United States Patent [19]

Tan

[11] **Patent Number:** **5,024,226**

[45] **Date of Patent:** **Jun. 18, 1991**

[54] **EPIDURAL OXYGEN SENSOR**

[75] Inventor: **Josef K. S. Tan,** Tampa, Fla.

[73] Assignee: **Critikon, Inc.,** Tampa, Fla.

[21] Appl. No.: **394,997**

[22] Filed: **Aug. 17, 1989**

[51] **Int. Cl.**[5] **A61B 5/00**

[52] **U.S. Cl.** **128/633;** 128/666

[58] **Field of Search** 128/632, 633, 634, 665, 128/666; 356/40

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,621,643	11/1986	New Jr. et al.	128/666
4,623,789	11/1986	Ikeda et al.	604/175
4,714,080	12/1987	Edgar Jr. et al.	128/666
4,784,150	11/1988	Voorhies et al.	128/664
4,825,872	5/1989	Tun et al.	128/665
4,865,038	9/1984	Rich et al.	128/665
4,867,557	9/1989	Takatani et al.	356/41
4,928,691	5/1990	Nicolson et al.	128/633
4,938,218	7/1990	Goodman et al.	128/633

FOREIGN PATENT DOCUMENTS

0094749	11/1983	European Pat. Off.	128/633
0135840	4/1985	European Pat. Off.	128/633
3152963	10/1983	Fed. Rep. of Germany	128/633

OTHER PUBLICATIONS

"Cerebral Oxidative Metabolism and Blood Flow During Acute Hypoglycemia and Recovery in Unaesthetized Rate", Journ. of Neurochem., 1982 p. 397.

"Regional Acetylcholine Metabolism in Brain During Acute Hypoglycemia and Recovery", Journ. Neurochem., 1985 at p. 94 et seq.

Yee, Sinclair et al., "A Proposed Minature Red/Infrared Oximeter . . .", IEEE Trans, Biomed. Eng. (USA), vol. BME-24 NO. 2 (Mar. 1977).

Primary Examiner—Lee S. Cohen
Assistant Examiner—John D. Zele
Attorney, Agent, or Firm—Paul A. Coletti

[57] **ABSTRACT**

A sensor for measuring the oxygen availability of blood flow within the skull is described. In a first embodiment the sensor comprises a photodetector and a pair of light emitting diodes surface mounted near the end of a length of flexible printed wiring. The sensor is sealed by a coating of rubber or polymeric material which has an optical window over the photodetector and light emitting diodes. The sensor is inserted through a burr hole drilled in the skull and slides between the skull and the dura of the drain. The light emitting diodes are pulsed to illuminate blood flow in the brain beneath the dura with light, and light reflected by the blood is received by the photodetector and converted to electrical signals. The signals are processed by a pulse oximeter to provide an indication of blood availability. In a second embodiment the photodetector and light emitting diodes are mounted at the end of a core of compressible foam extending from the end of a hollow bone screw. As the bone screw is screwed into a burr hole in the skull the photodetector and light emitting diodes will contact the dura and the foam will compress to maintain optical contact between the electrical components and the dura. Light from the diodes is reflected by blood in the dura and brain, received by the photodetector, and the resultant electrical siganls are processed by the pulse oximeter.

12 Claims, 3 Drawing Sheets

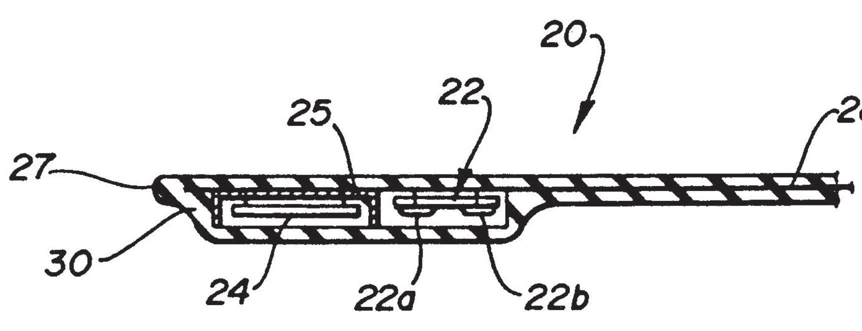


FIG-1

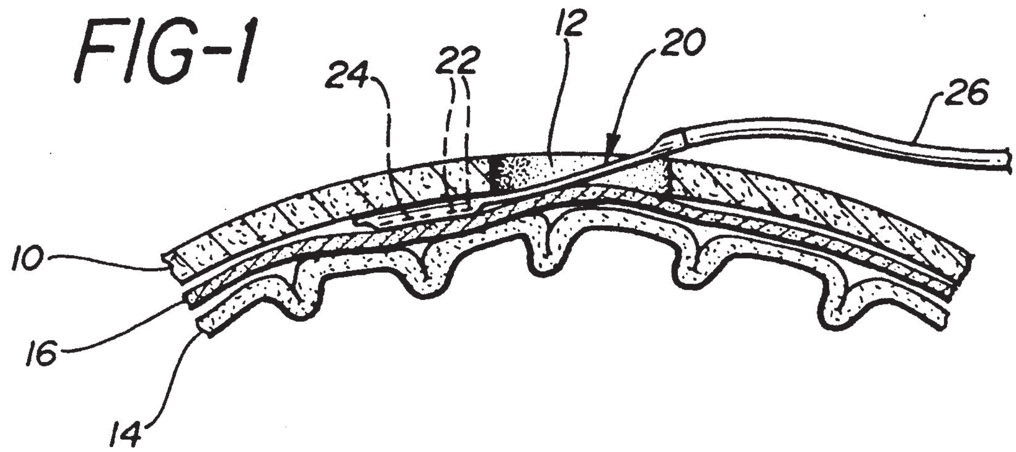


FIG-2

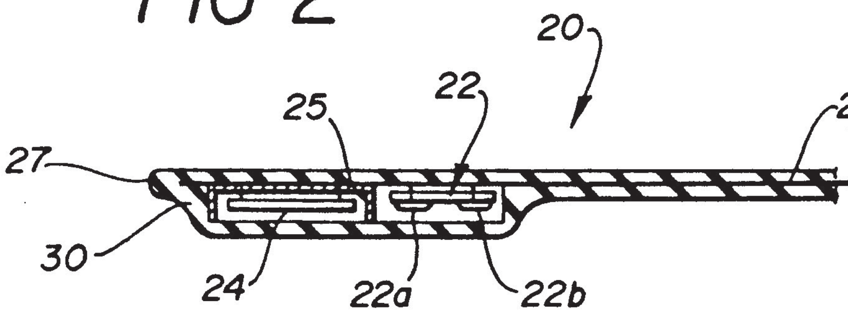


FIG-2a

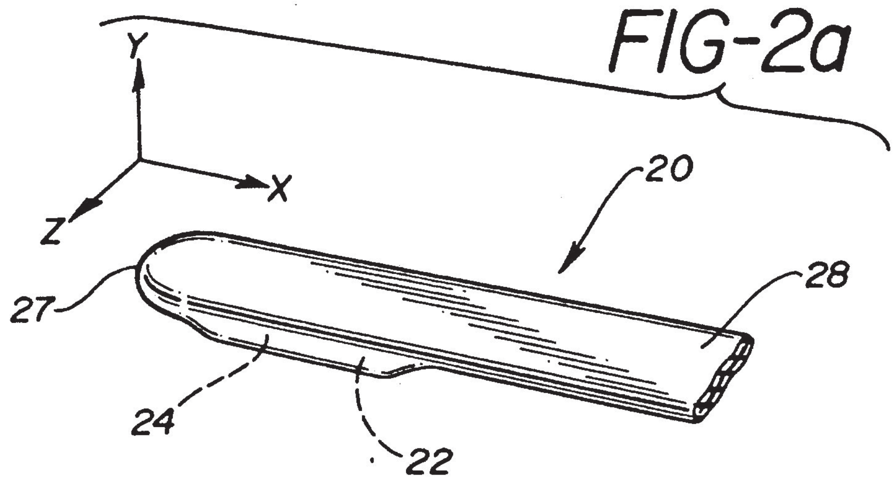


FIG-3a

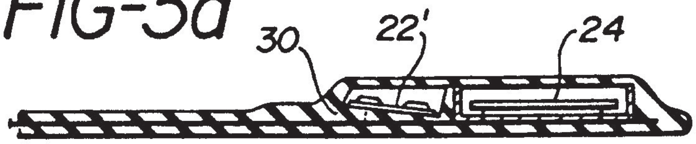


FIG-3b

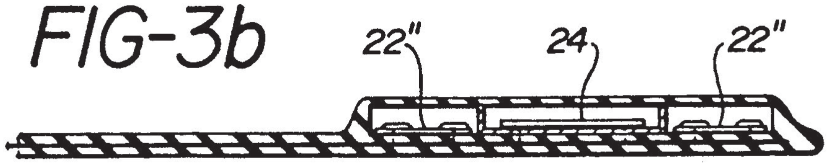


FIG-3c

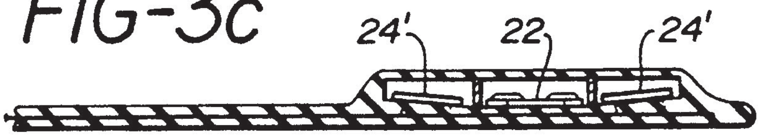


FIG-4a

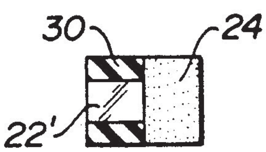


FIG-4b

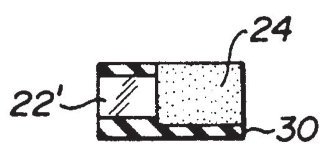


FIG-4c

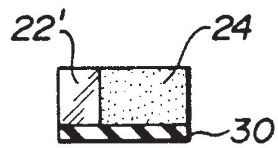


FIG-5a

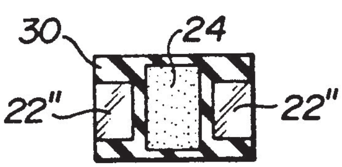


FIG-5b

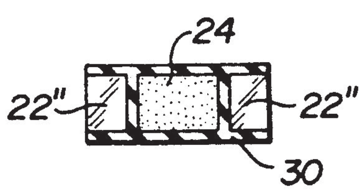


FIG-5c

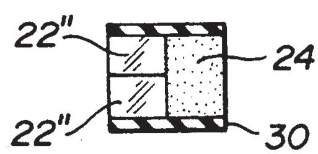


FIG-6a

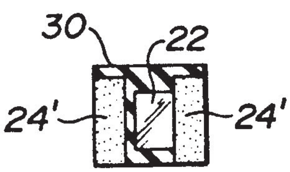


FIG-6b

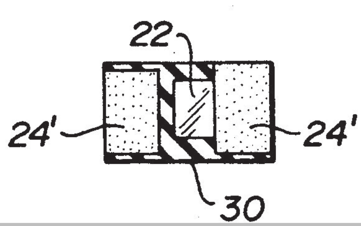
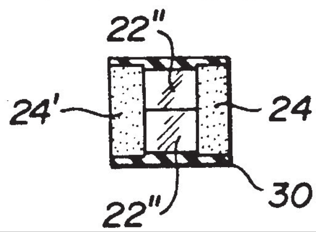


FIG-6c



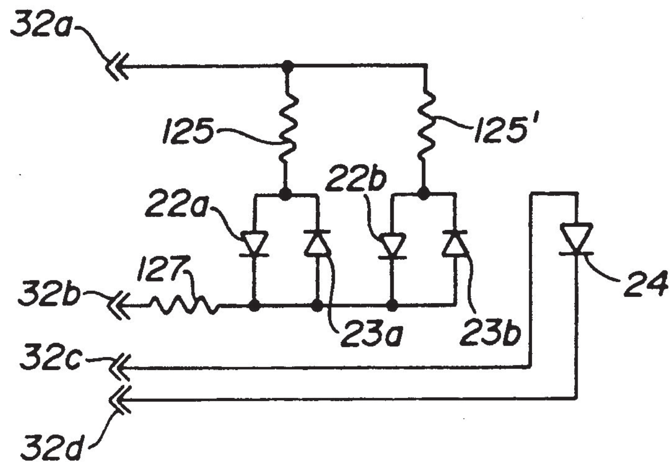


FIG-7

FIG-8a

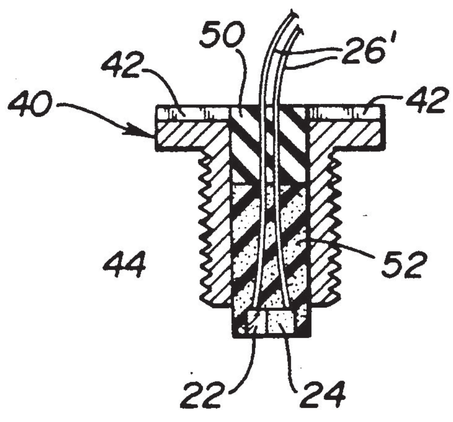


FIG-8b

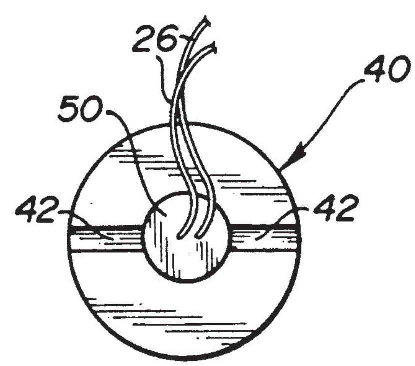
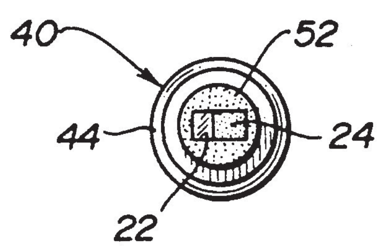


FIG-8c



EPIDURAL OXYGEN SENSOR

This invention relates to sensors for determining the oxygen availability of tissues within the skull and, in particular, to such sensor which are placed epidurally through the skull to measure oxygen availability.

During neurological and neurologically related surgical procedures it is oftentimes desirable to continuously monitor the oxygenation of blood which is supplied to the brain. Frequently access is gained to the brain through a borehole in the skull, and a sensor which optically measures oxygenation can then be inserted through such a borehole. An optical sensor should then exhibit numerous design and performance criteria in order to operate satisfactorily in this environment. The sensor must be capable of insertion through the borehole so as to contact tissue where oxygen availability is to be measured The sensor must be soft so that it does not damage neurological tissue, yet be sufficiently rigid in certain dimensions so that it can be maneuvered from outside the skull. It also must be sized to fit inside the borehole and in the location where measurements are to be taken. Furthermore, the sensor must be designed so as to eliminate detection of ambient light which will interfere with detection of the desired optical signals The sensor must also prevent the detection of directly transmitted light from the light source of the sensor.

In accordance with the principles of the present invention, an optical sensor is provided for epidural measurement of blood oxygenation In a first embodiment the sensor comprises a pair of light emitting diodes (LED's) which emit light at two predetermined wavelengths. The sensor also includes a photodetector for receiving light emitted by the LED's which has been reflected from adjacent blood perfused tissue. The LED's and the photodetector are mounted on flexible printed wiring which transmits signals to the LED's and from the photodiode. The components are encapsulated in a soft polymer which is biocompatible. The resultant sensor is thus capable of operation in an epidural environment, and is further capable of being maneuvered into the desired position for epidural measurements.

In a second embodiment the LED's and photodetector are located in a hollow bone screw, with the components opposing the tissue from which measurements are to be taken. The components are backed by a resilient member such as a spring or soft polymeric foam which will compress under gentle pressure within the bone screw to cause the components to contact the dura and maintain optical contact with the dura as it moves with the patient's respiration.

In the drawings:

FIG. **1** illustrates a cross-sectional view of the use of an epidural oxygenation sensor constructed in accordance with the present invention;

FIG. **2** is a side cross-sectional view of an epidural oxygenation sensor constructed in accordance with the principles of the present invention;

FIG. **2*a*** is a perspective view of an epidural oxygenation sensor constructed in accordance with the principles of the present invention;

FIGS. **3*a*–3*c*** are cross-sectional views of different embodiments of epidural oxygenation sensors of the present invention;

FIGS. **4*a*–4*c***, **5*a*–5*c*** and **6*a*–6*c*** are plan views of different placements of LED's and photodiodes of epidural oxygenation sensors of the present invention;

FIG. **7** is an electrical schematic of the components of the epidural oxygenation sensor of FIG. **2**; and

FIGS. **8*a*–8*c*** are cross-sectional, top, and bottom views of an epidural oxygenation sensor mounted in a hollow bone screw.

Referring first to FIG. **1**, a skull is shown in which a burr hole **12** has been drilled. Underlying the skull is the dura **16** which encases the brain, and beneath the dura is the cerebrum **14**. An epidural oxygenation sensor **20** is inserted through the burr hole **12** for measurement of the oxygenation of blood flowing in the brain. The sensor **20** is inserted through the burr hole and slides between the skull **10** and the dura **16**, where it is shielded from ambient light entering the burr hole. At the distal end of the sensor **20** is a photodetector **24** and LED's **22** which face the dura through optical windows in the sensor. The photodetector and LED's are mounted on flexible printed wiring which is connected to a sensor cable **26**. The sensor cable is connected to a pulse oximeter (not shown), which provides drive pulses for the LED's, receives electrical signals from the photodetector, and processes the received electrical signals to produce an indication of the oxygen availability of blood in the brain. The sensor is operated in a reflective mode, whereby light of different wavelengths emitted by the LED's is reflected by the blood in the brain and the reflected light is received by the photodetector.

As shown in FIG. **2**, the sensor **20** comprises a photodetector **24** and an adjacent pair of LED's **22*a*** and **22*b*** which are surface mounted to leads of flexible printed wiring **28** such as 0.001 inch Kapton TM based printed wiring. The use of surface mounted components and the printed wiring provide a thin sensor which minimizes cerebral compression. Separating the LED's and the photodetector is a light barrier **25** which prevents the direct transmission of light from the LED's to the photodetector. The light barrier may be provided by an opaque epoxy material, but in a preferred embodiment the light barrier is formed of a thin sheet of copper foil. The copper foil not only effectively blocks light from the LED's, but is also connected to a grounded lead of the flexible printed wiring. The copper foil thus shields the photodetector from radio frequency interference such as that emanated during pulsing of the LED's.

The foregoing components are encapsulated by a soft coating **30** of silicone rubber or polyurethane material. The soft coating smoothly rounds the corners and edges of the sensor which prevents injury to the dura by the sensor. The coating also seals the components from moisture and other environmental factors. The coating **30** is optically transmissive to light at the wavelengths of the LED's where it overlies the lower surfaces of the photodetector and the LED's from which light is transmitted and received by these components.

FIG. **2*a*** is a perspective view of the sensor **20** of FIG. **2**, referenced to x, y, and z axes. As mentioned above, the coating **30** provides the sensor with a smooth, gently rounded profile such as the rounded distal end **27**. The sensor is relatively stiff along the portion of the printed wiring where the components are mounted to maintain their relative alignment. In the x dimension the sensor is fairly stiff so that it may be inserted and guided beneath the skull and in contact with the dura. In the z dimension the sensor is stiff to provide maneuverability

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming inter-face) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.

WHAT WILL YOU BUILD? | sales@docketalarm.com | 1-866-77-FASTCASE