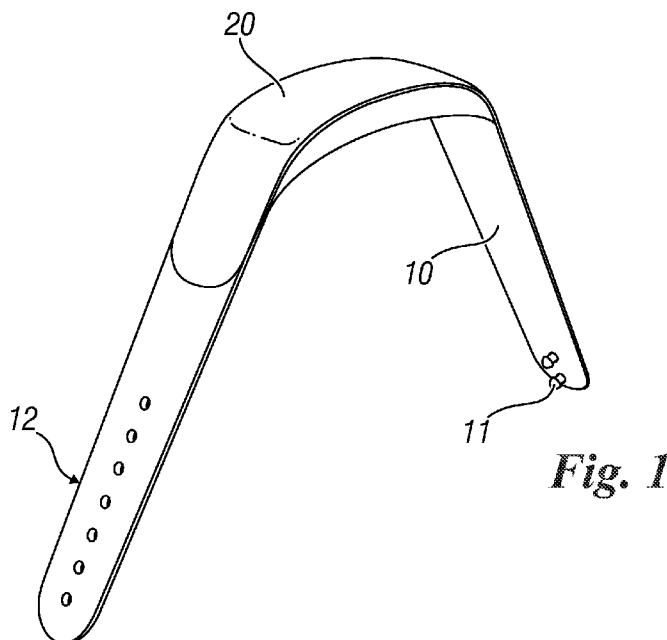




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(54) **Title:** WEARABLE DEVICE TO MANAGE AN EPILEPTIC SEIZURE OF A PERSON



(57) **Abstract:** Device for managing the epileptic seizure of a first person subjected to epileptic seizures, by a second person, wherein said device is worn by said second person and comprising: means for manually activating said device; alert means for providing information related to the time remaining to reach a pre-set time; means for deactivating said device; storing means for storing the start time of the seizure and the duration thereof; transmission means for sending the start time of the seizure and the duration thereof to a digital application; a control circuit which controls said alerting means.



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**“WEARABLE DEVICE TO MANAGE AN EPILEPTIC SEIZURE OF A
PERSON”**

DESCRIPTION

The present invention refers to a device to manage the epileptic seizure of a person, and in particular to a device that can be worn by a person other than the person who has epileptic seizures, and even more in particular wearable by a person who takes care of a person who has epileptic seizures.

Epilepsy is a pathological syndrome that consists of a complex of symptoms having in common a hyperexcitability of the central nervous system. The term epilepsy derives from the Greek word *epilambanein*, which means “to be overwhelmed, to be caught by surprise”. In fact, this syndrome is characterized by the sudden onset of epileptic seizures which, indeed, catch the patient by surprise.

There are different types of epileptic seizures. Seizures, in most cases, cause loss of consciousness. A seizure in a person with epilepsy is not per se a medical emergency, although it may appear so. In fact, the seizure generally ceases spontaneously in few minutes without leaving other consequences, if not the sensation of dizziness and fatigue.

If the seizure continues for more than 5 minutes, it then becomes necessary to intervene by administering life-saving drugs, which interrupt the seizure. One of the fundamental tools for a correct diagnosis of the disease and for the identification of an appropriate drug therapy is the seizure diary. Keeping an updated diary of the

seizures is not an easy activity, above all, due to the amount of information that should be reported each time, and due to the apprehension and panic of the situation that typically occurs during and following a seizure, which makes it difficult to remember exactly what happened.

The object of the present invention is to provide a device that facilitates the management of the epileptic seizure by people who take care of individuals affected by said disease.

Another aim is to provide a device that facilitates the organization of a seizure diary.

A further object is to provide a device that is easy to use.

According to the present invention, said purposes and others are achieved by a device to manage an epileptic seizure of a first person subjected to epileptic seizures, by a second person, wherein said device is worn by said second person and comprising: means for manually activating said device; alerting means for providing information related to the time remaining for reaching a pre-set time; means for deactivating said device; storing means for storing the start time and the duration time of the seizure; transmission means for sending the start time of the seizure and the duration thereof to a digital application; a control circuit that controls said alerting means.

These aims are also achieved by a method for managing the epileptic seizure of a first person subjected to epileptic seizures, by a second person, using a device according to claim 1 characterized by the steps of said second person wearing said device; activating said

device at the beginning of the seizure; deactivating said device at the end of the seizure.

Further characteristics of the invention are described in the dependent claims.

The advantages of this solution in respect to the solutions of the known art are different.

First of all, the device is aimed at helping to manage the seizure and to measure the duration thereof. A key aspect is the ability to monitor the duration of the seizure and to inform the user when it is necessary to administer the life-saving drug. This greatly simplifies the activities performed by the person who supports the person who has epileptic seizures, as currently, the duration of the seizure must be actively monitored by the person intervening during rescue. Said activity requires a significant effort in attention, which makes the rescue more difficult and is often difficult to carry out, considering the situation of apprehension and panic that a seizure unleashes in the person supporting the person who has epileptic seizures, such as parents, family or the like.

Secondly, the device simplifies the compilation of the seizure diary, which is one of the most important aid that the doctor receives to make a correct diagnosis of the disease. In fact, an exclusive aspect of the device is the possibility to register the beginning, duration and place of the seizure, and to send this data to a digital support application that will build a detailed diary, and that will allow further information relating to the seizure to be added later on.

The products on the market, normally, focus on the user who suffers from epilepsy and not on those who are there to assist. Generally, these products use wearable devices that monitor the patient by detecting the beginning of a seizure in progress and send an alert message to parents (typically via smartphone) when a seizure is detected. According to the present invention, the manual recording of a seizure reduces the complexity of the system, avoids problems related to the accuracy of the sensors and allows to drastically reduce the costs of the device.

Another innovative element of the device is the manner in which it conveys information concerning the occurring seizure and the severity thereof. In fact, the device does not use an alphanumeric language or a traditional display-based interface, but creates a sensorial and emotional communication based on light and colour patterns. Said communication does not require a cognitive effort to read numbers or words, but conveys information in a more intuitive and effective manner. The objective is to maintain the concentration of the user on rescue operations and to warn him/her when necessary (when approaching the maximum duration of the seizure). Moreover, the possibility of giving a qualitative feedback on the severity of the seizure, when the seizure ceases, can be a reassuring element for the parent, as it allows a greater awareness of the event that occurred to be obtained, through a delicate, emotional and non-invasive communication.

The device will therefore help to manage the seizure, in

particular by monitoring the duration of the seizure, and will help to compile a diary of the seizures of the patient. The information related to the seizures that have taken place will be sent to a support application, which will provide more detailed information on the severity of the seizure, the position, the actions to be taken and on the chronology of the events.

The characteristics and the advantages of the present invention will be apparent from the following detailed description of a practical embodiment thereof, illustrated as a non-limiting example in the accompanying drawings, wherein:

Figure 1 shows a device for managing the epileptic seizure of a person, according to the present invention;

Figure 2 shows a container of the electronic circuits of a device for managing the epileptic seizure of a person, according to the present invention;

Figure 3 shows an exploded view of a device for managing the epileptic seizure of a person, according to the present invention.

Referring to the accompanying figures, a device for managing the epileptic seizure of a person, according to the present invention, comprises a strap 10 having on one side a block 11 with pins, and on the other side, a series of holes 12 for fixing the block 11 and closing the strap around the wrist of a person.

The person that will wear the device is not the person who has epileptic seizures but is the person who takes care of the person who has epileptic seizures.

The strap 10 has a rectangular through hole 15 in the centre, inside which a container 16 for the electronic circuits can be placed.

On the side of the through hole 15 two recesses 17 are provided, one on each side, where two switches 18 are placed which, towards the through hole 15, each end with two contacts 19.

Above the through hole 15 a cover 20 is placed, which covers the through hole 15 and the recesses 17.

The container 16 internally comprises a battery 25, a vibration motor 26 an electronic board 27 on top of which, six LEDs 28 are mounted and spaced apart so as to position two on one side of the through hole 15, two in the centre and two on the other side of the through hole 15. The container 16 also comprises, laterally thereto, two further contacts 29, on each side, for connecting the contacts 19 of the switches 18.

The cover 20 is semi-opaque to the point where the LED light diffuses widely.

The electronic board 27 preferably comprises a storing unit to store the detected data and means to communicate said data and to receive setting data from the outside such as a Bluetooth device or a connector to connect a cable or the like. It can also comprise a GPS device.

The connections of the electronic elements and the circuit of the electronic board 27 will not be further described, since from the following description, one skilled in the art will be able to implement the same.

A transparent plastic protection component 30 is provided on top of the container 16.

The two switches 18 are arranged in the recesses 17, the cover 20 is set which is fixed with a suitable glue, the container 16 is inserted into the through hole 15 which is positioned by interference fitting, and the device is obtained.

The operation of the device is as follows.

The device is worn by parents/supervisors of patients suffering from epilepsy. The device is manually activated with an immediate gesture by means of a combined pressure on two sides of the strap, in the same position as the switches 18, at the beginning of a seizure.

Two switches have been provided to be pressed simultaneously to avoid being turned-on accidentally.

Other forms of activation are possible, for example, by providing the device with a touch screen, and therefore by using a swipe or a sequence for activation.

Information regarding the duration of the seizures is provided, for example, through the variation in colour of the surface of the device, which can be seen from the cover 20, which marks the passing of minutes by using different colours and/or by varying the extent of the illuminated area (which is equivalent to the number of activated LEDs), and/or by varying the intensity of the illuminated area.

The information on activation, deactivation, and reaching the

maximum duration limit of the seizures (in case it is reached), are provided alternatively or in combination by means of vibrations.

A pre-set time (modifiable by means of application) of the duration of an epileptic seizure is set in advance, fixed for example, at 5 minutes.

In an example of embodiment of the device, the flow of time is indicated as shown in Table 1.

That is, for 40% of the pre-set time (therefore in the case of 5 minutes for a time equal to 2 minutes), only two LEDs light up, from one side a light-blue colour, and upon activation, a vibration is provided.

For the next 40% of the pre-set time, four LEDs, two side ones and the two central ones, light up in a blue colour.

For the last 20% of the pre-set time all the six LEDs light up, in a purple colour.

Once the pre-set time has elapsed, the six LEDs light up in a red colour and a very quick continuous vibration (for about 10 seconds) takes place to indicate that it is the right time to administer the drug that blocks the seizure.

After administering the drug, the device continues recording the time until it is stopped. This helps to monitor the time needed for the drug to be effective and to stop the seizure.

When the seizure is over, the user of the device stops the operation of the device by pressing on two sides of the strap, in the same position as the switches 18.

The device at this point provides emotional information communicated to the parent/supervisor concerning the severity of the seizure, linked to the duration thereof. This feedback is based on the use of pulsating coloured light, and provides three levels of feedback (mild, medium, serious seizure).

In particular, the bracelet lights up and vibrates on the wrist, the number of times depends on the intensity of the seizures, that is, it will quickly flash the colour that the device is currently having, three times. If the seizures have stopped in the first phase, the device will flash in light-blue, indicating tranquillity. If the seizure has been of medium duration it will flash in a blue colour. If the seizures have been more severe, that is, it is in the third phase it will flash in purple. In the case wherein the time limit of administration of the drug has been exceeded, the flashing will be in a red colour.

When the device stops, all the information recorded by the bracelet, such as the start time of the seizure, the duration of the seizure, exceeding or not the pre-set time for the administration of the anti-seizure drug, the time passed, beyond the pre-set time, so that the drug will be effective and stop the seizure, are sent, for example via Bluetooth, to an online digital diary preferably integrated into a smartphone application, which preferably will integrate the received data with other detectable data, such as the date, the information on the event location (by using either the GPS on the device or the GPS on the smartphone), and/or other data.

The device has been made having a similar shape as a watch

but may have other shapes such as a brooch or a necklace.

The materials used for the strap, as well as the size, may be any according to the requirements and to the state of the art.

The device thus conceived is susceptible to numerous modifications and variations, all of which fall within the scope of the inventive concept; furthermore, all the details can be replaced by technically equivalent elements.

Elapsed Time	Number of activated LEDs	LED Colour	Vibration
0-40%	2 LEDs	Light-blue	At activation
40-80%	4 LEDs	Blue	-
80-100%	6 LEDs	Purple	At pre-set time
Beyond 100%	6 LEDs	Red	-

CLAIMS

1. A device for managing the epileptic seizure of a first person subjected to epileptic seizures, by a second person, wherein said device is worn by said second person and comprising: means for manual activation of said device; alerting means for providing information related to the time remaining to reach a pre-set time; means for deactivating said device; storing means for storing the start time and the duration of the seizure; transmission means for sending the start time of the seizure and the duration thereof to a digital application; a control circuit which controls said alert means.

2. The device according to one of the preceding claims, characterized in that said device can be worn by said second person.

3. The device according to one of the preceding claims, characterized in that said activation and deactivation means of said device comprise two switches to be pressed simultaneously.

4. The device according to claim 1 characterized in that said alert means comprise light means.

5. The device according to claim 4 characterized in that said light means comprise a plurality of coloured LEDs able to change colour on command.

6. The device according to claim 4 characterized in that said light means comprise a plurality of LEDs able to vary the amplitude of the illuminated area on command.

7. The device according to claim 1 characterized in that said alert means comprise a vibration motor.

8. The device according to claim 1 characterized in that said pre-set time corresponds to the time beyond which it is necessary to administer a life-saving drug.

9. The device according to claim 1 characterized in that said device is a bracelet.

10. A method for managing the epileptic seizure of a first person subjected to epileptic seizures by a second person using a device according to claim 1 characterized by the steps that said second person wears said device; activating said device at the beginning of the seizure; deactivating said device at the end of the seizure.

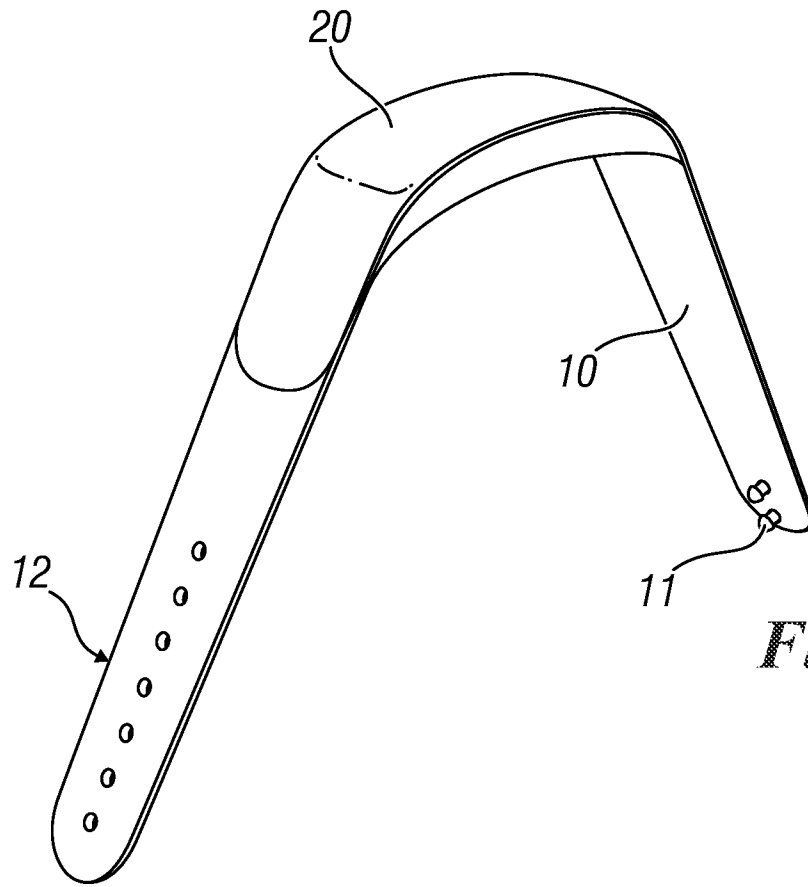


Fig. 1

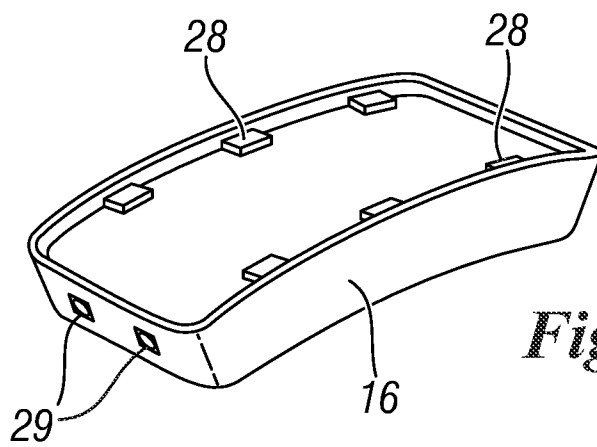


Fig. 2

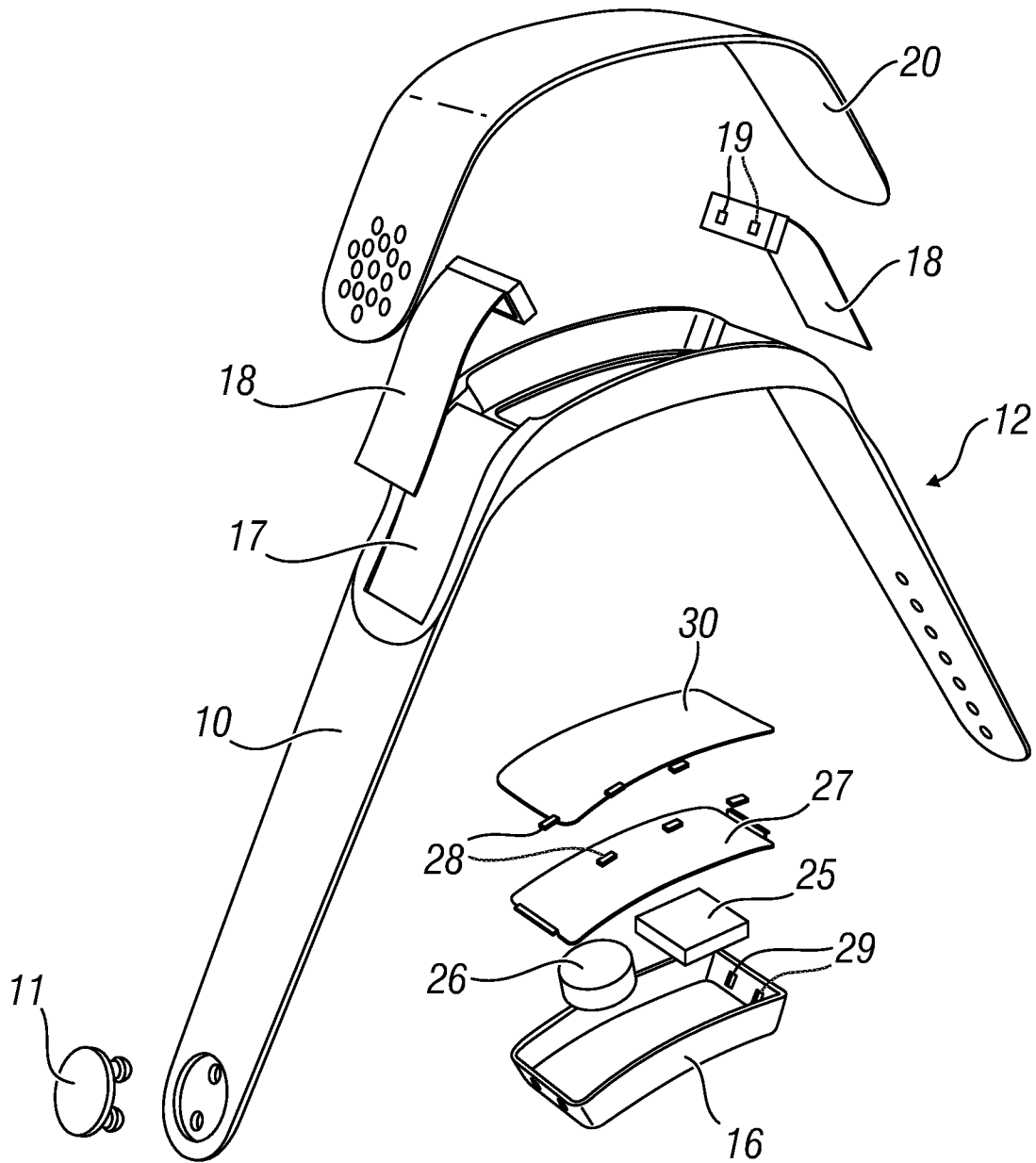


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2018/053612

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B5/00 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) 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 practicable, search terms used) EPO-Internal, WPI Data, BIOSIS, EMBASE		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2017/095194 A1 (KRAUSS GREGORY [US] ET AL) 6 April 2017 (2017-04-06) abstract; figure 1 paragraphs [0011], [0043], [0193] - [0196]	1-10
X	----- EP 2 123 221 A2 (NATHAN VAIDHI [US]) 25 November 2009 (2009-11-25) paragraphs [0021], [0033], [0041] - [0042], [0046], [0070]; figure 1B -----	1-10
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents :		
"A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
Date of the actual completion of the international search <p align="center">5 September 2018</p>		Date of mailing of the international search report <p align="center">13/09/2018</p>
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer <p align="center">Clevorn, Jens</p>

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2018/053612

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2017095194	A1	06-04-2017	NONE

EP 2123221	A2	25-11-2009	EP 2123221 A2 25-11-2009
			US 2009062696 A1 05-03-2009
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