



(51) International Patent Classification:

A61B 8/08 (2006.01) A61N 7/02 (2006.01)  
A61B 8/12 (2006.01) A61N 7/00 (2006.01)

(21) International Application Number:

PCT/IB2018/056926

(22) International Filing Date:

11 September 2018 (11.09.2018)

(25) Filing Language:

English

(26) Publication Language:

English

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

(54) Title: ULTRASONIC DEVICE

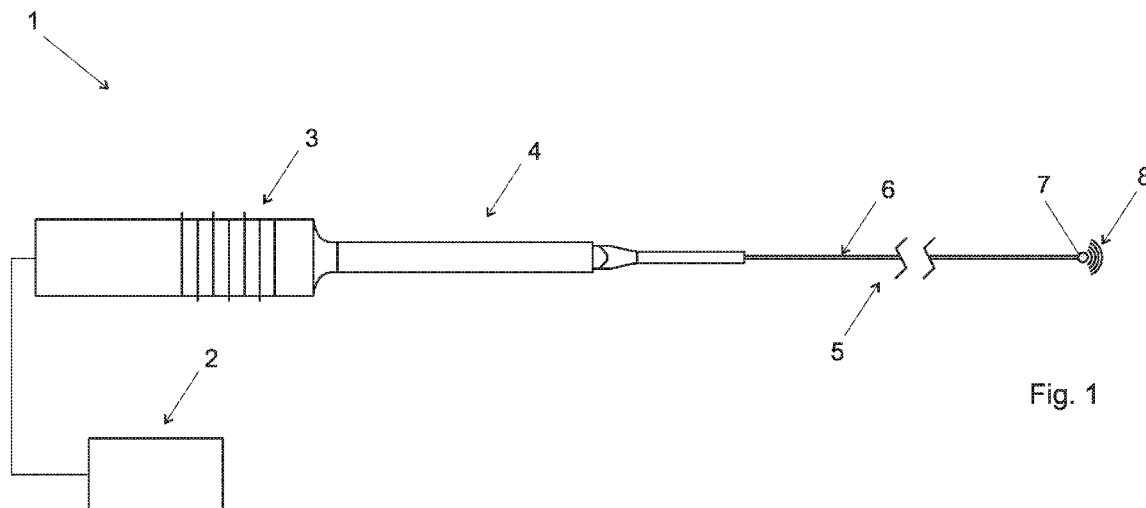


Fig. 1

(57) Abstract: The invention concerns an ultrasonic device comprising a sonotrode, a transmission wire and a tip, said sonotrode comprising a transducer and a horn, the transducer being coupled to the horn. The transmission wire is coupled on one end with the horn and on the opposite end with the tip, so that when the transducer vibrates, said vibration are amplified by the horn and transmitted to the transmission wire that displaces accordingly, said displacements of the wire inducing vibrations of the tip generating an acoustic field from said tip. The device comprises n sonotrode, n transmission wire, and at least one tip, n being superior or equal to two. The device further comprises a control module being arranged for controlling the amplitude of displacement of each transmission wire so as to set up the emitted acoustic field generated from said tip.



**Published:**

- *with international search report (Art. 21(3))*
- *with amended claims (Art. 19(1))*
- *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*

## Ultrasonic device

### Field of the invention

[0001] The present invention concerns an ultrasonic device.

### Description of related art

[0002] Ultrasound waves have been used for many years in numerous  
5 medical applications, for diagnostics and as therapy for various conditions.  
For instance, in medical imaging, ultrasonography is a widely used  
diagnostic technique that is used to see internal structures or organs of a  
patient, for instance muscles or tendons or for instance, in cardiovascular  
diagnostic technique to measure velocity of blood. Ultrasound is classically  
10 used in obstetric to examine a pregnant woman and provide reliable  
images of the child during pregnancy.

[0003] There are also various surgical applications based on ultrasound  
waves to solve cardiovascular disease (CVD). Cardiovascular disease is one of  
the leading causes of death worldwide. It is estimated that approximately  
15 18 million people die globally each year of CVD and it is predicted that this  
will rise to 20 million the next years. The main forms of CVD are stroke and  
coronary heart diseases (CHD). Coronary heart disease is the narrowing or  
blocking of coronary arteries, which results in a reduction of blood flow to  
heart muscle. Atherosclerosis is defined as the development of blockages  
20 due to presence of plaque. This is a gradual process starting with  
thickening of the arterial walls resulting in reduced blood flow and possible  
rapid total occlusion due to clotting, known as thromboembolism.  
Atherosclerosis is a pathological condition that is underlying cause of  
several important disorders including coronary artery disease,  
25 cerebrovascular disease and disease of the aorta and peripheral arterial  
circulation.

[0004] There are number of different hypotheses related to the  
incidence of atherosclerosis, such as the inflammatory hypothesis, the lipid

hypothesis (i.e. cholesterol), and the response to injury hypothesis. In general, atherosclerotic lesions are localised in the intima of the artery wall. In more advanced forms, these consist of fibrous caps and combination of macrophages, lipids and smooth muscle cells. These can also become  
5 heavily calcified.

**[0005]** Minimally interventional procedures are currently practiced restoring normal blood flow in the lumen of arteries or of the blood vessel that have full or partial blockage due to lesion. Minimally invasive mechanically based interventions concentrate on removing or de-bulking  
10 the lesion or blockage. Example of these are balloon angioplasty or percutaneous transluminal coronary angioplasty (PTCA), stenting, and rotational and directional atherectomy. The basic principle of a PTCA procedure is that a small balloon is moved across the lesion and inflated, applying a load to lesion walls and deforming it permanently, and hence  
15 increasing the diameter of the lumen of the artery and returning the blood flow closer the normal parameters. Stenting is also a procedure that was developed as a result of balloon angioplasty. During balloon angioplasty when the balloon is deflated there can be some recoil, depending on the type of the lesion. To reduce this, a wire mesh structure, known as stent, is  
20 placed around the balloon and is deployed as the balloon is inflated. The balloon is then removed, with the stent remaining to reduce lesion recoil. Other procedures such as rotational and directional atherectomy are based on removal rather than deformation of lesions

**[0006]** Most of these devices have a similar surgical method. The device  
25 is inserted into an artery either in the upper leg close to the inner thigh or the upper forearm, which allows direct access to the aorta and coronary arteries. A hollow tube, or catheter, is then manipulated to the location of the blockage, which acts as conduit for the main device. Generally, these devices aim to reduce the blockage in the arterial lumen by loading and  
30 permanently deforming the plaque. The three main complications of these procedures are (1) an abrupt closure, typically results from thrombotic occlusion, (2) restenosis, which is a re-closing of the lumen believed to be related to the stretching of healthy and diseased arterial tissue and its

remodelling after application of the balloon, and (3) chronic total occlusion (CTO), which are lesions that completely block, the arteries. The thrombotic occlusion responsible of an abrupt closure of the lumen, occurs generally within the first few hours after procedure. Damage to the arterial walls and  
5 denudation of endothelial cells appears to be the main initiator of restenosis. This will generally occur within the first few months after procedure. The restenosis rate for balloon procedure alone is higher for a same time of period than a procedure with a balloon and a stent deposit.

**[0007]** These procedures present two main challenges. Firstly, the lesion  
10 must be capable of being crossed by a guidewire. This act as a guide rail to direct the device into the place. In some cases, it may be extremely difficult, if not impossible, to cross the lesion to reopen the blockage. These cases are known as chronic total occlusion and are caused by advanced plaques, haemorrhaging and thrombosis and result in the total closure of vessel. If  
15 the lesion cannot be crossed due to total occlusion success levels of the procedure are greatly reduced.

**[0008]** Secondly, the mechanical properties of plaque ranging from soft distensible material to rigid plaque. The more rigid lesions, also known as calcified plaques, have a great resistance to deformation or stenting and  
20 sometimes despite high pressure applied to the balloon it's not possible to deform them. In this case the stenting is also not possible. These lesions vary from a fatty streak to advanced complicated lesions. The progression from one to the next is split into phases with specific morphologic characteristics. The shapes of lesions can be divided into following  
25 categories, such concentric and circular, such eccentric and circular, such eccentric and non-circular. These procedures work best with concentric lesions as the pressure is divided relatively evenly over the lesion. However, dilatation of eccentric lesions can be problematic because the lesions are located to one side of the vessel. This result in overstretched less diseased  
30 walls, increased risk of necrosis of cells and tearing and increasing the risk of restenosis. These complications seriously affect the success rates of these interventional procedures.

**[0009]** In the light of the problem described, a soft guidewire with capability of crossing all type of occlusions, including CTO, would be a major advantage. Ideally, a device that would be able to navigate in vascular vessels, which would specifically target diseased tissue and re-open  
5 blockages while causing little damage to the surrounding structure. Different solutions have been developed during 80s to improve the success rates of these procedure, such as intravascular sonotherapy and high power, low frequency, therapeutic ultrasound.

**[0010]** Intravascular sonotherapy is a prophylactic and therapeutic  
10 application of ultrasound, transmitted down a long wire waveguide. The ultrasound delivered has an operating frequency currently between 0.7 – 1.4 MHz. This technique has been used essentially after stenting to prevent restenosis. High power, low frequency, therapeutic ultrasound has been used to disrupt cardiovascular lesion. Using the right combination of  
15 frequency and amplitude, the ultrasound vigorously disrupts inelastic tissue while healthy tissue in the same region remains undamaged. It was conceived that this form of energy may be useful in disrupting cardiovascular lesions especially rigid calcified and fibrous plaques and would have advantages over standard procedures such as angioplasty or  
20 atherectomy. This technique and the device have been extensively described in the literature, for instance in US5156143 or US5427118.

**[0011]** An example of existing ultrasonic device 1 is illustrated in figure 1. Basically, ultrasonic device 1 for ultrasound angioplasty comprises an external power generator 2, a piezoelectric transducer 3, a horn 4 acting  
25 as principal amplificatory of displacement and a catheter 5 with a transmission wire 6, acting as waveguide, connected to the horn 4, and ending with a tip 7. The power generator 2 supplies the system with electrical energy that is required to produce ultrasonic energy, generally at the resonant frequency of the piezoelectric stack. The transducer 3 is  
30 generally made up of PZT crystals that convert the electrical energy of the generator 2 into mechanical displacements. The displacements achieved from transducers are still relatively small and too low for the intended application use, and therefore need to be amplified. This amplification is

performed via an acoustic horn 4 or a waveguide (i.e. wire 6), which is attached to the end of the transducer.

**[0012]** The horn is characterized by its shape optimized to amplify the displacements. For instance, it is solid metal rod manufactured from material with high dynamic fatigue, high strength and low acoustic loss properties, such as titanium alloys. The amplification of displacement outputs is achieved by two methods. First, the surface area of the horn 4 reduces from the output face of the transducer to the horn output face. This reduction in surface area compresses the input waves resulting in a larger displacement at the output. Secondly, horns can be manufactured to resonate at the frequency of the ultrasonic converter and are preferably designed to be exactly half the wavelength of the frequency.

**[0013]** Finally, in the goal to deliver the ultrasonic energy to the occlusion by traversing the tortuous vascular geometry, a waveguide, such as the wire 6, is necessary. This waveguide is a part of the catheter 5 which is connected at the proximal end of the horn 4 and is connected with the tip 7 at the distal end. The ultrasonic energy is transmitted through the catheter 5, thanks the wire 6 acting as a waveguide, until the tip 7, to generate a displacement at the distal end of the tip 7. This displacement generates an acoustic energy which is deposited at the target of occlusion to destroy it.

**[0014]** When electrical energy is provided to the PZT stack, it vibrates longitudinally. The vibrations are then transmitted toward the tip 7 via the transmission wire 6 to produce a distal vibration of the tip 7. The horn 4 and the transmission wire 6, for instance a tapered transmission wire, allow amplification of the vibrations so that the vibration at the tip 7 are larger than the displacement of the PZT stack. Vibrations of the tip 7 generate an acoustic field 8 with an acoustic pressure shape centered on the tip 7.

**[0015]** The existing ultrasonic device as shown in figure 1 are mainly effective to treat concentric and circular lesions, as the pressure generated by the tip is distributed relatively evenly over the lesion. The most

important part of the acoustic pressure field is centered in front of the tip so that the existing solution provides the best results for treating concentric and circular lesions.

5 [0016] However, when lesions are located on one side of the vessel so that the region to be treated is not in front of the tip, the existing solution fails to provide satisfying results because the most part of the acoustic pressure is not focused on the side of the wall where the lesions are located. Therefore, there is need to provide an improved ultrasonic vessel allowing to improve the treatment of the eccentric lesions located on the  
10 side of the vessel.

#### Brief summary of the invention

15 [0017] According to the invention, these aims are achieved by means of an ultrasonic device for generating an acoustic field in a lumen of a component of the cardiovascular system of a patient, in particular a blood vessel or a heart chamber, the device comprising a sonotrode, a  
transmission wire and a tip,

- said sonotrode comprising a transducer and a horn, the transducer being coupled to the horn,
- the transmission wire being coupled on one end with the horn and  
20 on the opposite end with the tip,

so that when the transducer vibrates, said vibrations are amplified by the horn and transmitted to the transmission wire that displaces accordingly, said displacements of the transmission wire inducing vibrations of the tip generating an acoustic field from said tip,

25 characterized in that the device comprises n sonotrode, n transmission wire, and at least one tip, n being superior or equal to two,

and in that the device further comprises a control module being arranged for controlling the amplitude of displacement of each transmission wire so as to set up the emitted acoustic field generated from said tip.

**[0018]** In the present invention, the device comprises at least two  
5 sonotrodes and two transmission wires to provide a multi wires device. With the existing solution with one wire, it is necessary to use a diameter of the wire sufficiently large to transmit the necessary power to minimize losses that would result in overheating of the wire. This impacts the flexibility of the wire and limits access to tortuous path vessels where great  
10 flexibility is required. In the multi wire device according to the invention, the power is distributed in the  $n$  wires, so that it is possible to use a plurality of wires with a smaller diameter than when using a single wire of a large diameter like in the existing solution. This allows maintaining the flexibility of the device.

15 **[0019]** The device according to the present invention comprises a control module. The control module allows changing the shape of the acoustic field emitted from the tip, whether from one tip or from a plurality of tips. For instance, when it comes to treating eccentric lesion located on the side of the vessel, it is advantageous to have the most important part of the  
20 acoustic pressure field not centered in front of the tip but shifted or oriented or positioned on one side. The control module allows for instance shaping the emitted acoustic field toward one side of the vessel to treat in particular this region. This would keep or increase the effectiveness of treatment on the target region while protecting areas where treatment is  
25 not desired.

**[0020]** According to an embodiment, the device comprises  $m$  sonotrodes,  $m$  transmission wires and one single tip, all the transmission wires being coupled to said tip,  $m$  being superior or equal to two. In this embodiment, all the transmission wires are connected to a single tip.

30 **[0021]** When all transmission wires are connected to the same tip, the shape of the acoustic field generated from the tip depends on the

amplitude of displacement of each wire and on the phase of the displacement between the wires. Figures 2,3 and 4 represents a model with two wires connected on one tip, but the invention is not limited to this embodiment.

5 **[0022]** In figures 2 a,2b, each wire oscillates in phase with the same amplitude of displacement around the point of rest R. The emitted acoustic field F1 is oriented in the axial direction, i.e. along the direction of the wires.

10 **[0023]** In figures 3a,3b, each wire oscillates in phase with a different amplitude of displacement around the point of rest R, the difference of amplitude d being induced by the control module. The tip follows a complex movement of rotation whose main direction is no longer along the main axis. The emitted acoustic field F2 is oriented mainly in the direction of the rotation of the tip.

15 **[0024]** In figures 4a,4b, each wires oscillates in opposition of phase (180° phase shift) with a different amplitude of displacement around the point of rest R, the difference of amplitude d and the phase shift being induced by the control module. The tip follows two mains complex movement of rotation whose main directions are no longer along the main axis. The  
20 emitted acoustic field F3 is oriented mainly in the two directions of the rotation of the tip.

**[0025]** The displacement of each transmission wire is triggered by the sonotrode coupled with said transmission wire via a horn. Each sonotrode is supplied with a power supply. In an embodiment, the control module  
25 controls the power supply, i.e. the electrical energy, provided to each sonotrode to control the amplitude of the displacement of each transmission wire. The control module is capable of balancing, in other word modulating, the power supply that is provided to the sonotrodes depending on the acoustic field that has to be generated from the tip. In  
30 other words, the control module acts as an upstream regulator of the ultrasounds waves emitted from the transducer.

**[0026]** In an embodiment represented in figure 17, the control module, composed of a microcontroller (DSP or FPGA for instance) is in charge of distributing and regulating the power, principally by adjusting the voltage and the frequency, to the sonotrodes. The microcontroller allows  
5 distributing the required power, through power stages, to the transducer of each sonotrode.

**[0027]** The control module can be connected to a user interface where the user can provide instructions to the control module, for instance to set the amplitude, the power, the shape of the emitted acoustic field. The user  
10 can also have a feedback on the status of the device in real time via this interface.

**[0028]** The control module comprise a computer program designed for controlling the parameters of the device. For instance, the program can comprise pre configured menu or table comprising the appropriate  
15 combination of parameters (frequency, tension, displacement of the wire) depending on the requested shape of emitted acoustic field. In other words, the user provide the shape of the emitted filed required (via coordinates in a three dimension space, and/or pressure value), and the program adjusts automatically the parameters to provide the requested  
20 emitter acoustic field.

**[0029]** The control module can comprise tables for the n tip/n-transmission wire solution, and tables for the solution with at least two wires on a tip.

**[0030]** The tables could have predefined parameters, and predefined  
25 control sequences such as displacement modulation, PWM control, Wobulation control, or automatic rotation of the main direction of the sound field in different user-selected ranges of angles.

**[0031]** In a preferred embodiment, the control module controls the emitted acoustic field by controlling the power supply to each sonotrode.

In particular, the control module controls the frequency and the tension applied to the transducer of each sonotrode, preferably continuously.

**[0032]** In another embodiment, a fixed tension is applied to each transducer and the control module controls the shape of the horn, for instance by applying torsion and/or compressions and/or release.

**[0033]** In another embodiment, a fixed tension is applied to each transducer, and the control module control the displacement of one or several masses placed on the sonotrodes to adjust the overall resonance frequency of the device in real time. According to an embodiment, the control module is arranged for providing a symmetrical and/or asymmetrical emitted acoustic field. In this embodiment, the control module manages the displacement of each transmission wire to provide either a symmetrical or an asymmetrical emitted acoustic field. For instance, if the device comprises two sonotrodes connected to one tip, and a symmetrical emitted field is required, the control module will ensure for an equal distribution of power supply to each of the sonotrode. On the contrary, if an asymmetrical emitted acoustic field is required, the control module will provide a biased distribution of energy supply in favor of one of the sonotrode, in other words one of the sonotrode will receive more power supply than the other one.

**[0034]** In some cases, it is advantageous to provide an asymmetrical emitted acoustic field if the thrombus is located on a side of the blood vessel for instance. Advantageously, the present device allows providing improved results in such cases compared to existing solutions.

**[0035]** In an embodiment, the control module is arranged for setting up the intensity and/or orientation of the emitted acoustic field. In particular, the control module can modulate the energy supply to provide a patterned emitted acoustic field or pressure field.

**[0036]** According to an embodiment, the control module allows setting up the emitted acoustic field in two dimensions defined in a plane (x,y).

**[0037]** In an embodiment, the control module allows setting up the emitted acoustic field in three dimensions defined in a space  $(x,y,z)$ .

**[0038]** In an embodiment, the device comprises  $n$  sonotrodes,  $n$  transmission wires and  $n$  tips, each sonotrode being coupled to one  
5 transmission wire and one tip,  $n$  being superior or equal to two. In this embodiment, the acoustic field generated from the tip corresponds to the result of the displacements of each of the transmission wires, and is called emitted acoustic field. In other words, the emitted acoustic field generated at the tip is the sum of the acoustic field generated by each tip of each  
10 sonotrode. Each sonotrode provides a contribution to the emitted acoustic field. Each transmission wire vibrates longitudinally and/or laterally thereby generating vibrations of the tip that provide an acoustic field. The control module of the claimed device aims at controlling the displacement of each transmission wire to set up, i.e. modulate or regulate, the emitted acoustic  
15 field generated from the tip. Preferably, the displacement of the transmission wire are the displacement along the longitudinal axis of said transmission wire. The control module allows controlling the displacement of the wire so as to set up the acoustic field generated from the tip.

**[0039]** In one embodiment, the transducers of said sonotrodes are  
20 placed outside the lumen when said tip is positioned within said lumen. In many existing ultrasonic device, the transducer is the source of ultrasonic waves and is placed within the lumen during operation.

**[0040]** In an embodiment, the center of the tip is free from transmission wire, said center of the tip further comprise a traversing hole for passing a  
25 guidewire. In many medical applications, for instance cardiology applications, angioplasty frequently comprises the use of use of ultrasound followed or associated with the use of a guidewire passing though the tip to mechanically disrupt the thrombus. Generally, the guidewire needs to pass though the center of the tip to ensure an efficient positioning with  
30 the lumen of the vessel. The device according to the present embodiment facilitates treatment ultrasound and guidewire based treatment.

**[0041]** According to an embodiment, wherein the tip has a spherical shape. Alternatively, the tip can have a cylindrical shape, ovoid, with concave cavity for instance like a golf ball, hemi spherical, spherical with lobes fixed thereon, ovoid with a cavity, cylindrical with a cavity in the body  
5 of the cylinder, preferably a spherical shape.. Preferably, the choice of the type of tip geometry will be according to the type of stenosis (position, hardness) and according to the choice of the control mode (PWM, wobulation, phase shift) privileged for the procedure.

**[0042]** In an embodiment, the tip has a maximal diameter comprised  
10 between 0.5 mm and 5 mm, preferably between 1.25 mm and 2.5, mm, more preferably between 1.5 and 2.25 mm.

**[0043]** According to an embodiment, the transducer is a chosen among piezoelectric transducer, for instance PZT, or comprises a magnetostrictive material. Preferably, the transducer is a PZT transducer comprising a stack  
15 of piezo electric material.

**[0044]** In an embodiment, the device further comprising a power generator for supplying energy to said sonotrodes. In particular, the device can comprise one generator for all the sonotrodes. Or the device can comprise a generator per sonotrode.

20 **[0045]** According to an embodiment, each sonotrode is supplied with a power comprises between 5 and 300 watts, preferably between 8 watts and 100 watts, more preferably between 10 watts and 50 watts.

**[0046]** In an embodiment, each transmission wire is received in a catheter, said tip exiting the catheter.

25 **[0047]** In the present invention, the terms « acoustic field » and « pressure field” are interchangeable.

**[0048]** In the present invention, the term transducer defines an element that converts the electrical energy into ultrasonic energy.

**[0049]** In the present embodiment, the terms “shape of the emitted acoustic or pressure field” define the dimensions of said field. In other word, the word shape is used to describe the distribution of the acoustic field around the tip.

## 5 Brief Description of the Drawings

**[0050]** The invention will be better understood with the aid of the description of an embodiment given by way of example and illustrated by the figures, in which:

Fig. 1 shows a view of an existing device of the prior art;

10 Figures 2,3,4 and 5 show a first embodiment of the device according to the invention;

Figure 6 shows the tip of the device according to the first embodiment;

15 Figures 7 a,b, and figure 8 show the distribution of the acoustic field of the tip of the device according to the first embodiment;

Figure 9 shows the evolution of the angle of the maximum of the absolute pressure generated from the tip in the first embodiment of the device according to the invention;

20 Figure 10 shows a second embodiment of the device according to the invention;

Figure 11 shows the tip of the device according to the second embodiment;

Figures 12a,b and 13 show the distribution of the acoustic field of the tip of the device according to the second embodiment;

Figure 14 shows the evolution of the angle of the maximum of the absolute pressure generated from the tips in the second embodiment of the device according to the invention;

5 Figure 15 shows a third embodiment of the device according to the present invention;

Figure 16 shows the distribution of the acoustic field of the tip of the device according to the third embodiment;

10 Figure 17 shows the control module of the device according to the first and second embodiments of the device according to the invention;

Figure 18 shows various embodiments of the tip of the device according to the invention;

#### Detailed Description of possible embodiments of the Invention

15 **[0051]** Figures 2 to 18 represent several embodiments of the present invention, but the invention is not limited to the disclosed embodiments.

20 **[0052]** Figure 5 represents a device 10 according to a first embodiment. In this embodiment, the device 10 comprises power generator 11 providing electrical energy to the device 10. The device 10 further comprises two sonotrodes 12 a,b, each sonotrode 12 a,b being connected to one transmission wire 13 a,b. In this embodiment, all the transmission wires 13 a,b are connected to the same single tip 14. Each sonotrode 12 a,b comprises one transducer 15 a,b that is connected to a horn 16 a,b.

25 **[0053]** In this first embodiment, the transducers 15 a,b are PZT stack. The transmission wires 13 a,b have a diameter of 0.5 mm and the tip 14 have a diameter of 2 mm. The tip 14 and the wire 13 a,b are made with  $\text{TiAl}_6\text{V}_4$  but the invention is not limited to this material, for instance Aluminium could also be used.

**[0054]** The control module 17 allows controlling the electrical energy provided to each transducer 15 a,b of each sonotrode 12 a,b to set up the emitted acoustic field 18.

**[0055]** Figure 6 shows the tip 14 of the device 10. The tip 14 comprises two blind holes 19 design for receiving the transmission wires 13 a,b. The tip 14 further comprises a traversing hole 20 for passing a guidewire (not represented in figure).

**[0056]** Figures 7 a,b and 8 represent the distribution of the acoustic field 8 in operation for the first embodiment.

10 **[0057]** Figures 7a represents a case where the each wire receive the amount of energy from the control module 17, to provide the same amplitude of displacement on the wires and where the wires oscillate in phase. The emitted acoustic pressure 8 is symmetrical and centered around an axis parallel to the longitudinal axis of the transmission wires 13a,b.

15 **[0058]** Figure 7b represents a case where there is a ratio of ten (10) between the transmission wire 13a,b, said ration being induced by the control module 17. In other words, the amplitude of displacement along the longitudinal axis of one transmission wire 13a is 50 microns, whereas the other transmission wire 13b is 5 microns and where the wires oscillate  
20 in phase. Consequently the emitted acoustic field 8 is asymmetric and oriented toward the transmission wire with the larger displacement. By selecting the wire on which a difference of amplitude is applied, it is possible to orient and to control in the plan (XY) the asymmetry of the acoustic field. In this embodiment, it is possible, when the device is placed  
25 in a vessel, to position the emitted acoustic field for instance toward a side of the vessel, to provide a major contribution of the acoustic field on the side of the vessel, and a minor contribution on the other side of the vessel. This permits to improve the treatment of an eccentric lesion by increasing the efficiency of the treatment on the area of the vessel where the  
30 treatment is needed and to protect, by limiting the acoustic field, the area where the treatment is not necessary.

**[0059]** Figure 8 represents a case where each wire oscillates in opposition of phase (180° phase shift), with a displacement around the point of rest. The control module 17 ensures that each transmission wire receives the amount of energy to provide the same amplitude of displacement but the control module 17 induces a phase shift of 180°. As shown in figure 8, the emitted acoustic field is divided in two main contributions each oriented toward the side of the vessel when the tip 14 is placed in a vessel. Therefore, in this embodiment, it is possible to target occlusion located on both sides of the vessel and to improve the treatment of complex eccentric lesions.

**[0060]** Figure 9 represents the angle of the maximum absolute pressure point on the tip distal face depending on the amplitude ration between the transmission wires. The plot shows that a ratio of 10, it is possible to shift maximum pressure point of 18° with respect to the position of said maximum pressure point when the ratio is 1. Therefore, this plot demonstrate that it is possible to control the shape, i.e. the orientation, of the emitted pressure field by controlling the relative displacement of the transmission wires of the device. This plot demonstrates also that this behavior, i.e. the orientation the maximum absolute pressure point, is not impacted by the initial choice of the amplitude of displacement applied on the wires (as example 100 microns instead of 50 microns), but only by the choice of the amplitude ratio between the transmission wires. On the other hand, the intensity of the field is dependent on the choice of the amplitude of displacement. Greater displacement amplitude induces a higher max pressure value.

**[0061]** Figure 10 represents a second embodiment of the device 100. In this embodiment, the device 100 comprises power generator 101 providing electrical energy to the device 100. The device 100 further comprises three sonotrodes 102 a,b,c each sonotrode 102 a,b,c being connected to a transmission wire 103 a,b,c that leads to a tip 104 at the distal end of said transmission wire 103 a,b,c. The three transmission wires 103 a,b,c are connected to the same tip 104. Each sonotrode 102 a,b,c comprises a transducer 105 a,b,c that is connected to a horn 106 a,b,c.

**[0062]** In this second embodiment, the transducers 105 a,b,c are PZT stack. The transmission wires 103 a,b,c have a diameter of 0.5 mm and the tip 104 have a diameter of 2 mm. The tip 104 and the wire 103 a,b,c are made with  $TiAl_6V_4$  but the invention is not limited to this material, for instance Aluminium could also be used.

**[0063]** The device 100 further comprises a control module 107 arranged for controlling the amplitude of displacement of the transmission wires 103 a,b,c along the longitudinal axis. The amplitude of displacement of the transmission wire 103 a,b,c depends on the energy supply provided to by the power generator 101 to the transducers 105 a,b,c. The amplitudes of vibrations of the PZT stack is correlated to the electrical energy provided by the power generator. In the present embodiment, the control module 107 allows controlling the electrical energy provided to each transducer 105 a,b,c of each sonotrode 102 a,b,c to set up the emitted acoustic field 108.

**[0064]** Figure 11 illustrates the tip 104 of the device 100 according to the second embodiment. The tip 104 comprises three blind holes 109 design for receiving the transmission wires 103 a,b, c. The tip 104 further comprises a traversing hole 110 for passing a guidewire (not represented in the figures).

**[0065]** Figures 12 a,b and 13 represent the distribution of the acoustic field 108 in operation for the second embodiment.

**[0066]** Figures 12a represents a case where the each wire receive the amount of energy from the control module 107 to provide the same amplitude of displacement on the wires, and where the wires oscillate in phase. The emitted acoustic pressure 108 is symmetrical and centered around an axis parallel to the longitudinal axis of the transmission wires 103a,b, c.

**[0067]** Figure 12b represents a case where there is a ratio of ten (10) between the transmission wires 103a,b,c said ratio being induced by the control module 107. In particular, two transmission wires receive the amount of energy to provide the same amplitude of displacement on each

one, the third one receive an amount of energy to provide an amplitude of displacement ten (10) times less than the two others transmission wires. In other words, the amplitude of displacement along the longitudinal axis of two transmission wires 103a,b is 50 microns, whereas the other transmission wire 103c is 5 microns, and where the three wires oscillate in phase. Consequently the emitted acoustic field 108 is asymmetric and oriented toward the transmission wires with the larger displacement. By selecting the wires on which a difference of amplitude is applied, it is possible to orient and to control in the space (XYZ) the asymmetry of the acoustic field. In this embodiment, it is possible when the device is placed in a vessel, to position the emitted acoustic field for instance toward a side of the vessel, to provide a major contribution of the acoustic field on the side of the vessel, and a minor contribution on the other side of the vessel. This permits to improve the treatment of an eccentric lesion by increasing the efficiency of the treatment on the area of the vessel where the treatment is needed and to protect, by limiting the acoustic field, the area where the treatment is not necessary.

**[0068]** Figure 13 represents a case where one wire oscillates in opposition of phase ( $180^\circ$  phase shift) of the two others, with a displacement around the point of rest. The control module 107 ensure that each transmission wire receives the amount of energy to provide the same amplitude of displacement on each wire but the control module 107 induces a phase shift of  $180^\circ$  between one of the wire and the two others. As shown in figure 13, the emitted acoustic field is divided in two main contributions. By selecting the wire on which the phase shift is applied, it is possible to orient in the space (xyz) these two contributions. Therefore, in this embodiment, it is possible to target occlusion located on both sides of the vessel and to improve the treatment of complex eccentric lesions.

**[0069]** Figure 14 represents the angle of the maximum absolute pressure point on the tip distal face depending on the amplitude ration between the transmission wires. The plot shows that a ratio of 10, it is possible to shift maximum pressure point of  $60^\circ$  with respect to the position of said maximum pressure point when the ratio is 1. Therefore, this plot

demonstrate that it is possible to control the shape, i.e. the orientation, of the emitted pressure field by controlling the relative displacement of the transmission wires of the device. This plot demonstrates also that this behavior, i.e. the orientation the maximum absolute pressure point, is not impacted by the initial choice of the amplitude of displacement applied on the wires (as example 100 microns instead of 50 microns), but only by the choice of the amplitude ratio between the transmission wires. On the other hand, the intensity of the field is dependent on the choice of the amplitude of displacement. Greater displacement amplitude induces a higher max pressure value.

**[0070]** A third embodiment of the device is represented in figure 15. In this embodiment, the device 200 comprises power generator 201 providing electrical energy to the device 200. The device 200 further comprises two sonotrodes 202 a,b each sonotrode 202 a,b being connected to a transmission wire 203 a,b that leads to a tip 204 a,b at the distal end of said transmission wire 203 a,b. In this embodiment, each transmission wire 203 a,b is connected to one tip 204 a,b. Each sonotrode 202 a,b comprises a transducer 205 a,b that is connected to a horn 206 a,b.

**[0071]** In this third embodiment, the transducers 205 a,b are PZT stacks. The transmission wires 203 a,b have a diameter of 0.5 mm and the tip 204 a,b have a diameter of 0.9 mm. The tips 204 a,b and the wires 203 a,b are made with  $TiAl_6V_4$  but the invention is not limited to this material, for instance Aluminium could also be used.

**[0072]** The figures 16a and b represents the shape of the acoustic field of the device according to the third embodiment in operation. In figure 16a, both sonotrodes 202 a,b received the amount of electrical energy from the control module 207, to provide the same amplitude of displacement on the wires and where the wires oscillate in phase so that the acoustic fields generated from the tips 204 a, b are similar. Therefore, each sonotrode 202 a,b contributes equally to the generated acoustic field 218 generated from the tips 204 a,b.

**[0073]** In figure 16b, the control module 207 is set up in favor of one sonotrode 202 a so that said sonotrode 202 a receives a bigger amount of electrical energy than the other one receives. As a result, the emitted acoustic field 208 corresponds more to the acoustic field contribution of the sonotrode 202a, that receives a higher amount of the electrical energy, than the acoustic field contribution from the other sonotrode that receives a lower amount of electrical energy. In this embodiment, it is possible, when the device is placed in a vessel, to position the emitted acoustic field for instance toward a side of the vessel, to provide a major contribution of the acoustic field on the side of the vessel, and a minor contribution on the other side of the vessel. This permits to improve the treatment of an eccentric lesion by increasing the efficiency of the treatment on the area of the vessel where the treatment is needed and to protect, by limiting the acoustic field, the area where the treatment is not necessary.

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**[0074]** Figure 17 is a chart representing the control module 17,107,207 used in the device according to the first, second and third embodiment 10,100,200. The controller 17, 107, 207 controls the energy supply to each sonotrode so as to set up de emitted acoustic field 18,108,208. The controller is composed of a central unit equipped of a microcontroller or DSP or FPGA. This central unit controls through n outputs stage (n corresponding of the number of transducer), the frequency and the voltage to apply (i.e. the correct amount of energy) to each transducer in the goal to obtain the desired amplitude of displacement on each wire. A feedback on the amplitude value of displacement comes from each transducer and is interpreted by the central unit which can, by a control loop, control in real time the amount of energy to give to each transducer. A lookup table contains all the parameters necessary for the proper functioning of the device, depending on the case of n wires on one tip, or n wires and n tip, or the geometry of the tip as well as the safety parameters. The central unit is connected to an user interface that permits to the user to control the device and to have feedback information on the status of the system.

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**[0075]** Figure 18 shows some embodiments of the tip 14, 104, 204 that can be used in the device according to the present invention. The shape of the tip 14, 104,204 can be :

- Spherical (figures 6 and 11);
- 5
- hemi spherical (figure 18a),
  - spherical with lobes fixed thereon (figures 18 b and e);
  - ovoid with a cavity (figures 18c);
  - cylindrical with a cavity in the body of the cylinder (figure 18d), or cylindrical (figure 18 f)
- 10
- [0076]** Advantageously, the shape of the tip can be chosen depending on the shape of the emitted acoustic field, according to the type of area to treat and according to the choice of the control mode privileged for the procedure (PWM, Wobulation, phase shift).

**References of the figures**

1	Device according to the prior art
2	Power generator
3	Piezoelectric transducer
4	Horn
5	Catheter
6	Transmission wire
7	Tip
8	Acoustic field
10	Device according to a first embodiment with two transmission wires on one tip
11	Power generator
12 a,b	Sonotrode
13 a,b	Transmission wire
14	Tip
15 a,b	Transducer
16 a,b	Horn
17	Control module
18	Emitted acoustic field
19	Blind hole
20	Traversing hole
100	Device according to a second embodiment with three transmission wires on one tip
101	Power generator
102 a,b,c	Sonotrode
103 a,b,c	Transmission wire
104	Tip
105 a,b,c	Transducer
106 a,b,c	Horn
107	Control module
108	Emitted acoustic field

109	Blind hole
110	Traversing hole
200	Device according to a third embodiment
201	Power generator
202 a,b	Sonotrode
203 a,b	Transmission wire
204 a,b	Tip
205 a,b	Transducer
206 a,b	Horn
207	Control module
208	Emitted acoustic field

## Claims

1. Ultrasonic device (10;100;200) for generating an acoustic field in a lumen of a component of the cardiovascular system of a patient, in particular a blood vessel or a heart chamber, the device (10;100;200) comprising a sonotrode (12a,b;102a,b,c;202a,b), a transmission wire (13a,b;103a,b,c;203a,b) and a tip (14;104;204a,b),
- 5
- said sonotrode (12a,b;102a,b,c;202a,b) comprising a transducer (15a,b;105a,b,c;205a,b) and a horn (16a,b;106a,b,c;206a,b), the transducer (15a,b;105a,b,c;205a,b) being coupled to the horn (16a,b;106a,b,c;206a,b),
- 10
- the transmission wire (13a,b;103a,b,c;203a,b) being coupled on one end with the horn (16a,b;106a,b,c;206a,b) and on the opposite end with the tip (14;104;204a,b),
  - so that when the transducer (15a,b;105a,b,c;205a,b) vibrates, said vibrations are amplified by the horn (16a,b;106a,b,c;206a,b) and transmitted to the transmission wire (13a,b;103a,b,c;203a,b) that displaces accordingly, said displacements of the transmission wire (13a,b;103a,b,c;203a,b) inducing vibrations of the tip (14;104;204a,b) generating an acoustic field from said tip (14;104;204a,b)
- 15
- 20 characterized in that the device (10;100;200) comprises n sonotrode (12a,b;102a,b,c;202a,b), n transmission wire (13a,b;103a,b,c; 203a,b), and at least one tip (14;104;204a,b), n being superior or equal to two,
- and in that the device (10;100;200) further comprises a control module (17,107;207) being arranged for controlling the amplitude of displacement of each transmission wire (13a,b;103a,b,c;203a,b) so as to set up the emitted acoustic field (18;108;208) generated from said tip (14;104;204a,b),.
- 25

2. Ultrasonic device (10;100;200) according to claim 1, wherein the device (10;100;200) comprises m sonotrodes (12a,b;102a,b,c;202a,b), m transmission wires (13a,b;103a,b,c;203a,b) and one single tip (14;104), all the transmission wires (13a,b;103a,b,c;203a,b) being coupled to said tip  
5 (14;104), m being superior or equal to two.

3. Ultrasonic device (10;100;200) according to claim 1, wherein the device (10;100;200) comprises n sonotrodes (12a,b;102a,b,c;202a,b), n transmission wires (13a,b;103a,b,c;203a,b) and n tips (14;104;204a,b), each sonotrode (12a,b;102a,b,c;202a,b) being coupled to one transmission wire  
10 (13a,b;103a,b,c;203a,b) and one tip (14;104;204a,b), n being superior or equal to two.

4. Ultrasonic device (10;100;200) according to claim 1, wherein the device (10;100;200) comprises n sonotrodes (12a,b;102a,b,c;202a,b), n transmission wires (13a,b;103a,b,c;203a,b) and a maximum of n-1 tips  
15 (14;104;204a,b), n being superior or equal to two, so that at least two transmission wires (13a,b;103a,b,c;203a,b) are connected to the same tip (14;104;204a,b).

5. Ultrasonic device (10;100;200) according to any one of claims 1 to 4, wherein the transducers (15a,b;105a,b,c;205a,b) of said sonotrodes  
20 (12a,b;102a,b,c;202a,b) are placed outside the lumen when said tip (14;104;204a,b) is positioned within said lumen.

6. Ultrasonic device (10;100;200) according to any one of claims 1 to 5, wherein the control module (17;107;207) controls the power supply provided to each sonotrode (12a,b;102a,b,c;202a,b) to control the  
25 amplitude of displacement of each transmission wire (13a,b;103a,b,c;203a.b).

7. Ultrasonic device (10;100;200) according to any one of claims 1 to 6, wherein the control module (17;107;207) allows setting up the emitted acoustic field (18;108;208) in two dimensions defined in a plane  
30 (x,y).

8. Ultrasonic device (10;100;200) according to any one of claims 1 to 7, wherein the control module (17;107;207) allows setting up the emitted acoustic field (18;108;208) in three dimensions defined in a space (x,y,z).
- 5 9. Ultrasonic device (10;100;200) according to any one of claims 1 to 8, wherein the control module (17;107;207) is arranged for providing a symmetrical and/or asymmetrical emitted acoustic field (18;108;208).
- 10 10. Ultrasonic device (10;100;200) according to any one of claims 1 to 9, wherein the control module (17;107;207) is arranged for setting up the intensity and/or orientation of the emitted acoustic field (18;108;208).
- 15 11. Ultrasonic device (10;100;200) according to any one of claims 1 to 10, wherein the center of the tip (14;104;204a,b) is free from transmission wire (13a,b;103a,b,c;203a,b), said center of the tip (14;104;204a,b) further comprises a traversing hole (20;110) for passing a guidewire.
- 20 12. Ultrasonic device (10;100;200) according to any one of claims 1 to 11, wherein the tip (14;104;204a,b) has a shape chosen among spherical shape, hemi spherical, spherical with lobes fixed thereon, ovoid with a cavity, cylindrical with a cavity in the body of the cylinder, or cylindrical, preferably a spherical shape.
13. Ultrasonic device (10;100;200) according to any one of claims 1 to 12, wherein the tip (14;104;204a,b) has a maximal diameter comprised between 0.5 mm and 5 mm, preferably between 1.25 mm and 2.5, mm, more preferably between 1.5 and 2.25 mm.
- 25 14. Ultrasonic device (10;100;200) according to any one of claims 1 to 13, wherein the transducer (15a,b;105a,b,c;205) is a chosen among piezoelectric transducer, for instance PZT, or comprises a magnetostrictive material.

15. Ultrasonic device (10;100;200) according to any one of claims 1 to 14, the device (10;100;200) further comprising a power generator (11;101;201) for supplying energy to said sonotrodes (12a,b;102a,b,c;202a,b).
- 5 16. Ultrasonic device (10;100;200) according to any one of claims 1 to 15, wherein each sonotrode (12a,b;102a,b,c;202a,b) is supplied with a power comprises between 5 and 300 watts, preferably between 8 watts and 100 watts, more preferably between 10 watts and 50 watts.
- 10 17. Ultrasonic device (10;100;200) according to any one of claims 1 to 16, wherein each transmission wire (13a,b;103a,b,c;203a,b) is received in a catheter, said tip (14;104;204a,b) exiting the catheter.

## AMENDED CLAIMS

received by the International Bureau on 09 January 2020 (09.01.20)

1. Ultrasonic device (10;100;200) for generating an acoustic field in a lumen of a component of the cardiovascular system of a patient, in particular a blood vessel or a heart chamber, the device (10;100;200) comprising a sonotrode (12a,b;102a,b,c;202a,b), a transmission wire (13a,b;103a,b,c;203a,b) and a tip (14;104;204a,b),
- 5
- said sonotrode (12a,b;102a,b,c;202a,b) comprising a transducer (15a,b;105a,b,c;205a,b) and a horn (16a,b;106a,b,c;206a,b), the transducer (15a,b;105a,b,c;205a,b) being coupled to the horn (16a,b;106a,b,c;206a,b),
  - the transmission wire (13a,b;103a,b,c;203a,b) being coupled on one end with the horn (16a,b;106a,b,c;206a,b) and on the opposite end with the tip (14;104;204a,b),
  - so that when the transducer (15a,b;105a,b,c;205a,b) vibrates, said vibrations are amplified by the horn (16a,b;106a,b,c;206a,b) and transmitted to the transmission wire (13a,b;103a,b,c;203a,b) that displaces accordingly, said displacements of the transmission wire (13a,b;103a,b,c;203a,b) inducing vibrations of the tip (14;104;204a,b) generating an acoustic field from said tip (14;104;204a,b)
- 10
- 15

characterized in that the device (10;100;200) comprises n sonotrodes (12a,b;102a,b,c;202a,b), n transmission wires (13a,b;103a,b,c; 203a,b), and at least one tip (14;104;204a,b), n being superior or equal to two,

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and in that the device (10;100;200) further comprises a control module (17,107;207) being arranged for controlling the amplitude of displacement of each transmission wire (13a,b;103a,b,c;203a,b) so as to set up the emitted acoustic field (18;108;208) generated from said tip (14;104;204a,b).

- 25
2. Ultrasonic device (10;100;200) according to claim 1, wherein the device (10;100;200) comprises m sonotrodes (12a,b;102a,b,c;202a,b), m transmission wires (13a,b;103a,b,c;203a,b) and one single tip (14;104), all the transmission wires

(13a,b;103a,b,c;203a,b) being coupled to said tip (14;104), m being superior or equal to two.

3. Ultrasonic device (10;100;200) according to claim 1, wherein the device (10;100;200) comprises n sonotrodes (12a,b;102a,b,c;202a,b), n transmission wires (13a,b;103a,b,c;203a,b) and n tips (14;104;204a,b), each sonotrode (12a,b;102a,b,c;202a,b) being coupled to one transmission wire (13a,b;103a,b,c;203a,b) and one tip (14;104;204a,b), n being superior or equal to two.

4. Ultrasonic device (10;100;200) according to claim 1, wherein the device (10;100;200) comprises n sonotrodes (12a,b;102a,b,c;202a,b), n transmission wires (13a,b;103a,b,c;203a,b) and a maximum of n-1 tips (14;104;204a,b), n being superior or equal to two, so that at least two transmission wires (13a,b;103a,b,c;203a,b) are connected to the same tip (14;104;204a,b).

5. Ultrasonic device (10;100;200) according to any one of claims 1 to 4, wherein the transducers (15a,b;105a,b,c;205a,b) of said sonotrodes (12a,b;102a,b,c;202a,b) are placed outside the lumen when said tip (14;104;204a,b) is positioned within said lumen.

6. Ultrasonic device (10;100;200) according to any one of claims 1 to 5, wherein the control module (17;107;207) controls the power supply provided to each sonotrode (12a,b;102a,b,c;202a,b) to control the amplitude of displacement of each transmission wire (13a,b;103a,b,c;203a,b).

7. Ultrasonic device (10;100;200) according to any one of claims 1 to 6, wherein the control module (17;107;207) allows setting up the emitted acoustic field (18;108;208) in two dimensions defined in a plane (x,y).

8. Ultrasonic device (10;100;200) according to any one of claims 1 to 7, wherein the control module (17;107;207) allows setting up the emitted acoustic field (18;108;208) in three dimensions defined in a space (x,y,z).

9. Ultrasonic device (10;100;200) according to any one of claims 1 to 8, wherein the control module (17;107;207) is arranged for providing a symmetrical and/or asymmetrical emitted acoustic field (18;108;208).
10. Ultrasonic device (10;100;200) according to any one of claims 1 to 9, wherein the control module (17;107;207) is arranged for setting up the intensity and/or orientation of the emitted acoustic field (18;108;208).
11. Ultrasonic device (10;100;200) according to any one of claims 1 to 10, wherein the center of the tip (14;104;204a,b) is free from transmission wire (13a,b;103a,b,c;203a,b), said center of the tip (14;104;204a,b) further comprises a traversing hole (20;110) for passing a guidewire.
12. Ultrasonic device (10;100;200) according to any one of claims 1 to 11, wherein the tip (14;104;204a,b) has a shape chosen among spherical shape, hemispherical, spherical with lobes fixed thereon, ovoid with a cavity, cylindrical with a cavity in the body of the cylinder, or cylindrical, preferably a spherical shape.
13. Ultrasonic device (10;100;200) according to any one of claims 1 to 12, wherein the tip (14;104;204a,b) has a maximal diameter comprised between 0.5 mm and 5 mm, preferably between 1.25 mm and 2.5, mm, more preferably between 1.5 and 2.25 mm.
14. Ultrasonic device (10;100;200) according to any one of claims 1 to 13, wherein the transducer (15a,b;105a,b,c;205) is a chosen among piezoelectric transducer, for instance PZT, or comprises a magnetostrictive material.
15. Ultrasonic device (10;100;200) according to any one of claims 1 to 14, the device (10;100;200) further comprising a power generator (11;101;201) for supplying energy to said sonotrodes (12a,b;102a,b,c;202a,b).
16. Ultrasonic device (10;100;200) according to any one of claims 1 to 15, wherein each sonotrode (12a,b;102a,b,c;202a,b) is supplied with a power comprises between 5 and 300 watts, preferably between 8 watts and 100 watts, more preferably between 10 watts and 50 watts.

17. Ultrasonic device (10;100;200) according to any one of claims 1 to 16, wherein each transmission wire (13a,b;103a,b,c;203a,b) is received in a catheter, said tip (14;104;204a,b) exiting the catheter.

18. A method of operating of an ultrasonic device as claimed in one of the preceding claims, wherein the method comprises:  
5 - controlling the electrical energy provided to each transducer of each sonotrode so as to set up the acoustic field emitted from the at least one tip.

19. The method as claimed in claim 18, wherein controlling the electrical energy provided to each transducer of each sonotrode includes controlling:  
10 - the frequency, and/or  
- the voltage, and/or  
- the wobulation, and/or  
- the PWM, and/or  
- the phase shift,  
15 to apply to each transducer in the goal to obtain the desired amplitude of displacement on each wire.

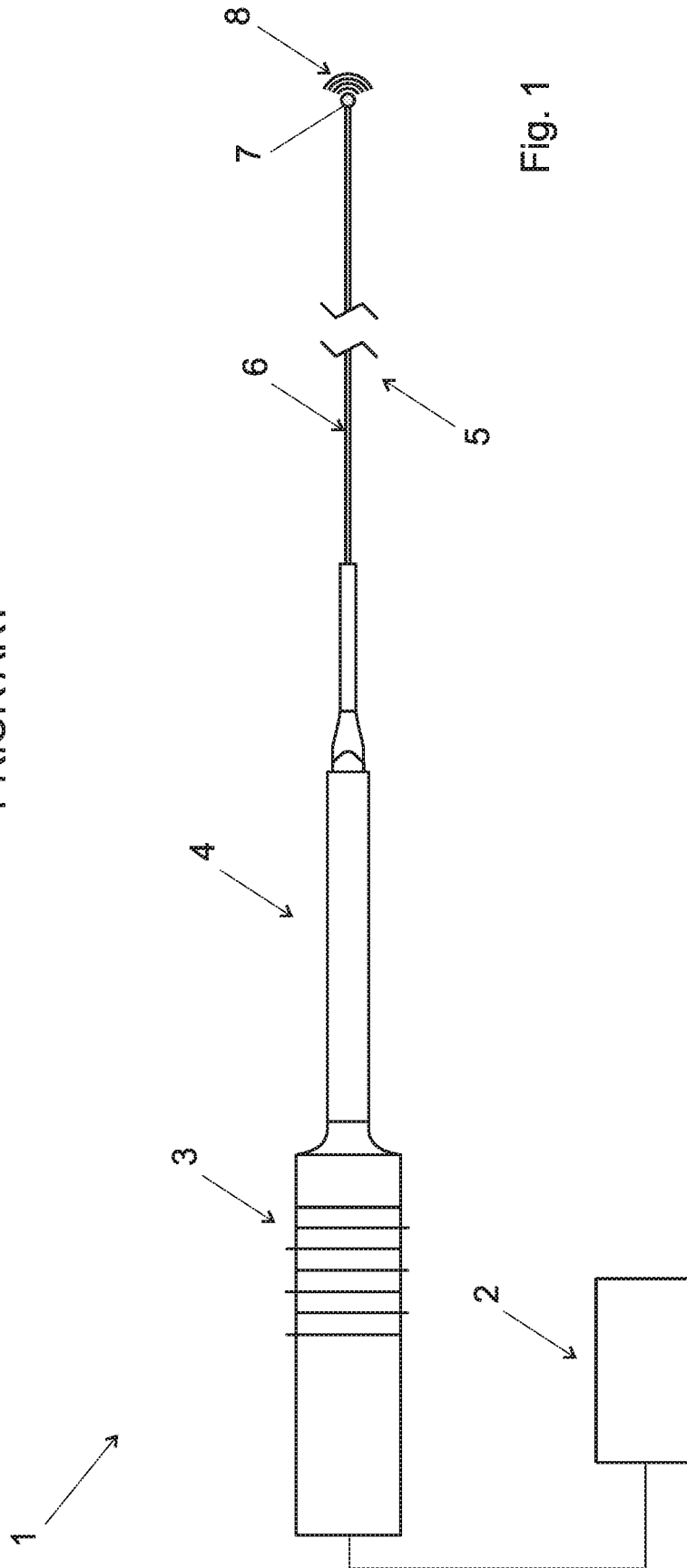
20. The method as claimed in claim 18 or 19, wherein the method comprises:  
-receiving and interpreting a feedback on the amplitude value of displacement from  
20 each transducer for controlling in real time the amount of energy to give to each transducer.

21. The method as claimed in one of claims 18 to 20, wherein the method comprises:  
- selecting a wire on which a different amplitude is applied so as to orient and to  
25 control the asymmetry of the acoustic field.

22. The method as claimed in one of claims 18 to 21, wherein the method comprises:  
- controlling the shape or the orientation of the emitted pressure field by controlling the relative displacement of the transmission wires of the device.

30

PRIOR ART



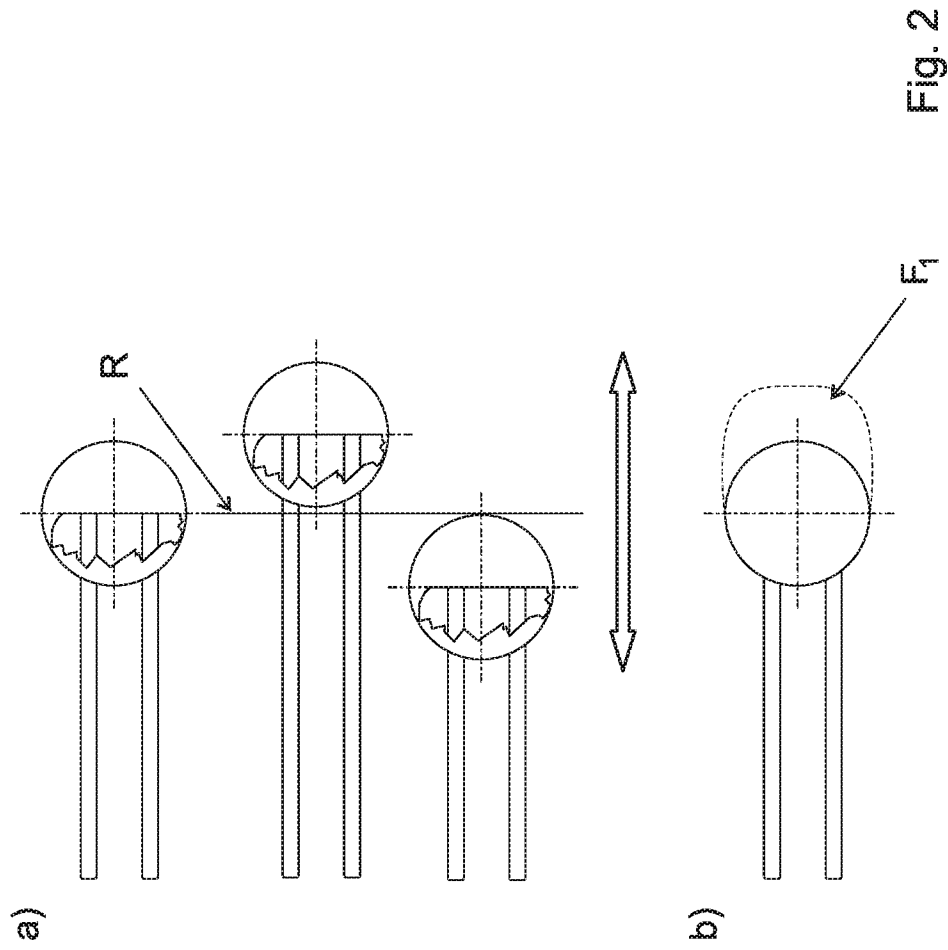


Fig. 2

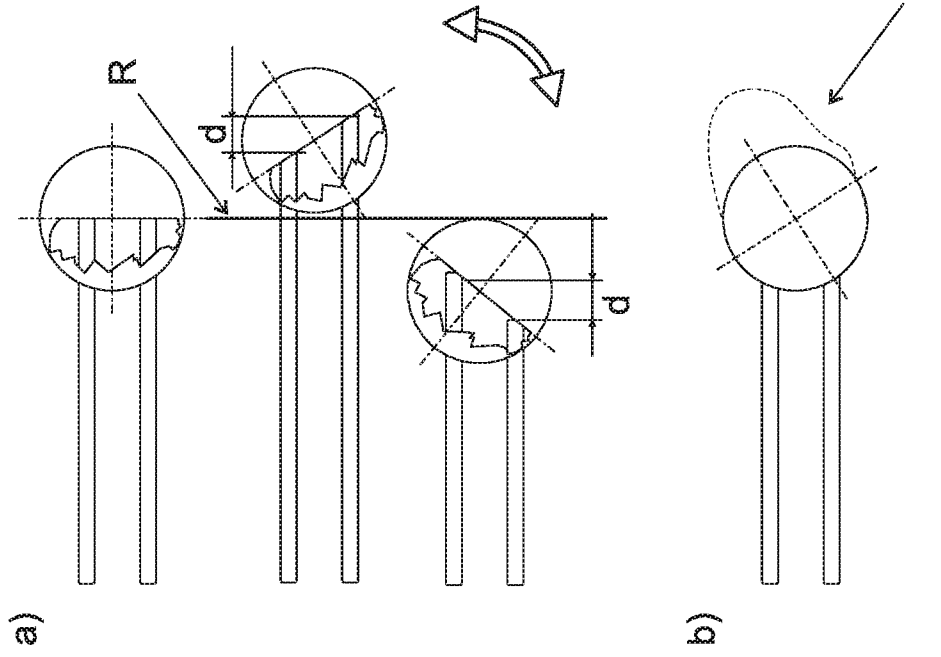


Fig. 3

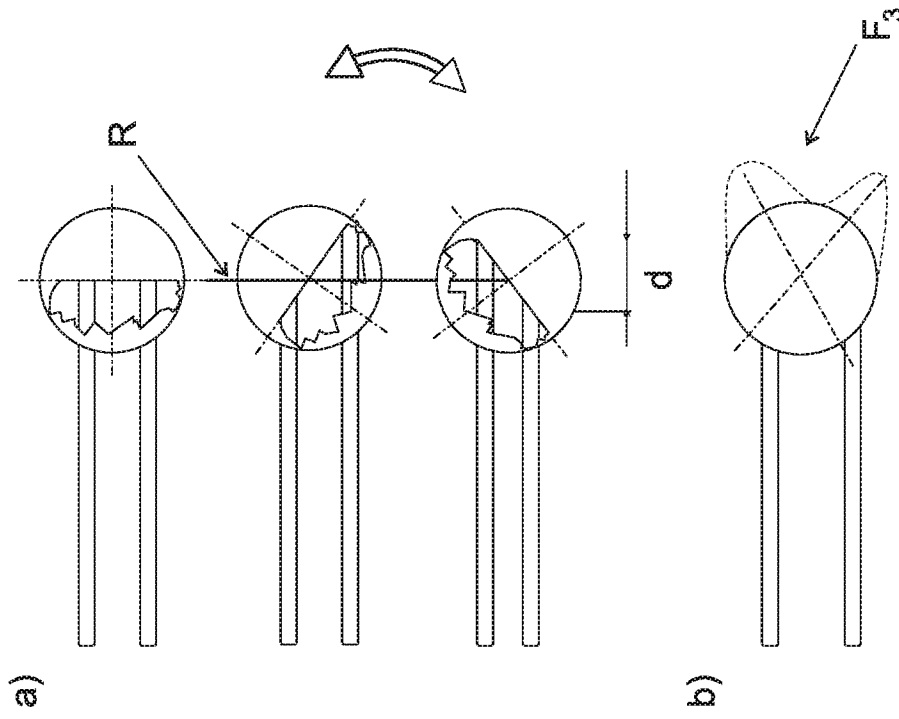


Fig. 4

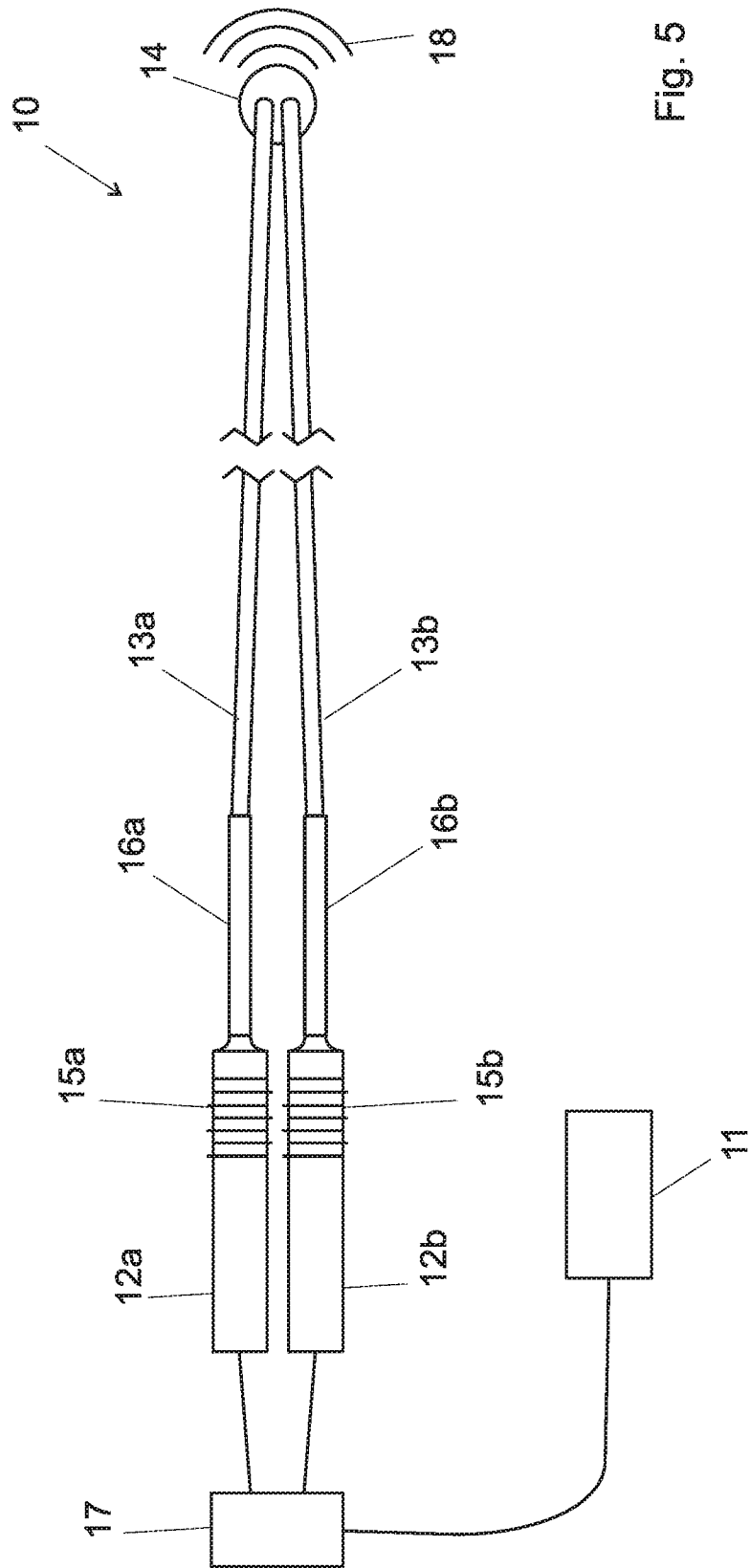


Fig. 5

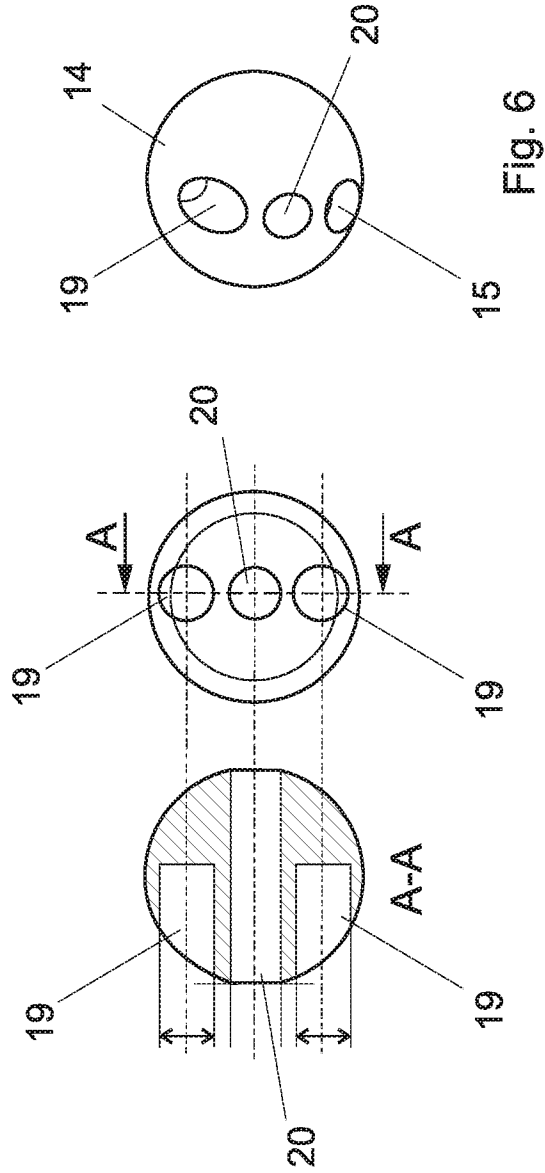


Fig. 6

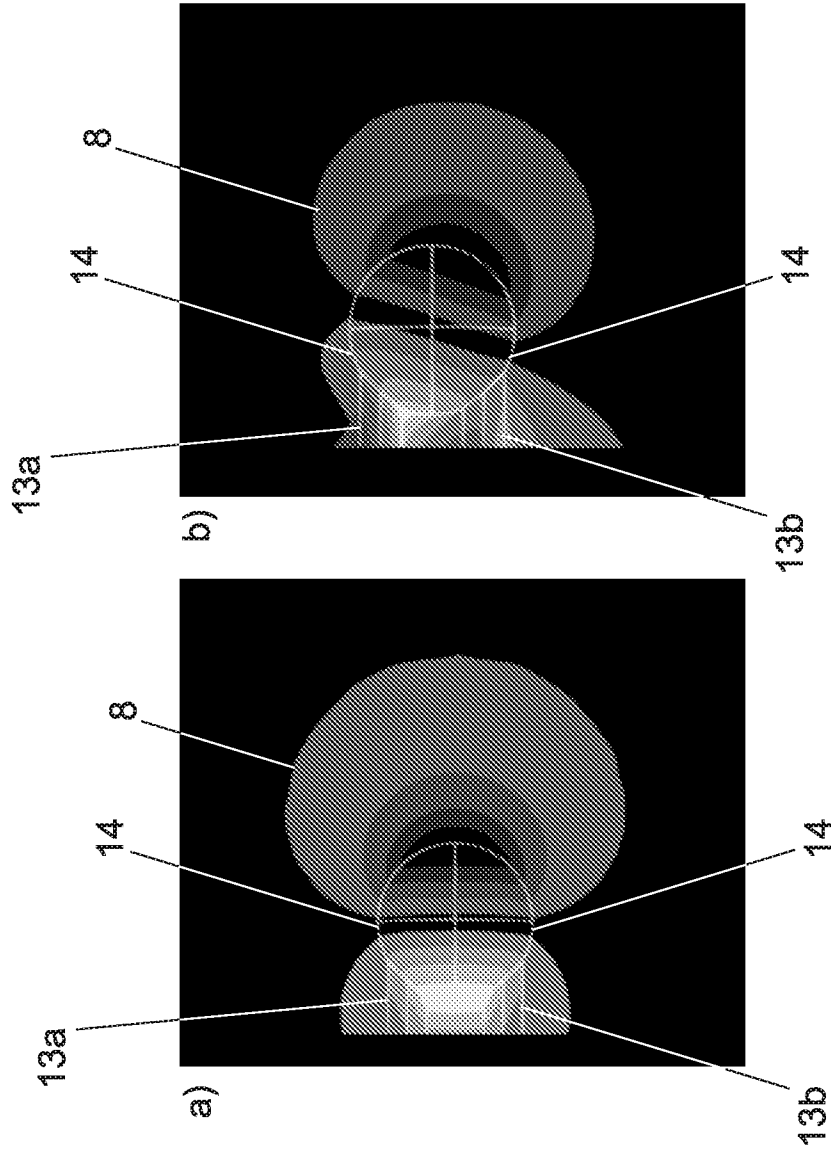
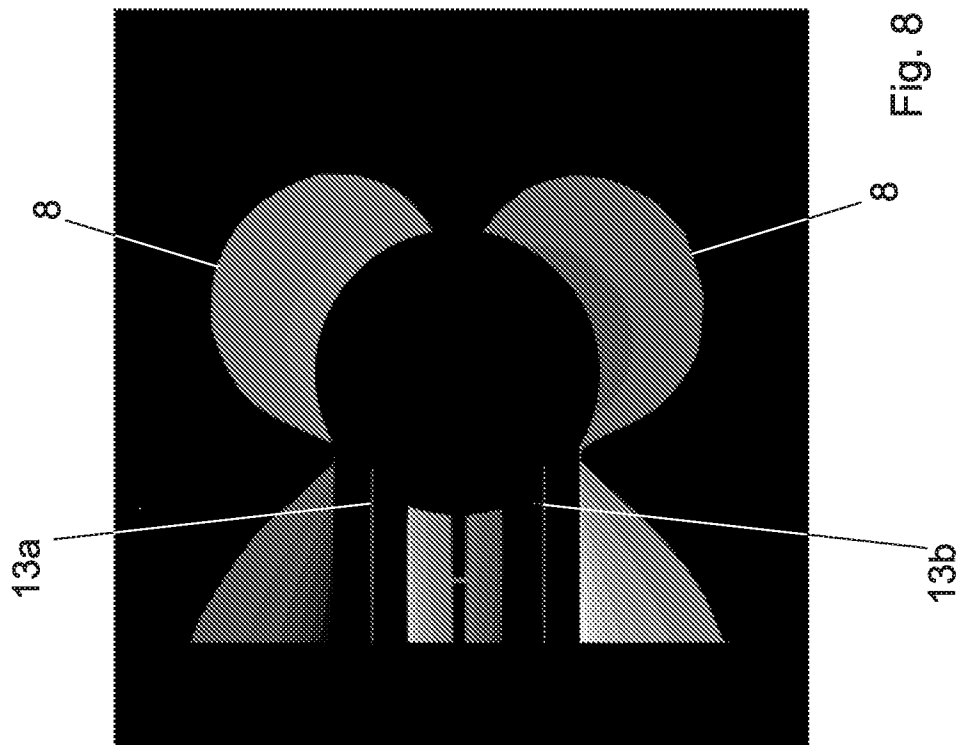


Fig. 7



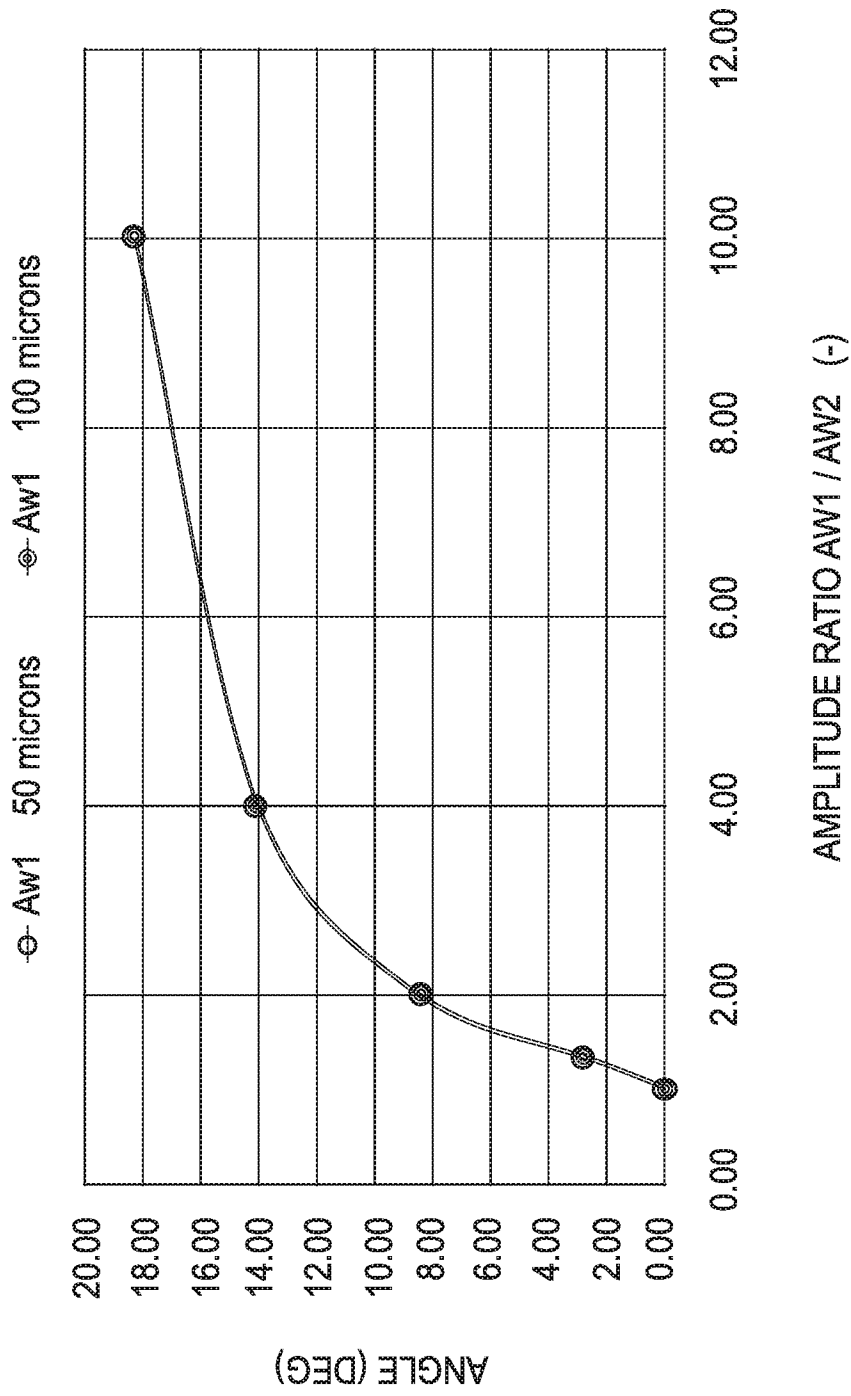


Fig. 9

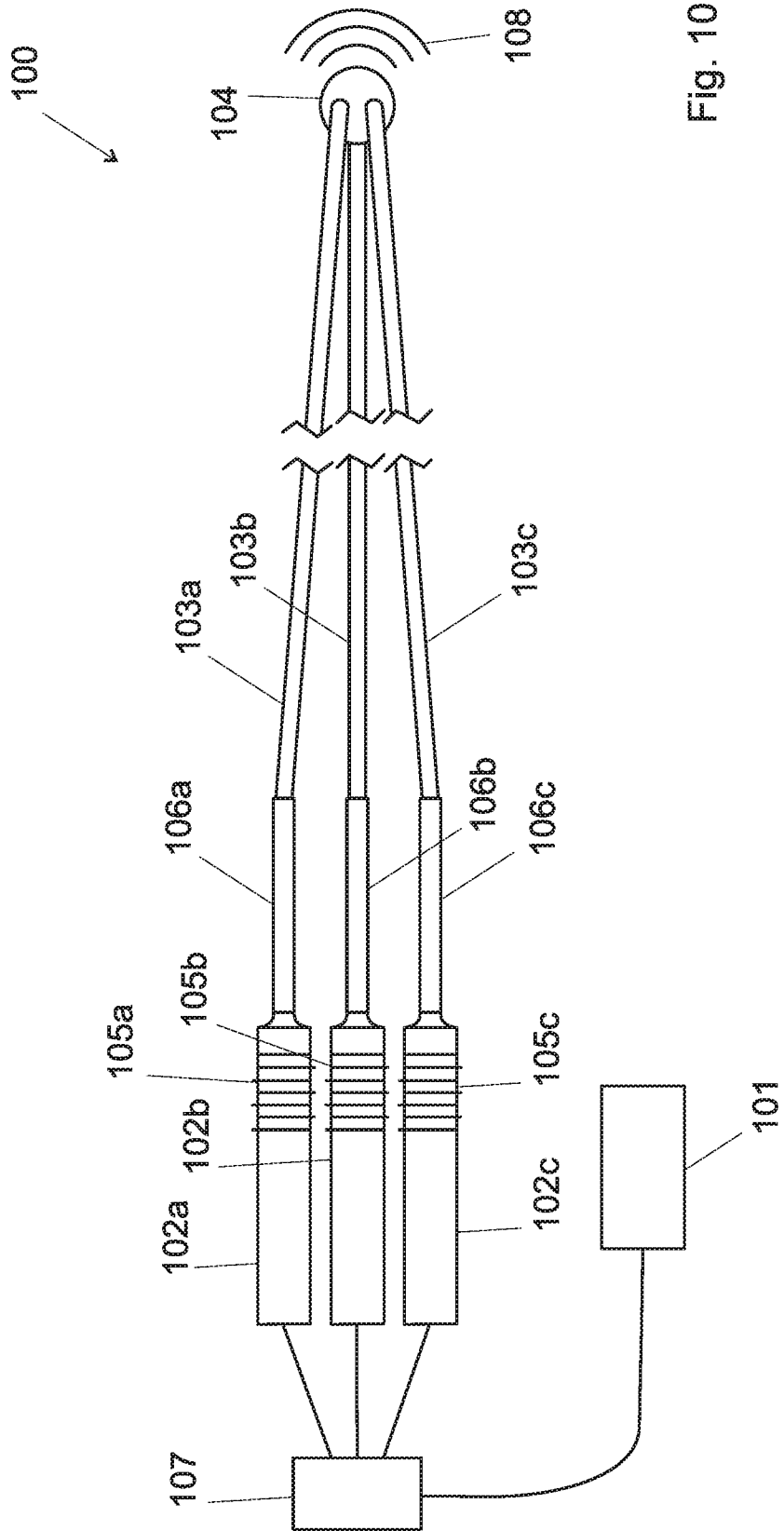


Fig. 10

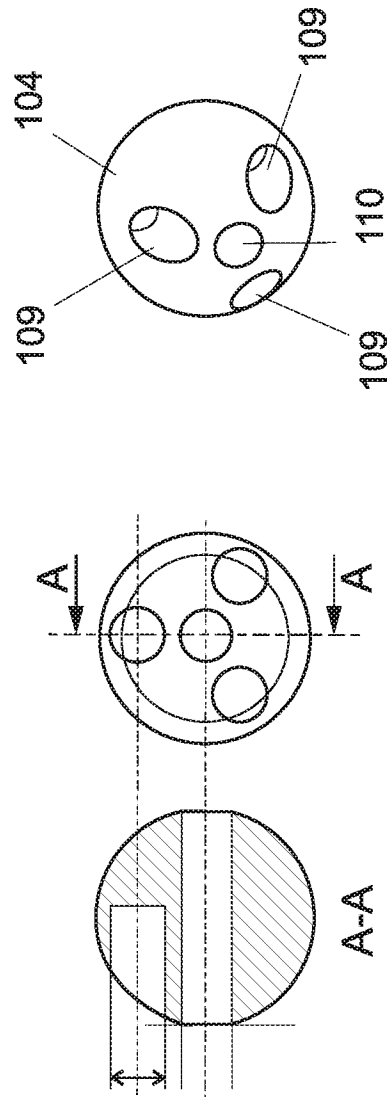


Fig. 11

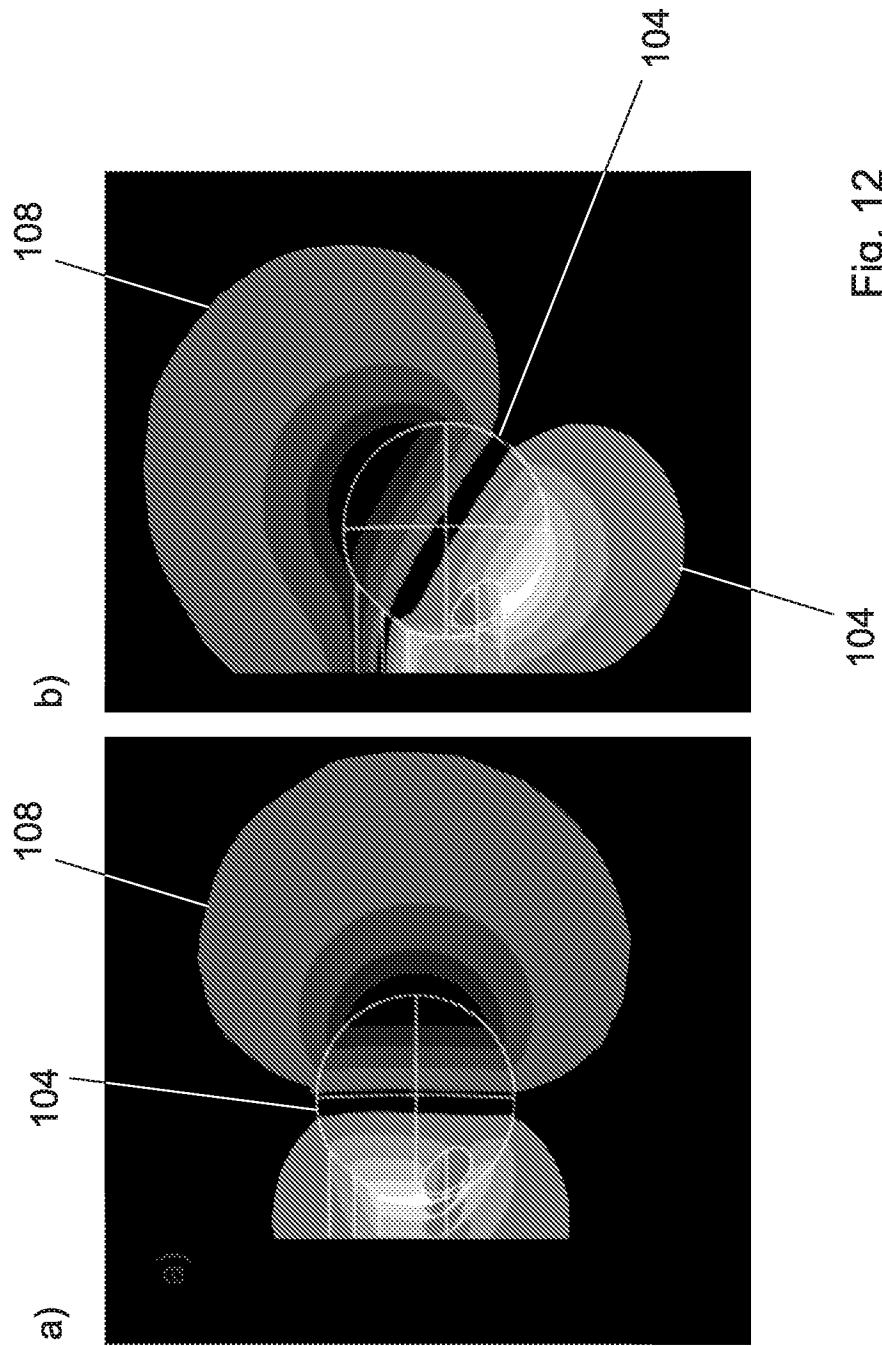


Fig. 12

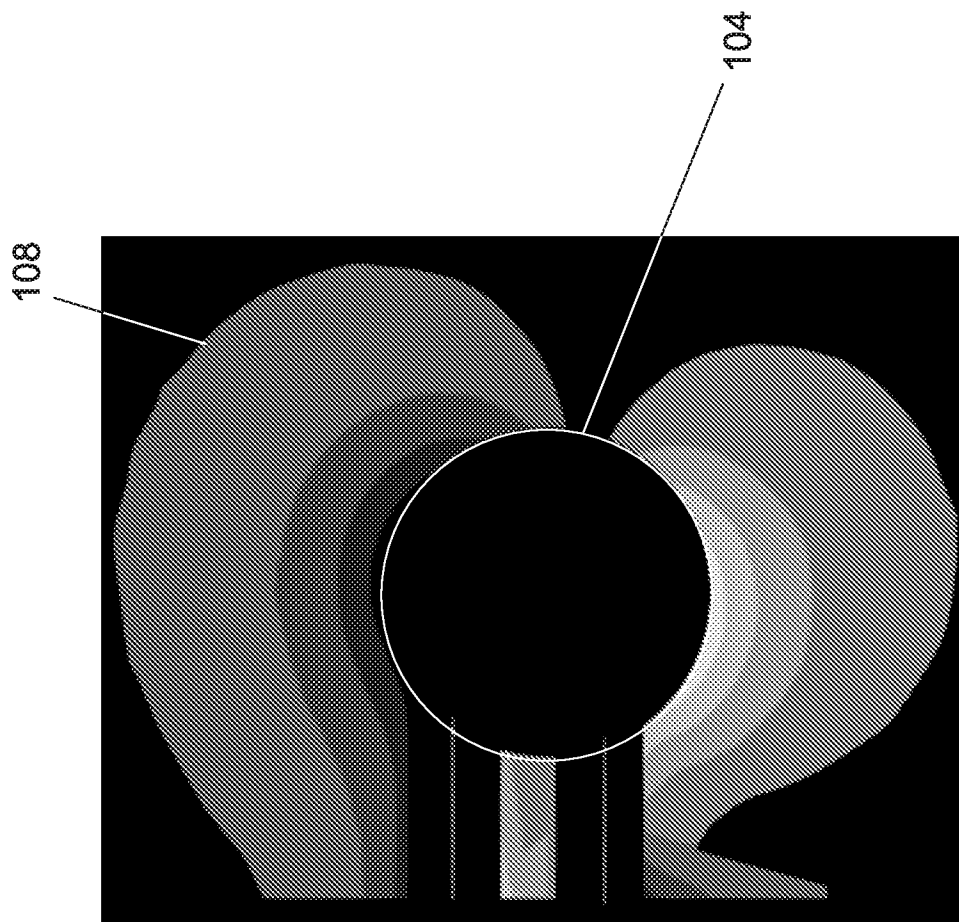


Fig. 13

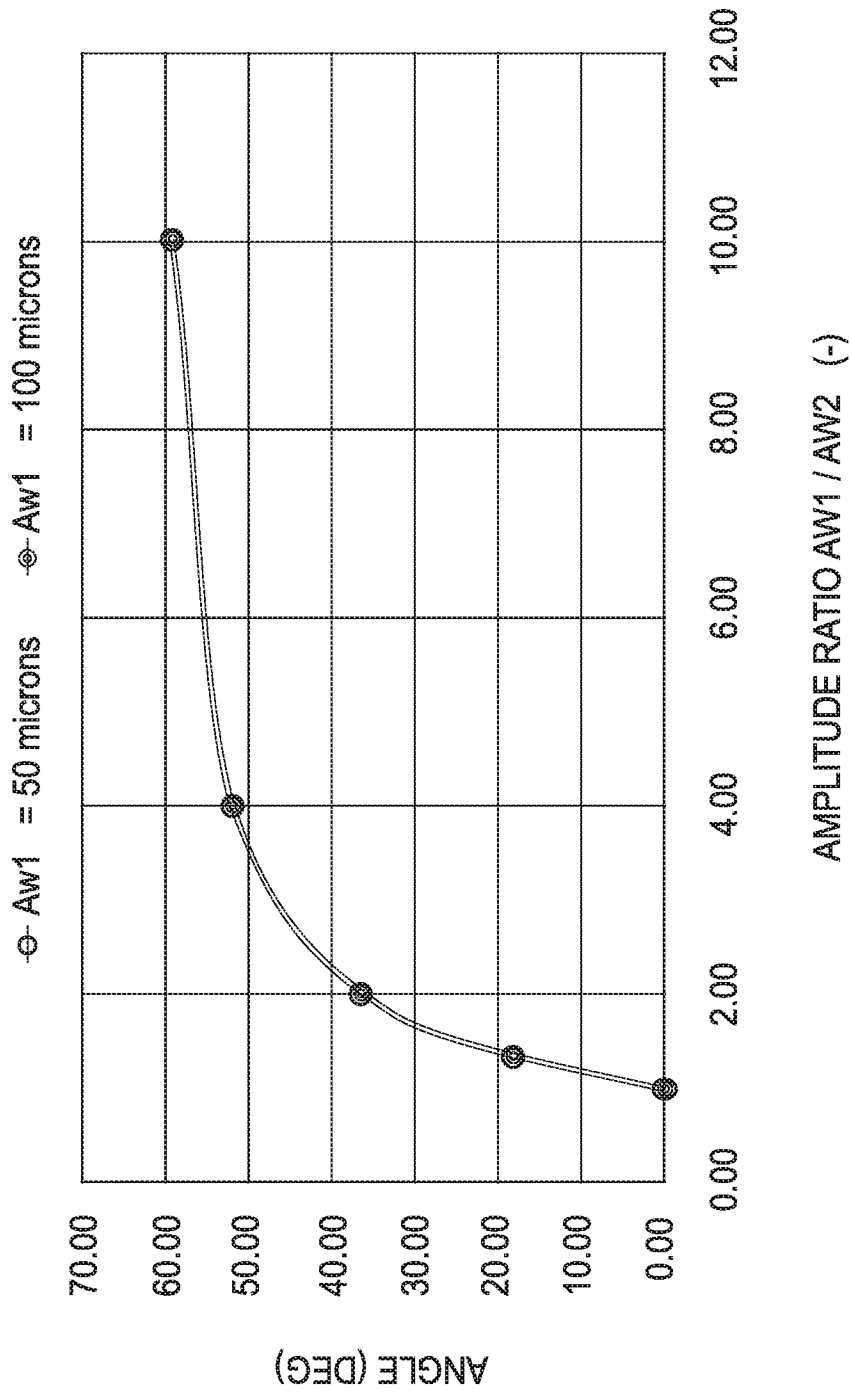


Fig. 14

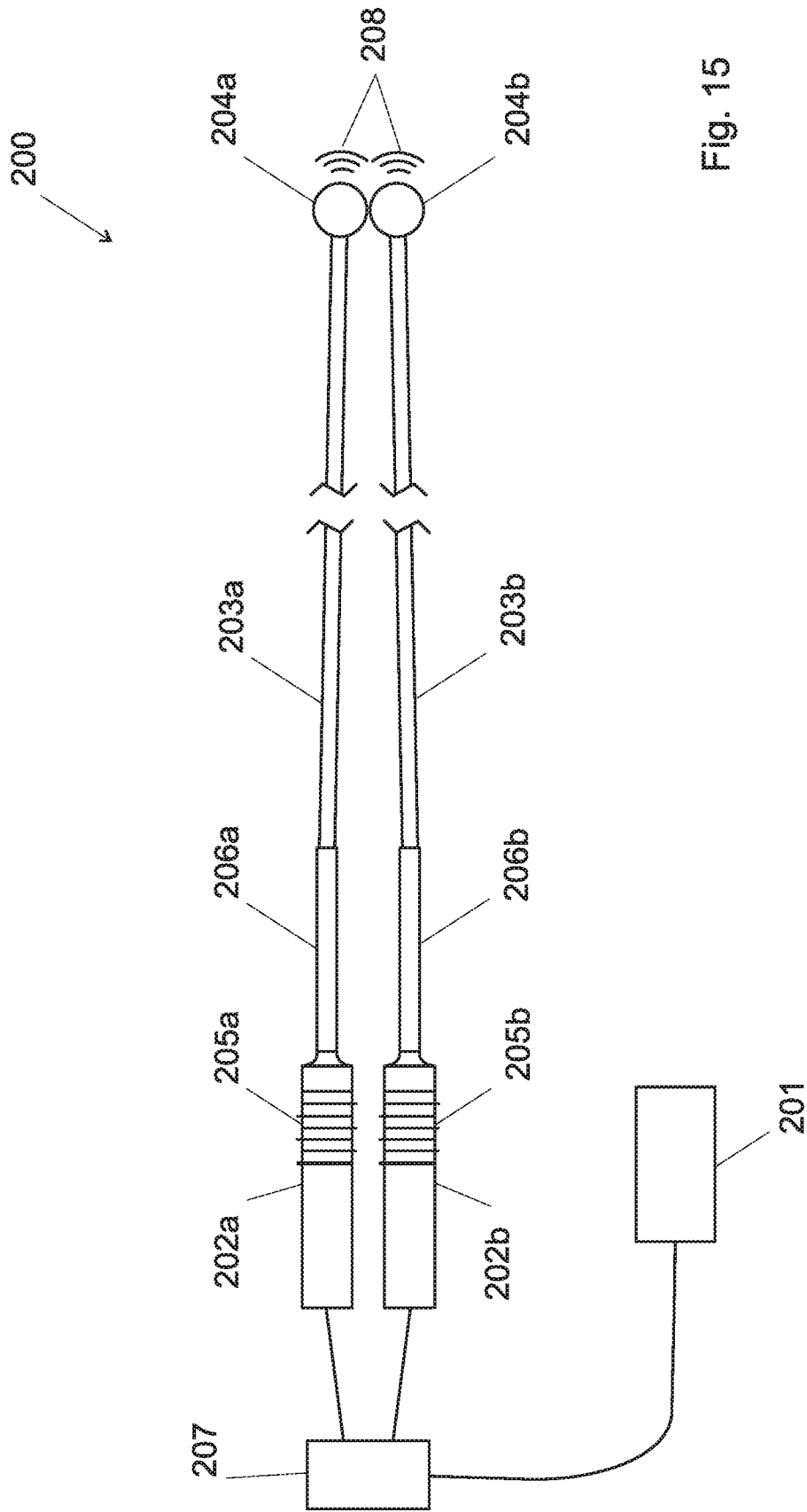
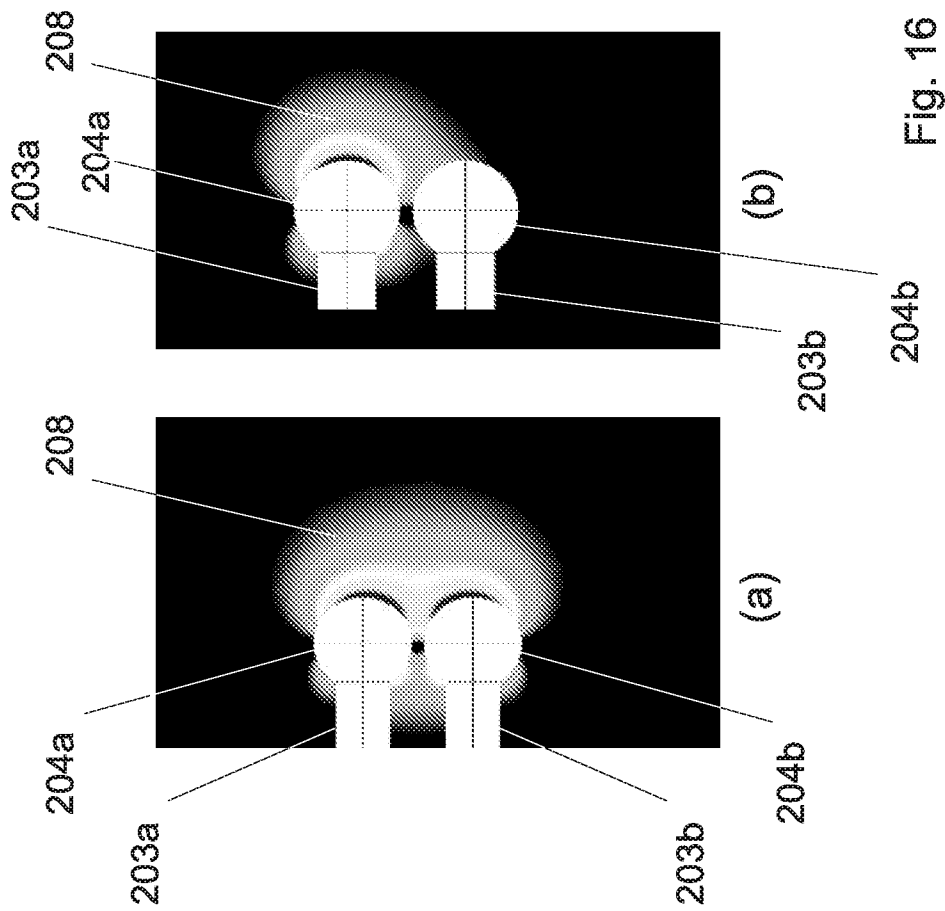


Fig. 15



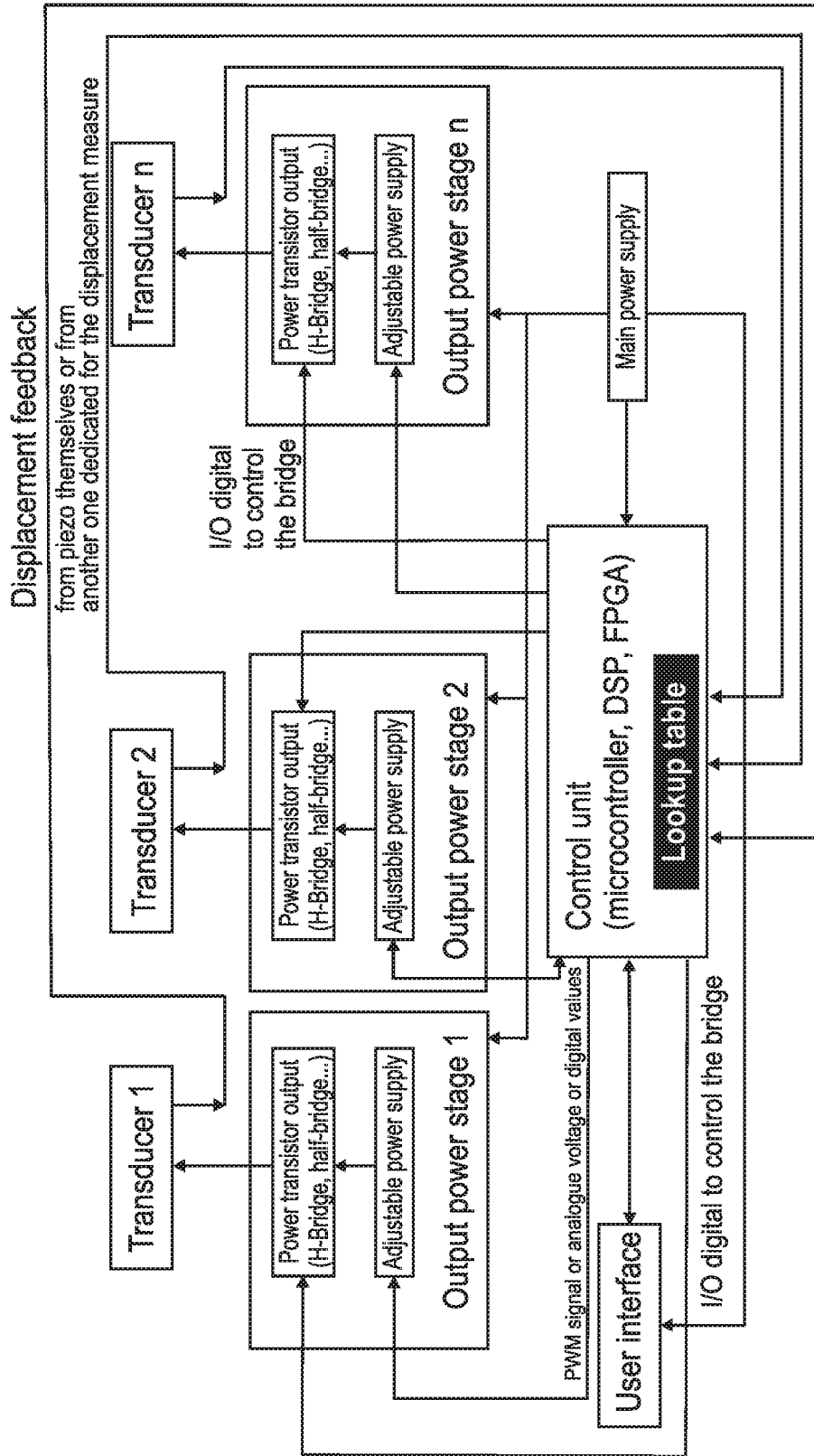


Fig. 17

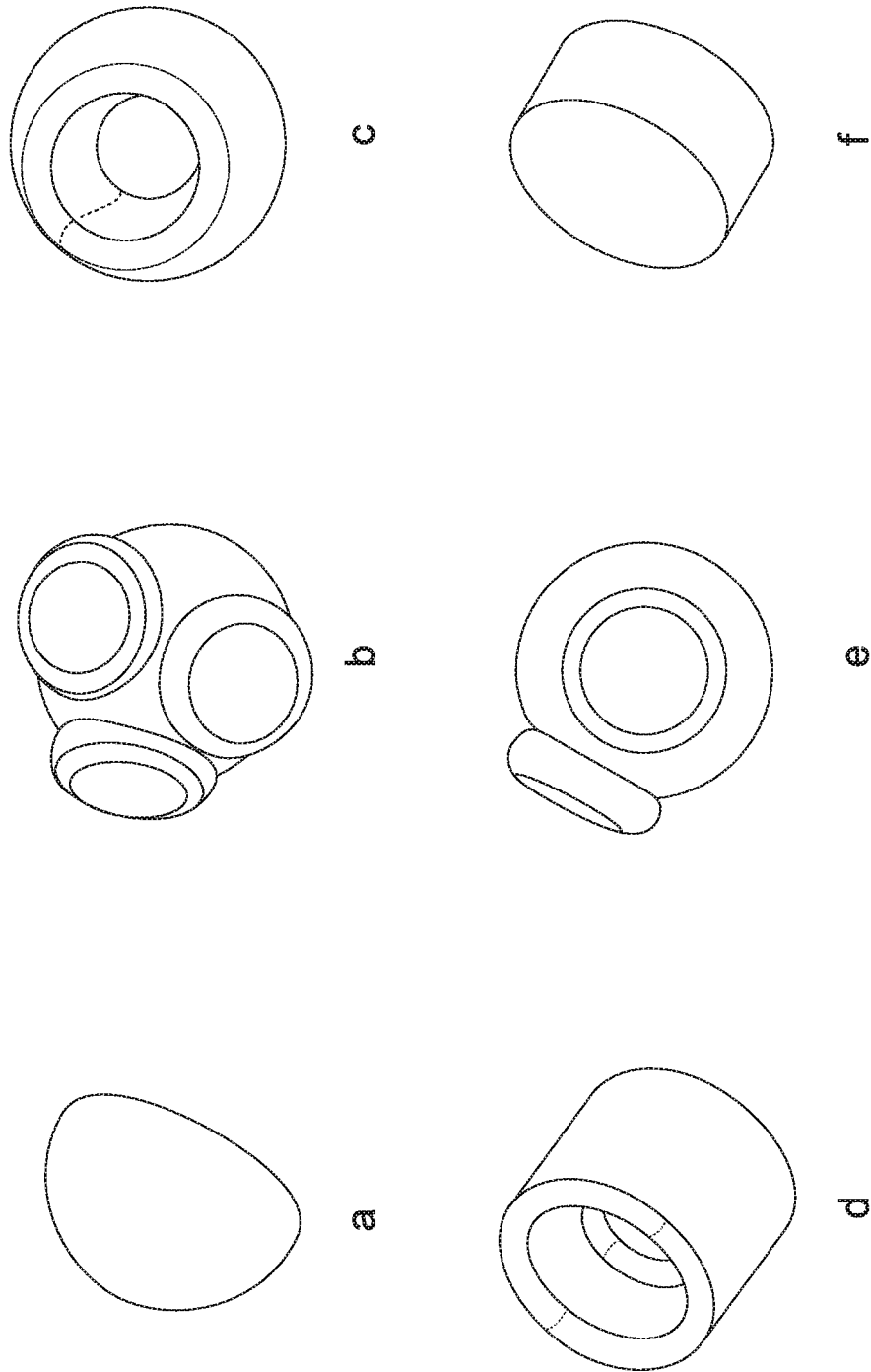


Fig. 18

# INTERNATIONAL SEARCH REPORT

International application No <b>PCT/IB2018/056926</b>
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<b>A. CLASSIFICATION OF SUBJECT MATTER</b> INV. A61B8/08      A61B8/12      A61N7/02      A61N7/00 ADD.				
According to International Patent Classification (IPC) or to both national classification and IPC				
<b>B. FIELDS SEARCHED</b>				
Minimum documentation searched (classification system followed by classification symbols) A61B 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				
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
A	US 5 722 979 A (KUSLEIKA RICHARD S [US]) 3 March 1998 (1998-03-03) abstract figures 1/5-5/5 column 4, line 53 - column 5, line 61 -----	1-17		
A	US 2018/250031 A1 (MIKUS PAUL [US] ET AL) 6 September 2018 (2018-09-06) abstract figures 1-26 paragraph [0082] - paragraph [0132] -----	1-17		
A	US 2011/237982 A1 (WALLACE MICHAEL P [US]) 29 September 2011 (2011-09-29) abstract figures 1-8 paragraph [0061] - paragraph [0135] ----- -/--	1-17		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.				
* Special categories of cited documents : <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none; vertical-align: top;">                     "A" document defining the general state of the art which is not considered to be of particular relevance                      "E" earlier application or patent but published on or after the international filing date                      "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)                      "O" document referring to an oral disclosure, use, exhibition or other means                      "P" document published prior to the international filing date but later than the priority date claimed                 </td> <td style="width: 50%; border: none; vertical-align: top;">                     "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention                      "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone                      "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art                      "&amp;" document member of the same patent family                 </td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family			
Date of the actual completion of the international search	Date of mailing of the international search report			
27 May 2019	13/06/2019			
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  Moehrs, Sascha			

# INTERNATIONAL SEARCH REPORT

International application No PCT/IB2018/056926
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>Tao Li ET AL: "Horn-Type Piezoelectric Ultrasonic Transducer: Modelling and Applications"                      In: "Advances in Piezoelectric Transducers",                      25 November 2011 (2011-11-25), InTech, XP055592149,                      ISBN: 978-953-30-7931-8                      DOI: 10.5772/28753,                      Sections 2 and 5</p> <p style="text-align: center;">-----</p>	1-17

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Information on patent family members

International application No PCT/IB2018/056926
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