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(54) **Titre : SYSTEME IPG DUPLEX INTEGRAL ET FIL PERCUTANE ELECTRO-OPTIQUE**
(54) **Title: FULL-DUPLEX IPG SYSTEM AND ELECTRO-OPTICAL PERCUTANEOUS LEAD**

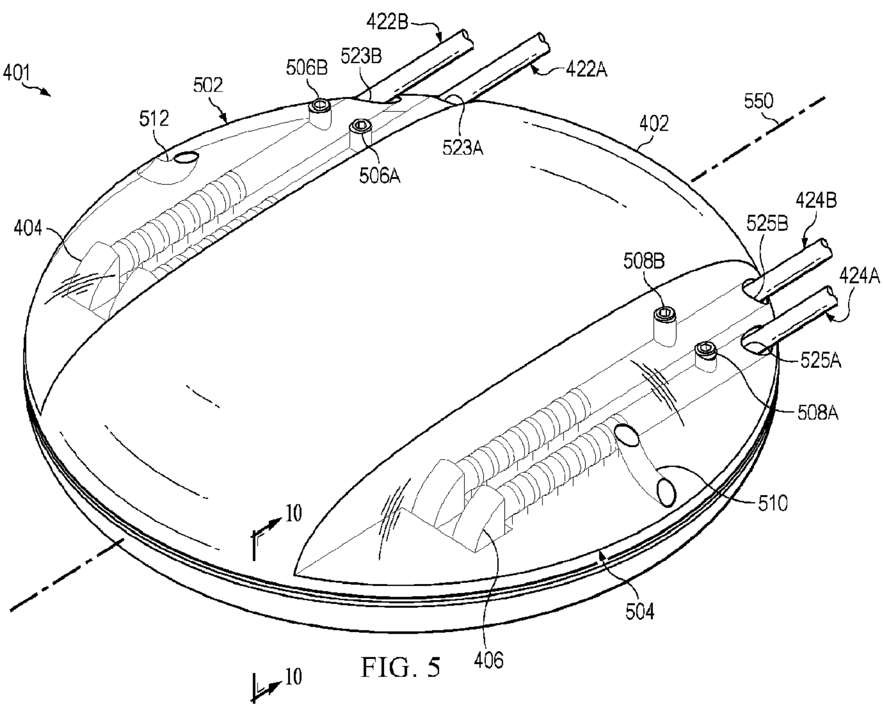

FIG. 5

(57) **Abrégé/Abstract:**
The invention provides an IPG and lead configuration which boasts both a novel optical folding assembly and an optical processor assembly which offers the advantages of low heat generation and compact package size. The surgical leads provided offer additional advantages over the prior art including integral formation of optical and electrical components in a compact size. The invention further provides processing advantages which measure and compensate for degradation in the optical system over time.

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Abstract:

The invention provides an IPG and lead configuration which boasts both a novel optical folding assembly and an optical processor assembly which offers the advantages of low heat generation and compact package size. The surgical leads provided offer additional advantages over the prior art including integral formation of optical and electrical components in a compact size. The invention further provides processing advantages which measure and compensate for degradation in the optical system over time.

FULL-DUPLEX IPG SYSTEM AND ELECTRO-OPTICAL PERCUTANEOUS LEAD

FIELD OF THE INVENTION

[0001] The present invention relates to an improved implantable pulse generator ("IPG") and header combination using optical reflectometry in spinal cord stimulation ("SCS").

BACKGROUND OF THE INVENTION

[0002] Chronic pain may arise from a variety of conditions, most notably from nerve injury as in the case of neuropathic pain, or from chronic stimulation of mechanical nociceptors such as with spinal pain. Functional ability may be severely impacted by pain, which often is refractory to pharmacological and surgical treatment. In such cases, SCS can be an effective treatment for pain by modulating physiological transmission of pain signals from the periphery to the brain. This may be achieved by applying electrical impulses to the spinal cord via an electrode array implanted adjacent the spinal canal.

[0003] Referring to Figures 1, 2 and 3, a typical IPG system of the prior art will be described. Spinal column **1** is shown to have a number of vertebrae, categorized into four sections or types: lumbar vertebrae **2**, thoracic vertebrae **3**, cervical vertebrae **4** and sacral vertebrae **5**. Cervical vertebrae **4** include the 1st cervical vertebra (C1) through the 7th cervical vertebra (C7). Just below the 7th cervical vertebra is the first of twelve thoracic vertebrae **3** including the 1st thoracic vertebra (T1) through the 12th thoracic vertebra (T12). Just below the 12th thoracic vertebrae **3**, are five lumbar vertebrae **2** including the 1st lumbar vertebra (L1) through the 5th lumbar vertebra (L5), the 5th lumbar vertebra being attached to sacral vertebrae **5** (S1 to S5), sacral vertebrae **5** being naturally fused together in the adult.

[0004] Representative vertebra **10**, a thoracic vertebra, is shown to have a number of notable features which are in general shared with lumbar vertebrae **2** and cervical vertebrae **4**. The thick oval segment of bone forming the anterior aspect of vertebra **10** is vertebral body **12**.

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Vertebral body **12** is attached to bony vertebral arch **13** through which spinal nerves **11** run. Vertebral arch **13**, forming the posterior of vertebra **10**, is comprised of two pedicles **14**, which are short stout processes that extend from the sides of vertebral body **12** and bilateral laminae **15**. The broad flat plates that project from pedicles **14** join in a triangle to form a hollow archway, spinal canal **16**. Spinous process **17** protrudes from the junction of bilateral laminae **15**. Transverse processes **18** project from the junction of pedicles **14** and bilateral laminae **15**. The structures of the vertebral arch protect spinal cord **20** and spinal nerves **11** that run through the spinal canal.

[0005] Surrounding spinal cord **20** is dura **21** that contains cerebrospinal fluid (CSF) **22**. Epidural space **24** is the space within the spinal canal lying outside the dura.

[0006] One or more electrodes **30** are positioned in epidural space **24** between dura **21** and the walls of spinal canal **16** towards the dorsal aspect of the spinal canal nearest bilateral laminae **15** and spinous process **17**. Electrode **30** has electrode leads **31** which are connected to IPG **32** and controller **33**.

[0007] IPG **32** provides the electrical stimulation in the form of current pulses to the spinal cord through lead **31** to electrode **30**. The pulses generate an electric field. The electric field impinges on targeted neurons of the spinal cord and disrupts the perception of pain. The amplitude of the electrical field is critical to success of spinal cord stimulation. An inadequate electric field will fail to depolarize the targeted neurons, rendering the treatment ineffective. An excess electric field stimulates neighboring cell populations which results in a noxious stimulation.

[0008] Establishing a consistent, therapeutic, and non-noxious level of stimulation is predicated upon establishing an ideal current density within the spinal cord's targeted neurons.

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Fundamentally, this should be a simple matter of establishing an optimal electrode current given the local bulk conductivity of the surrounding tissues. But in practice, the optimal electrode current changes as a function of patient position and activity due to motion of the spinal cord as the spinal cord floats in cerebrospinal fluid within the spinal canal. Significant changes in distance between the epidural electrode array and the targeted spinal cord neurons have been shown to occur. Consequently, optimal stimulation requires dynamic adjustment of the electrode stimulating current as a function of distance between the electrode array and the spinal cord.

[0009] Dynamic modulation of spinal cord stimulator electrode current as a function of distance between the electrode array and the spinal cord thus has several benefits. Excess stimulation current can be avoided, thus reducing the prospects of noxious stimulation and potentially reducing device power consumption. Inadequate stimulation current can also be avoided, thus eliminating periods of compromised therapeutic efficacy.

[0010] Dynamic modulation of electrode current can be controlled through the use of optical reflectometry to determine the thickness of the dorsal cerebrospinal fluid (dCSF) column between the spinal cord and the electrode array. An optical signal is transmitted into the surrounding tissue and collected by a sensor to calculate the approximate distance between the electrode and the spinal cord. The stimulus magnitude is modified accordingly to provide the optimal current for pain relief. Examples of this technology are shown in U.S. Patent Nos. 10,035,019 and 9,656,097, both to *Wolf II*, and both incorporated herein by reference.

[0011] One challenge, to IPG implantation and usage is package size. Long-term survival of the IPG in the in vivo environment, mitigates that the package size be as small as possible to reduce rejection rates and to lower scarring times. A small package size also decreases the possibility of migration of the package and the surgical leads which emanate from

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it.

[0012] Another challenge to IPG systems is proper interpretation of the reflected optical signal. Half duplex systems of the prior art require that multiple surgical leads be precisely placed by the targeted neurons. Such placement during surgery is difficult. The problem is further exacerbated by lead migration, which may disalign the fibers and degrade optical feedback which controls modulation of the stimulation signal.

[0013] Yet another challenge to IPG systems is power constraints and heat generation. Power usage of the IPG must be kept to a minimum in order to assure long term battery life of the IPG package. Further, heat generation in the in vivo environment must be minimized to prevent rejection. Therefore, power consumption and heat generation both must be as low as possible.

[0014] Yet another challenge to optical IPG systems is Fresnel reflections. Fresnel reflections occur at all optical interfaces of the lead and through fiber and can be assumed to account for about 4% signal loss per optical interface. Interface losses are generally constant over time. Fiber degradation caused by bending also produces Fresnel losses. However, fiber degradation losses are not constant and change over time. Optical losses effect the accuracy of the optical feedback which controls the stimulation signal.

[0015] Another challenge to optical IPG systems is that laser output changes due to power variations and due to part age, thereby altering the characteristics of the optical system over time. The changes in the optical system reduce the effectiveness of the stimulation signal control and so reduce the efficacy of the stimulation signal.

[0016] The prior art has attempted to address these challenges in a number of ways, yet all have fallen short.

[0017] For example, U.S. Patent No. 9,656,097 to *Wolf, II* describe a full duplex IPG lead, which allows both a transmit ray and receive ray to travel down the same fiber. However, *Wolf* discloses use of a circulator to separate the two rays. A circulator is not practical because of the size of the circulator package and because of the optical losses incurred.

[0018] As another example, U.S. Patent No. 7,742,817 to *Malinowski, et al.* describes an IPG with connectors for electrical leads and an epoxy coating for biocompatibility. However, *Malinowski* does not disclose the use of optical feedback to achieve proper stimulation signal strength.

[0019] As another example, U.S. Publication No. 2021/0001114 to *Wolf, II*, discloses coupling of an optical lead to an IPG header adjacent a ruby passthrough window, vertically aligned with a photo detector. However, *Wolf* fails to disclose a way to recognize or compensate for optical system degradation over time.

[0020] U.S. Publication No. 2018/0154152 to *Chabrol* discloses a system for deep brain stimulation using a probe with stimulation electrodes and a light emitting optical fiber. However, *Chabrol* fails to address using the light signal to control a stimulation signal to the spinal cord. *Chabrol* also fails to recognize optical signal degradation over time or a way to test for resulting losses.

[0021] Deficiencies exist in the prior art related to power usage constraints, heat generation, and maintaining accurate optical feedback over time. Thus, there is a need in the art for an improved IPG including header orientation, connectors, leads and electrodes which provide a stable optical signal while tracking optical signal degradation due to Fresnel reflections and reducing power consumption and heat generation.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] In the detailed description of the preferred embodiments presented below, reference is made to the accompanying drawings.

[0023] Figure 1 is a side view of the human spine showing the approximate position of a percutaneous lead and IPG for spinal cord stimulation.

[0024] Figure 2 shows an axial view of a thoracic vertebra indicating the position of the spinal cord and a percutaneous lead pair.

[0025] Figure 3 shows a sagittal cross-sectional view of the human spine showing the approximate position of a percutaneous lead.

[0026] Figure 4 shows a schematic diagram of an IPG system of a preferred embodiment.

[0027] Figure 5 is an isometric view of a preferred IPG device.

[0028] Figure 6 is an exploded isometric view of a preferred IPG device.

[0029] Figure 7 is an exploded isometric view of a preferred IPG case.

[0030] Figure 8 is an exploded isometric view of a preferred IPG header.

[0031] Figure 9 is an exploded isometric view of a preferred die stack.

[0032] Figure 10 is a partial cross-section view of a preferred header assembly.

[0033] Figure 11 is an isometric view of a lead assembly of a preferred embodiment.

[0034] Figure 12 is a cross-section view of a lead assembly of a preferred embodiment.

[0035] Figure 13 is a flowchart of a preferred control program for operation of the IPG.

[0036] Figure 14 is a flowchart of a preferred method of Fresnel compensation.

[0037] Figure 15 is a flowchart of a preferred method of normalizing source emission.

[0038] Figure 16 is a flowchart of a preferred method of correcting for source power variation.

DETAILED DESCRIPTION OF THE INVENTION

[0039] In the description that follows, like parts are marked throughout the specification and figures for the same numerals. The figures are not necessarily drawn to scale and may be shown in exaggerated or generalized form in the interest of clarity and conciseness. Unless otherwise noted, all tolerances and uses of the term "about" indicate plus or minus 5%.

[0040] Referring then to Figure 4, preferred embodiment of stimulation system **400** will be further described. Stimulation system **400** further comprises IPG **401** in operative communication with controller **450**.

[0041] IPG **401** is housed in hermetically sealed composite case **402**, as will be further described. Composite case **402** houses the operative components of the IPG and serves to anchor leads **422A**, **422B**, **424A** and **424B**, , as will be further described.

[0042] The operative components of the system comprise optical folding assembly **406**, optically aligned with leads **424A** and **424B**. Similarly, the operative components include optical folding assembly **404**, optically aligned with leads **422A** and **422B**. Optical folding assembly **406** sends and receives optical signals from leads **424A** and **424B** to be interpreted by optical signal processor **405**. Likewise, optical folding assembly **404** sends and receives optical signals from leads **422A** and **422B** to be interpreted by optical signal processor **403**. Optical signal processor **405** and optical signal processor **403** are operatively connected to main processor **407**, which controls the functions of the IPG, as will be further described. Main processor **407** is operatively connected to signal generator **409**, which generates electrical stimulation signals which are transmitted through leads **424A**, **424B**, **422A** and **422B** to the spinal cord to targeted nerve populations, as will be further described. Communications circuit **411** is also operatively connected to main processor **407**. Main processor **407** receives programming instructions and control signals from the communications circuit, as will be further described.

[0043] IPG **401** includes battery **415**. Battery **415** is operatively connected to all the electrical components of the system. Battery **415** receives recharging current from induction coil **413**, as will be further described.

[0044] IPG **401** is surgically implanted beneath dermis **430**.

[0045] Controller **450** exists outside dermis **430**. Controller **450** includes main processor **454**, which controls the functions of the controller. Main processor **454** is connected to I/O keyboard and display unit **458**, which is fixed in the exterior casing. Main processor **454** is operatively connected to communications circuit **456**. Communications circuit **456** is wirelessly connected to communications circuit **411**. Main processor **454** includes sufficient memory to receive instructions from I/O keyboard and display unit **458** and transfer them through communications circuit **456** and communications circuit **411** to main processor **407** for controlling the operation of IPG **401**. Main processor **454** is further operatively connected to induction coil **452**. Induction coil **452** is inductively coupled to induction coil **413** which transfers power for the charging of the battery.

[0046] Referring then to Figure 5, IPG **401** will be further described.

[0047] Composite case **402** mechanically supports header assembly **502** and header assembly **504**, which are both positioned on opposite sides of the IPG, parallel to a single lateral axis **550**. Positioning the header assemblies at opposite sides of the case is important because it improves the dispersion of the heat generated by the lasers, as will be further described. Each header assembly preferably is manufactured from a transparent epoxy resin which serves to fix the optical and electrical components in place.

[0048] Header assembly **502** includes optical folding assembly **404**. Optical folding assembly **404** is optically aligned with lead retainer holes **523A** and **523B**. Leads **422A** and **422B** are positioned in and optically aligned by lead retainer holes **523A** and **523B**. Leads **422A** and **422B** are removably secured in the header by virtue of set screws **506A** and **506B**, respectively. The leads abut optical folding assembly **404**, as will be further described.

[0049] Header assembly **502** further comprises tie down portal **512**, for use in securing the IPG to the fascia during surgery.

[0050] Header assembly **504** includes optical folding assembly **406**. Optical folding assembly **406** is optically aligned with lead retainer holes **525A** and **525B**. Leads **424A** and **424B** are positioned in and optically aligned by lead retainer holes **525A** and **525B**. Leads **424A** and **424B** are removably secured in the header by virtue of set screws **508A** and **508B**, respectively. The leads abut optical folding assembly **406**, as will be further described.

[0051] Header assembly **504** further comprises tie down portal **510**, for use in securing the IPG to the fascia during surgery.

[0052] Referring then to Figure 6, IPG **401** will be further described.

[0053] Composite case **402** further comprises header bay **604** and header bay **606**. Each header bay is an angular indention in the composite case. The header bays are generally parallel and diametrically opposed. Header bay **604** houses header assembly **502**. Likewise, header bay **606** houses header assembly **504**.

[0054] Header bay **604** includes rectangular receiving window **618**, and electrical pass-through holes **614**. The receiving window and the electrical pass-through holes allow for connections between header assembly **502** and the internal components of the IPG.

[0055] Likewise, header bay **606** includes rectangular receiving window **620** and electrical pass-through holes **616** for connection of the components of header assembly **504** with the internal components of the IPG.

[0056] Header assembly **502** includes integrally formed positioning block **610**. Positioning block **610** fits within receiving window **618** and optically aligns the header bay with the optical components in the case. Header assembly **504** includes integrally formed positioning block **612**. Positioning block **612** fits within receiving window **620** and optically aligns the header bay with the optical components in the case.

[0057] Composite case **402** including both headers forms an elliptical surface of revolution as described in U.S. Publication No. 2021/0001114 to *Wolf*, incorporated herein by reference.

[0058] Referring to Figure 7, composite case **402** will be further described.

[0059] Composite case **402** includes top section **702** joined to bottom section **704**. Top section **702** is preferably a hollow shell manufactured from a titanium alloy. The titanium alloy is relatively easily machined and can hold tolerances sufficient to allow proper alignment of headers and optical components, as will be further described. Bottom section **704** is preferably a hollow shell comprised of a ceramic material. The ceramic material facilitates radio communication between the communication circuits and inductive coupling between the inductive coils. The combination of a ceramic material with a metallic material for the case is also important because the heat generated from the IPG is directed toward the metallic section of the case. The metallic section of the case may be positioned toward the dermis during surgery, thus allowing the IPG to be positioned for superior heat dispersion while in use.

[0060] Optical window **710** is positioned adjacent top section **702** and centered beneath receiving window **618**. Likewise, optical window **712** is positioned adjacent top section **702** and centered beneath receiving window **620**. Both optical windows are preferably welded and sealed to the underside of the top section.

[0061] Die stack **718** is functionally positioned beneath optical window **710** and adjacent optical signal processor **405**, as will be further described. Die stack **720** is functionally positioned beneath optical window **712** and adjacent optical signal processor **403**, as will be further described.

[0062] Connector card **714** is positioned adjacent top section **702** and directly beneath electrical pass-through holes **614**. Connector card **716** is positioned adjacent top section **702** directly beneath electrical pass-through holes **616**. Connector card **714** and connector card **716** are electrically connected to contacts in the headers and main processor **407**, and allow for transmission of stimulation current to the leads, as will be further described.

[0063] Composite case **402** houses processor card **722**. Processor card **722** structurally and electrically connects main processor **407** to optical signal processors **405** and **403**, signal generator **409** and communications circuit **411**. In a preferred embodiment, main processor **407** is Part No. MSP430, available from Texas Instruments of Dallas, Texas. Signal generator **409** is available under the tradename Saturn, available from Cactus Semiconductor. Communications circuit **411** is preferably Part No. ZL70103, available from Microsemi Corporation of Aliso Viejo, California. Optical signal processors **403** and **405** are both preferably Part No. ADPD4100, available from Analog Devices of Wilmington, Massachusetts.

[0064] Composite case **402** further houses battery **415** which is electrically connected to processor card **722**. The operational components of the IPG are preferably positioned adjacent top section 7**02** and held in place by an epoxy encapsulation. After encapsulation, bottom section **704** is hermetically sealed to top section **702** by weldment **706**.

[0065] Referring then to Figure 8, header assembly **504** will be further described. It should be understood that header assembly **502** is structurally and functionally identical to header assembly **504**, with the exception of the components being in reversed positions. Only header assembly **504** will be described in detail here as an example.

[0066] Header assembly **504** includes header body **800**. Header body **800** preferably is manufactured from a transparent epoxy resin, or acrylic plastic, cast and machined to tolerance. Header body **800** is formed in a semi-ellipsoidal shape, sufficient to fit seamlessly within header bay **606** and comport with the surface of revolution formed by top section **702** and bottom section **704**.

[0067] Header body **800** includes lead retainer holes **525A** and **525B**. Lead retainer hole **525A** includes central optical axis **804**. Lead retainer hole **525B** includes central optical axis **802**. Optical axis **802** and optical axis **804**, preferably, are generally parallel.

[0068] Lead retainer hole **525A** includes metallic toroidal contacts **814**. In a preferred embodiment, eight toroidal contacts are included, each individually addressable by the main processor. Toroidal contacts **814** are each connected to a lead wire **818**. Lead wires **818** are positioned to intersect electrical pass-through holes **616** and be connected to the connector card which further connects them to the main processor. Lead retainer hole **525A** terminates in cavity **808**, adjacent positioning block **612**, as will be further described.

[0069] Lead retainer hole **525B** includes metallic toroidal contacts **812**. In a preferred embodiment, eight toroidal contacts are included, each individually addressable by the main processor. Toroidal contacts **812** are each connected to a lead wire **816**. Lead wires **816** are positioned to intersect electrical pass-through holes **616** and be connected to the connector card which further connects them to the main processor. Lead retainer hole **525B** terminates in cavity **806** adjacent positioning block **612**, as will be further described.

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[0070] Lead retainer hole **525A** includes threaded perpendicular hole **840**. When lead **424A** is positioned within lead retainer hole **525A**, set screw **508A** is positioned in threaded perpendicular hole **840** directly adjacent anchor ring **832** and secures lead **424A** in lead retainer hole **525A**.

[0071] Likewise, lead retainer hole **525B** includes threaded perpendicular hole **838**. Set screw **508B** is positioned within threaded perpendicular hole **838** directly adjacent to lead anchor ring **830**. Set screw **508B** is advanced to contact lead anchor ring **830** and holds lead **424B** in lead retainer hole **525B**.

[0072] Optical folding assembly **406** further comprises parabolic redirector **820** and parabolic redirector **822**. Parabolic redirector **820** includes integral lens **824**. Parabolic redirector **822** includes integral lens **826**. Parabolic redirector **820** and parabolic redirector **822** are rigidly secured in cavity **806** and cavity **808**, respectively, in contact with and adjacent to optical window **712**, as will be further described. In a preferred embodiment, the parabolic redirectors are cast in place in the header. Integral lens **824** is optically aligned with optical axis **802**. Integral lens **826** is optically aligned with optical axis **804**.

[0073] Die stack **720** is positioned directly below and in contact with optical window **712**. Die stack **720** includes vertical cavity surface emitting laser ("VCSEL") **850** and VCSEL **852**, as will be further described. In each case, the VCSELs are capable of emitting light in an intrinsic wavelength range, but preferably in the range of about 400 – 810 nanometers or from blue (about 400 nanometers to about 500 nanometers), to green (about 520 nanometers to about 532 nanometers) to near IR (about 700 nanometers to about 810 nanometers). In a preferred embodiment, each VCSEL is Part No. V00146, available from Vixar, Inc. of Plymouth, Minnesota. Each laser produces about 10 milliwatts in the range of near IR and about 5

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milliwatts in the blue range. Other lasers may be utilized in the wavelength range of about 400 – 580 nanometers (blue, aqua, green and yellow) as well as other visible ranges. VCSEL **850** is positioned to emit light vertically toward the central vertical optical axis of parabolic redirector **820**. Likewise, VCSEL **852** is positioned to emit light vertically toward the central vertical optical axis of parabolic redirector **822**.

[0074] Toroidal contacts **812** are designed to engage and electrically contact rings **860** of lead **424B**, as will be further described. Toroidal contacts **814** are designed to engage and electrically contact rings **862** of lead **424A**, as will be further described.

[0075] Lead **424B** is positioned to align with optical axis **802** by lead retainer hole **525B**. Lead **424A** is positioned to align with optical axis **804** by lead retainer hole **525A**.

[0076] Lead **424B** terminates in collet **880**, as will be further described. Lead **424A** terminates in collet **882**, as will be further described. When assembled, lead **424B** and collet **880** are held adjacent to integral lens **824** by set screw **508B**. Lead **424A** and collet **882** are held adjacent integral lens **826** by set screw **508A**. An index matching gel is provided to minimize Fresnel reflections between the lenses and the leads.

[0077] Referring in to Figure 9, die stack **720** will be further described. It should be understood that die stack **718** and die stack **720** are functionally and structurally identical. Only die stack **720** will be described in detail.

[0078] Die stack **720** includes photodiode package **914**. In a preferred embodiment, photodiode package **914** is Part No. S5980-09(ESI), available from Hamamatsu Photonics K.K. of Shizuoka, Japan.

[0079] The preferred photodiode package has four photodiodes. In one embodiment, all four photodiodes are used as photoreceivers. In another embodiment, two photodiodes **906A**

and **906B** may be used as photoreceivers, one for each lead, and two photodiodes **906C** and **906D**, are used as monitor photodiodes one for each laser. The two monitor photodiodes act as output monitors to normalize the laser emission and correct for source power variations over time, as will be further described.

[0080] Photodiodes **906A**, **906B**, **906C** and **906D** are recessed and fixed in housing **916**. Housing **916** is preferably a ceramic composite. Housing **916** is held in position in the case by epoxy encapsulation and rigidly fixes the position of the photodiodes. Each of the photodiodes typically provides a sensitivity of about 0.72 A/W. Photodiodes **906A**, **906B**, **906C** and **906D** are bounded by electrical contacts **908** and **910**. These contacts are operatively connected to the appropriate optical signal processor by flexible cables (not shown). Cover plate **912** is positioned adjacent to and in contact with the four photodiodes. In a preferred embodiment, cover plate **912** is formed of a crystal glass polished to have optically parallel opposing faces. Cover plate **912** includes gold trace **902** and gold trace **904**. The gold traces are preferably deposited on the glass surface opposite the photodiodes using photolithography or vapor deposition. VCSEL **850** is rigidly fixed to cover plate **912** adjacent to and in electrical contact with gold trace **902**. VCSEL **852** is rigidly fixed to optical window **712** adjacent to and in electrical contact with gold trace **904**. The gold traces provide power to the VCSELs and allow the main processor to select which wavelength laser to activate, as will be further described. Gold trace **902**, gold trace **904**, and contacts **908** and **910** are electrically connected to the appropriate optical signal processor and main processor **407** by flexible cables (not shown).

[0081] Referring then to Figure 10, a partial cross section view of IPG **401**, in use, will be further described. It should be understood that each parabolic redirector, die stack and mating components in the header and lead are structurally and functionally identical, hence only one set will be described here as an example.

[0082] Parabolic redirector **822** is further comprised of parabolic body **1001** and integral lens **826**. Parabolic body **1001** and integral lens **826** are preferably integrally formed from a crystal glass having an index of refraction of between about 1.46 and 1.68, similar to that of silicone resin.

[0083] Parabolic body **1001** includes parabolic surface **1022**. Parabolic surface **1022** is preferably a paraboloid having a curvature designed to produce one focal point at the VCSEL and another focal point at the face of and aligned to the optical axis of the fiber.

[0084] Parabolic surface **1022** includes an exterior reflective coating, preferably vapor deposited silver. In other embodiments, parabolic surface **1022** is coated with a titanium dioxide compound. Preferably, parabolic surface **1022** is also polished.

[0085] Parabolic body **1001** further includes interface surface **1020** adjacent optical window **712**. Interface surface **1020** is flat to within an acceptable optical tolerance. Preferably, an index matching material, such as an epoxy is resident adjacent the surface and the optical window to provide low reflection loss and part stability. In another preferred embodiment, interface surface **1020** may be positioned adjacent optical window **712** with an index matching gel and fixed in place with a suitable epoxy adhesive.

[0086] Parabolic redirector **822** is further comprised of integral lens **826**. Integral lens **826** is a collimating lens and includes convex lens surface **1014** which is directed inward toward parabolic surface **1022**. In one preferred embodiment, convex lens surface **1014** is fixed to parabolic body **1001** by a suitable index matching epoxy. In another preferred embodiment, the parabolic body and the integral lens are integrally formed. In this case, the convex lens surface is created by an appropriate density change between integral lens **826** and parabolic body

1001. Integral lens **826** includes interface surface **1024** adjacent fiber **1002**. Interface surface **1024** is preferably ground flat within appropriate optical tolerances.

[0087] Header body **800** includes frustroconical receiver surface **1050** at the proximal end of lead retainer hole **525A**. Interface surface **1024** is positioned parallel to and against fiber **1002** of lead **424A** at optical interface **1012** and held in place by the interference between collet **882** and frustroconical receiver surface **1050** of lead retainer hole **525A**.

[0088] Positioning block **612** forms an extension of the header body and serves to position the parabolic redirector. The position block is positioned within receiving window **620** of top section **702**. The interface between receiving window **620** and positioning block **612** fixes the vertical optical axis of the parabolic redirector above VCSEL **852** and in position to reflect light from parabolic surface **1022** to optical axis **804** of fiber **1002** of lead **424A**.

[0089] In use, VCSEL **852** produces laser light pulses **1004** which proceed vertically upward toward parabolic surface **1022**. The parabolic surface reflects the light about 90 degrees from vertically upward to horizontal and aligns the light through the integral lens and into fiber **1002**, along optical axis **804**, exiting the fiber at its distal end toward the spinal cord. In all cases, the pulses from the VCSELs will be specularly reflected from the spinal cord, given its high multispectral albedo. However, blue, aqua, green or yellow pulses will be preferentially absorbed by surrounding tissues and by any hemoglobin, if present, while in the case of IR, the pulses will be preferentially reflected from these tissues. Upon reflecting from the spinal cord, receive rays **1006** are collected and retransmitted through fiber **1002** back to the parabolic redirector. Receive rays **1006** are not well aligned along the fiber and so impact integral lens **826** at various angles. Receive rays **1006** are expanded by convex lens surface **1014** where they are incident upon parabolic surface **1022**, where they are collected and directed about 90 degrees

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from horizontal to vertically downward, toward optical window **712**. Receive rays **1006** pass through optical window **712** and are incident on cover plate **912** where they are directed toward photodiodes **906B** and **906D**.

[0090] When VCSEL **852** is in operation, some small percentage of light pulses **1004** are back reflected from optical window **712**. These back reflected pulses **1075** are incident immediately on cover plate **912**, where they are transmitted to photodiode **906D**. The back reflected pulses are converted to signals by the photodiode that are used by the main processor to normalize the power output of the VCSEL and correct for source power variation, as will be further described.

[0091] Photodiodes **906B** and **906D** convert receive rays **1006** into electrical signals which are communicated to optical signal processor **405** for further processing, as will be further described.

[0092] Referring then to Figures 11 and 12, lead **424A** will be further described. Lead **424A**, lead **424B**, lead **422A** and lead **422B** are identical in structure and function. Only one will be described here, by way of example.

[0093] Lead **424A** further comprises lead body **1101**. Lead body **1101** is generally a flexible cylindrical extrusion distally terminated by transmission tip **1109** and proximally terminated by collet **882**. In a preferred embodiment, the lead body is comprised of a flexible polymer, such as Pellethane 55D or similar biocompatible material. The lead body is preferably a multi-lumen extrusion having embedded and integrally formed components, as will be further described.

[0094] Transmission tip **1109** is an optically transparent cylinder fused to the distal terminus of the lead body. In a preferred embodiment, the transmission tip is a suitable optically

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transparent material such as a thermoplastic polyurethane. Transmission tip **1109** is terminated by semi-spherical cap **1111**. In a preferred embodiment, semi-spherical cap **1111** and transmission tip **1109** are integrally formed. Transmission tip **1109** further includes embedded radiopaque marker **1152**. Radiopaque marker **1152** is preferably titanium cylinder axially embedded adjacent semi-spherical cap **1111**.

[0095] Fiber **1002** is positioned along the central optical axis of lead **424A** and extends from collet **882** to concave lexicon **1150**. The transmission tip is fused to fiber **1002**. Fiber **1002** includes concave lexicon **1150** at its distal end. In a preferred embodiment, concave lexicon **1150** includes internally reflective coating such as titanium dioxide. Transmission tip **1109** further includes stylet channel terminus **1151**. In a preferred embodiment, stylet channel terminus **1151** is a cylindrical opening. Stylet stop **1154** is positioned at the distal end of stylet channel terminus **1151**. Stylet stop **1154** is preferably a titanium cylinder.

[0096] Stylet channel **1105** is coaxial with and extends from stylet channel terminus **1151** to stylet channel opening **1153**, in collet **882**. The stylet channel is a cylindrical cavity which runs parallel with the optical fiber and serves the purpose of housing a guide stylet for use during placement of the lead during surgery. In preferred embodiment, stylet channel **1105** is lined with a polytetrafluoroethylene (PTFE) lining **1107**, which extends the length of the lead body. The low surface friction afforded by the lining facilitates insertion of the stylet during surgery.

[0097] Lead body **1101** further supports metallic anchor **1110** positioned at its proximal end. The metallic anchor is generally cylindrical and is permanently affixed to the exterior of the lead body.

[0098] Adjacent metallic anchor **1110**, are eight cylindrical proximal metallic contacts, **1108A**, **1108B**, **1108C**, **1108D**, **1108E**, **1108F**, **1108G**, and **1108H** are fixed to the exterior of the lead body at even axial distances and are positioned to electrically contact the toroidal contacts in the header assembly.

[0099] Likewise, eight cylindrical metallic electrodes **1106A**, **1106B**, **1106C**, **1106D**, **1106E**, **1106F**, **1106G**, and **1106H** are fixed to the distal end of the lead body. The metallic electrodes are each permanently fixed to the exterior surface of the lead body, at equal axial distances.

[0100] The lead body further comprises eight radially oriented lumens, **1131A**, **1131B**, **1131C**, **1131D**, **1131E**, **1131F**, **1131G**, and **1131H**. Conductors **1120A**, **1120B**, **1120C**, **1120D**, **1120E**, **1120F**, **1120G** and **1120H** are integrally formed in the lumens and extend from their respective proximal contacts to their respective distal electrodes. In a preferred embodiment, the conductors are comprised of MP35N, or another conductive material similarly resistant to corrosion. Each of the conductors to connect exactly one proximal contact with exactly one paired metallic electrode.

[0101] In a preferred embodiment, fiber **1002** and the conductors are integrally formed into the lead body during manufacture.

[0102] In a preferred embodiment, collet **882** is formed from a suitable ceramic or crystal sapphire material. Collet **882** includes frustoconical surface **1170** at its proximal end. The frustoconical surface mates with an identical frustoconical receiver surface **1050** in header body **800** and aids in positioning fiber **1002** against optical interface **1012**, and in radially compressing the fiber to aid in optical alignment with the parabolic redirector.

[0103] Referring to Figure 13, method of IPG operation **1300** will be further described. In preferred embodiment, the method is carried out by programming instructions, which are resident in onboard memory of main processor **407**.

[0104] At step **1302**, the method begins.

[0105] At step **1304**, the main processor sets an initial channel for operation. In a preferred embodiment, an initial channel includes one of the group of four leads **422A**, **422B**, **424A** and **424B**. In other preferred embodiments, the initial channel includes one of the group of only two or three of the leads.

[0106] In each case, the main processor addresses only eight electrodes on one lead at any one time. Each of the eight electrodes on the lead selected may be individually addressed by the main processor with a different current level for the stimulation signal.

[0107] At step **1306**, main processor **407** activates the VCSEL for the specified channel. Preferably, the VCSEL produces a light pulse in the IR wavelength range. A small percentage of the light pulse is immediately back reflected by the optical window. The majority of the light pulse is sent to the base of the parabolic redirector where it passes to the parabolic surface which turns the light about 90 degrees from vertical to the horizontal and focuses it along the optical axis of the optical fiber for the chosen lead where it traverses the lead and exits from the concave lexicon through the transmission tip. The transmitted ray then is incident on the spinal cord, hemoglobin and other surrounding tissues, where it is reflected and received by the fiber at the concave lexicon. The received ray is transmitted down the fiber returning to the parabolic redirector where it is turned about 90 degrees, from the horizontal to vertically downward, and focused on the die stack.

[0108] At step **1307**, main processor **407** uses the back reflected pulse to normalize the source emission, as will be further described.

[0109] At step **1308**, the main processor uses the back reflected pulse to correct for power variation over time, will be further described.

[0110] At step **1309**, the main processor polls the photodiode to obtain a feedback signal.

[0111] At step **1310**, the main processor calculates a stimulation signal based on the signal from the photodiode. The stimulation signal is preferably generated according to a table, accurately disclosed in U.S. Patent No. 9,550,063 to *Wolf II*, incorporated herein by reference. Of course, other stimulation routines may be used.

[0112] At step **1312**, the main processor modifies the stimulation signal to compensate for the reduced optical feedback, according to the reflection compensation value, as will be further described.

[0113] At step **1313**, the main processor activates the signal generator to send the compensated stimulation signal to the toroidal contacts for the lead for the chosen channel. The compensated stimulation signal is transmitted to the electrodes, which creates an electric field adjacent the target neurons at the spinal cord.

[0114] At step **1314**, the main processor polls the communication circuit for a shutdown signal.

[0115] At step **1316**, the main processor determines whether or not a shutdown signal is present. If not, the main processor moves to step **1320**. If so, the main processor moves to step **1318**.

[0116] At step **1320**, the main processor advances to the next lead channel in the group of leads and returns to step **1306**.

[0117] At step **1318**, the main processor shuts down the routine and returns to a holding state.

[0118] Referring then to Figure 14, a preferred method of deriving a compensated stimulation current value of step **1312**, will be further described.

[0119] At step **1402**, the method begins.

[0120] At step **1404**, the main processor activates the VCSEL to generate a second light pulse. Preferably, the VCSEL produces a light pulse in the blue wavelength range. However, other wavelengths may be used to long as they are a different wavelength than the first pulse. The blue laser signal proceeds through the parabolic redirector where it enters the fiber and is transmitted to the concave lexicon at the transmission tip. However, the blue light is preferentially absorbed by the surrounding tissues and hemoglobin. Most or all of the blue signal is absorbed by these tissues. As a result, the blue signal reflected is due primarily to Fresnel reflections in the optical system. Hence, the reflected blue signal represents optical system signal loss between the blue signal origination at the VCSEL and the blue signal reception at the photoreceiver. By monitoring the blue light reflections periodically, the optical system signal loss and increase in system noise over time can be recognized.

[0121] The optical system signal loss and noise are the same for each light signal regardless of wavelength. Hence, the optical signal system loss for the IR signal pulse will be the same as the optical signal system loss for the blue signal pulse. The preferred electro-optical controller generally increases stimulation current when the optical signal is decreased in intensity, based on the assumption that the spinal cord is farther away from the electrodes. So, as the optical losses in the system increase, the controller gradually increases the stimulation current. By decreasing the stimulation current by the same percentage that the optical losses increase, the optical degradation and Fresnel loss in the system can be compensated for, thereby providing the correct stimulation signal.

[0122] At step **1406**, the return blue laser signal is measured by the photodiode which returns a current value to the main processor.

[0123] At step **1408**, the main processor preferably calculates the percentage signal loss in the blue optical signal, known as the reflection compensation value, according to the following equation.

$$RCV = \frac{I_t - I_r}{I_t} \times 100$$

Where:

RCV = percentage optical signal loss;

I_t = the transmitted optical signal current to the VCSEL; and,

I_r = the received optical signal current from the photodiode.

[0124] At step **1410**, the stimulation current value, "I_{stim}", is retrieved. I_{stim} is the current value calculated by the processor according to the correlation table between the return optical signal and the stimulation current, as previously described.

[0125] At step **1412**, the stimulation current correction value, "I_{new}", is preferably calculated according to the following equations.

$$RCV \times I_{stim} = I_{new}$$

Where:

I_{stim} = calculated stimulation current;

RCV = percentage optical signal loss; and

I_{new}= compensated stimulation current value.

[0126] At step **1414**, the main processor returns the I_{new} value.

[0127] At step **1416**, the method concludes.

[0128] Referring then to Figure 15, a preferred method of normalizing source emission of step **1307** will be further described. The method is the same for each die stack.

[0129] At step **1502**, the method begins.

[0130] At step **1504**, main processor **407** retrieves from memory the output of monitor photodiode one. In this example, photodiode one is photodiode **906C** adjacent VCSEL **850**.

[0131] At step **1506**, the main processor reads the output value of monitor photodiode two. In this example, photodiode two is photodiode **906D** adjacent VCSEL **852**.

[0132] At step **1508**, the main processor compares the output of monitor photodiode one and the output of monitor photodiode two. If the output of photodiode one is greater than the output of photodiode two, then the method moves to step **1512**. If not, the method moves to step **1514**.

[0133] At step **1512**, the difference between the output of photodiode one and the output of photodiode two is calculated by subtracting the output of photodiode two from the output of photodiode one.

[0134] At step **1513**, the drive current to photodiode one is reduced by the difference.

[0135] At step **1514**, the output of photodiode two is compared to the output of photodiode one. If the output of photodiode two is greater than the output of photodiode one, then the method moves to step **1515**. If not, the method moves to step **1518**.

[0136] At step **1515**, the difference between the output of photodiode two and the output of photodiode one is calculated by subtracting the output of photodiode one from the output of photodiode two.

[0137] At step **1516**, the drive current to photodiode two is reduced by the difference.

[0138] At step **1518**, the method returns the normalized power levels for photodiode one and photodiode two.

[0139] At step **1520**, the method ends.

[0140] In a preferred embodiment, the differences are calculated as percentages which can be directly applied to the photodiode current to normalize the source of emission.

[0141] In one preferred embodiment, method **1307** is applied between the two VCSELs in one photodiode stack, such as VCSEL **850** and VCSEL **852**. However, in other embodiments, normalization may take place over all four VCSELs in the system, so that each produces the same level of source emission.

[0142] Referring then to Figure 16, a preferred method of correcting for source power variation of step **1308** will be further described.

[0143] At step **1602**, the method begins. Ideally, the method takes place only periodically, such as once a week, so as to conserve system power usage.

[0144] At step **1604**, the main processor retrieves the initial power output level of the VCSEL from memory. Preferably, the initial power output level is measured by measuring the current from the monitor photodiode adjacent the VCSEL when the VCSEL is initially activated during system startup.

[0145] At step **1606**, the main processor activates the chosen VCSEL.

[0146] At step **1608**, the main processor polls the monitor photodiode for the chosen VCSEL.

[0147] At step **1610**, the main processor stores the monitor photodiode power level.

[0148] At step **1612**, the main processor derives a difference between the monitor photodiode power level and the initial monitor photodiode power level. According to the following equation:

$$PL_I - PL_m = \Delta$$

Where:

Δ = the difference;

PL_I = the initial power level; and

PL_m = the measured power level.

[0149] At step **1614**, the difference is stored as a percentage according to the following equation:

$$PL_{DIFF} = \frac{PL_I - PL_m}{100}$$

Where:

PL_{DIFF} = the percentage power level difference;

PL_I = the initial power level; and

PL_m = the measured power level.

[0150] At step **1616**, the corrected power level is calculated according to the following equation:

$$I_1 \times PL_{DIFF} = I_2$$

Where:

I_1 = the initial current level;

PL_{DIFF} = the percentage difference; and

I_2 = the new power level.

[0151] At step **1618**, the main processor returns the new power level.

[0152] At step **1620**, the method concludes.

CLAIMS:

1. An implantable pulse generator system comprising:

a case;

a lead retainer hole, longitudinally positioned in the case, having an optical axis;

a parabolic redirector, having a first interface surface perpendicular to a second interface surface connected by a parabolic surface, focused on the optical axis;

a die stack, adjacent the parabolic redirector, perpendicular to the optical axis and parallel to the second interface surface;

a laser, fixed on the die stack, directed vertically toward to the second interface surface;

a photo receiver, positioned around the laser and parallel to the second interface surface; and

a processor, having a memory, operatively connected to the laser and the photo receiver.

2. The implantable pulse generator system of claim 1, wherein the laser is a VCSEL.

3. The implantable pulse generator system of claim 1, wherein the parabolic redirector includes a collimating lens centered on the optical axis.

4. The implantable pulse generator system of claim 1, wherein the laser is fixed on the die stack by an optical window.

5. The implantable pulse generator system of claim 4, wherein the laser is electrically connected to the processor by a metallic trace, fixed on the optical window.

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6. The implantable pulse generator system of claim 1, wherein the case further comprises:

a metallic first section forming a header bay;

a header, containing the lead retainer hole, fixed in the header bay; and

a ceramic second section, hermetically sealed to the metallic first section.

7. The implantable pulse generator system of claim 1, further comprising:

a set of toroidal electrical contacts, fixed in the lead retainer hole, axially aligned with the optical axis.

8. The implantable pulse generator system of claim 7, further comprising:

a flexible lead, fixed in the lead retainer hole;

a centrally disposed optical fiber, integrally formed in the flexible lead, coaxial with the optical axis;

a set of cylindrical contacts, fixed on an exterior surface of the flexible lead, electrically connected to the set of toroidal electrical contacts; and

a set of cylindrical electrodes, fixed on the exterior surface of the flexible lead, electrically connected to the set of cylindrical contacts.

9. The implantable pulse generator system of claim 8, wherein the flexible lead further comprises:

a longitudinal stylet lumen, radially disposed adjacent and parallel to the centrally disposed optical fiber.

10. The implantable pulse generator system of claim 9, wherein the longitudinal stylet lumen

terminates distally in a stylet stop.

11. The implantable pulse generator system of claim 9, wherein the flexible lead further comprises:

a transparent optical transmission tip, integrally formed with the centrally disposed optical fiber.

12. The implantable pulse generator system of claim 11, wherein the transparent optical transmission tip further comprises a centrally disposed radiopaque marker.

13. The implantable pulse generator system of claim 8, further comprising:

a set of instructions, resident in the memory, that when executed cause the implantable pulse generator system to:

generate a first transmit ray, at a first wavelength, from the laser;

send the first transmit ray through the parabolic redirector down the centrally disposed optical fiber;

receive a first receive ray, from the centrally disposed optical fiber, through the parabolic redirector, incident on the photo receiver;

generate a variation variable from the first receive ray;

create a modulated stimulation signal based on the variation variable; and

send the modulated stimulation signal to the set of cylindrical electrodes.

14. The implantable pulse generator system of claim 13, wherein the set of instructions comprises further instructions, resident in the memory, that when executed cause the implantable

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pulse generator system to:

generate a second transmit ray, of a second wavelength, from the laser;

send the second transmit ray through the parabolic redirector down the centrally disposed optical fiber;

receive a second receive ray, from the centrally disposed optical fiber, through the parabolic redirector incident on the photo receiver;

generate a compensation value from the second receive ray; and

alter the modulated stimulation signal based on the compensation value.

15. An implantable pulse generator system comprising:

a case;

a first header bay, formed in the case;

a second header bay, diametrically disposed to the first header bay, formed in the case;

a first header assembly, fixed in the first header bay, having a first lead retainer channel and a second lead retainer channel;

a second header assembly, fixed in the second header bay, having a third lead retainer channel and a fourth lead retainer channel;

a first electro-optical lead, having a first optical axis, positioned in the first lead retainer channel;

a second electro-optical lead, having a second optical axis, positioned in the second lead retainer channel;

a third electro-optical lead, having a third optical axis, positioned in the third lead retainer channel;

a fourth electro-optical lead, having a fourth optical axis, positioned in the fourth lead retainer channel;

a first parabolic redirector, centered on the first optical axis, optically coupled to the first electro-optical lead;

a second parabolic redirector, centered on the second optical axis, optically coupled to the second electro-optical lead;

a third parabolic redirector, centered on the third optical axis, optically coupled to the third electro-optical lead;

a fourth parabolic redirector, centered on the fourth optical axis, optically coupled to the fourth electro-optical lead;

a first die stack, having a first perpendicularly oriented laser, surrounded by a first photodiode, optically coupled to the first parabolic redirector;

the first die stack, having a second perpendicularly oriented laser, surrounded by a second photodiode, optically coupled to the second parabolic redirector;

a second die stack, having a third perpendicularly oriented laser, surrounded by a third photodiode, optically coupled to the third parabolic redirector; and

the second die stack, having a fourth perpendicularly oriented laser, surrounded by a fourth photodiode, optically coupled to the fourth parabolic redirector.

16. The implantable pulse generator system of claim 15 wherein the first electro-optical lead further comprises:

an optical fiber, positioned coaxially with the first optical axis;

a set of electrical contacts, fixed on a proximal surface of the first electro-optical lead; and

a set of electrodes, fixed on a distal surface of the first electro-optical lead, electrically

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connected to the set of electrical contacts.

17. The implantable pulse generator system of claim 16, wherein the first header bay further comprises:

a set of fixed contacts, rigidly positioned in the first lead retainer channel, and operatively connected to an electro-optical signal generator;

wherein the electro-optical signal generator is programmed to:

send a first transmit ray, of a first wavelength, from the first perpendicularly oriented laser into the first parabolic redirector and the optical fiber;

receive a first return signal from the first photodiode, based on a first receive ray;

generate a stimulation signal based on the first return signal; and

send the stimulation signal to the set of fixed contacts, for transmission to the set of electrodes.

18. The implantable pulse generator system of claim 17, wherein the electro-optical signal generator is further programmed to:

send a second transmit ray, of a second wavelength, from the first perpendicularly oriented laser into the first parabolic redirector and the first electro-optical lead;

receive a second receive ray at the first photodiode;

generate a compensation value from the second receive ray; and

modify the stimulation signal based on the compensation value.

19. The implantable pulse generator system of claim 17, wherein:

the first die stack further comprises a second photodiode;

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wherein the electro-optical signal generator is further programmed to:

normalize a first supply current to the first photodiode and a second supply current to the second photodiode.

20. The implantable pulse generator system of claim 19, wherein the step of normalizing further comprises:

reducing the first supply current if the first supply current is greater than the second supply current; and

reducing the second supply current if the second supply current is greater than the first supply current.

21. The implantable pulse generator system of claim 19, wherein the electro-optical signal generator is further programmed to:

correct for a time based variation in the first supply current.

22. The implantable pulse generator system of claim 21, wherein the step of correcting further comprises:

deriving a difference between an initial supply current to the first photodiode and the first supply current.

23. The implantable pulse generator system of claim 18, wherein:

the first wavelength is between about 700 nanometer and about 800 nanometers; and

the second wavelength is between about 400 nanometers and about 500 nanometers.

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24. The implantable pulse generator system of claim 18, wherein:

the first wavelength is between about 700 nanometer and about 800 nanometers; and

the second wavelength is between about 520 nanometers and about 532 nanometers.

25. The implantable pulse generator system of claim 15, wherein the first parabolic redirector further comprises:

a collimating lens centered on the first optical axis; and

a parabolic surface, for reflecting a transmit ray toward the first electro-optical lead and a receive ray toward the first photodiode.

26. The implantable pulse generator system of claim 25, wherein the parabolic surface includes a reflective coating.

27. The implantable pulse generator system of claim 15, further comprising:

a transparent cover plate, between the first perpendicularly oriented laser and the first die stack, positioning the first perpendicularly oriented laser adjacent the first parabolic redirector.

28. The implantable pulse generator system of claim 27, further comprising:

a window, sealed to the case, between the first perpendicularly oriented laser and the first parabolic redirector.

29. A pulse generator lead comprising:

a flexible lead body;

a centrally disposed optical fiber, integrally formed in the flexible lead body, coaxial with an optical axis;

a set of cylindrical contacts, fixed on an exterior surface of the flexible lead body, electrically connected to a set of toroidal electrical contacts;

a set of cylindrical electrodes, fixed on the exterior surface of the flexible lead body, electrically connected to the set of cylindrical contacts, by a set of wires integrally formed in the flexible lead body; and

a longitudinal stylet lumen, radially disposed adjacent and parallel to the centrally disposed optical fiber.

30. The pulse generator lead of claim 29, wherein the longitudinal stylet lumen terminates distally in a stylet stop cylinder.

31. The pulse generator lead of claim 30, further comprising:

a transparent optical transmission tip, integrally formed with the centrally disposed optical fiber.

32. The pulse generator lead of claim 31, wherein the transparent optical transmission tip further comprises a centrally disposed radiopaque marker.

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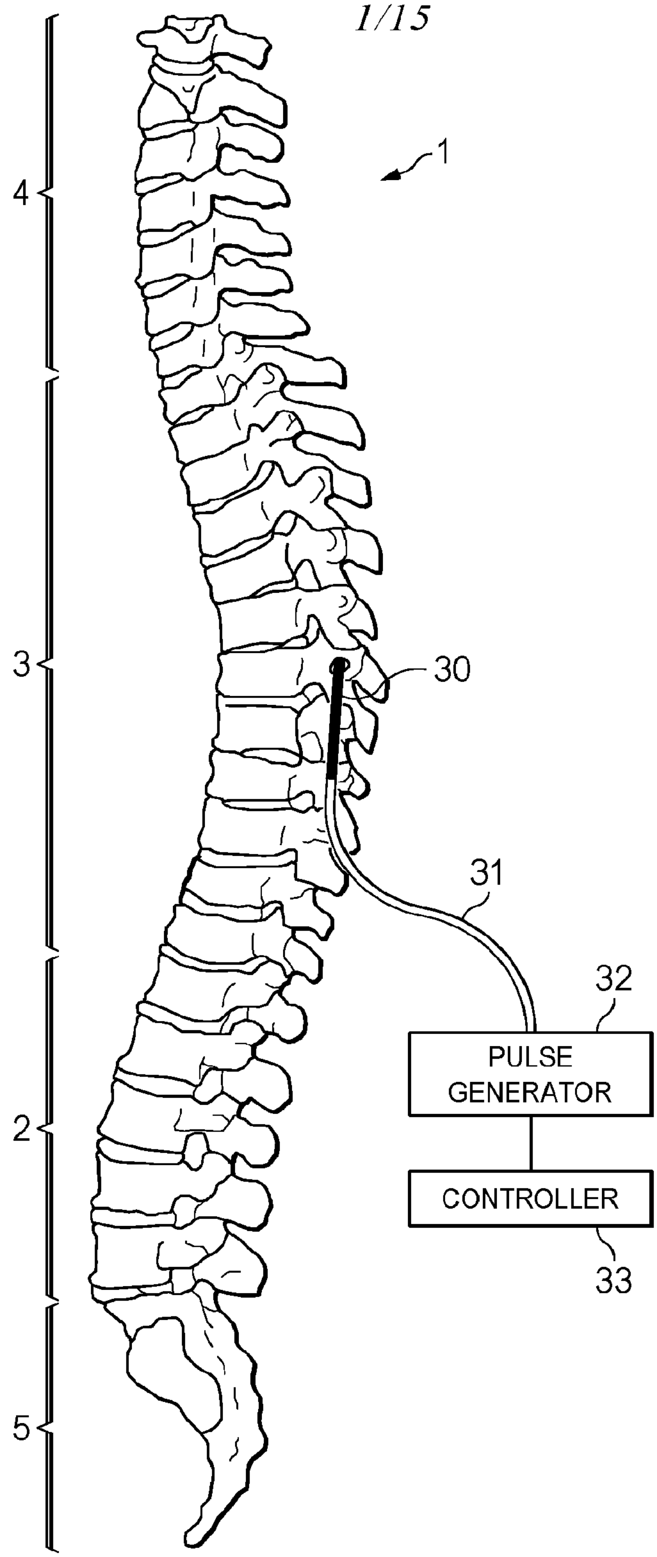


FIG. 1
(PRIOR ART)

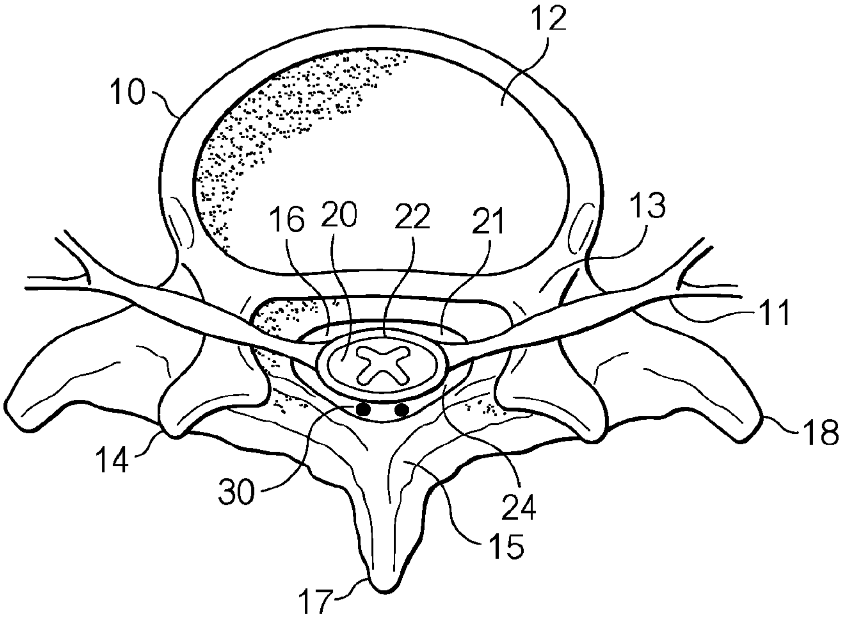


FIG. 2
(PRIOR ART)

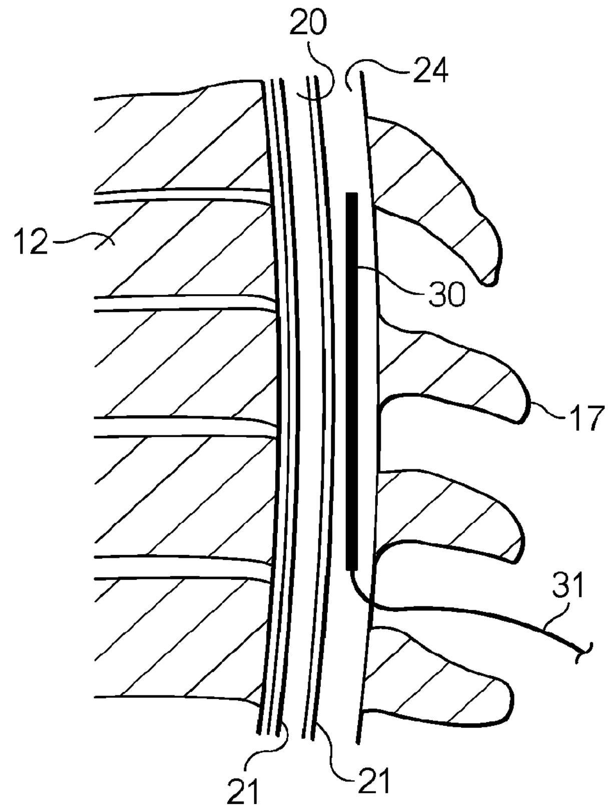


FIG. 3
(PRIOR ART)

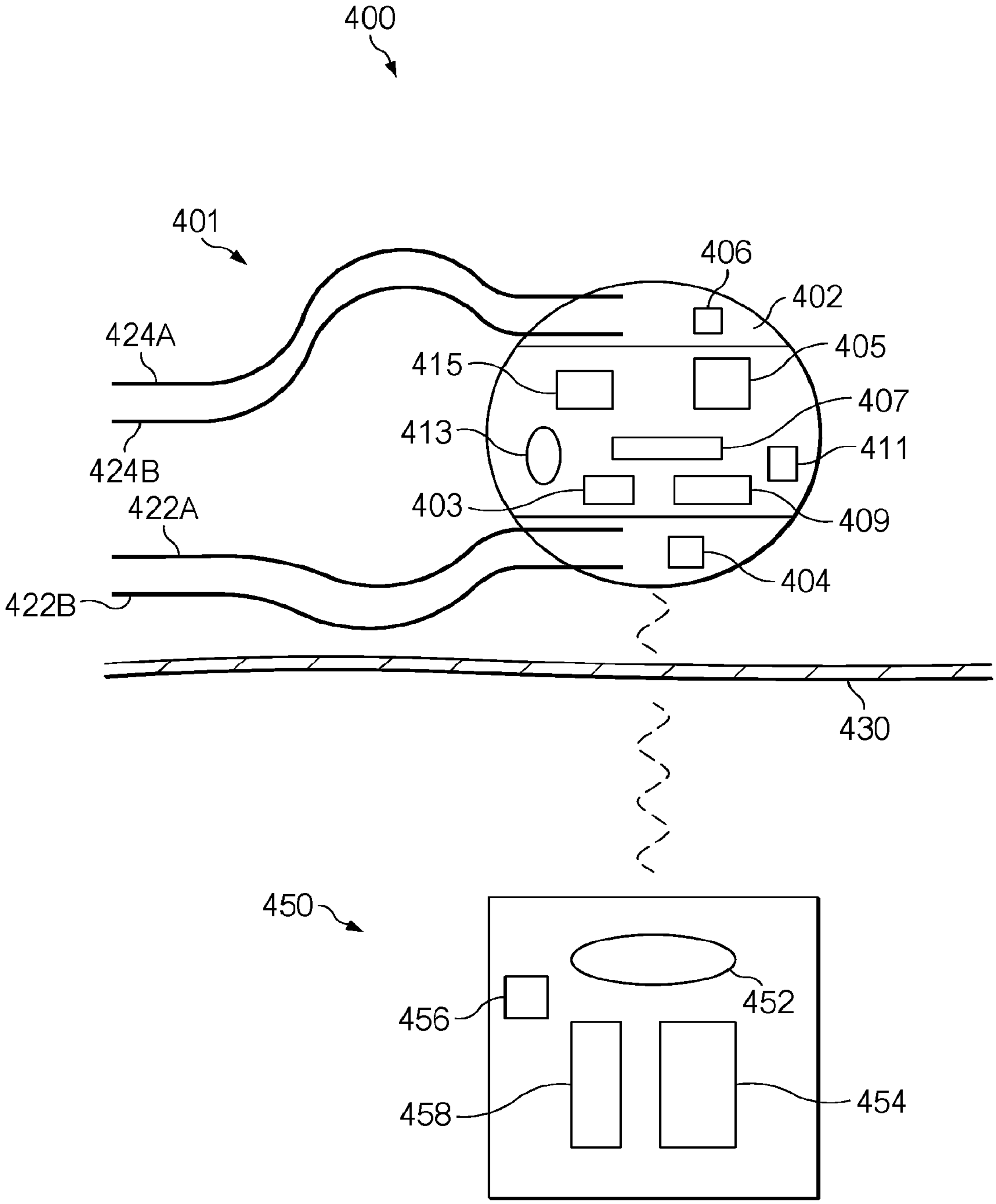
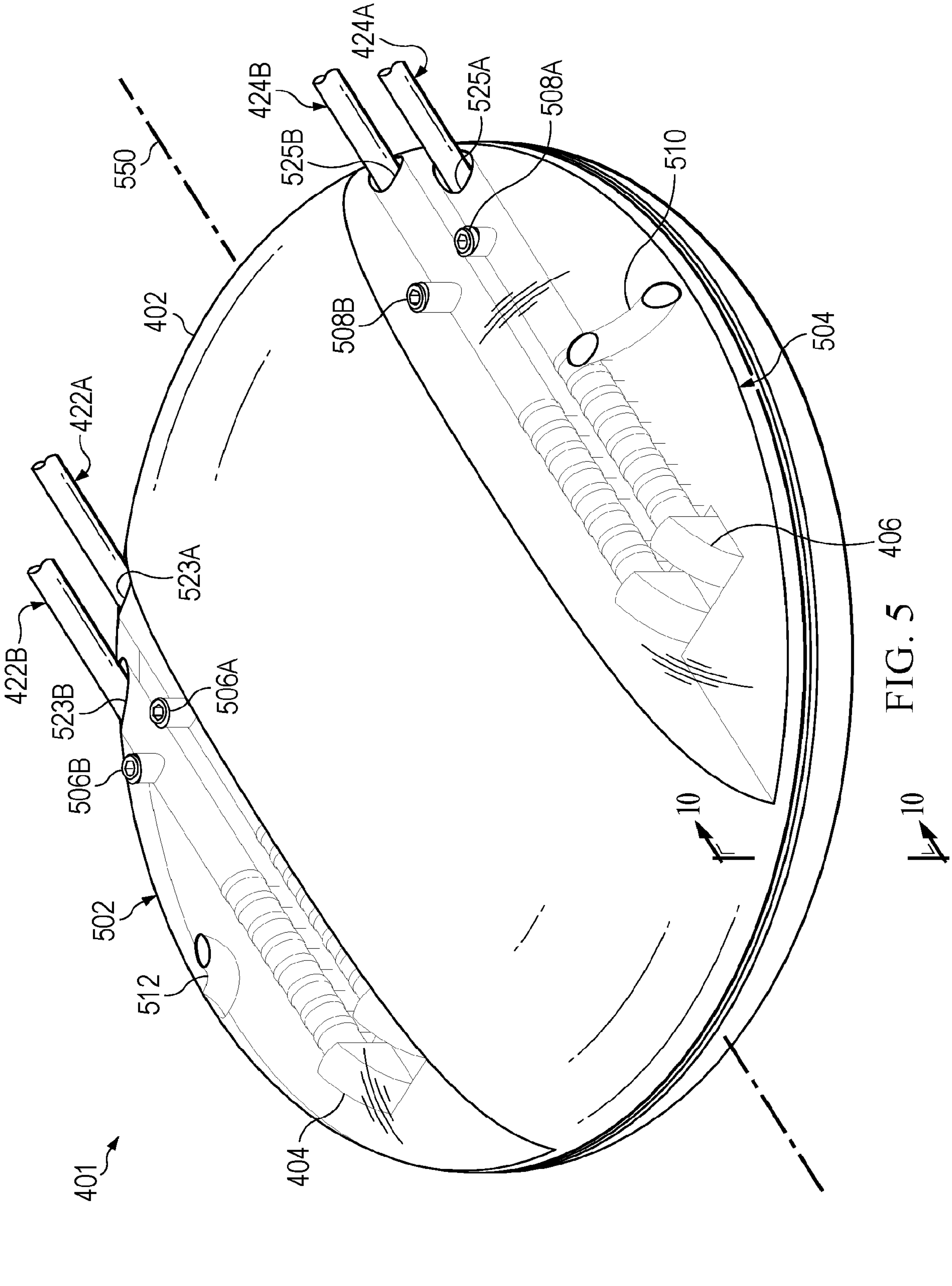

400
401
406
402
424A
405
415
407
413
411
424B
422A
403
409
404
422B
430
450
452
456
458
454

FIG. 4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424B
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525B
550
510
402
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422A
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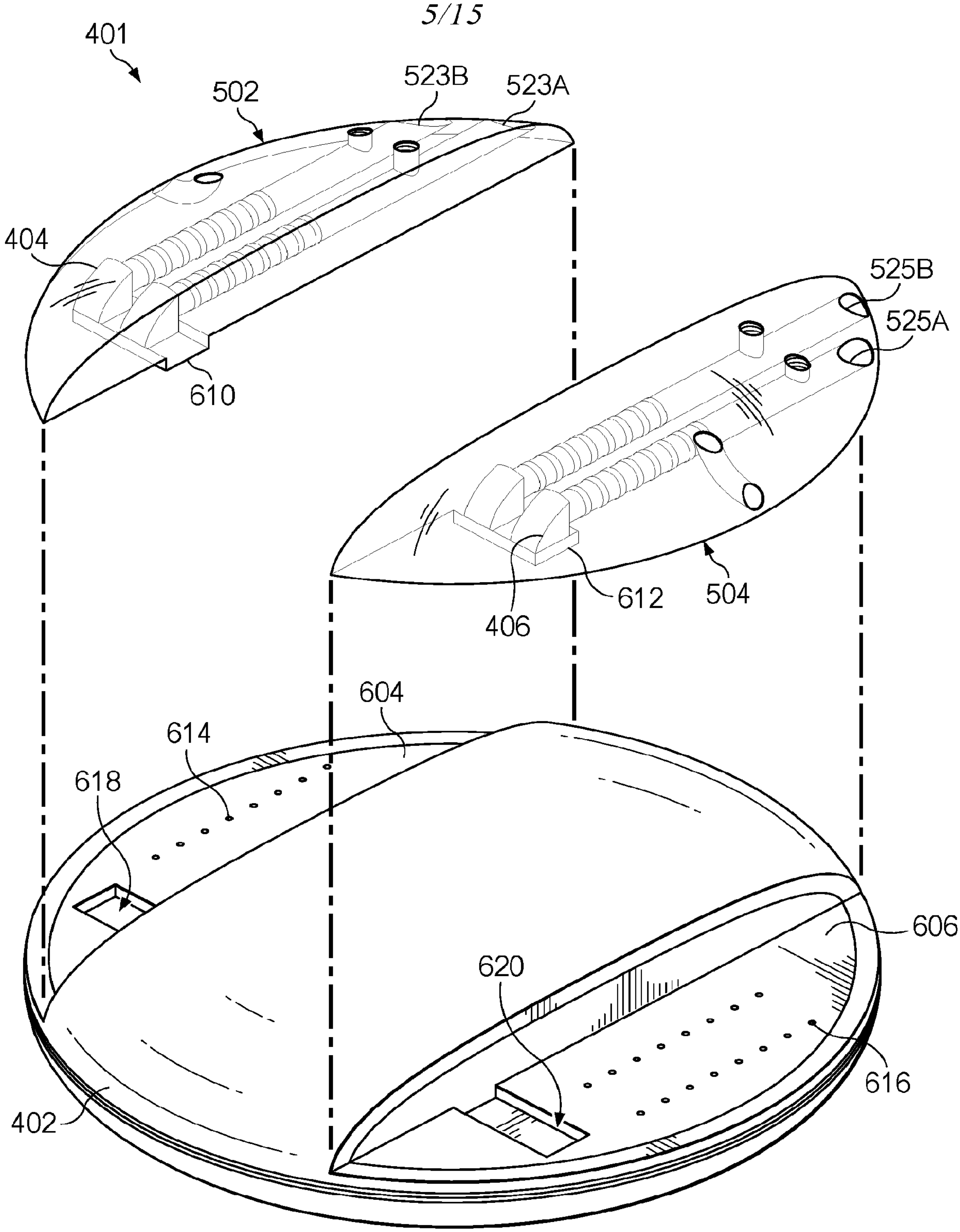
523A
422B
506A
523B
506B
10
10
502
512
404
401

FIG. 5


401
502
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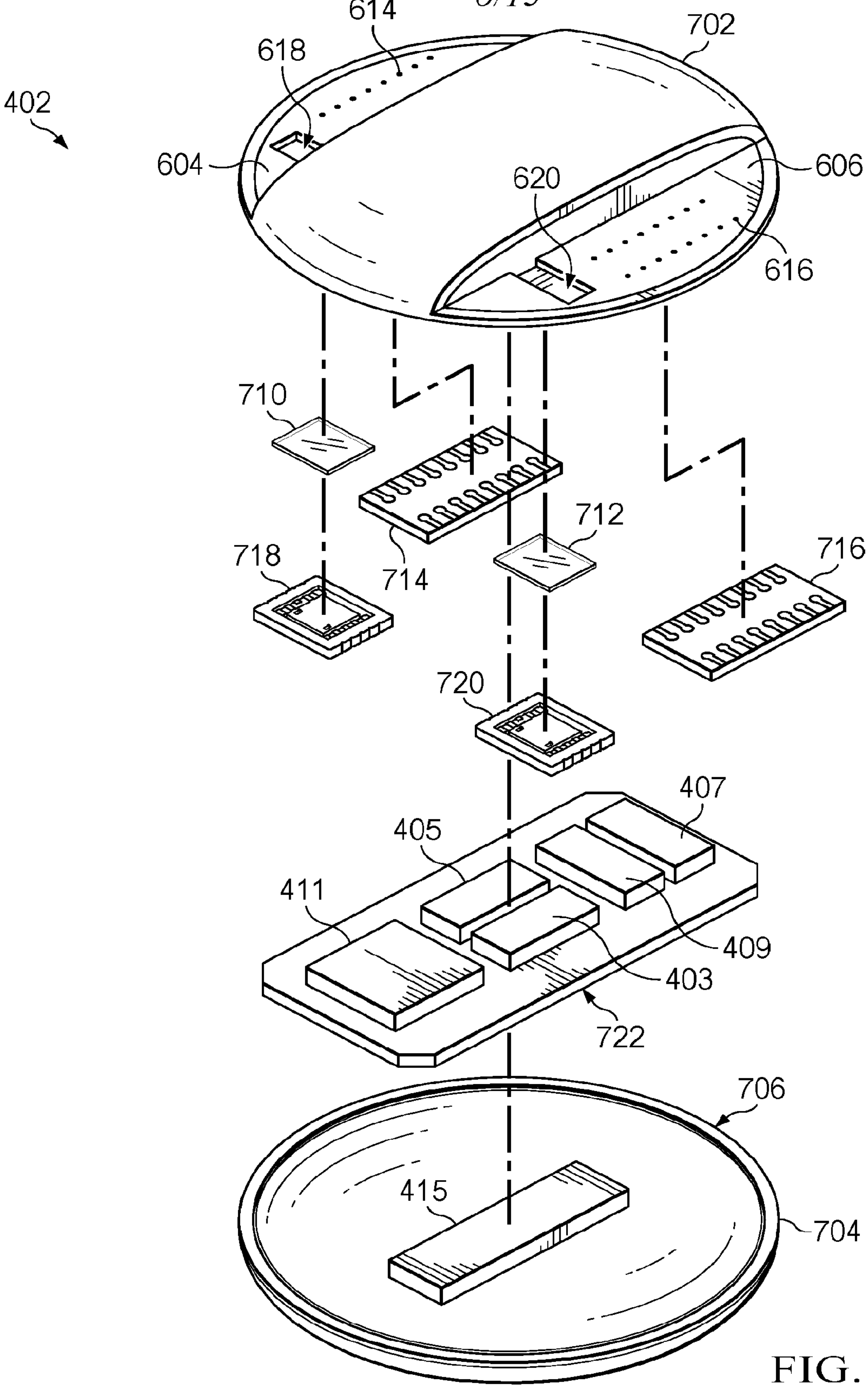
404
610
525B
525A
406
612
504
604
614
618
606
620
616
402

FIG. 6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618
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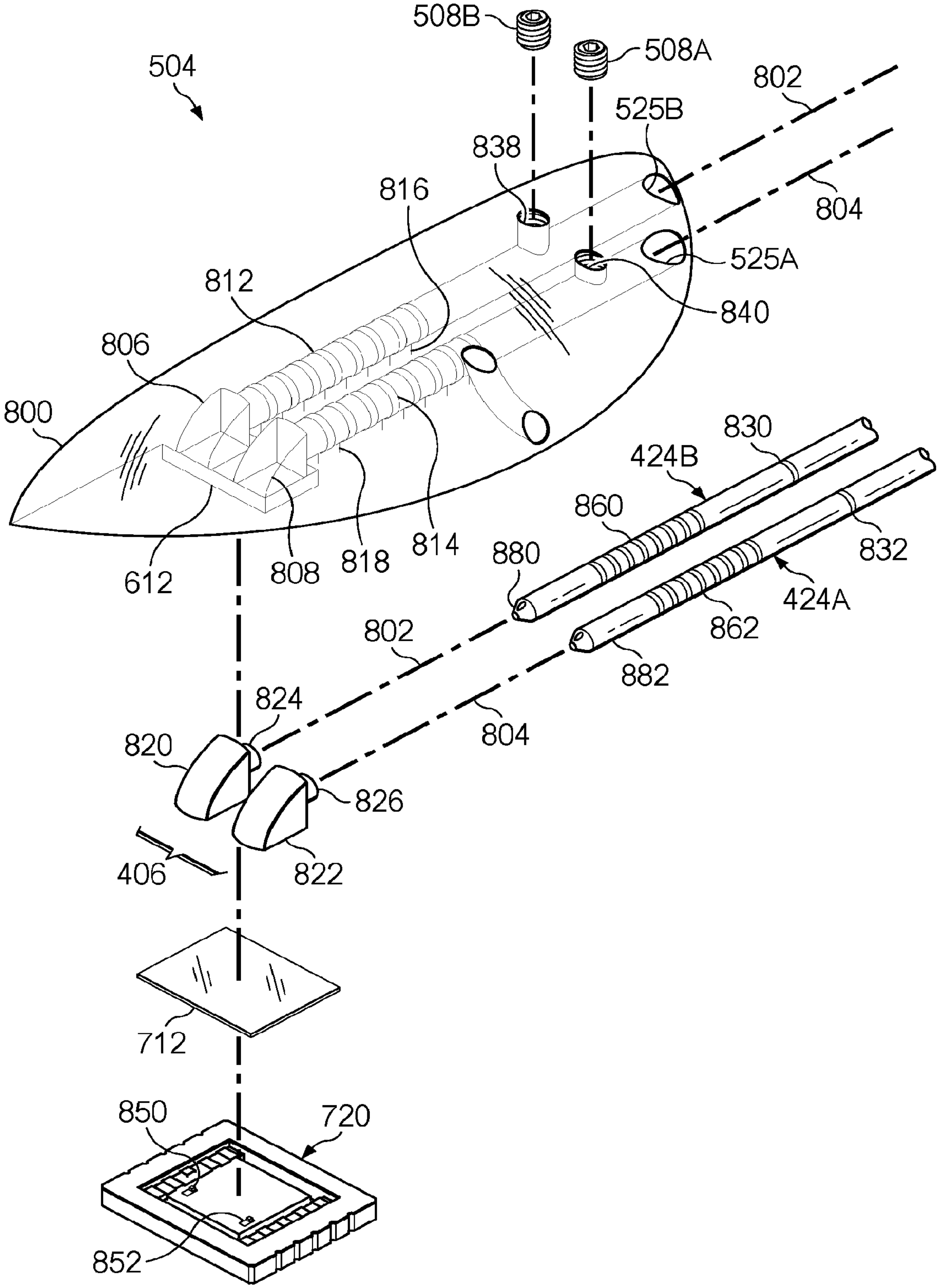
415
704

FIG. 7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612
808
818
814
862
802
882
824
804
820
826
406
822
712
850
720
852

FIG. 8

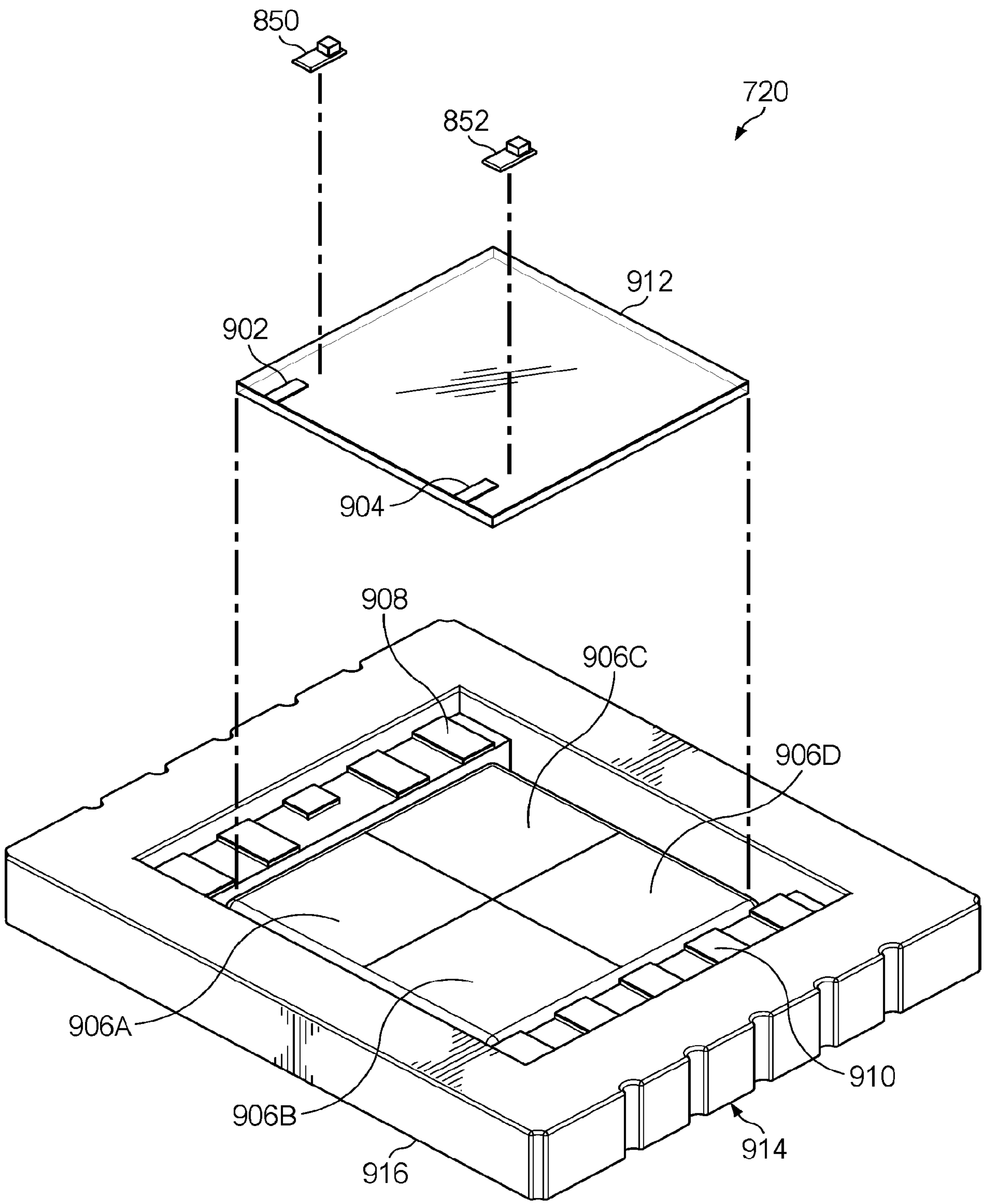

FIG. 9

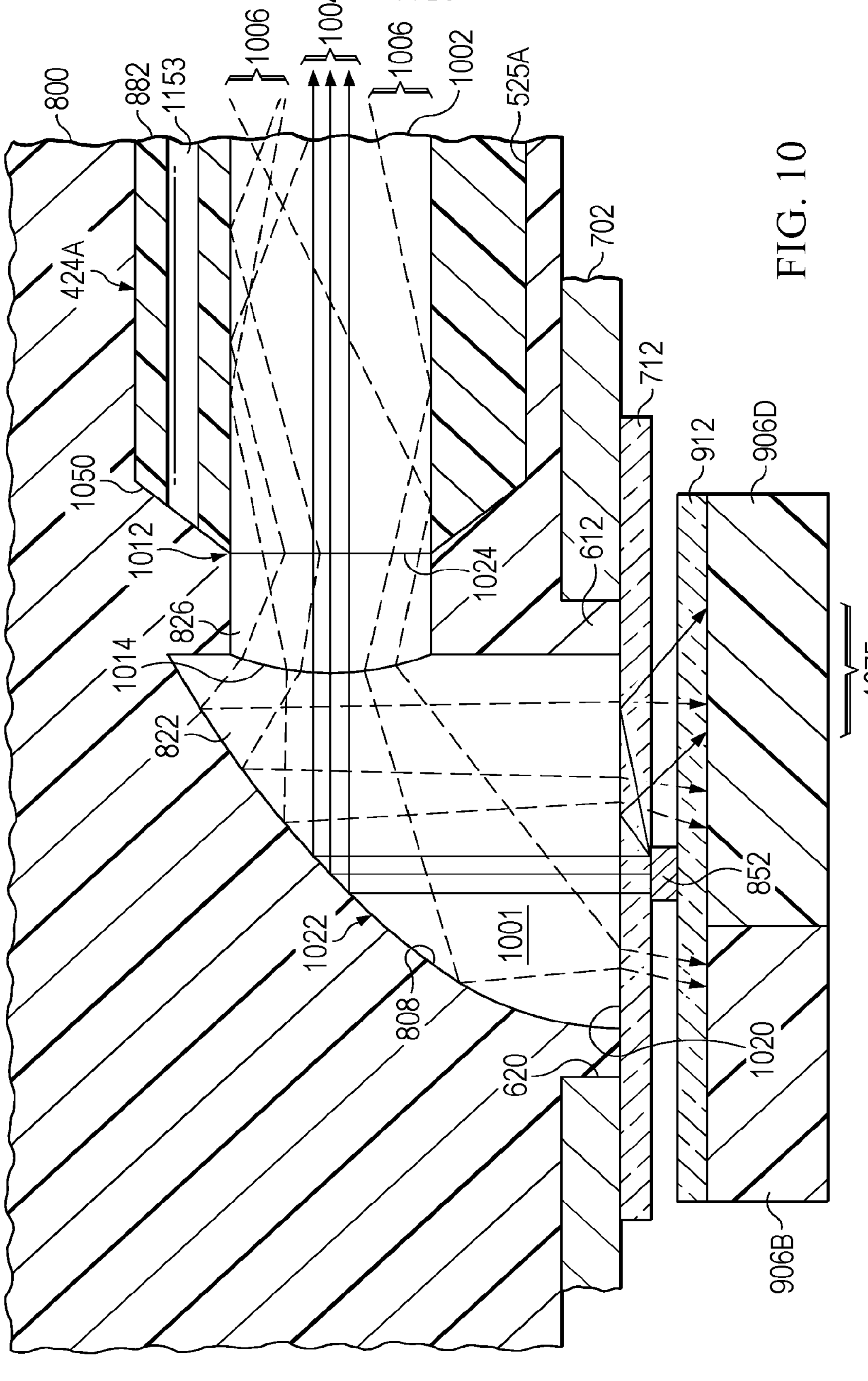
800
882
1153
1006
1004
1006
1002
525A
702
712
912
906D
424A
1050
1012
1024
612
826
1014
822
1075
852
1022
1001
808
620
1020
906B

FIG. 10

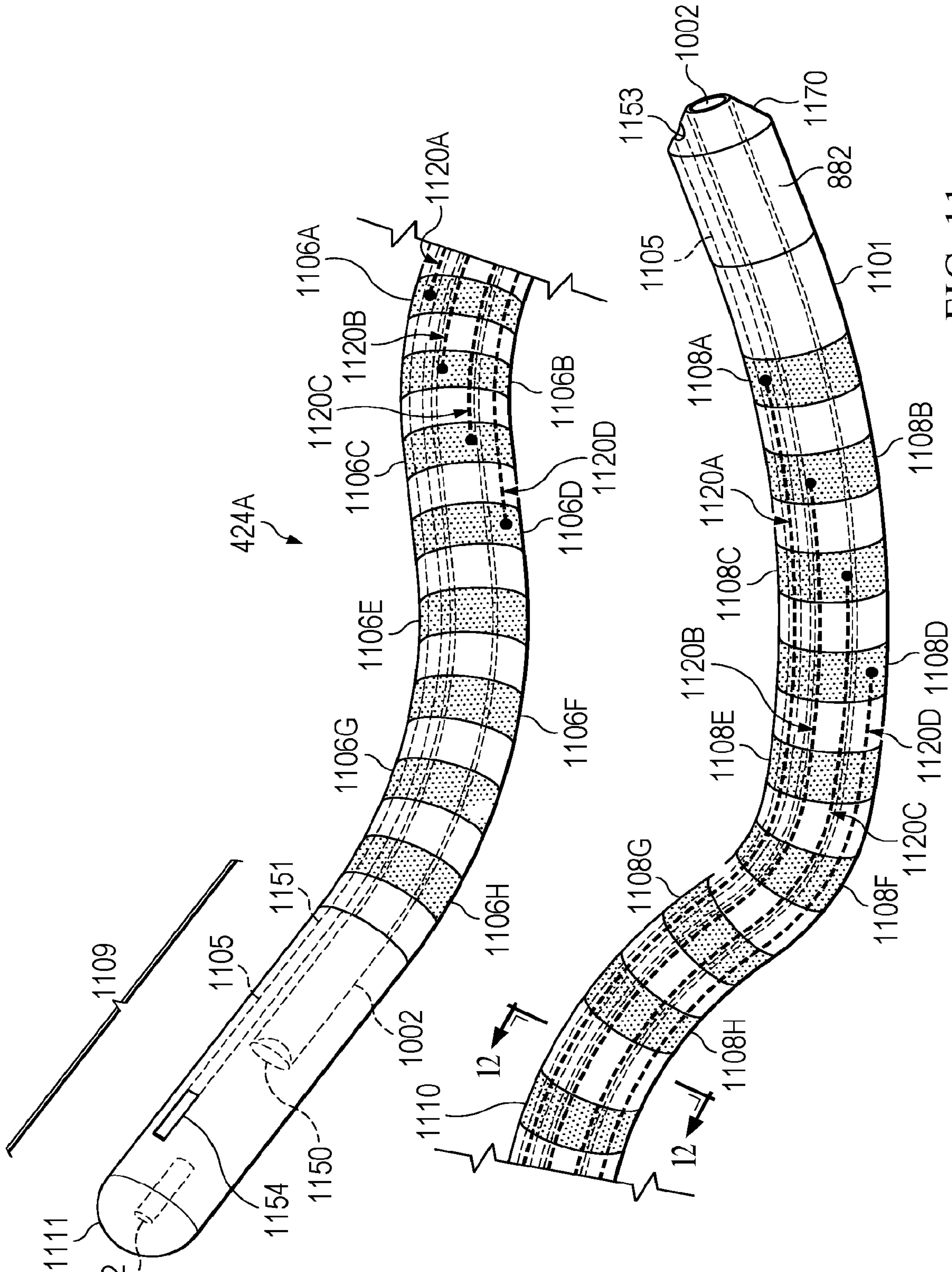
1002
1153
1170
882
1120A
1106A
1105
1101
1120B
1108A
1120C
1106B
1108B
1106C
1120D
1120A
424A
1106D
1108C
1106E
1120B
1108D
1108E
1120D
1106F
1106G
1120C
1108G
1108F
1151
1106H
1109
1105
1002
12
1108H
1110
12
1150
1154
1111
1152

FIG. 11

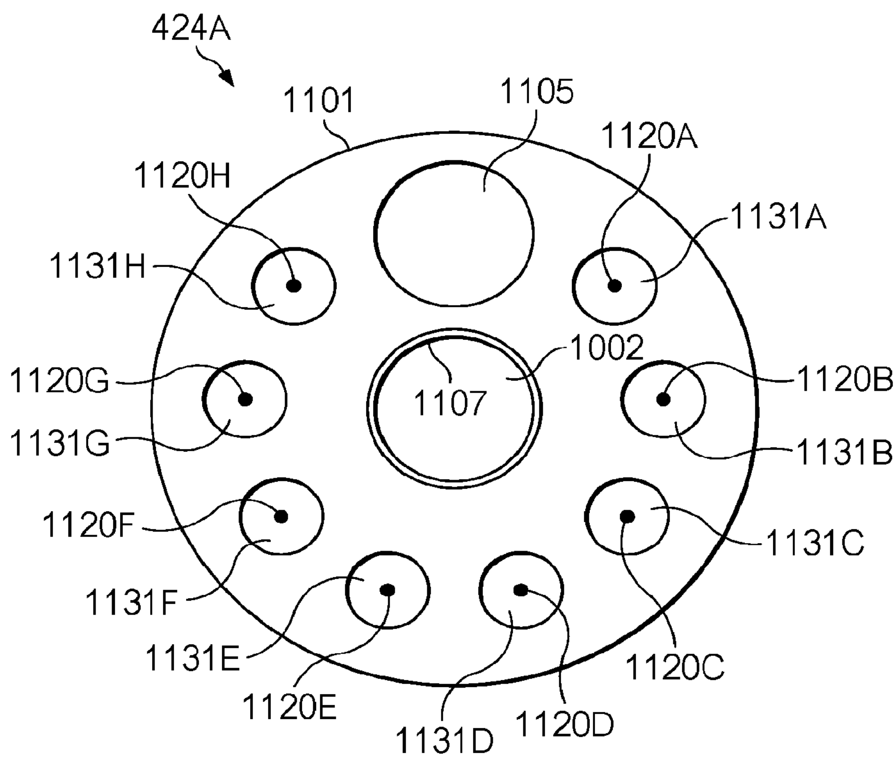
424A
1101
1105
1120A
1120H
1131A
1131H
1002
1120G
1107
1120B
1131G
1131B
1120F
1131C
1131F
1131E
1120C
1120E
1131D
1120D

FIG. 12

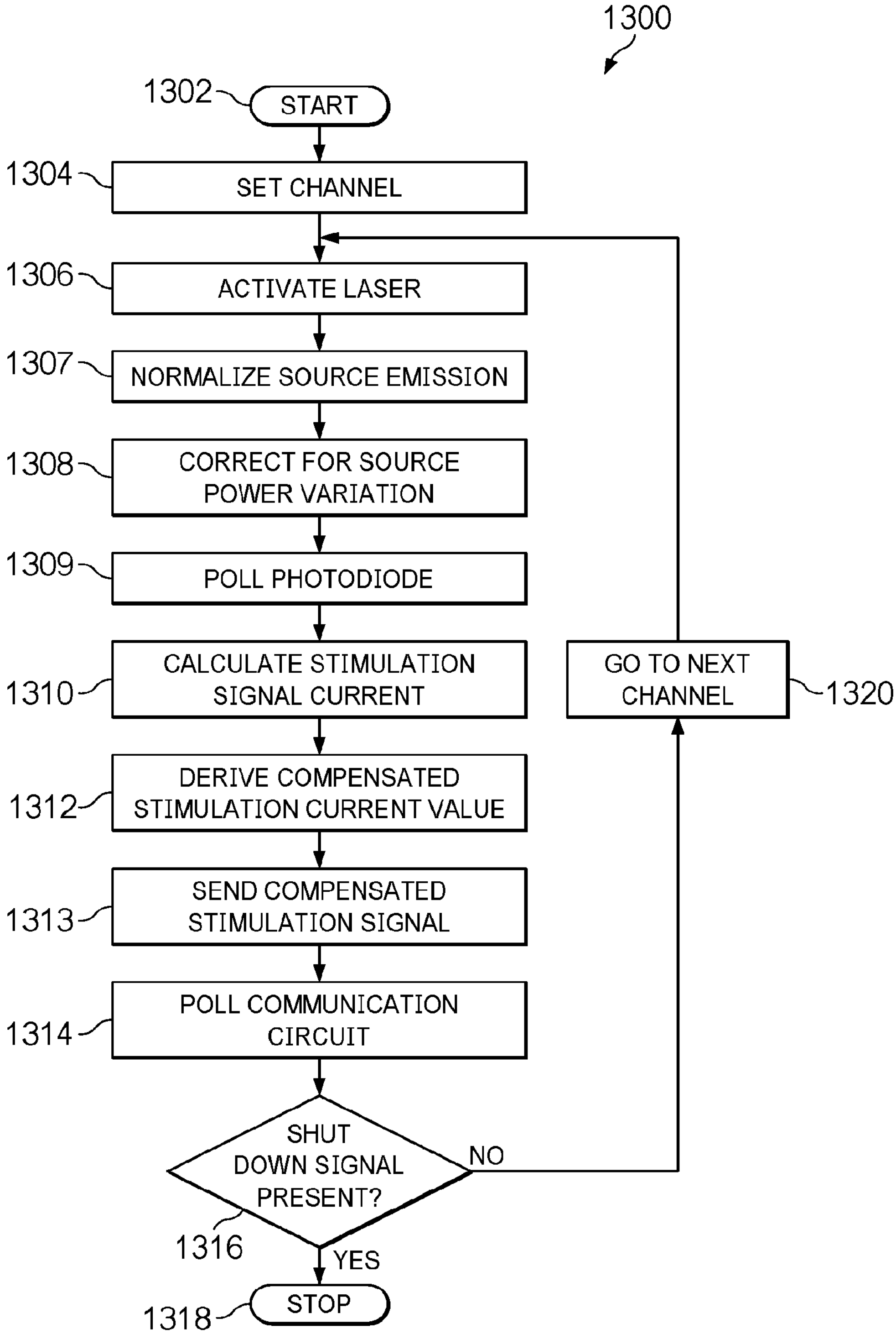
1300
1302
START
1304
SET CHANNEL
1306
ACTIVATE LASER
1307
NORMALIZE SOURCE EMISSION
1308
CORRECT FOR SOURCE POWER VARIATION
1309
POLL PHOTODIODE
1310
CALCULATE STIMULATION SIGNAL CURRENT
1312
DERIVE COMPENSATED STIMULATION CURRENT VALUE
1313
SEND COMPENSATED STIMULATION SIGNAL
1314
POLL COMMUNICATION CIRCUIT
SHUT DOWN SIGNAL PRESENT?
NO
YES
1316
GO TO NEXT CHANNEL
1320
STOP
1318

FIG. 13

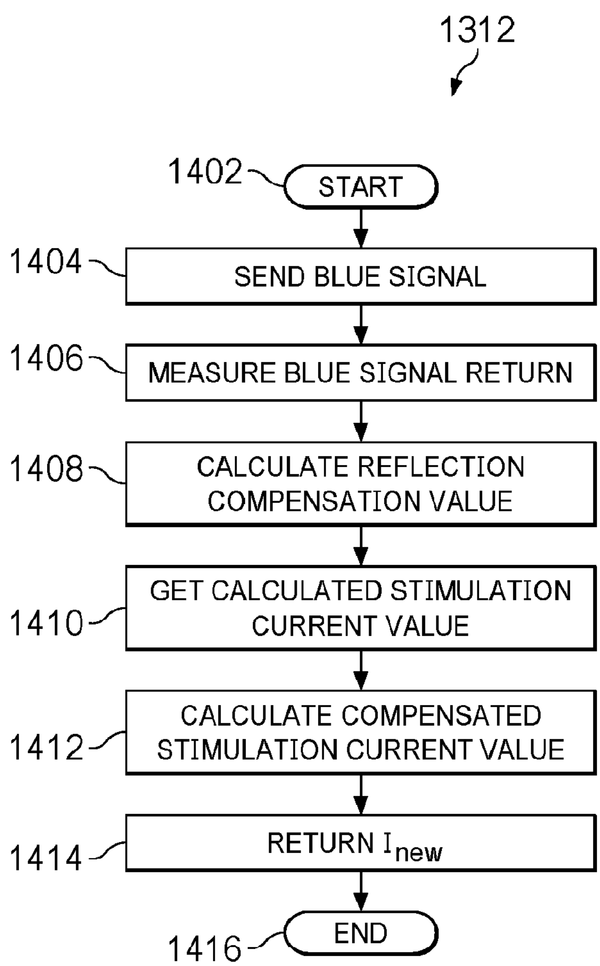
1312
1402
START
1404
SEND BLUE SIGNAL
1406
MEASURE BLUE SIGNAL RETURN
1408
CALCULATE REFLECTION COMPENSATION VALUE
1410
GET CALCULATED STIMULATION CURRENT VALUE
1412
CALCULATE COMPENSATED STIMULATION CURRENT VALUE
1414
RETURN I_{new}
1416
END

FIG. 14

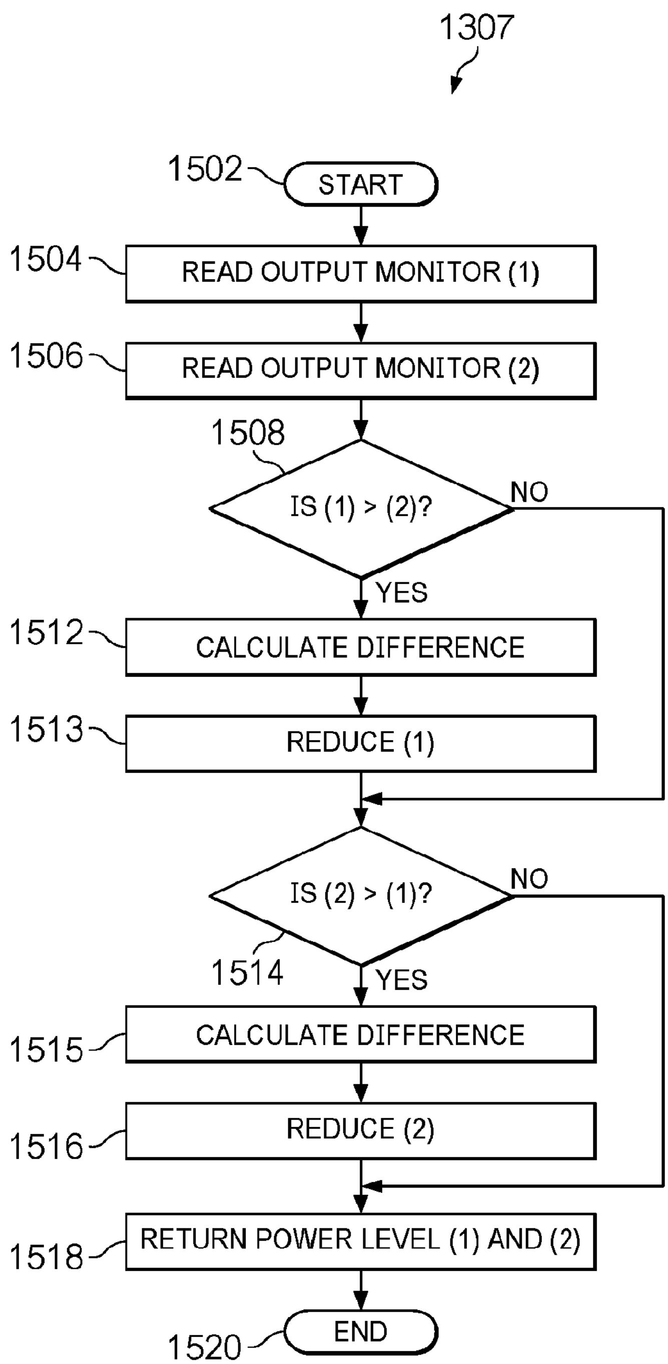
1307
1502
START
1504
READ OUTPUT MONITOR (1)
1506
READ OUTPUT MONITOR (2)
1508
IS (1) > (2)?
NO
YES
1512
CALCULATE DIFFERENCE
1513
REDUCE (1)
IS (2) > (1)?
NO
1514
YES
1515
CALCULATE DIFFERENCE
1516
REDUCE (2)
1518
RETURN POWER LEVEL (1) AND (2)
1520
END

FIG. 15

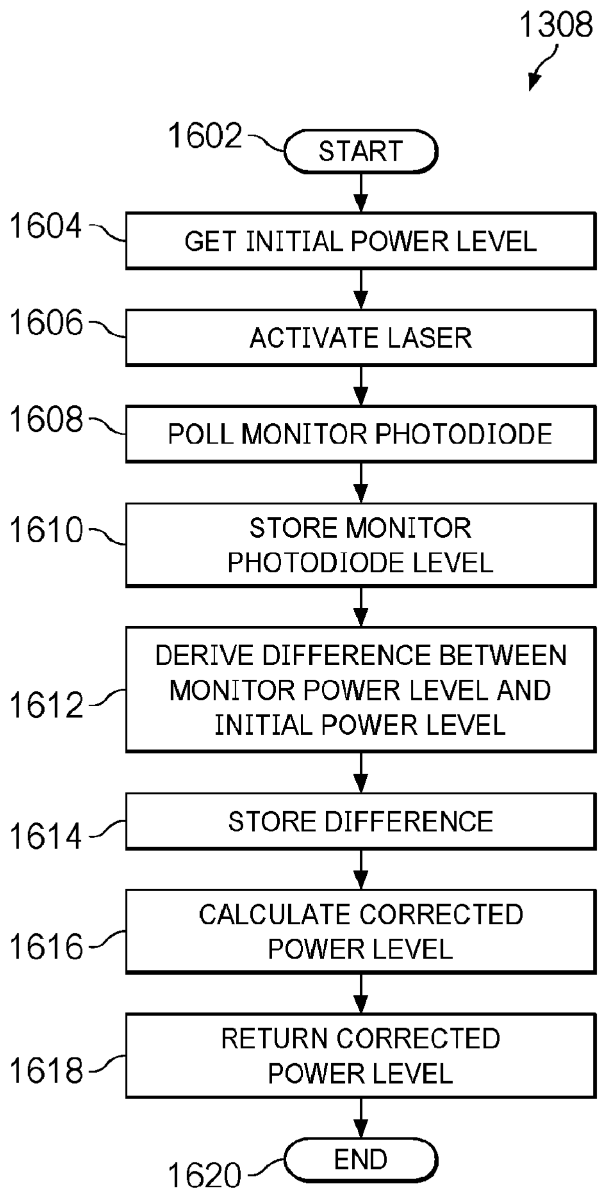
1308
1602
START
1604
GET INITIAL POWER LEVEL
1606
ACTIVATE LASER
1608
POLL MONITOR PHOTODIODE
1610
STORE MONITOR PHOTODIODE LEVEL
1612
DERIVE DIFFERENCE BETWEEN MONITOR POWER LEVEL AND INITIAL POWER LEVEL
1614
STORE DIFFERENCE
1616
CALCULATE CORRECTED POWER LEVEL
1618
RETURN CORRECTED POWER LEVEL
1620
END

FIG. 16

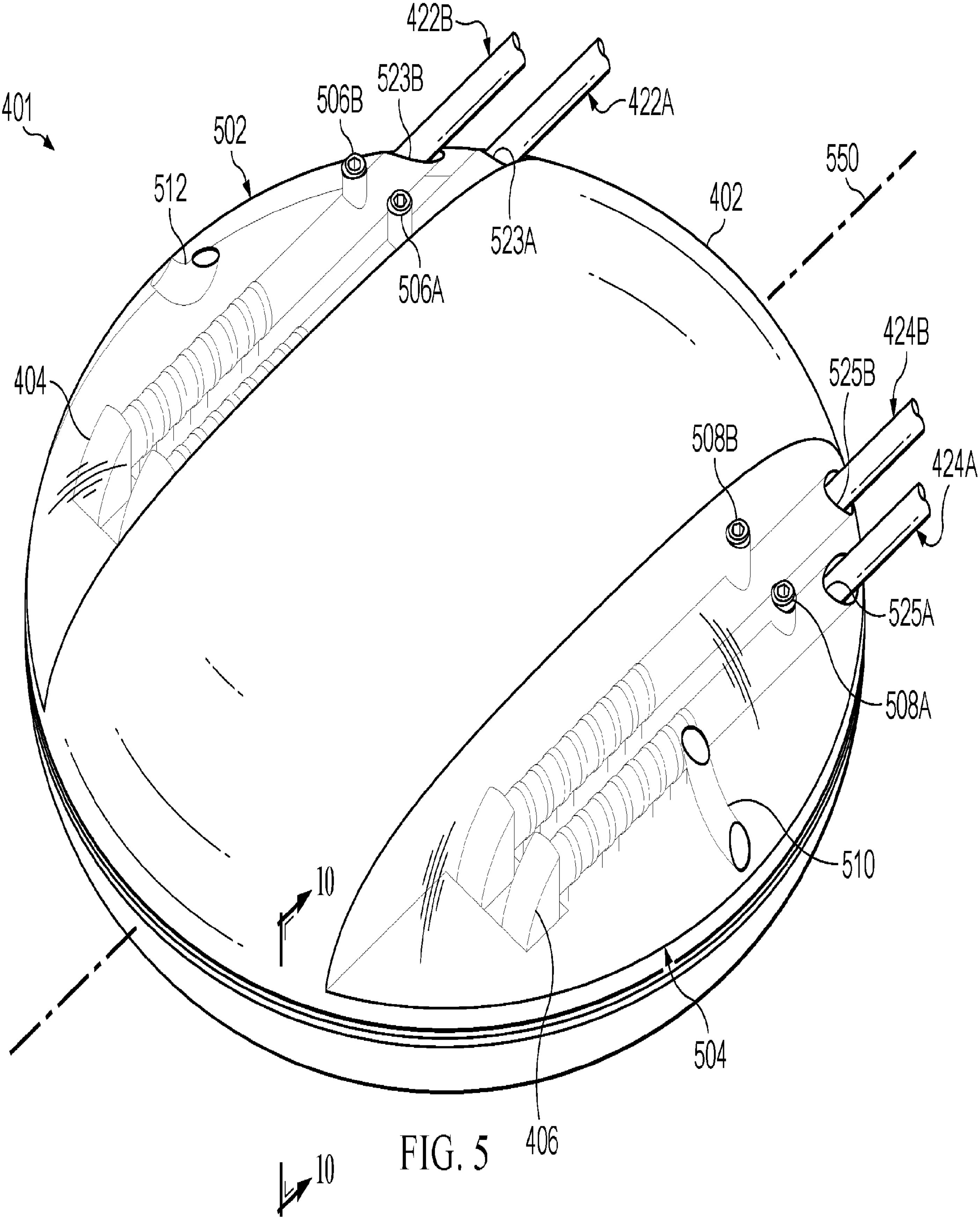
401
422B
523B
506B
502
512
422A
550
402
523A
506A
404
424B
525B
508B
424A
525A
508A
510
10
504
406
10

FIG. 5