Title: NON-INVASIVE DEVICE FOR NEURO-MUSCULAR MONITORING

Abstract: Device (1) for neuro-muscular monitoring, comprising a pressure sensor (2) apt to detect contractions of the musculature innervated by the facial or the laryngeal nerve and to be received within the oral or laryngeal cavity of a subject, and a remote unit (3) connected to the sensor (2) and apt to signal the detected contraction to an operator.
NON-INVASIVE DEVICE FOR NEURO-MUSCULAR MONITORING

Description

The present invention relates to a device for neuro-muscular monitoring, and in particular to a device for facial nerve and inferior laryngeal nerve monitoring. However, the device of the invention is generally useful for monitoring the muscular activity induced by stimulating any specifically pertinent nerve. Hence, the invention relates to a device useful during otolaryngology and general surgery, especially those involving the hearing apparatus and the thyroid gland, and/or useful in assessing the conductivity of a nerve, and in particular of the facial nerve.

Various surgical procedures are carried out near nerve structures that need preserving. Every day, even the most skilled surgeon faces the big technical problem of identifying and preserving the finer nerve structures, without the aid of any nerve-monitoring device. In fact, though theoretically available on the market, devices of this kind are still far from being routinely used due to the high costs and to the complexity of their operation.

As concerns specifically the facial nerve, as it is known to the persons skilled in the art, the facial nerve is a mainly motor nerve, regulating facial motility and also carrying out important secondary functions such as tear and saliva production control. Moreover, always via the facial nerve the gustatory sensations of the front part of the tongue reach the central nervous system.

The facial nerve has an articulated and complex course, consisting of an intracranial section, an intratemporal section and an extracranial section. For this reason as well, the facial nerve is prone to iatrogenic damage, and often it actually undergoes such damage, during otolaryngology surgery, especially middle ear and mastoid surgery. In particular, during this latter type of surgery the facial nerve can be injured due to its close anatomical relations with the cochlea, the oval window, the stapes, the lateral semicircular canal, the incus and the vestibule.

Facial nerve dehiscence is the most significant risk factor for iatrogenic damage in ear and mastoid surgery. In fact, in the absence of the bone wall separating the facial nerve fibers from the middle ear cavity in the intratympanic section of the facial nerve itself, the latter is easily damageable during surgery. Moreover, histological studies showed that the facial nerve might also physiologically have dehiscence areas. The risk of an iatrogenic damage to the nerve increases, even considerably, in middle ear resurgery, due to anatomical alterations and to possible iatrogenic dehiscences often due to the surgical act. Moreover, dehiscences of the
tympanic or vertical portion of the facial nerve are frequently found in middle ear cholesteatoma, envisaging its sole effective treatment in surgery.

Furthermore, also an aberrant course of the facial nerve in its intratemporal portion, very frequent in congenital pathologies of the ear, like e.g. atresia and microtia, enormously increases the risk of iatrogenic damage, as do the facial nerve anomalies that can be found in some non-congenital pathologies, like e.g. ear tumors, middle ear adenomas and facial tumors, and as a consequence of petrous bone traumas.

In order to prevent said iatrogenic damages to the facial nerve, in the course of surgery for acoustic neurinoma and neurinoma of the pontocerebellar angle this nerve is monitored with electromyography techniques. However, the electromyography devices employed are invasive, costly, and require the intervention of skilled technical staff. Moreover, such devices are not very handy in the surgical field, and threaten to hamper the surgeon and/or to interfere with the remaining instrumentation. Moreover, these devices, due to their very nature, require specific measures to avoid the risk of electrocuting the monitored patient.

All this discourages several otosurgeons and sanitary structures from using known-art monitoring devices. Therefore, in spite of the hereto-highlighted marked risk of iatrogenic damage to the facial nerve, a routine monitoring of this nerve in the course of surgery is almost never performed, to the serious detriment of surgery safety.

Moreover, as far as the inferior laryngeal nerve is concerned, in thyroid surgery there is reported an incidence of permanent or transitory damage to the recurrent laryngeal nerve of 0.1% to 4%, respectively. Unilateral nerve damage causes dysphonia, becoming apparent at +2-3 days. Due to the closure of the glottis by loss of action of the adductor muscles of the larynx, a bilateral nerve lesion, though transitory, entails dramatic sequels immediately at extubation at the end of surgery; the patient has to be readily reintubated and ventilated; in various instances emergency tracheotomy is required.

A ready identification of the recurrent laryngeal nerve would significantly lower the risk of iatrogenic damage thereto. However, not seldom — and especially in advanced benign thyroid pathologies and in malignant thyroid tumors — such an identification can prove very difficult with the sole anatomic-surgical reports.

Therefore, the technical problem underlying the present invention is that of providing a device for neuro-muscular monitoring allowing to overcome the
drawbacks mentioned above with reference to the known art.
Such a problem is solved by a device according to claim 1.
Preferred features of the present invention reside in the dependent claims thereof.

The present invention provides some relevant advantages. First of all, the choice of
making the monitoring device sensitive to a mechanical variable to detect
contractions of the nerve-innervated musculature prevents any chance of
electromagnetic interference thereof with the remaining surgical instrumentation
and any risk of electrocution harming the patient.

Moreover, the proposed device is extremely simple to use and inexpensive to
implement. Furthermore, it has extremely reduced dimensions, does not hamper the
surgeon and is non-invasive for the patient.

For these reasons as well, the device enables an effective routine monitoring of the
facial nerve during any surgery, and specifically during surgery involving the hearing
apparatus, entirely to the advantage of surgery safety.

Moreover, the device enables the surgeon to identify the course of the nerve — and
especially of the facial nerve — even in the most difficult cases, to immediately
ascertain any iatrogenic damage and to carry on the surgical act with greater speed
and safety, even remarkably expediting the surgical, and above all the otosurgical,
learning curve.

Moreover, the device can be used for ambulatory assessment of the functional
recovery of paralyzed muscles, especially of the facial muscles.

Therefore, the use of a device for monitoring the muscular activity induced by the
stimulation of the nerve of specific pertinence generally enables to control the
location of the recurrent nerve. For this purpose, the detecting means can be
positioned onto the anesthesiological tube, e.g., in the case of application for
inferior laryngeal nerve monitoring, among the vocal cords. Facial nerve control
instead takes place with the detecting means positioned below the cheek. Of
course, in other applications the detecting means will be positioned in a related
body cavity.

Other advantages, features and operation steps of the present invention will be
made apparent in the following detailed description of some embodiments thereof,
given by way of example and not for limitative purposes. It will be made reference to
the figures of the annexed drawings, wherein:

– Figure 1 shows a schematic representation of an embodiment of the apparatus
  of the invention;
Figure 2 shows a block diagram related to some internal components of the device of Figure 1; and

Figure 3 shows a schematic representation of part of the device of Figure 1 during its use in surgery.

Referring initially to Figure 1, a device for facial nerve monitoring is generally indicated by 1.

The device 1 comprises first of all a pneumatic sensor 2 apt to be received within a patient's oral cavity. In the present embodiment, the pneumatic sensor 2 comprises in particular an inflatable balloon apt to deform in response to contractions of the musculature innervated by the facial nerve, as it will be detailed later on.

Additionally, the device 1 comprises a remote control unit 3 apt to generate an alarm signal following the detecting, by the balloon 2, of a contraction of the musculature innervated by the facial nerve, said control unit 3 being connected to the balloon 2 by a pneumatic circuit generally indicated by 4.

More precisely, the pneumatic circuit 4 in its turn comprises:

- a first branch 41, interposed between the balloon 2 and a first port of a first three-way valve 401;
- a second branch 42, connecting a second port of the first valve 401 to a first inlet 51, referred to as measurement inlet, of the control unit 3;
- a third branch 43, connecting a third port of the first valve 401 to a first port of a second three-way valve 402; and
- a fourth branch 44, connecting a second port of the second valve 402 to a second inlet 52, referred to as reference inlet, of the control unit 3.

The different branches of the circuit 4 can be implemented by simple catheter portions or the like.

Further, the third port of the second three-way valve 402 is apt to be connected to a pneumatic source S, which in Figure 1 has schematically been depicted as a syringe, but that of course can also consist of a compressor or equivalent means.

Therefore, a person skilled in the art will understand that the two valves 401 and 402 are apt to selectively fraction the pneumatic circuit 4 into sub-portions, so as to selectively connect the balloon 2 with the control unit 3 and/or with the source S, and the latter with the control unit 3.

Moreover, the device 1 comprises transducing means 6, incorporated into the remote control unit 3 and apt to take a measurement signal, i.e. the pressure at the
first inlet 51, and a reference signal, i.e. the pressure at the second inlet 52, and to
output a differential electric signal corresponding just to the difference between said
measurement and reference mechanic signals.

In particular, the transducing means 6 is of the phase discrimination type, and
therefore apt to output both the amplitude difference and the phase difference
between the measurement and the reference signals taken at the two inlets 51 and
52.

In short, therefore, the transducing means 6 is apt to transform mechanic signals,
and in particular pressure pulsing variations at the inlets 51 and 52, into
the corresponding electric signals, and in particular into voltage signals.

Preferably, the transducing means 6 is implemented so that the device 1 has a high
rapidity of response and sensitivity to pulsing pressure inputs, i.e. to pressure
variations in the higher frequency fields (> 70 Hz), and concomitantly a low
sensitivity for slow-variable pressure inputs. Thus, there is prevented the generation
of alarm signals in case of interferences with facial nerve due to non-harmful
events, like e.g. a mere resting of the surgeon’s hand on the cheek or any weighing
on the latter.

The transducing means 6 can be implemented e.g. by deformable membranes
located at the inlets 51 and 52 and by associated strain gauge devices. However,
since to a person skilled in the art plural implementation options of such means will
be immediately apparent, a further description thereof will be omitted.

In the present embodiment, the control unit 3 further comprises comparing means
7, apt to compare the electric signal outputted by the transducing means 6 with a
preset threshold. When this threshold is exceeded, the means 7 activates an alarm
device, and in particular an audio alarm 8 in form of a so-called “buzzer” and/or a
visual alarm 9 in form of a blinker light.

In particular, always in order to attain an elevated sensitivity of the device to high-
frequency pressure variations and a low sensitivity to slowly-variable pressure
signals, the comparing means 7 can be implemented so that only pressure pulsing
variations of amplitude higher than a preset threshold are signaled to the operator.

In the present embodiment, the control unit 3 also comprises means 10 for
adjusting said threshold preset by a user, so as to enable a varying of the device
sensitivity. Such adjusting means 10 can e.g. be based on a potentiometer.

The adjusting means at issue can allow a threshold adjustment in amplitude. A
variant embodiment foresees instead the control unit to comprise a single inlet and
the comparing means to directly compare the signal detected thereof to a preset threshold.

Another variant foresees that the detecting means detect the entity of the pressure applied in order to assess the recovery trend of the nerve conductive functionality in a rehabilitation context.

Preferably, in order to allow the use of the device 1 in an operating room and to ensure patient safety from electrocution due to failure of component or of component insulation, the components of the device are powered by a low-voltage battery.

Since all the hereto-introduced components of the device 1 are implementable with hardware and/or software elements immediately apparent to a person skilled in the art, a further description thereof will be omitted.

The operation steps of the device 1 will be illustrated hereinafter with specific reference to its use for facial nerve monitoring during middle ear and mastoid surgery.

As it is shown in Figure 2, the balloon 2 is received within the oral cavity of the subject, and precisely it is positioned below the cheek at the buccinator muscle level. The balloon 2 can optionally be mounted on a support apt to facilitate its positioning and the holding of a stable position thereof.

After insertion in the patient’s oral cavity or immediately prior thereto, the balloon 2 is inflated by the source S. In particular, during this inflating step the valves 401 and 402 are opened so as to interconnect all adjacent branches of the pneumatic circuit 4. Therefore, all branches of the circuit 4 are brought to the same pressure, i.e. just that for inflating the balloon 2.

To facilitate the inflating step and to ensure that the balloon 2 be brought to a desired pressure, onto the case of the control unit 3 there can be provided a pressure indicator, which, in association with the transducing means 6 or with suitable further measurement means, enables the operator to control the actual inflation pressure.

Moreover, the device 1 can provide means apt to automatically signal that a predetermined pressure value has been reached. Optionally, such means can be configured so as to hold constant the pressure value reached.

After inflation has been made, the valve 402 is operated so as to deny the connection between the source S and the rest of the circuit.

At this point, the device 1 is ready to provide an alarm signal in response to the
detecting of a contraction of the musculature innervated by the facial nerve.

In particular, if, during surgery, the surgeon touches or even merely grazes the facial nerve or a structure proximal thereto, the nerve itself is interested by stretching, tractions or coagulations and a consequent contraction of the musculature innervated thereby occurs.

This contraction causes the deforming, and in particular a local squeezing, of the balloon 2, thereby originating a pressure pulse thereinside that propagates into the pneumatic circuit 4, and in particular into the branches 41, 42, 43 and 44 of the latter down to the inlets 51 and 52. To cross the branch 42 such a pulse employs a time lower than that it employs to cross the branches 43 and 44, hence due to the phase difference of the two pulses, the transducing device is set in oscillation. Such an oscillation is detected by the transducing means 6, which outputs a corresponding electric signal. The comparing means 7 compares this signal to the preset threshold, and optionally activate the buzzer 8 and/or the pilot light 9, thereby signaling a situation harmful to the integrity of the normal functionality of the facial nerve to the surgeon.

It will be appreciated that the presence of differential transducing means enables an automatic compensation of the pressure variations due to events unrelated to the muscular contraction, like e.g. a temperature variation due to heat exchange with the patient, etc., a variation in the operating theatre air conditions and/or in the atmospheric pressure.

Moreover, it will be appreciated that the device of the invention is susceptible of an embodiment as a portable device having very reduced dimensions.

Furthermore, the device is easily employable in all otosurgical acts, comprising those executable in outpatient regimen.

It will be understood that, though the device of the invention has hereto been described with reference to its application for facial nerve monitoring, it can effectively be used for inferior laryngeal nerve monitoring, in this case housing the pneumatic sensor 2 in the laryngeal cavity, and in particular between the vocal cords.

Likewise, the sensor can be received in another body cavity of the subject and the device employed to detect the contraction of the related local musculature.

Of course, the present invention is susceptible of several embodiments and variant embodiments alternative to the hereto-described ones, some of which will briefly be
illustrated hereinafter with reference to the sole aspects differentiating it from the hereto-considered ones.

First of all, the device can have muscular contraction detecting means alternative to the abovedisclosed balloon and associated differential transducer.

Likewise, the device can have means apt to signal the detecting of a contraction to an operator by detecting means alternative to the abovedescribed remote control unit.

Moreover, though the device of the invention has hereto been described as applied in a surgical context, it can advantageously be employed also as indicator of the degree of conduction of the facial nerve fibers. For example, the device of the invention may be useful in assessing the level of extension and seriousness of a facial nerve paralysis and, in general, be a useful diagnostic support in the selection of the most suitable therapy for any type of disorder or pathology somehow associated to the condition of the facial nerve. In such an alternative application, the device of the invention may have an implementation different from or in all identical to the one described hereto with reference to the figures. For example, the device may have means for detecting a contraction of the musculature innervated by the facial nerve comprising a mechanic sensor like said balloon, and signaling means comprising, instead of the means for generating an alarm signal described with reference to the first embodiment, a different interface communicating the detecting of a contraction, and optionally the type, the entity and/or the duration thereof, to the operator.

The present invention has been hereto described with reference to preferred embodiments thereof. It is understood that other embodiments might exist, all falling within the concept of the same invention, and all comprised within the protective scope of the claims hereinafter.
Claims

1. A non-invasive device (1) for neuro-muscular monitoring, comprising:
   - detecting means (2), apt to be received within a body cavity of a subject and to detect the contraction of local musculature; and
   - signaling means (8, 9), connected to said detecting means (2) and apt to signal the detection of a contraction by the latter to an operator,

wherein said detecting means (2) is sensitive to a mechanical variable.

2. The device (1) according to claim 1, wherein said detecting means (2) is apt to be received within the oral cavity of the subject.

3. The device (1) according to claim 1 or 2, wherein said detecting means (2) is apt to be received within the laryngeal cavity of the subject.

4. The device (1) according to any one of the preceding claims, wherein said detecting means (2) is sensitive to the pressure exerted thereon following a contraction of the local musculature.

5. The device (1) according to any one of the preceding claims, wherein said detecting means (2) is of a pneumatic type.

6. The device (1) according to the preceding claim, wherein said detecting means comprises an inflatable member (2) apt to be received within body cavity of the subject.

7. The device (1) according to the preceding claim, wherein said inflatable member is a balloon sensor (2).

8. The device (1) according to claim 6 or 7, comprising a pneumatic circuit (4) apt to allow the inflating of said inflatable member (2).

9. The device (1) according to any one of claims 5 to 8, comprising a pneumatic circuit (4) for connecting said detecting means (2) to said signaling means (8, 9).

10. The device (1) according to claims 8 and 9, comprising a single pneumatic circuit (4) for inflating said inflatable member (2) and for connecting said detecting means (2) to said signaling means (8, 9), said circuit (4) comprising one or more valves (401, 402) for selectively connecting said inflatable member (2) to an inflating fluid source (S) and to said signaling means (8, 9).

11. The device (1) according to any one of the preceding claims, wherein said signaling means (8, 9) is apt to generate an alarm signal upon detection of a contraction by said detecting means (2).

12. The device (1) according to any one of the preceding claims, wherein said
signaling means (8, 9) comprises an audio signaling device (8).

13. The device (1) according to any one of the preceding claims, wherein said signaling means (8, 9) comprises a luminous signaling device (9).

14. The device (1) according to any one of the preceding claims, wherein the overall configuration is such that the device itself be sensitive to pulsing variations of said mechanical variable.

15. The device (1) according to the preceding claim, wherein the overall configuration is such that said signaling means (8, 9) signal to the operator only variations of said mechanical variable of amplitude and frequency greater than a preset threshold.

16. The device (1) according to the preceding claim, comprising adjusting means (10) for adjusting said amplitude threshold preset by a user.

17. The device (1) according to any one of the preceding claims, comprising comparing means (7), apt to compare a signal corresponding to the muscular contraction detected by said detecting means (2) with a preset threshold and to activate said signaling means (8, 9) according to the outcome of such a comparison.

18. The device (1) according to the preceding claim, comprising adjusting means (10) for adjusting said threshold preset by the user.

19. The device (1) according to any one of the preceding claims, comprising a remote unit (3), connected to said detecting means (2) and at which there are located said signaling means (8, 9).

20. The device (1) according to the preceding claim, wherein said remote unit (3) comprises a first inlet (51), at which there is detected a measurement signal generated by said detecting means (2), a second inlet (52), at which there is detected a reference signal, and means (6) for generating a differential signal from said reference and measurement signals.

21. The device (1) according to any one of the preceding claims, wherein said detecting means comprises a sensor (2) and a support for said sensor apt to facilitate the housing thereof within the oral cavity of the subject.
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

**IPC** 7 A61B5/11

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 database consulted during the international search (name of database and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>FR 2 625 092 A (UZIEL ALAIN ; VIDAL DOMINIQUE (FR)) 30 June 1989 (1989-06-30) page 2, line 20 - line 44</td>
<td>1-21</td>
</tr>
<tr>
<td>A</td>
<td>US 5 609 161 A (TURA RONALD E ET AL) 11 March 1997 (1997-03-11) column 1, line 59 - column 2, line 11 column 2, line 66 - column 3, line 31</td>
<td>1-21</td>
</tr>
</tbody>
</table>

□ Further documents are listed in the continuation of box C.  X Patent family members are listed in 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 document 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
- **X**: document member of the same patent family

Date of the actual completion of the international search: 4 February 2004

Date of mailing of the international search report: 11/02/2004

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

Martelli, L
<table>
<thead>
<tr>
<th>Patent document cited in search report</th>
<th>Publication date</th>
<th>Patent family member(s)</th>
<th>Publication date</th>
</tr>
</thead>
</table>