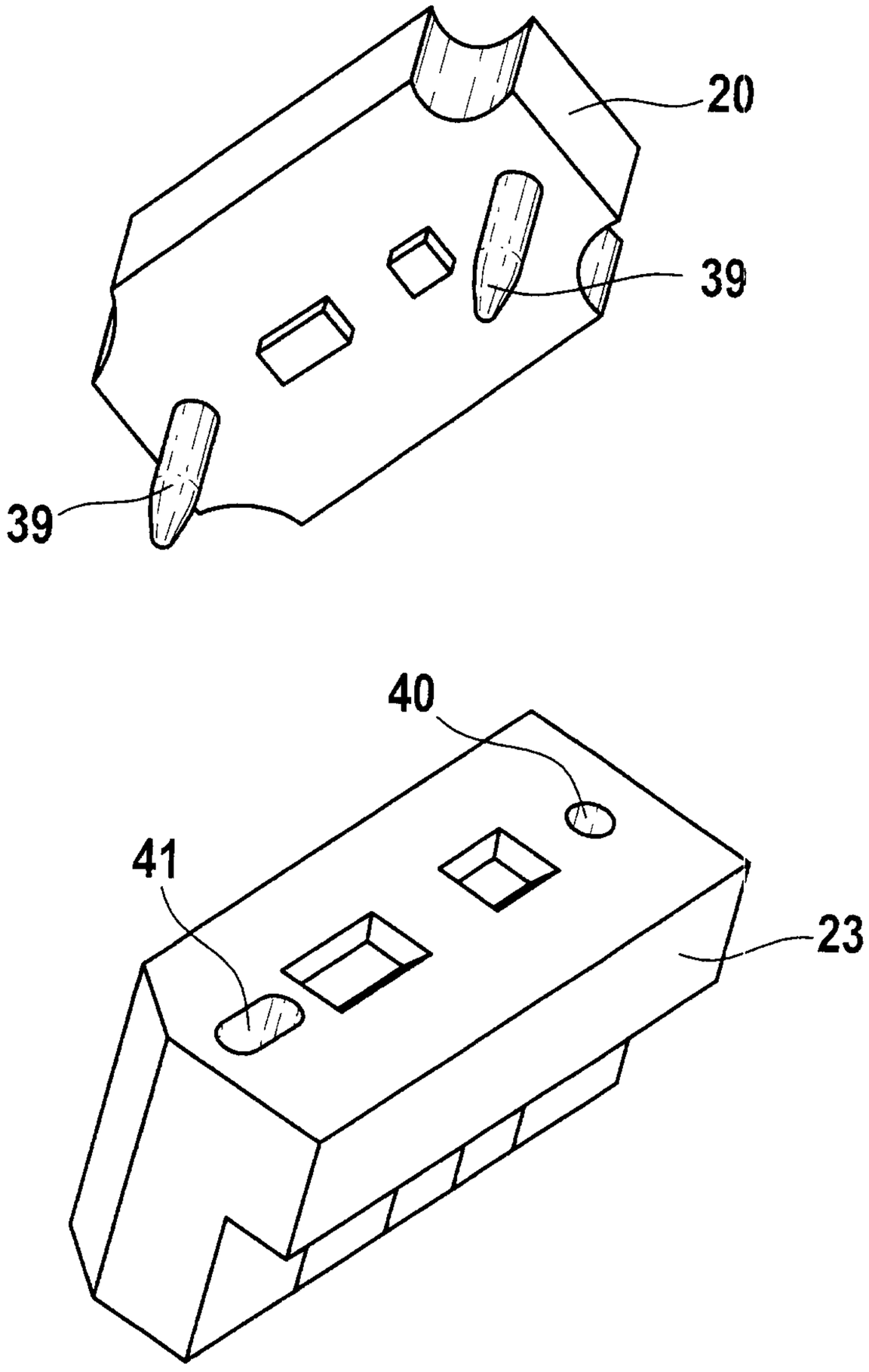


Fig. 8

Fig. 9a

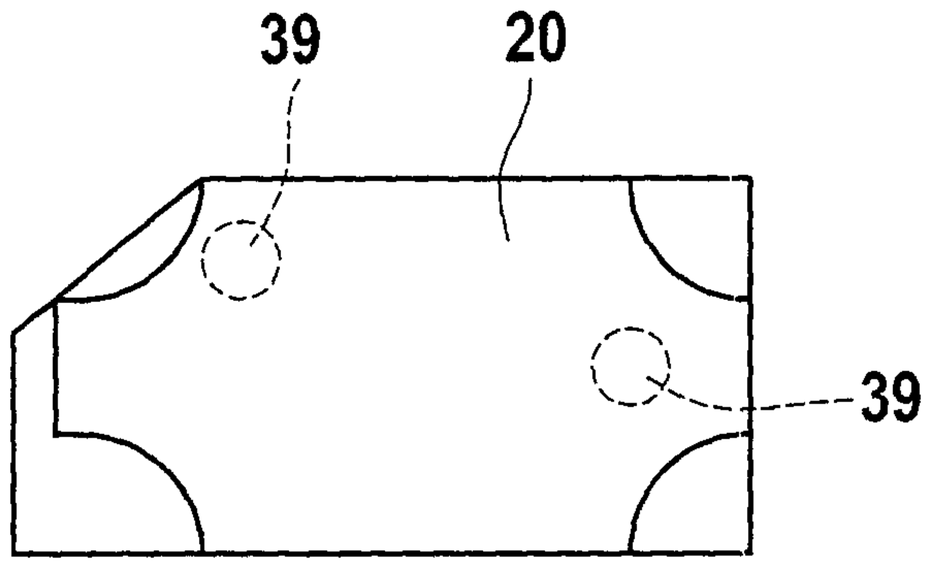


Fig. 9b

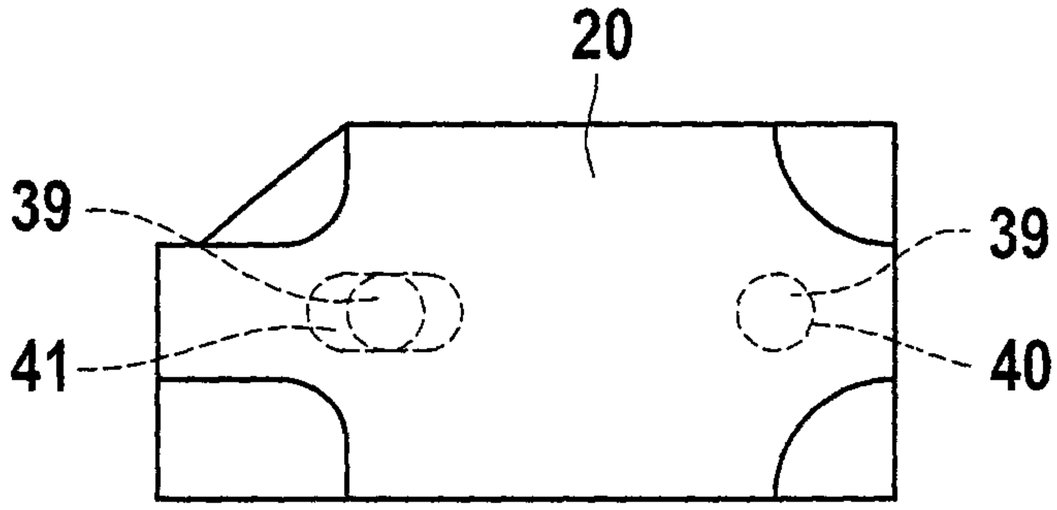
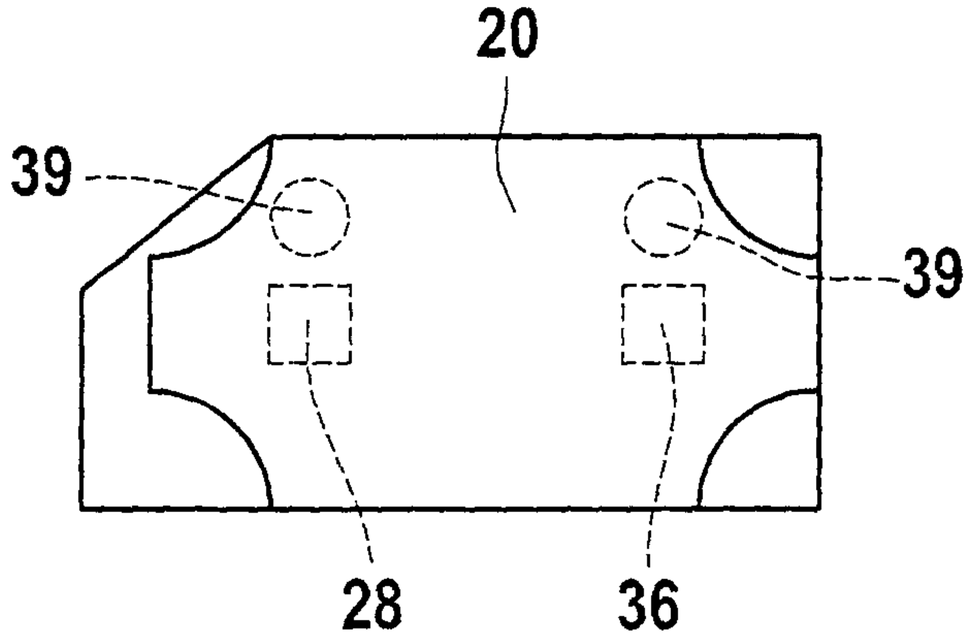
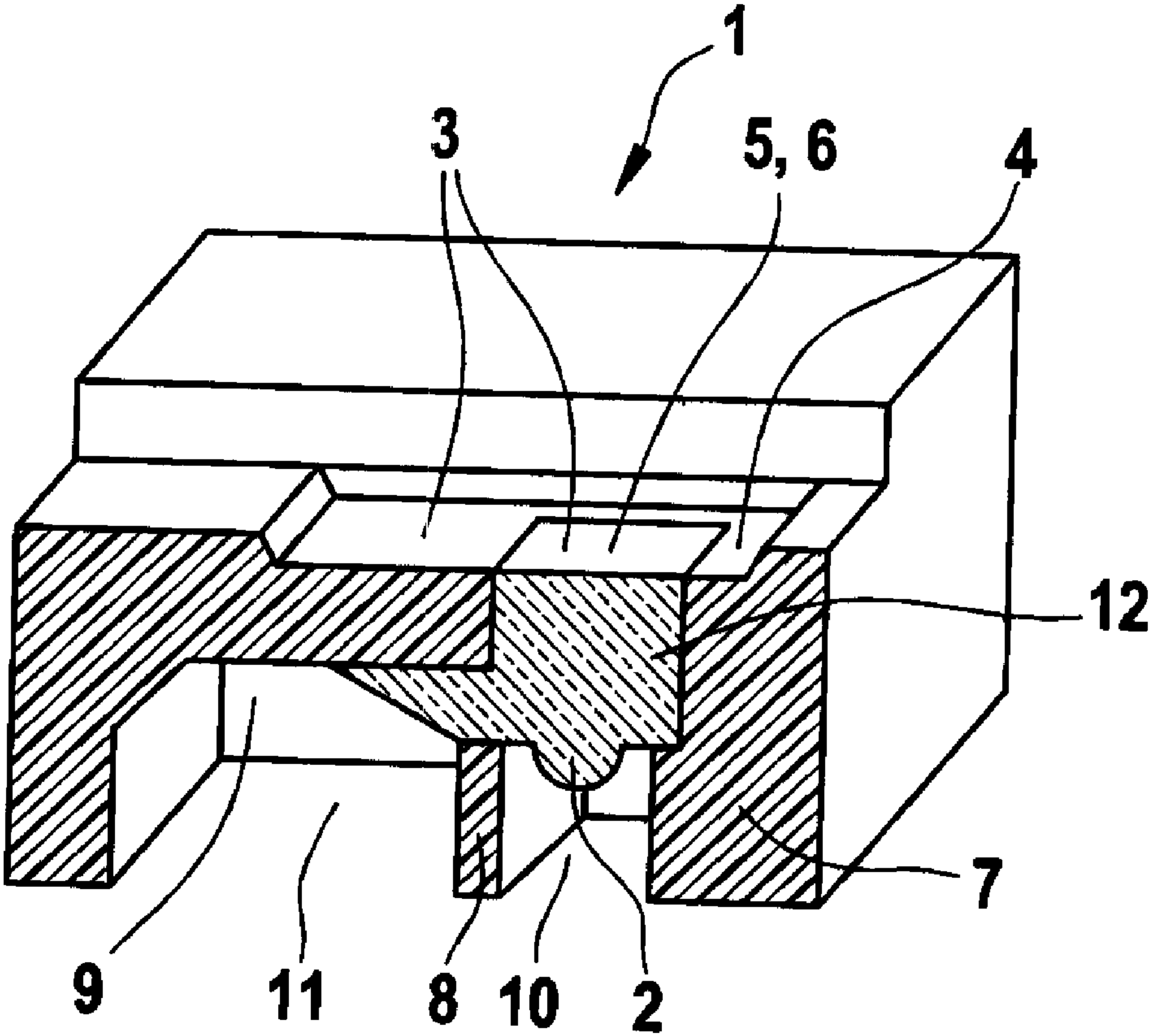


Fig. 9c

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