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(54) Title: ULTRASOUND PROBE FOR TREATING BODY TISSUES

(57) Abstract: An ultrasound probe for treating body tissues, which includes a focused ultrasound emitter arranged inside a main body provided with a part that can be gripped, and a means for connection to a remote unit for the power supply and control of the probe. The particularity of the present invention resides in that it includes a means for adjusting the penetration depth of a beam of focused ultrasound, emitted by the emitter, in a tissue of a patient.

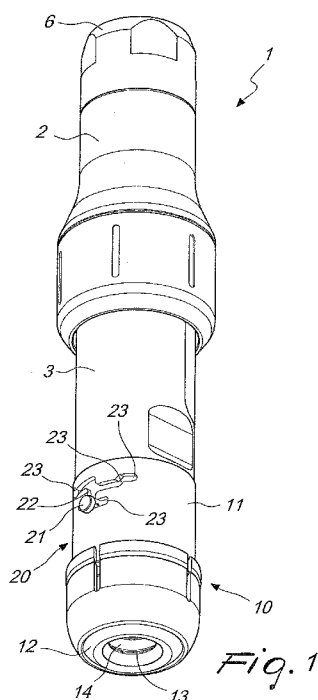


Fig. 1



ULTRASOUND PROBE FOR TREATING BODY TISSUES

The present invention relates to an ultrasound probe for treating body tissues.

As is known, currently there are many methods and apparatuses for dealing with and solving problems linked to skin blemishes, such as for example wrinkles, scars and
5 lack of skin tonicity.

Among the various technologies used, techniques for treating skin with high-intensity focused ultrasound (HIFU) are becoming increasingly important.

HIFU technology, developed initially for the treatment of various oncologic pathologies, is currently used in the beauty sector to induce a temperature increase, at
10 different skin depths, such as to create a targeted thermal damage which destroys the target tissue and promotes the forming of new fibers capable of filling the lesion.

The concept on which the use of high-intensity focused ultrasound is based is fundamentally the concept of tissue thermoablation, obtained by converting into heat the energy carried by an elastic wave that is focused on the cells to be treated.

15 The elastic wave is generated by an ultrasound wave transducer which is usually constituted by a spherical dome made of piezoelectric material; the dome is conceived so as to concentrate the emitted energy in a limited region, commonly termed focal point.

The focal distance, i.e., the distance between the surface of the emitter and the focal point, is a construction parameter that characterizes every ultrasound wave
20 transducer and directly conditions the penetration depth of the focused ultrasound in the tissues.

Accordingly, in order to perform treatments at different depths, currently it is necessary to use ultrasound transducers with different focal distances.

In practice, therefore, it is indispensable to replace the ultrasound wave
25 transducer every time that the treatment is changed, and in some cases even several times during the same session.

This obviously entails drawbacks, both in terms of time and in terms of costs.

It should also be noted that since air is an almost totally reflective medium for ultrasounds, ultrasound transducers are generally contained in hermetically closed
30 chambers filled with water.

However, while on the one hand water ensures the acoustic coupling of the ultrasound wave transducer with the skin of the patient, on the other hand the energy flow entails the heating of the water, causing phenomena such as the forming of air bubbles or the creation of convective motions in the chamber.

5 These alterations of the state of the liquid interfere with the transmission of the elastic wave.

Also, the heat accumulation of the water contained in the chamber tends to heat the ultrasound wave transducer, with the risk of causing unwanted frequency switches or other operating anomalies.

10 The aim of the present invention is to provide an ultrasound probe for the treatment of body tissues that overcomes the drawbacks of the cited prior art.

Within the scope of this aim, a particular object of the invention is to provide a probe that allows to perform treatments at different skin depths without having to change the ultrasound wave transducer each time.

15 Another object of the invention is to provide a probe that allows to perform multiple types of treatment.

A further object of the invention is to provide a probe in which attenuation and reflection during the HIFU application are minimal and at the same time unwanted alterations of the transmission medium are avoided.

20 Another object of the invention is to provide a probe which, by virtue of its particular constructive characteristics, is capable of giving the greatest assurances of reliability and safety in use.

Another object of the invention is to provide a probe that is relatively simple to manufacture and is also competitive from an economic standpoint.

25 This aim, these objects and others which will become better apparent hereinafter are achieved by an ultrasound probe for treating body tissues, comprising at least one focused ultrasound emitter, said emitter being arranged within a main body which forms a portion that can be gripped, said probe further comprising a means for connection to a remote unit for the power supply and control of said probe, said probe being
30 characterized in that it comprises a penetration depth adjustment means for adjusting

the penetration depth of a beam of focused ultrasound emitted by said emitter, said penetration depth adjustment means adjusting the penetration depth of said focused ultrasound beam in a tissue of a patient.

Further characteristics and advantages will become better apparent from the description of a preferred but not exclusive embodiment of a probe according to the invention, illustrated by way of non-limiting example in the accompanying drawings, wherein:

Figure 1 is a perspective view of a probe according to the invention;

Figure 2 is a perspective view of a component of the probe according to the invention;

Figure 3 is an axial sectional view of the probe according to the invention, shown in an example of use;

Figure 4 is an axial sectional view of the component of Figure 2;

Figure 5 is another axial sectional view of the component of Figure 2;

Figure 6 is an enlarged-scale view of a detail of Figure 4.

With reference to the cited figures, an ultrasound probe, particularly for treating body tissues, is designated generally by the reference numeral 1.

The probe 1 includes a main body 2 which forms a portion that can be gripped and an end portion 3; the end portion 3 has a substantially cylindrical shape and an axis 100.

Preferably, the end portion 3 is joined to the main body 2 detachably, by virtue of an engagement and disengagement means 4 which allows its interchangeability.

A focused ultrasound emitter is arranged in the end portion 3. The focused ultrasound emitter includes an ultrasound transducer 5, in particular of a type suitable for generating high intensity focused ultrasound (HIFU).

For example, the ultrasound transducer 5 can be constituted by a hemispherical dome that has a monolithic structure and is made of a material having piezoelectric properties.

The ultrasound transducer 5 is powered and controlled by appropriate devices, such as for example a driver and an electronic controller, which are not shown in the

figures. These devices are preferably installed in a remote unit, not shown in the figures.

The probe 1 can be connected to the remote unit by a connecting means 6.

According to the present invention, the probe 1 includes an adjustment means 10 for adjusting the penetration depth. The adjustment means 10 adjusts the penetration
5 depth of a beam 50 of focused ultrasound, emitted by the ultrasound transducer 5, in a tissue 200 to be treated, in particular in an epithelial tissue.

In practice, the adjustment means 10 allows to adjust axially the position of the focal point 51 of the focused ultrasound beam 50 with respect to the surface of a tissue 200 on which the probe 1 is rested in order to perform a treatment.

10 The expressions "axially" or "axial" herein generally refer to a direction that is substantially parallel to the axis of extension 100 of the end portion 3.

The adjustment means 10 includes a terminal member 11 which can move axially with respect to the end portion 3 of the main body 2.

Specifically, the terminal member 11 essentially consists of a cylindrical sleeve
15 which has a substantially cylindrical side wall, which is mounted coaxially on the end portion 3, and an end wall 12, which is substantially dome-shaped.

The relative axial sliding between the terminal member 11 and the end portion 3 can be locked reversibly by virtue of a locking means 20.

Preferably, the locking means 20 are configured in such a manner that the
20 relative locking between the terminal member 11 and the end portion 3 occurs at a position that is chosen from a plurality of predetermined positions.

In the specific case, the locking means 20 include a pin 21 which protrudes radially from the end portion 3 and engages slidingly in a contoured slot 22 provided on the side wall of the terminal member 11.

25 Advantageously, the contoured slot 22 is extended parallel to the axis 100 and has a plurality of transverse seats 23 for the pin 21.

The transverse seats 23 are mutually spaced axially, so as to define respectively the positions of relative locking between the terminal member 11 and the end portion 3.

In the example of embodiment shown in the figures, the transverse seats 23 are
30 six; however, these seats may vary in number and shape, so long as they in any case

ensure a sufficient number of work positions and optimum locking of the pin 21.

Conveniently, the contoured slot 22 is provided with a graduation, not shown in the figures, which distinguishes each transverse seat 23 in such a manner as to indicate to an operator the functional configuration of the probe 1.

5 The terminal member 11 forms a chamber 30 together with the end portion 3. The chamber 30 has a variable volume and the ultrasound transducer 5 is arranged inside it.

More precisely, the chamber 30 is delimited laterally by the side wall of the terminal member 11, at one axial end by the end wall 12 of the terminal member 11 and
10 at the opposite axial and by the ultrasound transducer 5.

Conveniently, the end wall 12 is provided with a window 13 that has a substantially circular shape and is closed by a membrane 14 made of a material that is substantially flexible and transparent to ultrasound.

In practice, the window 13 has the purpose of allowing the focused ultrasound
15 beam emitted by the ultrasound transducer 5 to penetrate the tissue to be treated.

Advantageously, the chamber 30 is fluid-tight and is filled with a liquid, in the specific case water, which ensures acoustic coupling with the tissue to be treated.

In the specific case, in order to ensure the tightness of the chamber 30, sealing gaskets 15a and 15b, such as for example O-rings, are arranged between the end
20 portion 3 and the terminal member 11.

According to a further aspect of the invention, the water that fills the chamber 30 is replaced continuously in order to eliminate the heat generated by the ultrasound.

Efficient heat removal allows to ensure both durable and correct operation of the ultrasound transducer 5, avoiding for example unwanted frequency switches, and to
25 avoid the forming of bubbles and/or convective motions in the liquid that fills the chamber 30.

Also, by avoiding the overheating of the liquid contained in the chamber 30, the overheating of the end wall 12, which is in contact with the tissue to be treated and might thus cause discomfort to the patient, is also avoided.

30 The liquid is fed by a pumping device, not visible in the figures, which is

connected to the chamber 30 by intake and discharge ducts, designated respectively by 31 and 32, which extend within the main body 2 and in the end portion 3.

The operation of the ultrasound probe according to the present invention is simple and intuitive.

5 Initially, the operator checks the operating configuration of the probe 1, i.e., detects the axial position of the terminal member 11 with respect to the end portion 3, using also the graduation that distinguishes each transverse seat 23.

Then, if the operator deems it necessary to change the depth of the focal point 51 of the focused ultrasound beam 50 with respect to the surface of the tissue 200 to be
10 treated, the operator sets the probe 1 by acting on the adjustment means 10.

More particularly, the operator must first rotate slightly the terminal member 11 with respect to the end portion 3, so as to disengage the pin 21 from the transverse seat 23 that accommodates it.

Once the pin 21 has been disengaged from the transverse seat 23, it is possible
15 to make it slide within the contoured slot 22, causing the axial sliding of the terminal member 11 with respect to the end portion 3.

After identifying the correct relative position between the end portion 3 and the terminal member 11, the terminal member 11 is again rotated with respect to the end portion 3, so as to engage again the pin 21 in another transverse seat 23.

20 In order to increase the depth of the focal point 51 of the focused ultrasound beam 50 with respects to the surface of the tissue 200 to be treated it is necessary to retract the terminal member 11 with respect to the end portion 3, whereas in order to decrease the depth of the focal point 51 it is necessary to extract the terminal member 11 with respect to the end portion 3.

25 When the probe 1 is configured correctly, the operator places the probe on the tissue 200 to be treated, preferably keeping the axis 100 of the terminal portion 3 substantially perpendicular to the surface of the tissue 200 to be treated, and starts dispensing the focused ultrasound beam 50.

The pumping device also begins operating simultaneously with the ultrasound
30 transducer 50 and, by means of the intake duct 31 and discharge duct 32, changes

continuously the liquid that fills the chamber 30, with all the advantages that have already been described.

In practice it has been found that the invention achieves the intended aim and objects, an ultrasound probe for treating body tissues having been provided which allows
5 to perform treatments at different skin depths without having to change the ultrasound wave transducer each time.

The probe according to the invention in fact allows to vary simply and repeatably the position of the focal point in the tissue, so as to be able to choose among multiple types of treatment without changing device.

10 Also, the probe according to the invention allows to minimize attenuation and reflection during the application of the HIFU and simultaneously to avoid the forming of bubbles or convective motions in the transmission medium.

The materials used, so long as they are compatible with the specific use, as well as the contingent shapes and dimensions, may of course vary according to the
15 requirements and the state of the art.

CLAIMS

1. An ultrasound probe for treating body tissues, comprising at least one focused ultrasound emitter, said emitter being arranged within a main body which forms a portion that can be gripped, said probe further comprising a means for connection to a remote
5 unit for the power supply and control of said probe, said probe being characterized in that it comprises a penetration depth adjustment means for adjusting the penetration depth of a beam of focused ultrasound emitted by said emitter, said penetration depth adjustment means adjusting the penetration depth of said focused ultrasound beam in a tissue of a patient.

10 2. The probe according to claim 1, characterized in that said penetration depth adjustment means comprises a terminal member which can move axially with respect to an end portion of said main body; said probe comprising a locking means adapted to lock the relative axial movement between said terminal member and said main body.

15 3. The probe according to claim 2, characterized in that said locking means is configured to lock the relative axial sliding between said terminal member and said main body at a position chosen from a plurality of predetermined positions.

20 4. The probe according to claim 2, characterized in that said terminal member comprises a cylindrical side wall and an end wall, said side wall being associated slidingly and coaxially with said end portion of said main body, said end portion having a cylindrical shape.

25 5. The probe according to claim 4, characterized in that said locking means comprises at least one pin which protrudes from said end portion of said main body and is engaged slidingly in a contoured slot provided on said side wall of said terminal member, said contoured slot extending substantially axially and having a plurality of transverse seats for said pin; said transverse seats being mutually spaced axially in order to define respectively said predetermined positions.

30 6. The probe according to claim 4, characterized in that said focused ultrasound emitter comprises an ultrasound transducer arranged inside a variable-volume chamber formed at said end portion of said main body; said chamber being at least partly delimited by said side wall of said terminal member and by said end wall of said terminal

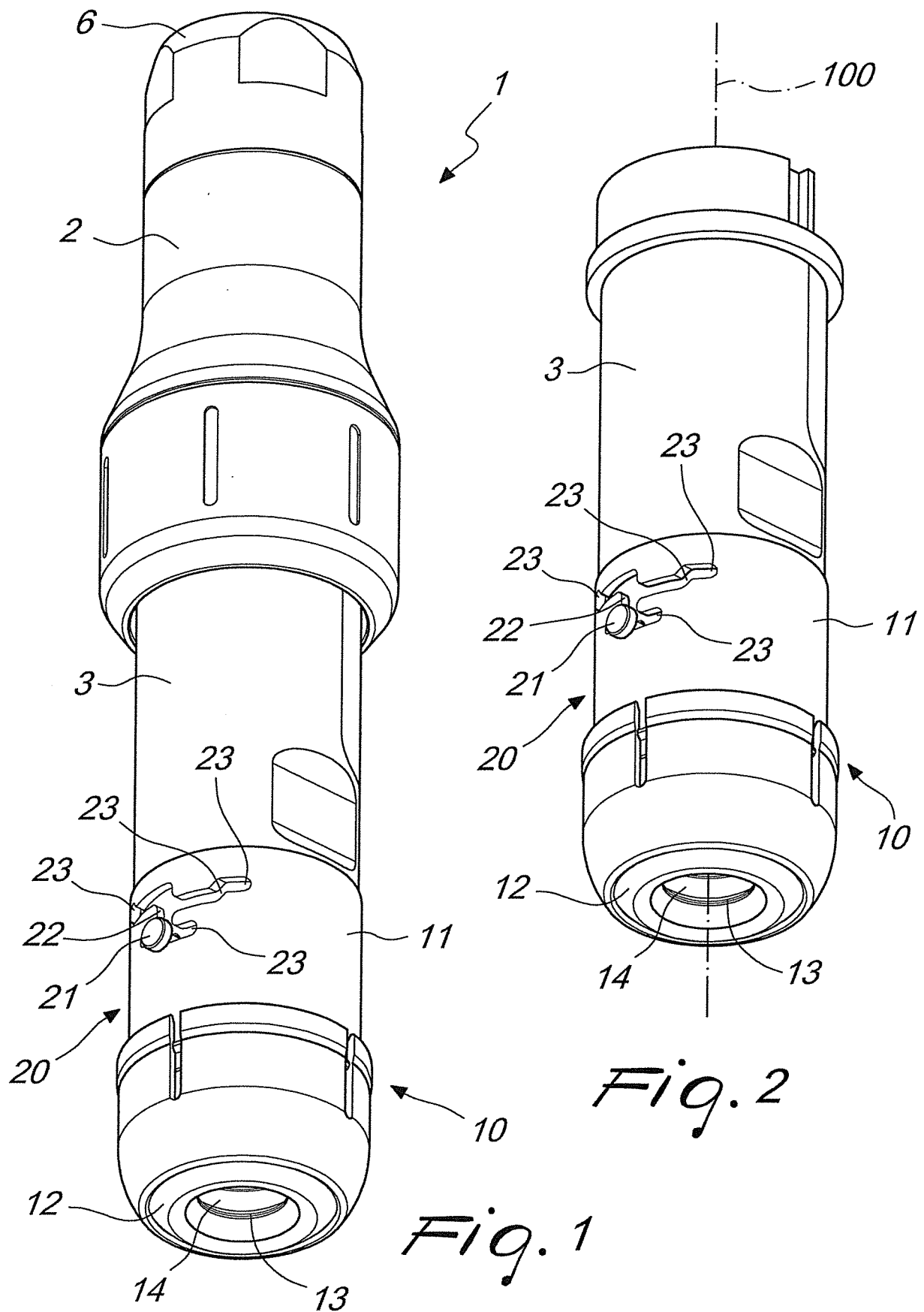
member; said end wall being provided with a window that is closed by a membrane which is flexible and transparent to ultrasound.

7. The probe according to claim 6, characterized in that said chamber is fluid-tight and contains a liquid that is replaced continuously; said liquid being fed by a pumping
5 device which is connected to said chamber by means of intake and discharge ducts.

8. The probe according to one or more of the preceding claims, characterized in that said ultrasound transducer is of the type suitable for generating high intensity focused ultrasound.

9. The probe according to claim 2, characterized in that said end portion is joined
10 to said main body detachably, by virtue of an engagement/disengagement means which allows its interchangeability.

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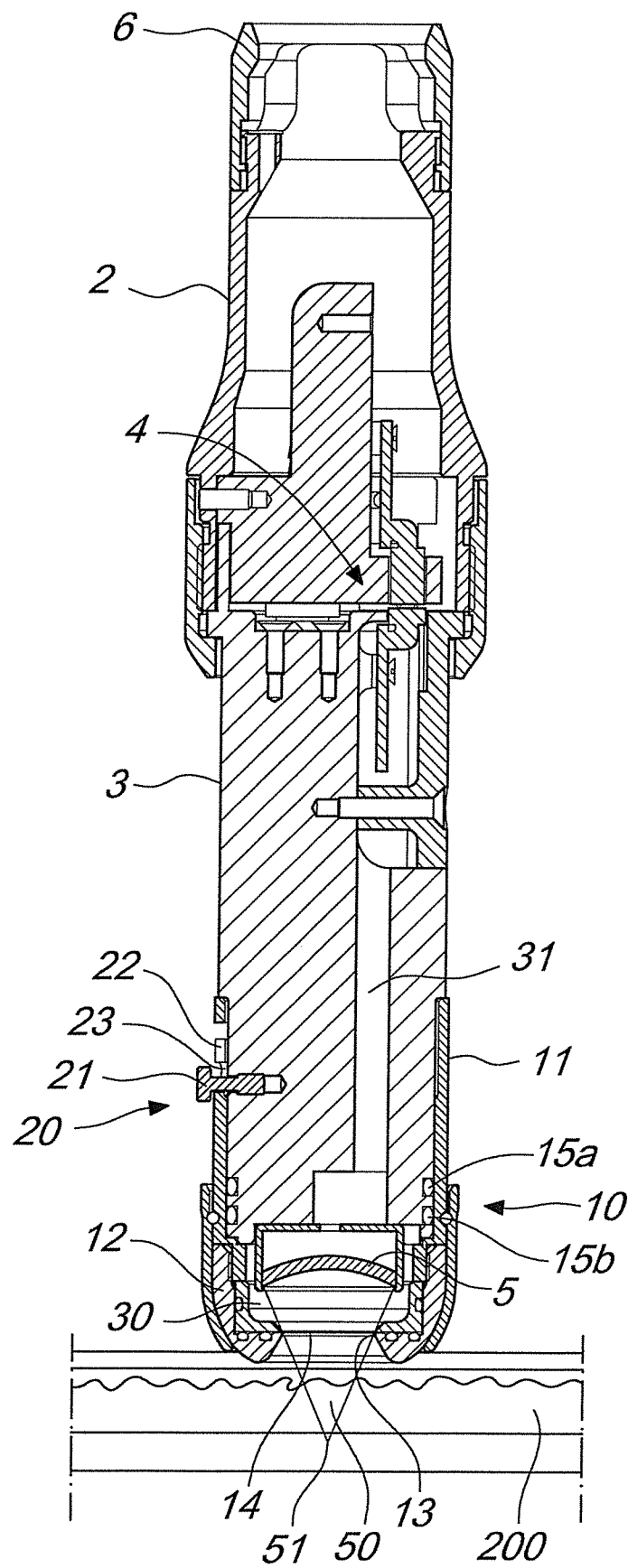


Fig. 3

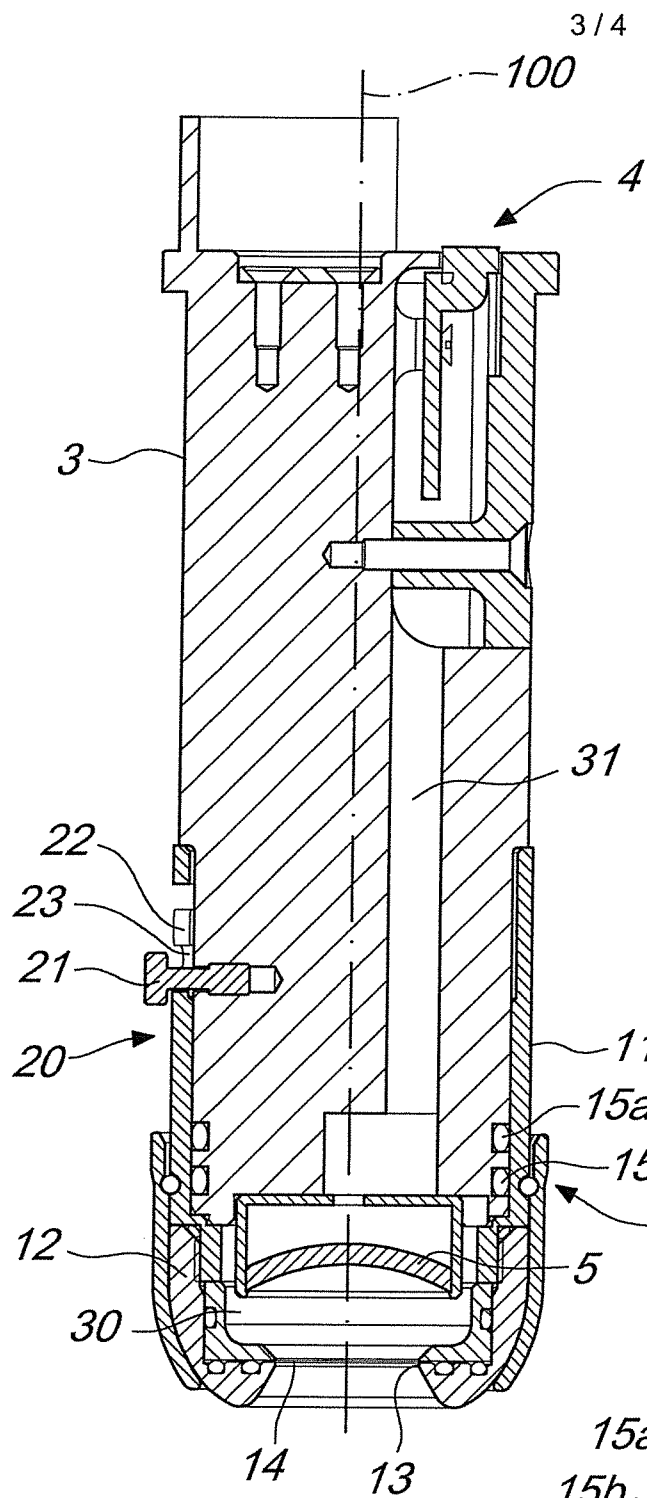


Fig. 4

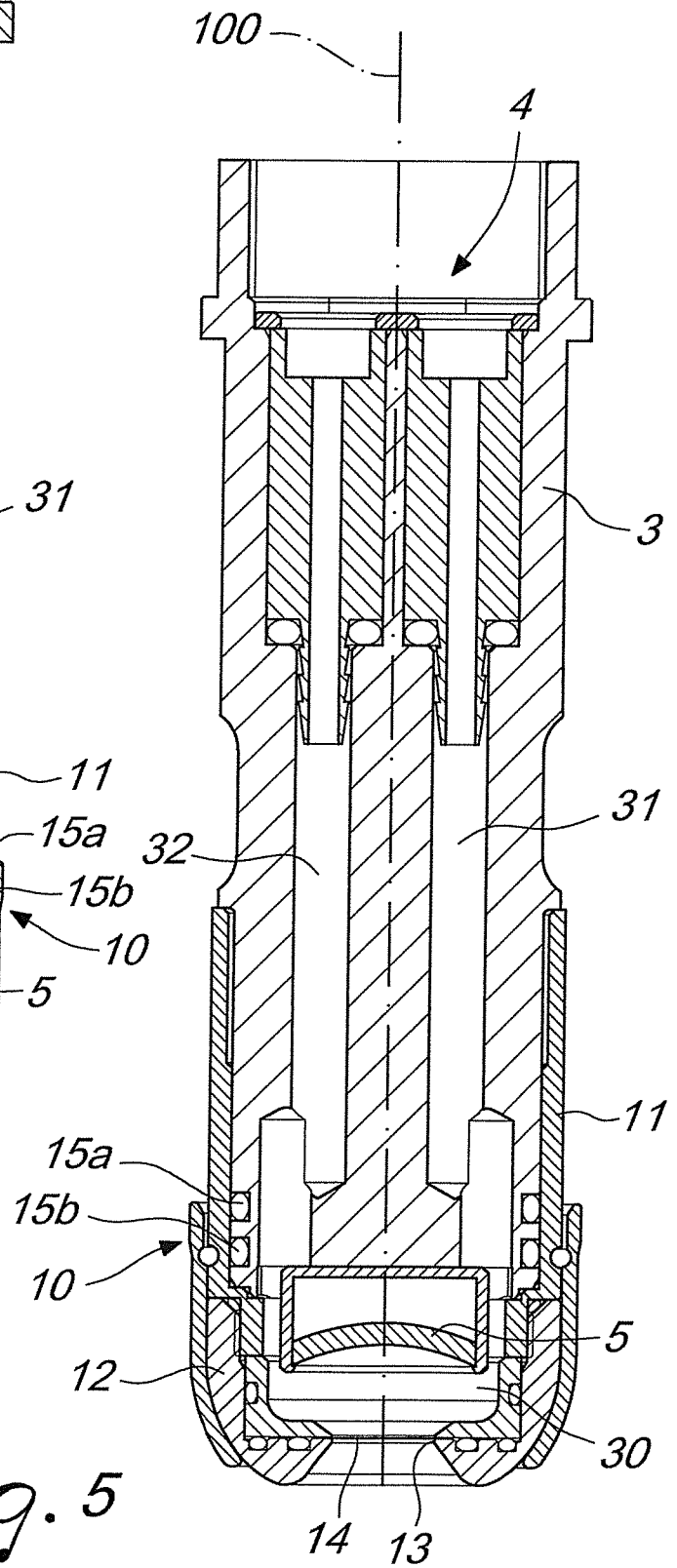
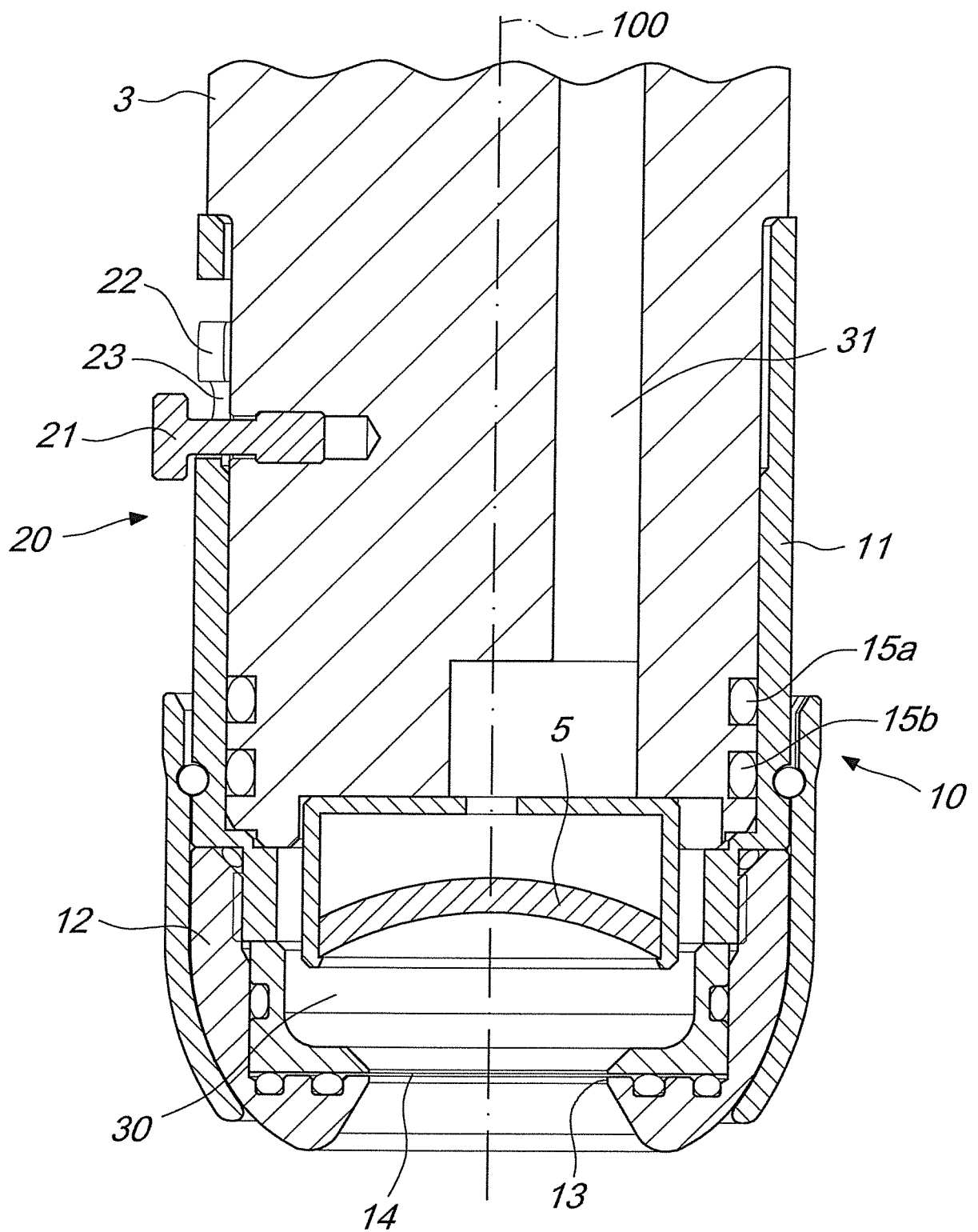


Fig. 5

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*Fig. 6*

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2019/000004

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N7/02
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	US 5 762 066 A (LAW WING K [US] ET AL) 9 June 1998 (1998-06-09) column 10, line 65 - column 12, line 32; figures 1-3 column 17, line 13 - column 19, line 40; figures 4, 15-17	1-4,6-9
X	WO 2017/200246 A1 (CLASSYS INC [KR]) 23 November 2017 (2017-11-23) see US family member -/--	1-6,8,9



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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17 September 2019

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Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2019/000004

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
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