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(54) Title: OPHTHALMIC SURGERY DEVICE

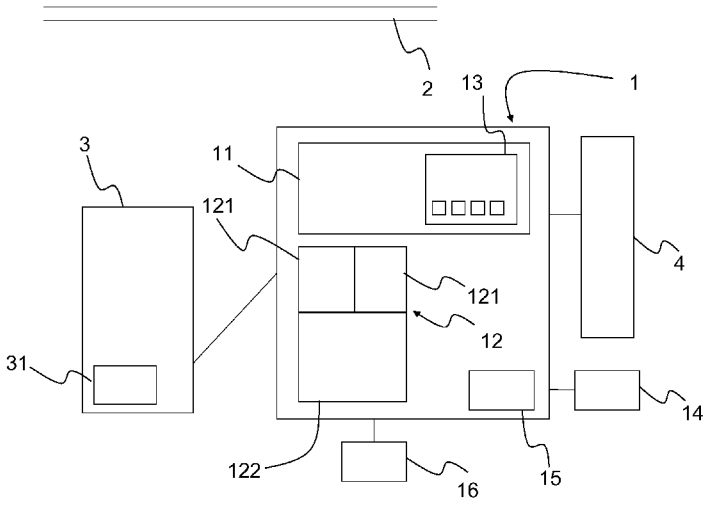

Fig. 1

(57) Abstract: An ophthalmic surgery device (1) including a processing module (11). The device is connected or can be connected (2) to a compressed air and power (2) supply network. In addition, the device has an input for the connection with a phacoemulsification machine (3); this machine presents at least one control unit (31), generating driving signals for the activation of at least one vitrectomy instrument (4) connected or connectable to device (1). The processing module (11) includes processors for the implementation of a logic program. The operation of this program commands a driving unit to generate the first driving pulses for the actuation of the vitrectomy instrument (4), the first driving pulses being generated on basis of predefined and predetermined settings of the logic program, in function of the inputs coming from the phacoemulsification machine.

Ophthalmic surgery device

The present invention relates to an ophthalmic surgery device comprising a processing module.

The device of this invention is connected or can be connected to a compressed air and power supply network .

Furthermore, the device is equipped to be connected in input to a phacoemulsification machine, which has at least one command unit.

The device generates driving signals for the activation of at least one vitrectomy instrument connected or connectible to it.

As anticipated, the device of the invention refers to a machine for ophthalmic surgery, particularly, instruments for vitrectomy.

Vitrectomy is an ophthalmic surgery which consists in the removal of the vitreous humor, that is, the liquid content of the main cavity of the eyeball, and its substitution with a similar mean, so-called vitreous substitute, using an instrument called vitrectomy instrument, an example of which is described in the patent application WO2014 / 002040.

Vitrectomy is performed when the vitreous body becomes clouded, following hemorrhage (vitreous hemorrhage) , but also due to inflammation or after traction on the retina (which may be damaged) .In addition, surgery may be necessary in the presence of epiretinal membrane or of strange bodies inside the eyeball .

Vitrectomy is useful to prevent further serious eye pathologies .

Vitrectomy is a delicate surgery, which presents risks and complications in both pre- and post-surgery phases .

Different types of vitrectomy are known in the art, for example, pneumatic actuated probes, with spring return or double-pneumatic systems, electrically or piezoelectrically actuated probes , hydraulic probes , and probes having reciprocating blades (guillotine-like blades) or rotational blades, etc.

Independently of the type, the use of vitrectomy instruments has become always more sophisticated and has permitted in these last years to achieve a decrease in risks and complications .

The complexity of known state-of-the-art vitrectomy instruments usually requires the realization of always more complex systems for the activation and command of the same, being necessary the use of equipment, like pumps, aspirations means, etc., of big dimensions, bulky and expensive.

These equipments are usually available in health care units, but are not usable because destined to other instrumentation and not easily integrated with the vitrectomy instrument.

Therefore there is a need to realize an ophthalmic surgery device which resolves the disadvantages of the already existing devices, and which is adaptable, manageable, modular and economical .

This invention achieves the above-mentioned aims with a device as described above, wherein the processing module comprises processing means for the execution of a logic program, which execution

commands a driving unit apt to generate first pulses of activations for the activation of the vitrectomy instrument.

The first driving pulses are generated on the basis of a predefined and predetermined setting of the logic program in function of the inputs coming from the phacoemulsification machine.

The device may include an ocular pressure control and vitreous substitute injection module which can be made of an injection module of low pressure air/gas/fluids and of a high pressure injection module of vitreous substitute.

As one can understand from the description above, the invention regards the realization of an adaptor, an interface between a phacoemulsification machine and a vitrectomy instrument which therefore permits to perform vitrectomy surgeries using equipments which are not originally made for this kind of surgery, but using some functions, like the fluidic part and the electrical or pneumatic pulses generation, for example, for connection to a module for anterior segment surgeries at low cutting rate.

Consequently, the final device is very versatile, economical, secure, precise and easy to use. In fact, this allows using a common phacoemulsification system to perform vitrectomy surgeries with performance similar to the best machines actually present in the market, assuring all their functionalities .

In addition to what is described above, the device of this invention has the following advantages : it is an interface that can be connected with an actuation machine already being used and

present in operating rooms, such as a phacoemulsifier provided with an output for connection to a module for anterior segment surgeries at low cutting rate, which is not designed to be used in posterior vitrectomy and which disposes of an excellent fluidic apparatus, even better than the ones used on machines dedicated only for vitrectomy.

The device of this invention consequently provides better or higher performance in relation to the actual vitrectomy machines, but with lower costs and with less complex technology.

Furthermore, the device of this invention allows obtaining an interface for all the types of vitrectomy instruments described above.

Therefore, it is possible to provide the use of either electrical vitrectomy instrument or pneumatic vitrectomy instruments.

According to the type of vitrectomy instrument used, the first driving pulses vary. Particularly in the case of electrical vitrectomy instrument, the first pulses generated are electric, while in the case of pneumatic vitrectomy instrument the first pulses generated are of compressed air.

Both types of pulses can be generated thanks to the connection of the device of this invention to a supply network of compressed air and electric power supply network in addition to the phacoemulsifier with its command unit.

So, preferably the activation pulses are of compressed air/electric pulses.

In addition, the device of this invention presents further components, which will be described, and which can be used either in combination to an

electric vitrectomy instrument or in combination to a pneumatic vitrectomy instrument, without substantial modifications to the components.

It will become clear that, after the following descriptions, another important aspect is the stability behavior both of the machine and of the vitrectomy instrument obtained through improvement of the architectural hardware and software of the processing module of the device of this invention. This stability is mechanic, electronic and pneumatic: the device guarantees, therefore, higher precision and usability of the vitrectomy instrument connected to it. At last, it permits to increase the cutting velocity, increasing the CPM (cut per minute) range of the cuts of the vitrectomy instrument in relation to the specifications of the machine to which it is connected to.

According to an improvement, the logic program can be set so that the generation of the first driving pulses follows determined rules.

For example, an automatic generation can be programmed, that is, the user sets a fixed cutting velocity and the program controls the actuation unit in such a way to generate a number of pulses to obtain the desired cutting velocity.

According to a possible operating mode, the phacoemulsification machine includes a generation unit of second driving pulses, controlled by the command unit.

Also in this case, the second driving pulses can be of compressed air or electric pulses, according to the construction specifications and to the type of vitrectomy instrument used.

It is also possible to introduce a mixed system wherein the second driving pulses are made of compressed air pulses and in which the first driving pulses are made of electric pulses or vice-versa.

Furthermore, the processing module may include means capable of recognizing the second driving pulses in such a way that the first driving pulses are generated based on the number of the second driving pulses .

Therefore, a user can control the vitrectomy instrument through the command unit of the machine for phacoemulsification, in particular, can regulate the number of first driving pulses which correspond to the cutting velocity of the vitrectomy instrument by the command unit.

With many advantages , the execution of the logic program controls the driving unit so that the number of the first driving pulses is equivalent to the number of second driving pulses multiplied by a factor which is set and can be adjusted.

The multiplication factor can be a constant or a function, linear or not.

Preferably, the user sets the multiplication factor to obtain an increase in the number of first driving pulses in relation to the second driving pulses .

According to a preferred operational mode, the command unit of the phacoemulsification machine is made of a command unit like a pedal or similar.

Such variation is particularly advantageous as the command of the vitrectomy instrument is easier in relation to the known vitrectomy instruments.

In fact, in the case where the number of first driving pulses is higher than the second driving pulses , the rotation of the pedal permits a better "resolution", as the same rotation angle corresponds to a wider velocity range in relation to the velocity range of the phacoemulsification machine.

It is evident that this permits a better regulation of the operation of the vitrectomy instrument.

According to a preferable operational mode, at least one user interface is provided, allowing the user to insert the settings of the logic program.

Such user interface can be composed of a visualization interface for visualization, for example, of the functioning parameters of the vitrectomy instrument and of an input/output interface to permit the entry of commands by the user.

As will be seen further ahead, thanks to the illustration of an operational example, the user interface is preferably composed of a touch-screen.

According to a further executive example, the control module of the ocular pressure and the injection of the vitreous substitute comprise at least one pressure controlled irrigation system to maintain the intraocular pressure (IOP) , to be inserted through injection of controlled air/f luid/gas and at least an insufflation system of silicon oil.

In detail, both the IOP (intraocular pressure) control system and the irrigation system of air/f luid/gas present pumps dedicated to maintain

constant the level of intraocular pressure and the injection pressure.

The choice of using dedicated pumps for the irrigation/injection module and for the IOP control system instead of using the compressed air network is due to some factors, as patient safety, very high pressure values and of the requested capacity and need of a very fine adjustment of these parameters.

For the injection of viscous fluids (for example, but not limited to, the injection of silicone oil) , a dedicated pump is not employed, but, instead, the pressure air for injecting the fluid is supplied by the hospital's network of compressed air and then controlled through a series of valves and pressure switches.

To facilitate the operations of a user using a vitrectomy instrument on a patient, it is possible to install an illumination module for the internal part of the eye.

A further improvement of the illumination module provides a control unit to detect the generation of first driving pulses for the activation of the vitrectomy instrument.

The presence of the control unit permits to adjust the intensity of the light emission based on the number of first pulses of compressed air.

The adjustment of the light intensity happens automatically in function of the velocity of use of the vitrectomy instrument, particularly, the illumination module reduces the intensity of the light emissions when there is an increase of the number of driving pulses .

One of the advantages of this automatic adjustment is that, with the increase of velocity of the vitrectomy instrument, the light intensity can be modulated to avoid phenomena of photophobia or inadequate illumination of the tissues, preventing excessive reflection or poor contour definitions. Such advantage results particularly evident in the vitrectomy surgery called "shave", in the peripheral zone of the retina, when trying to reduce the forces of tractions applied to it, the cutting velocity is increased at the same time to decrease the distance between the active part of the vitrectomy instrument and the retinal surface .

Therefore, the presence of an illumination module is not due to an addition of a known illumination system, but, in combination to the characteristics described above, permits to obtain a synergy effect which facilitates vitrectomy surgeries and the handling of the vitrectomy instrument.

Alternatively, it is possible to provide that the illumination system can work through a fixed illumination in relation to the cutting velocity, that is, to the frequency of the first driving pulses. Furthermore, it is also provided the possibility to set many different levels of illumination intensity: also in this case, the illumination intensity is independent of the cutting velocity .

In addition, according to a further embodiment, at least one electric supply system can be connected to at least one vitrectomy instrument with electric actuation .

At last, a further operational mode is provided with an auxiliary command.

The auxiliary command unit can be made of a pedal or similar, and can control one or more components and the modules pertaining to the device of this invention and previously described.

In this way the user can have complete control of the device itself, acting on the command unit and on the auxiliary unit through his proper lower limbs, having his hands free to operate and handle the pneumatic/electric vitrectomy instrument

This and other characteristics and advantages of the present invention result clearer from the following description in the attached drawings where:

Fig.l shows a principle diagram for functional blocks of a functioning variation of the device of this invention

It is to be noted that the diagram reported shows an exemplary device according to the invention, to better understand the advantages and the characteristics thereof.

Such example is, therefore, not to be considered as limiting the scope of the invention which is that of realizing a device that can be used as an interface between a vitrectomy instrument and a phacoemulsification machine, easily adaptable and handled, economic and modular.

In particular, the ophthalmic surgery device 1 comprises a processing module 11 and at least a control module 12 of the ocular pressure and of injection of a vitreous substitute.

The device 1 is connected to or can be connected to a compressed air and to a power supply network 2.

Furthermore, the device 1 is configured to be connected to a phacoemulsification machine 3, which has at least one control unit 31 capable of providing electrical or pneumatic pulses at one or more output ports, for example for connection to a module for anterior segment surgeries at low cutting rate.

The device 1 generates activations signals for the activation of at least one vitrectomy instrument 4 connected to device 1.

Based on the characteristics introduced relative to the device of this invention and based on the following descriptions, it is clear how the device can be set for the generation of a commanding signal of two or more vitrectomy instruments 4, without the need to make any particular modification to the setting just described

It shall be sufficient to design a connection for each vitrectomy instrument 4 and an internal control of the processing module 11 which permits the equal or diverse generation of the train of driving pulses for each vitrectomy instrument 4.

As described before, since the first driving pulses can be, for example, composed of first pulses of compressed air or of first electric pulses, the device of this invention permits to connect two vitrectomy instruments 4 of different types, for example, one pneumatic 4 vitrectomy instrument and one electric vitrectomy instrument 4.

Preferably, two air outputs of compressed air for the actuation of two vitrectomy instruments 4

with spring return contemporary or of a double pneumatic vitrectomy instrument 4 or of two vitrectomy instruments with electric actuation are provided .

The processing module 11 comprises processors for the implementation of a logic program, which operation commands a driving unit to generate first driving pulses for the actuation of the vitrectomy instrument 4 .

The first driving pulses are generated based on a predefined and predetermined setting of the logic program.

Preferably, the phacoemulsification machine 3 comprises a generation unit of second driving pulses controlled by the control unit 31. In this case, the processing module 11 comprises detection means capable of recognizing the second driving pulses in such a way that the first driving pulses are generated based on the number of the second driving pulses .

With many advantages , the execution of the logic program controls the activation unit so that the number of the first pulses of activation is equivalent to the number of second pulses of activation multiplied by a factor which is set and can be adjusted.

Since the first driving pulses are proportional to the number of cuts the vitrectomy instrument 4 can make, the device 1 permits to increase the cutting velocity of the vitrectomy instrument 4 multiplying the number of driving pulses per minute done by the phacoemulsification machine 3 by a factor defined by the user.

Specifically, the displacements made by the guillotine, that is, the cutting part of the vitrectomy instrument 4, are increased because considering equal displacement and, therefore, frequency of pulses, according to the geometry, a vitrectomy instrument can perform a higher number of cuts.

According to a preferred embodiment, at least one user interface 13 is provided, allowing the user to insert the settings of the logic program.

Combining the characteristics described above, the user sets the value of the desired cutting rate through the user interface; the elaboration unit identifies both the value set and the second pulses, and generates the first pulses to obtain the cutting rate desired by the user.

For example, the cutting rate can be enhanced up to 6000 cpm.

According to an operational example, the processing module 11 is composed of:

- Digital pulse reader
- Electrical circuit multiplier
- Electro valve and output circuit
- Interface display 13

The processing module 11 can be composed of components as pressure switches, flow regulators or pressure reducers which guarantee the operational stability and surgery security.

The module 11 is powered by a hospital network of compressed air of 4 - 6 bars. The air flow and pressure are regulated through a valve and pressure switch based on the conditions of use requested.

The pulse reader detects the frequency of the second pulses of compressed air coming from the phacoemulsification machine 3. The module 11 is provided with an interface 13 through which the user can set the multiplication factor desired.

The logic program, through an electric multiplier circuit, commands the electro valve which provides an output of the first pulses of compressed air according to the calculated frequency based on the multiplication factor set.

According to the user's choice, the increase of frequency can follow a linear or non-linear trend.

In the case of using an electric vitrectomy instrument 4 instead of a pneumatic one, its operation is totally similar to what described above: the electric multiplier circuit commands a generator of electric pulses or directly an electric motor, instead of an electro valve, following a proper logic of generation of first pulses having at input the second pulses .

Through the user interface 13, composed of a touch-screen 13, the user can set the desired multiplication factor. The logic program elaborates the information and commands the electro valve which provides in output the train of the first pulses of compressed air or pulses/electric tensions for the actuation of the vitrectomy instrument 4 at the desired frequency.

The whole system is controlled by means of the pedal 31, which is the command unit of the phacoemulsification machine, whose fluidic and aspiration system is used.

Alternatively, it is possible to regulate the logic program with the actuator at a fixed parameter: in this case, the pulse reader simply reveals the presence of active compressed air, not corresponding to the frequency of the second pulses and sends the actuation signal of the vitrectomy instrument 4. The command also comes through the pedal 31, which is not used anymore for the modulation of the cutting rate, which is fixed.

According to a further operation example, the control module 12 of the ocular pressure and of the injection of vitreous substitute are made of at least one pressure controlled irrigation system to maintain the intraocular pressure, and an injection system of air/fluid/gas 121 and at least an insufflation system of silicon oil 122.

In detail, the systems 121 have dedicated pumps to maintain constant level of intraocular and injection pressure.

Advantageously, it is possible to install a pressure transducer positioned downstream of the pumps and feedback control to avoid both excessive and too low pressure.

In a preferred embodiment, the pressure control of the eyeball (intraocular pressure IOP) can be achieved indirectly by detecting the depression that is created in the infusion bottle and consequently adjusting the air pressure: as well known in the prior art, the above described method consists of injecting air at a predetermined pressure in the empty part of the infusion bottle so as to force the infusion fluid to fall into the eye socket at the

preset pressure. In this way, the IOP can be maintained, for example, between 0 and 80 mrtiHg.

According to figure 1, the device 1 according to an embodiment of the invention is made of:

- a processing module 11 which has one or more characteristics previously described,

– a control module of ocular pressure, of air/f luid/gas injection and of vitreous substitute injection composed of:

a. Two irrigation and intraocular pressure maintenance systems 121 with dedicated pumps, a pressure regulation system and a transducer for the feedback control system

b. An insufflation system of silicon oil 122 supplied by the hospital's network of compressed air,

- an illumination module 14 of the internal part of the eye

- an electric power system 15 for vitrectomy instruments with electric actuators, not illustrated.

As anticipated, the irrigation system 121 is composed of a pump, a pressure transducer and a pressure regulator.

The system 121 is also composed of components as pressure switches, flow regulators or pressure reducers for a correct actuation of the operation.

The dedicated pump permits to obtain compressed air which permits the infusion of the desired pressure of the vitreous substitute during vitrectomy surgeries .

As anticipated, according to a possible embodiment, the system 121 can have two outputs of compressed air, one for the air and one for the infusion of the vitreous substitute.

During surgery, a vitreous substitute can be injected in pressure or compressed air, according to the needs .

In addition, the system 121 is composed of a regulation and feedback control system: a transducer reads the value of the output pressure fluid and sends a signal to an elaboration system which, in the case of too high pressure, commands the actuation of the pressure regulator. Such regulator can, for example, be composed of a reducer made up of a three-way valve which discharges air to bring back the pressure in the circuit to values under the established limit.

The pressure of the output fluid can preferably vary between 0 mrtiHg and 80 mmHg. The pressure value is set using a display and the infusion is controlled through an auxiliary command unit 16, like a pedal or similar, operating on-off .

As an alternative or in combination, it is possible to control the output fluid through the command unit 31, or through a value set by the user on the user interface 13.

The injection system 122 preferably comprises a piping system and a proportional valve.

The system 122 can provide silicon oil at the desired pressure, between, for example, 0 bars and 5 bars, regulating the pressure of the input air coming from the network through a proportional valve.

The output fluid pressure can vary between 0 and 5 bar. The pressure value is set through the display and the infusion is controlled by an auxiliary pedal 16 for linear progressive operation or on-off, according to the user's settings.

With reference to figure 1, the device 1 may comprise an illumination module 14 of the internal part of the eye

Such illumination module 14 provides a control unit to detect the generation of first driving pulses for the activation of the vitrectomy instrument 4, so that the intensity of the light emissions vary based on the number of the first driving pulses.

Advantageously, the illumination module 14 comprises at least a lamp, optic fiber and a terminal for an endoscopy probe.

The endoscopic illumination can be a Xenon or LED type. In this last case, it is possible to make the intensity of the light emissions automatically varying in function of the cutting velocity of the vitrectomy instrument 4, acting on the difference of the supply potential of the LED.

The intensity of the light emissions is controlled by the electronic control and not by a mechanical one .

Therefore, the control does not happen on the light ray by a mechanical obturator with an illumination source with fixed power, but operating on a power differential which excites the LED.

At last, another variation of the illumination system is two lighting source, identical and which can work in parallel .

CLAIMS

1. Ophthalmic surgery device (1) comprising a processing module (11),

the device being connected or connectible to a compressed air supply network and to an electrical power supply network (2).

the device having an input for the connection to a phacoemulsification machine (3),

the device generating driving signals for driving at least one vitrectomy instrument (4) connected or connectable to said device (1),

characterized in that

said processing module (11) comprises processing means for executing a logic program, whose execution controls a driving unit intended to generate first driving pulses for driving the vitrectomy instrument (4),

the first driving pulses being generated on the basis of predefined and specific settings of the logic program in function of the inputs coming from the phacoemulsification machine (3).

2. Device (1) according to claim 1, characterized in that it is provided in combination with a phacoemulsification machine (3), which phacoemulsification machine (3) comprises at least one control unit (31) and a generation unit for the generation of second driving pulses controlled by the control unit (31),

the processing module (11) including detection means capable of recognizing the second driving pulses in such a way that the first driving pulses are generated on the basis of the number of the second driving pulses.

3. Device (1) according to claim 2, where the execution of the logic program controls the driving unit so that the number of the first driving pulses is equivalent to the number of second driving pulses multiplied by an adjustable factor.

4. Device (1) according to one or more of the preceding claims, wherein at least one user interface (13) is included, allowing the user to insert the settings of the logic program.

5. Device (1) according to one or more of the preceding claims, characterized in that it has at least a control module (12) of the ocular pressure and of injection of a vitreous substitute.

6. Device (1) according to claim 5, wherein said control module (12) of the ocular pressure and the injection of vitreous substitute comprises at least one pressure controlled irrigation system (121) to maintain the intraocular pressure, and at least an insufflation system of silicon oil (122).

7. Device (1) according to claim 6, wherein said at least one irrigation system (121) has a dedicated pump to maintain constant the intraocular pressure.

8. Device (1) according to claim 6, wherein said at least one irrigation system (121) has a dedicated pump to control the pressure value of the vitreous substitute.

9. Device (1) according to one or more of the preceding claims, further comprising at least one illumination module (14) for the internal part of the eye.

10. Device (1) according to claim 9, wherein the illumination module (14) comprises a control unit to detect the generation of first driving pulses for

driving the vitrectomy instrument (4), so that the intensity of the light emissions vary based on the number of the first activation pulses.

11. Device (1) according to claim 9 or 10, wherein the illumination module (14) is configured to reduce the intensity of the light emissions when there is an increase of the number of driving pulses.

12. Device (1) according to one or more of the preceding claims, further comprising at least one power supply system (15) to connect one or more vitrectomy instruments with electric actuation.

13. Device (1) according to one or more of the preceding claims, comprising at least one auxiliary command unit (16).

14. Device (1) according to one or more of the preceding claims, characterized in comprising an electrical driving unit for driving a vitrectomy instrument of the electric type and a pneumatic driving unit for driving a vitrectomy instrument of the pneumatic type.

15. Device (1) according to one or more of the preceding claims, wherein the phacoemulsification machine (3) has at least a port for outputting the second driving pulses, such port being of the type suitable for connection to a module for anterior segment surgeries at low cutting rate.

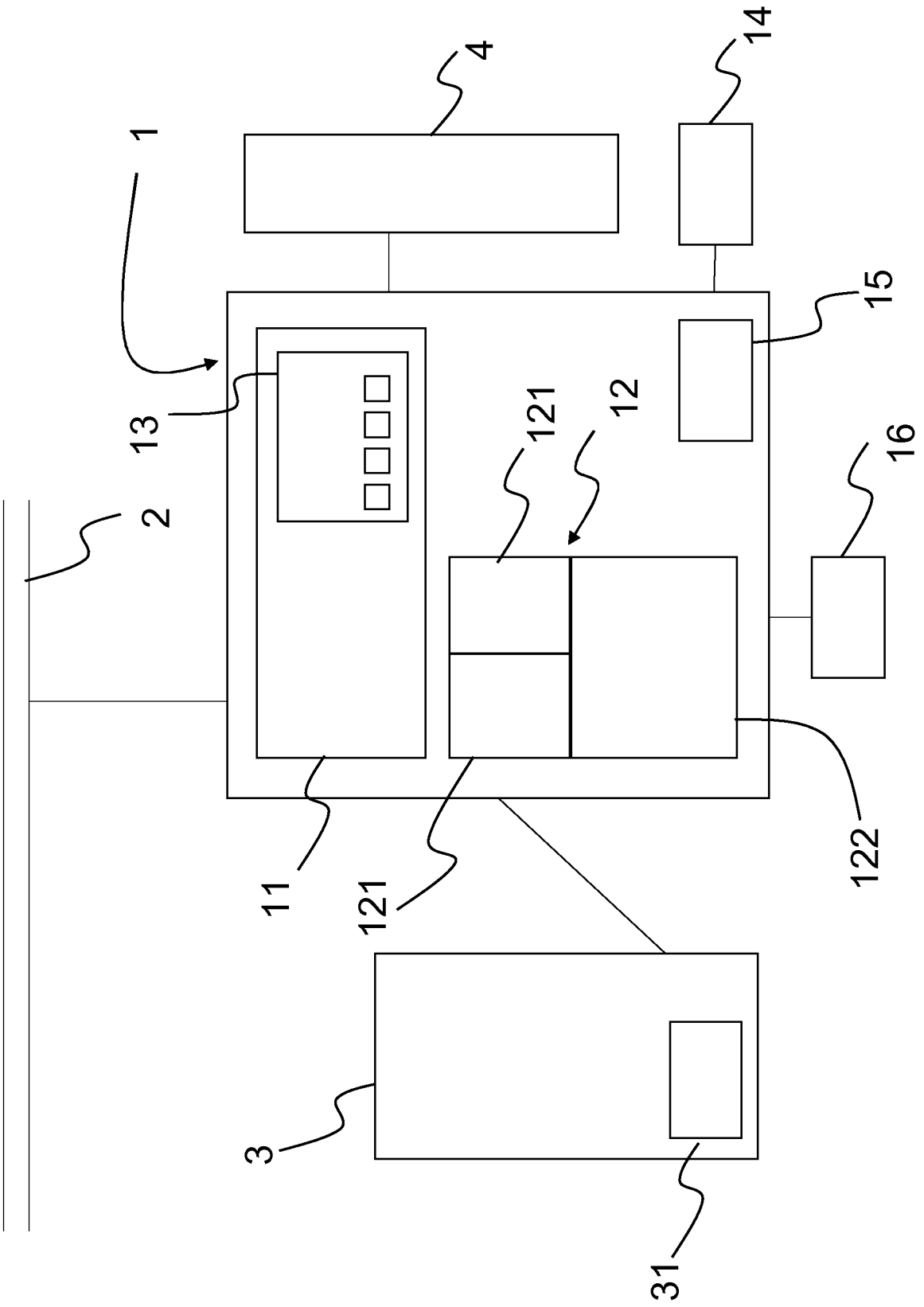

Fig. 1

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/025062

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F9/007
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)
A61F

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 006 892 B1 (BAUSCH & LOMB SURGICAL INC [US]) 3 June 2009 (2009-06-03) paragraphs [0001], [0017], [0027], [0064], [0079], [0118] - [0119], [0124], [0126], [0128], [0134], [0142] -----	1,4-9, 12-15
A	US 5 417 246 A (PERKINS JAMES T [US] ET AL) 23 May 1995 (1995-05-23) figures 1a, 1b column 1, line 45 - line 51 column 5, line 15 - page 7, line 13 column 8, line 55 - column 10, line 50 column 13, line 60 - column 14, line 55 column 15, line 55 - column 16, line 35 column 20, line 25 - line 55 column 22, line 34 - line 66 -----	1-15

-/- .

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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Date of the actual completion of the international search	Date of mailing of the international search report
3 December 2015	17/12/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Jansen, Birte

1

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/025062

C(Continuation). 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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