

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
24 October 2002 (24.10.2002)

PCT

(10) International Publication Number
WO 02/082991 A1

(51) International Patent Classification⁷: **A61B 5/0484**,
5/04

[IT/IT]; Via San Camillo de Lellis, 3, I-35128 Padova (IT).
DAM, Mauro [IT/IT]; Via S. Antonio, 9, I-35037 Teolo
(IT). **FURLAN, Roberto** [IT/IT]; Via Monte Vodice, 6,
I-35138 Padova (IT).

(21) International Application Number: PCT/EP02/03737

(22) International Filing Date: 4 April 2002 (04.04.2002)

(74) Agent: **MODIANO, Guido**; Modiano & Associati, Via
Meravigli, 16, I-20123 Milan (IT).

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PD2001A000088 10 April 2001 (10.04.2001) IT

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,
SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ,
VN, YU, ZA, ZM, ZW.

(71) Applicant (*for all designated States except US*):
KHYMEIA S.R.L. [IT/IT]; Piazza Europa, 9, I-35027
Noventa Padovana (IT).

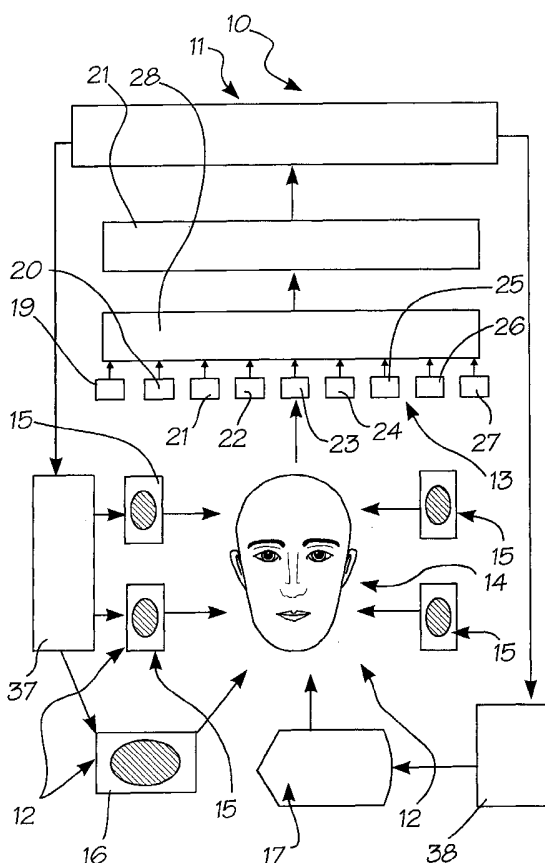
(72) Inventors; and

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

(75) Inventors/Applicants (*for US only*): **PIRON, Lamberto**

[Continued on next page]

(54) Title: MEDICAL APPARATUS PARTICULARLY FOR COMATOSE PATIENTS



(57) Abstract: A medical apparatus (10) particularly for comatose patients, comprising, in connection with information processing and control means (11), a unit (12) for emitting sensory and sensorial stimuli toward the patient which cooperates with a unit (13) for sensing and measuring the reactions of the patient as a consequence of the stimuli and for emitting in feedback the stimuli for which a reaction is sensed.

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Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

MEDICAL APPARATUS PARTICULARLY FOR COMATOSE PATIENTS

Technical Field

The present invention relates to a medical apparatus particularly for
5 comatose patients.

Background Art

It is known that methods aimed at stimulating comatose patients from the cognitive and/or sensory standpoint have long been studied and analyzed.

It is hypothesized that recovery of consciousness from a coma due to
10 various causes can be facilitated by stimulations of a sensory, sensorial, motor and vibratory type applied to the patient.

These stimulations are currently entrusted to individuals (health workers, relatives of the patient, et cetera) who administer them empirically, partially and randomly.

15 An important parameter in the effectiveness of the stimulation is its constant administration over time, in a multimodal manner, allowing adequate sensing of the reactions of the patient so as to be able to calibrate the type of stimulation and optionally manage the steps of the patient's arousal.

20 Moreover, many disorders require an extremely high level of hygiene of the environment in which the patient is placed, and therefore for example sensorial stimulation, even just of the auditory kind, on the part of human beings is unfeasible.

Disclosure of the Invention

25 The aim of the present invention is to provide a medical apparatus particularly for comatose patients that is capable of managing a programmed and/or controlled constant administration of cognitive-sensory stimulations to the comatose patient and of sensing his reactions to these stimulations in order to calibrate alternative stimulation strategies and manage the steps of
30 arousal.

Within this aim, an object of the present invention is to provide a medical apparatus which, once programmed, can operate entirely autonomously even for long periods of time and in environments that are perfectly aseptic or in any case normally reserved for various reasons, including hygiene-related reasons, only to medical and/or paramedic personnel.

Another object of the present invention is to provide a medical apparatus that is particularly flexible in relation to the various kinds of disorder of the patient and is optionally able to act selectively in response to given reactions of the patient being treated.

Another object of the present invention is to provide an apparatus that can be managed precisely and in real time by optional operators performing monitoring and whose output, in terms of measurement and sensing, allows to give a general and exhaustive picture of the physiological conditions of the patient and of his reactions to stimulations of the cognitive, sensorial, sensory and motor type.

Another object of the present invention is to provide an apparatus that can also be controlled remotely by operators, for example by means of a local area network, a telephone line and a modem, et cetera.

Another object of the present invention is to provide a medical apparatus that can optionally be transported to different sites and appropriately folded in compact form during transport.

Another object of the present invention is to provide a medical apparatus that allows personnel, relatives of the patient, volunteers, by means of microphones, video cameras, loudspeakers and viewers, to connect from a location that is not the patient's location in order to attempt a merely visual and auditory interaction, complying with the organizational requirements of the hospital and with adequate protection of the patient from contact with external agents.

Another object of the present invention is to provide a medical apparatus that can be manufactured with known technologies and equipment.

This aim and these and other objects that will become better apparent hereinafter are achieved by a medical apparatus particularly for comatose patients, characterized in that it comprises, in connection with information processing and control means, a unit for emitting sensory and sensorial stimuli toward the patient which cooperates with a unit for sensing and measuring the reactions of the patient as a consequence of said stimuli and for emitting in feedback the stimuli for which a reaction is sensed.

Brief description of the drawings

Further characteristics and advantages of the present invention will become better apparent from the following detailed description of an embodiment thereof, illustrated only by way of non-limitative example in the accompanying drawings, wherein:

- Figure 1 is a schematic view of an apparatus according to the invention;
- Figure 2 is another schematic view of the apparatus of Figure 1;
- Figure 3 is another schematic view of the apparatus of Figure 1;
- Figure 4 is a perspective view of a detail of the apparatus of Figure 1;
- Figure 5 is a perspective view of the detail of Figure 4 during application;
- Figure 6 is a perspective view of the apparatus of Figure 1 during operation;
- Figure 7 is a perspective view of the apparatus of Figure 1 in the configuration for transport.

Ways to carrying out the Invention

With reference to Figures 1 to 7, a medical apparatus particularly for comatose patients is generally designated by the reference numeral 10.

In the figures, the apparatus 10 and its components are shown schematically in different manners for the sake of clarity and in order to highlight particular aspects thereof, but the reference numeral of an individual component is assigned identically and univocally independently of the appearance of the schematic representation adopted in a particular figure.

The apparatus 10 comprises, in connection with information processing and control means designated by the reference numeral 11, a unit 12 for emitting auditory stimuli, which is programmable and is suitable to emit signals toward the patient according to preset positions, and a unit 13 for sensing and measuring, in feedback to the audio emission, the reactions of the patient, who is designated by the reference numeral 14 in the figures.

The emission unit 12 emits, in this case, stimuli of the auditory type, but can advantageously comprise components, not shown in the figures for the sake of simplicity, for emitting stimuli of the gustative, olfactory, tactile, thermal, algescogenic, vibratory, motor types, such as for example sounds, videos, static images or images that move randomly or in a programmed fashion, screens with uniform or patterned coloring, dynamic images of the fractal type, odors, fragrances, vibrations of various amplitudes, heat or cold.

In particular, in this case the audio emission unit 12 comprises four audio emission devices with multiple sources (positional audio) which are typically constituted by audio speakers, designated by the reference numeral 15 in the figures, which are connected to an amplifier, not shown, which is of a per se known type.

The speakers 15 can be arranged so as to surround the patient 14 in order to ensure, also in relation to the environment in which the patient is placed, the best possible administration of sound.

In this embodiment, the unit 12 also comprises a low-frequency sound wave emission device 16 of a per se known type.

The apparatus 10 also comprises a video emission unit, generally designated by the reference numeral 17, which in this case comprises a TFT flat screen 18.

In other cases, however, it is possible to provide visual outputs produced by means of conventional projection devices.

By way of example, the visual output can consist of photographs, videos, graphic effects obtained by means of software programs, stroboscopic

effects, fractal images, light-immersion effects, et cetera.

The sensing and measurement unit 13 is constituted, in this case, by a coordinated set of medical devices, which are per se known and are listed hereafter.

5 More specifically, the unit 13 consists, in this case, of an electroencephalogram (EKG) sensing device 19, a device 20 for measuring evoked visual, auditory and electrical potentials, an electrocardiogram (ECG) sensing device 21, a surface and deep electromyograph (EMG) sensing device 22, an EDA or EDC skin conductance (electrodermal
10 activity) sensing device 23, an eye motion (EOG) sensing device 24, a body temperature sensing device 25, a respiration sensing device 26, and finally an arterial pressure sensing device, a blood gas analysis sensing device, and a heart rate sensing device, which are not shown in the figure for the sake of simplicity.

15 In particular, in this embodiment, the apparatus 10 also has a television camera 27, which is associated with position sensors 27a of a per se known type for sensing the position of the face and/or body of the patient 14.

All of the above listed devices are connected to a signal amplification unit 28, which is in turn connected to a signal digitizing unit 29 to allow
20 acquisition on the part of the processing means 11.

The apparatus 10 also comprises a device, generally designated by the reference numeral 30, which is particularly suitable to allow sensing of the position of the head of the patient 14, in cooperation with the monitor 18, and to allow the patient, once aroused, to emit voice signals in relation to the
25 stimuli.

In particular, the device comprises, on a supporting structure 31 to be fixed to the forehead of the patient, a nosepiece 32, earpieces 33, an appendage with a microphone 34 with a bite- or breath-operated control switch, and a forehead-mounted infrared pointing/sensing device 35 which
30 cooperates with per se known sensors applied to the monitor 18 and not

shown in the figures for the sake of simplicity.

In this embodiment, the unit 11 is constituted by an electronic information processor, such as a personal computer or equivalent device, generally designated by the reference numeral 36, which is provided with
5 audio and video interfacing cards, designated by the reference numerals 37 and 38 respectively, and with mass storage units capable of acquiring and recording digitally the data supplied by the sensing devices, so that assigned operators can, over time, formulate any corrections and analyze the behavior of the patient subjected to cognitive and sensory stimulations.

10 In more complete configurations, or in configurations dedicated to particular operating conditions, it is possible to associate with the information processor 36 devices and interfaces, typically modems or network cards of various kinds, including wireless ones based on radio waves or infrared rays et cetera, for remote connection to intranets and to the
15 Internet.

With particular reference to Figures 6 and 7, the embodiment described above is advantageously accommodated in a container 39 which can be folded into a compact form during transport so as to become a suitcase 40 with wheels for easier sliding.

20 The container 39, once opened, ensures the ergonomic availability of all the output and input devices for the operator in a rather limited space, so that the apparatus 10 can also be applied in situations in which the patient is confined in small spaces.

In practice it has been observed that the present invention has achieved
25 the intended aim and objects.

In particular, it should be noted that the apparatus according to the invention effectively achieves all the actions of sensory and sensorial stimuli (auditory, visual, gustative, olfactory, tactile, thermal, algesiogenic, vibratory, motor stimuli, such as for example sounds, videos, static images
30 or images with random or programmed motion, screens with a uniform or

patterned coloring, dynamic images of the fractal type, odors, fragrances, vibrations of various amplitudes, heat or cold) of the patient, ensuring sensing of the main physiological parameters of said patient so that the operator or operators can follow and manage, even in real time, the effectiveness of the administration treatments, optionally calibrating the administrations of said stimuli if positive reactions on the part of the user are detected.

It should also be noted that the apparatus according to the invention achieves a precise and localized monitoring of the status of the patient which is suitable to ensure that the patient is in optimum conditions and receives adequate multimodal stimulation in order to increase the probabilities of arousal from the coma and/or of accelerating said arousal.

It should also be noted that the apparatus according to the invention can work effectively even in a fully automatic manner over time, so as to ensure constancy of the stimulations and the possibility to continue the treatment without excessive personnel costs even for rather long periods of time.

Attention is also called to the flexibility of application of the apparatus according to the invention, which can also be configured as a compact kit suitable to ensure its applicability even in situations where the patient is confined in rather small spaces.

The present invention is susceptible of numerous modifications and variations, all of which are within the scope of the inventive concept.

The technical details may be replaced with other technically equivalent elements.

The materials and the dimensions may be any according to requirements.

The disclosures in Italian Patent Application No. PD2001A000088 from which this application claims priority are incorporated herein by reference.

CLAIMS

1. A medical apparatus particularly for comatose patients, characterized in that it comprises, in connection with information processing and control means, a unit for emitting sensory and sensorial stimuli toward the patient
5 which cooperates with a unit for sensing and measuring the reactions of the patient as a consequence of said stimuli and for emitting in feedback the stimuli for which a reaction is sensed.

2. The apparatus according to claim 1, characterized in that said emission unit, in the case of audio emission, comprises audio emission devices with at
10 least four audio sources.

3. The apparatus according to claim 2, characterized in that said audio emission devices are constituted by four audio emission speakers.

4. The apparatus according to claims 2 and 3, characterized in that said audio emission unit comprises a low-frequency sound wave emission device.

15 5. The apparatus according to claim 1, characterized in that it comprises at least one odor emission device.

6. The apparatus according to claim 1, characterized in that it comprises at least one tactile stimulation device.

7. The apparatus according to claim 1, characterized in that it comprises
20 at least one device for stimulation by means of vibrations.

8. The apparatus according to claim 1, characterized in that it comprises at least one device for stimulation by heat emission.

9. The apparatus according to claim 1, characterized in that it comprises at least one device for stimulation by emission of cold.

25 10. The apparatus according to claim 1, characterized in that it comprises at least one device for stimulation by emission of substances having a gustative flavor.

11. The apparatus according to claim 1, characterized in that it comprises at least one device for motor stimuli.

30 12. The apparatus according to claim 1, characterized in that it comprises

at least one device for administering stimuli for pain-receptive terminations.

13. The apparatus according to claim 1, characterized in that it comprises at least one video emission device.

14. The apparatus according to claim 13, characterized in that said video
5 emission device comprises devices suitable to reproduce photographs, videos and/or graphical effects obtained by a software program and/or stroboscopic effects and/or fractal images and/or light inversion effects.

15. The apparatus according to claim 1, characterized in that said sensing and measurement unit comprises at least one video camera.

10 16. The apparatus according to claim 1, characterized in that said sensing and measurement unit comprises at least one sensor for sensing the position of the head and/or of other body segments of the patient.

17. The apparatus according to claim 1, characterized in that said sensing and measurement unit comprises one or more eye motion sensors.

15 18. The apparatus according to claim 1, characterized in that said sensing and measurement unit comprises at least one electroencephalogram (EEG) sensing device.

19. The apparatus according to claim 1, characterized in that said sensing and measurement unit comprises at least one electrocardiogram (ECG)
20 sensing device.

20. The apparatus according to claim 1, characterized in that said sensing and measurement unit comprises at least one surface and deep electromyograph (EMG) sensing device.

21. The apparatus according to claim 1, characterized in that said sensing
25 and measurement unit comprises at least one skin conductance (EDA or EDC) sensing device.

22. The apparatus according to claim 1, characterized in that said sensing and measurement unit comprises at least one device suitable to sense eye motion (EOG).

30 23. The apparatus according to claim 1, characterized in that said sensing

and measurement unit comprises at least one device suitable to sense body temperature.

24. The apparatus according to claim 1, characterized in that said sensing and measurement unit comprises at least one device suitable to sense
5 respiration.

25. The apparatus according to claim 1, characterized in that said sensing and measurement unit comprises at least one device suitable to sense arterial pressure.

26. The apparatus according to claim 1, characterized in that said sensing
10 and measurement unit comprises at least one device suitable to sense the heart rate.

27. The apparatus according to claim 1, characterized in that said sensing and measurement unit comprises at least one device for video imaging of the face of the patient and/or of the entire body.

28. The apparatus according to claim 1, characterized in that said sensing
15 and measurement unit comprises at least one device suitable for blood gas analysis sensing.

29. The apparatus according to one or more of the preceding claims, characterized in that said devices that compose said sensing and
20 measurement unit are connected to a signal amplification unit, which is in turn connected to a signal digitizing unit that allows acquisition by the processing means.

30. The apparatus according to one or more of the preceding claims, characterized in that it comprises a device for sensing the position of the
25 head of the patient, in cooperation with at least one monitor, and for emitting voice signals in relation to said stimuli.

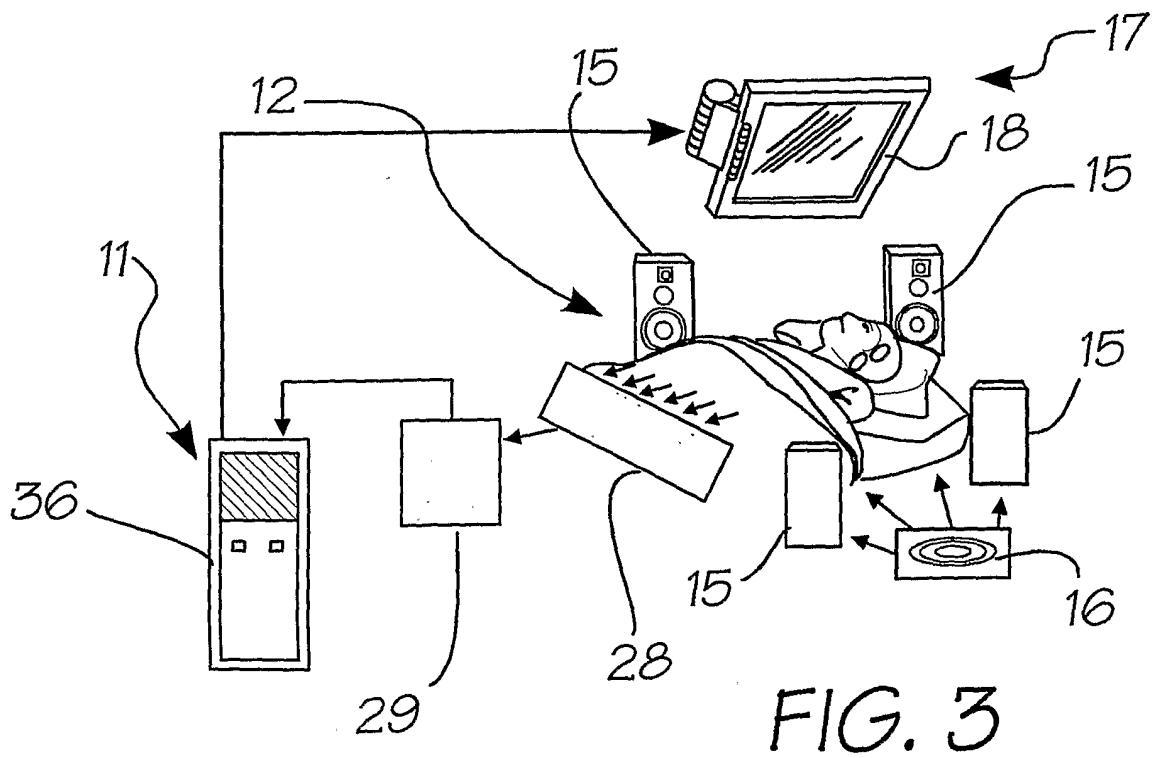
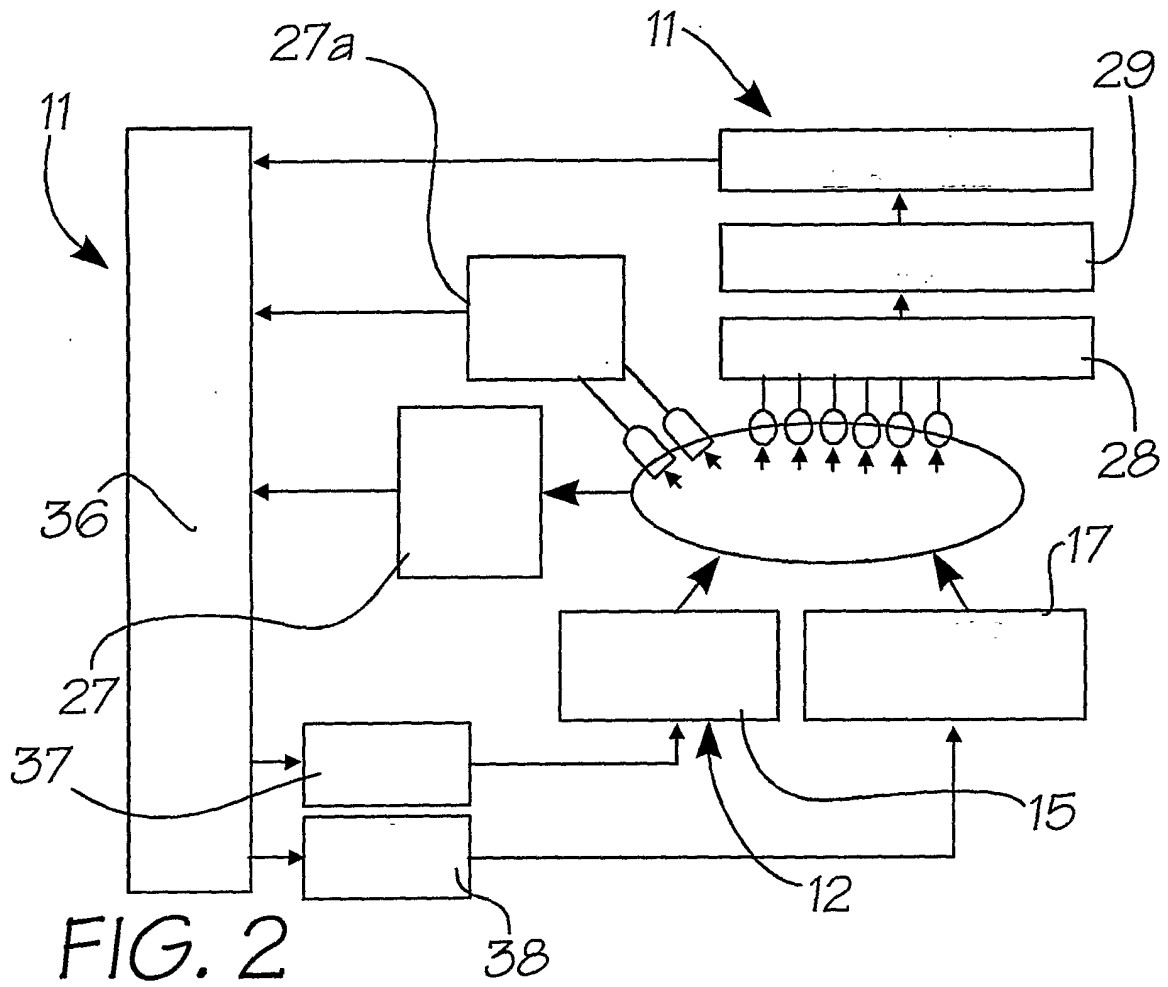
31. The apparatus according to claim 30, characterized in that said device comprises, on a supporting structure to be fixed to the head of the patient, earpieces, a microphone with a bite-operated and/or breath-operated switch,
30 and an infrared forehead-mounted pointing/sensing device that cooperates

with sensors applied to said monitor.

32. The apparatus according to one or more of the preceding claims, characterized in that said information processing and control means comprise a digital electronic information processor, which is provided with mass storage devices suitable to acquire the sensings of said measurement
5 and control devices, and cards for interfacing with said devices.

33. The apparatus according to claim 32, characterized in that said digital information processor comprises one or more remote connection devices for remote management.

10 34. The apparatus according to one or more of the preceding claims, characterized in that it is configured as a container which is suitable to form, when folded in compact form, a suitcase with wheels for easier carrying.



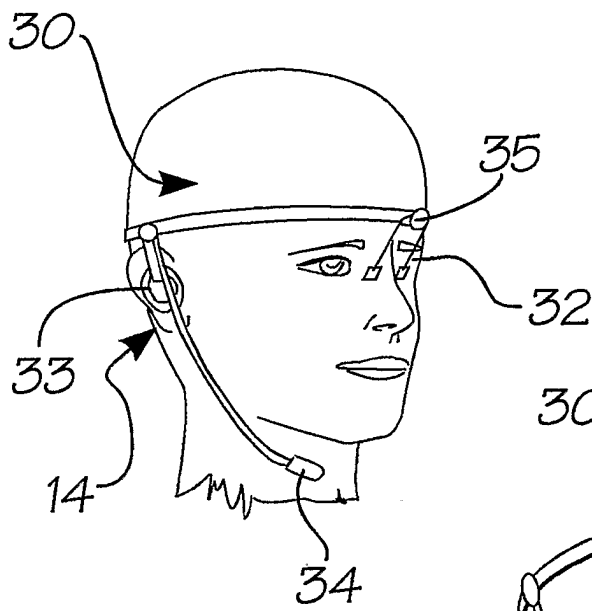
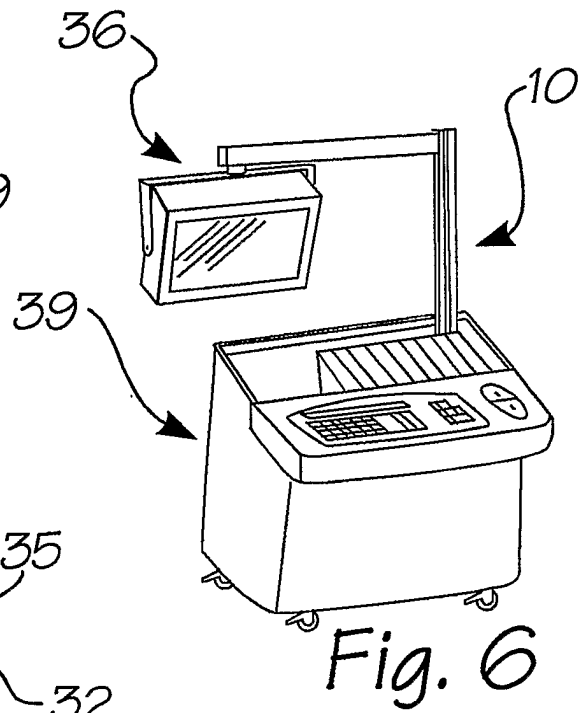
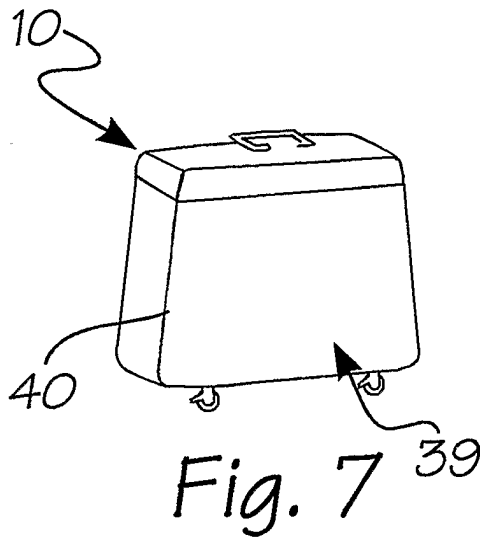


Fig. 5

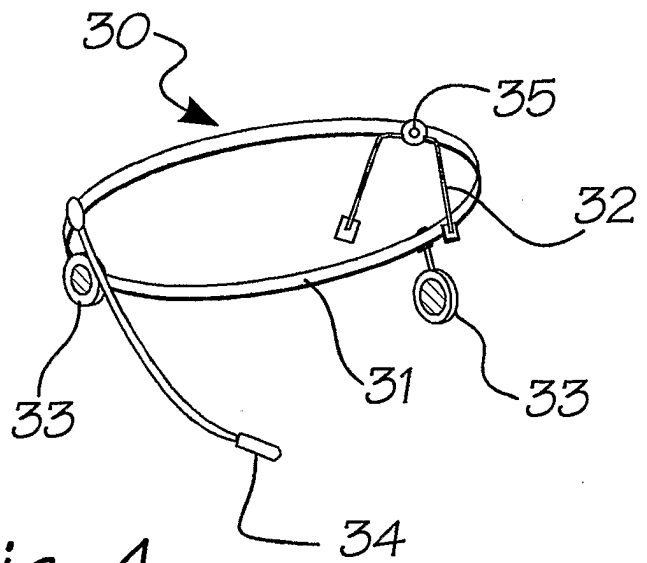


Fig. 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 02/03737

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/0484 A61B5/04

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)
IPC 7 A61B

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 practical, search terms used)
EPO-Internal, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 611 350 A (JOHN MICHAEL S) 18 March 1997 (1997-03-18) column 2, line 3 -column 3, line 8 column 6, line 14 - line 58; claims ---	1,6,7, 11,13, 18-20, 25,32
X	WO 00 64348 A (WITHINGTON DEBORAH JANE ;SOUND ALERT TECHNOLOGY PLC (GB)) 2 November 2000 (2000-11-02) page 7, line 1 - line 15 page 9, line 1 -page 13, line 21 page 6, line 22 - line 25; figures --- -/--	1-12,18, 19,21, 24,32-34

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search 22 July 2002	Date of mailing of the international search report 29/07/2002
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Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Manschot, J
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INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 02/03737

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 195 626 A (SCHWEIZER HELGI-JON) 1 April 1980 (1980-04-01) column 6, line 59 -column 8, line 28 column 9, line 11 - line 51; figure 2A -----	1-4, 6, 8, 9, 11, 13, 14, 18-21, 23, 24, 26
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Information on patent family members

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PCT/EP 02/03737

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