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(54) Title: DEVICES FOR AND METHODS OF DIAGNOSING AND/OR MONITORING DYSPHAGIA

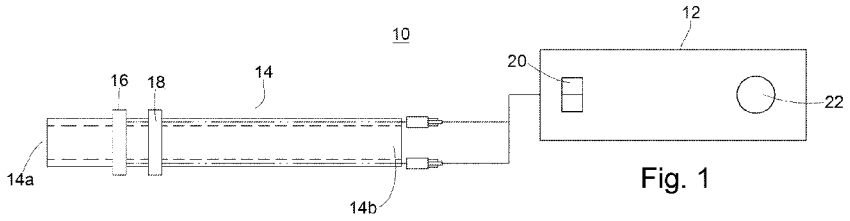

Fig. 1

(57) Abstract: The use of a device to measure patient sensory response through the application of an incrementally increased electrical current to the oropharynx.

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DEVICES FOR AND METHODS OF DIAGNOSIS AND/OR MONITORING DYSPHAGIA

FIELD

The present invention relates to devices for and methods of diagnosis and/or monitoring dysphagia.

BACKGROUND

Dysphagia is a medical term given to an inability to swallow or an inability to swallow in a safely controlled way. It has been reported that 7%-10% of all adults older than 50 years of age present with clinically significant dysphagia. Of those over the age of 60, this increases to 14% of the entire adult population. In total 10 million Americans are evaluated each year in clinics and hospitals for swallowing difficulties. It has also been reported that >51% of institutionalised elderly patients present with oropharyngeal dysphagia.

Collectively these figures reflect the fact that neurogenic dysphagia (dysphagia arising from neurological damage) can develop due to a very wide range of underlying conditions such as traumatic brain injury, cerebral palsy, head and neck cancer and neurodegenerative diseases like MS, Parkinson's and Alzheimer's. It is however stroke that is probably the most recognized single cause of dysphagia - greater than 50% of patients who have a stroke will present with dysphagia.

Complications that have been associated with dysphagia post-stroke include pneumonia, malnutrition, dehydration, poorer long-term outcome, increased length of hospital stay, increased rehabilitation time and the need for long-term care assistance, increased mortality, and increased health care costs. These complications impact the physical and social well being of patients, quality of life of both patients and caregivers, and the utilization of health care resources.

Dysphagia can be difficult to diagnose and to monitor. Symptoms may improve or worsen over even short periods of time. Gold standard diagnostic methods for swallowing assessment involve the use of instrumental exams that visualise the movement of materials from the oral spaces to the oesophagus. Examples of such methods include videofluoroscopy (VFS) and Fibroscopic Endoscopic Evaluation of Swallowing (FEES). These allow quantification of the time involved in the movement of a bolus of material through the oral spaces, the amount of swallowed material that pools in the pharynx and the amount of material that enters into the airways. They can also capture the response of the patient to material entering into the airways as a determinant of level of awareness the patient has to this risk associated event and their ability to respond to it. These methods can be difficult or traumatic for the patient and require substantial expertise and training.

Other diagnostic methods include bedside assessments such as the Toronto Bedside Swallow Test (TORBST). These are observational methods that test the ability of the subject to swallow a variety of different materials. These methods are more qualitative in nature and are designed to screen for the presence or absence of a normal swallow. Whilst they have the advantage of being easy to carry out they lack the diagnostic sensitivity of instrumental methods and in particular are poor at identifying so called silent aspirators whose sensory processes are so compromised they do not react to even substantial amounts of material entering the airways.

The pharyngeal phase of swallowing is initiated voluntarily. This first requires input and oversight from the parts of the brain involved in motor planning. These higher centres receive information about the nature of the material, size of the bolus etc., and modulate the involuntary sequences that will follow. The duration and intensity of muscle contraction can be modified to accommodate a larger bolus for example. Only when the food or liquid bolus is voluntarily pushed through the faucial pillars (the structures to the left and right of the uvula), or in older individuals, when the food is in contact with the base of the tongue, is the reflexive involuntary component of the pharyngeal swallow triggered. This is where the central pattern generator within the medulla (brain stem), modulated by the higher centres

comes into play. The reflexive sequence that follows has two key functions: i) controlled passage of food or secretions from the pharynx to the oesophagus; and ii) airway protection.

A common manifestation in neurogenic dysphagia is that whilst the pattern generating processes that control the sequence of activities in swallowing (located in the brain stem) may be intact, the triggers to begin or modulate the swallowing processes are absent or compromised. This can reflect the fact that the sensory input provided by the bolus of material at the back of the throat or base of the tongue is no longer sufficient to be detected and to trigger the reflexive swallowing process. In effect the sensory threshold for that individual has been raised. Whilst the consequences of this increase in sensory threshold may be seen with existing diagnostic methods, the increase and absolute level of the threshold is not measured by these methods.

Pharyngeal Electrical Stimulation (PES) is a method for treating neurogenic dysphagia. It involves the application of electrical stimulation to the pharyngeal mucosa and this results in an increase in activity in the motor cortex and other areas of the brain. These changes facilitate a functional reorganisation of the centres in the brain responsible for controlling and coordinating swallow function.

SUMMARY OF THE INVENTION

As used herein, the term patient sensory response data shall be interpreted as meaning the patient's sensory threshold, i.e. the weakest electrical current that a patient can detect.

As used herein, the term control sensory response data shall be interpreted as meaning either: i) a sensory response range as would be expected from a healthy individual who is not suffering from dysphagia, ii) a sensory response range as would be expected from an individual suffering from dysphagia or ii) at least one previous patient sensory response data entry obtained from a specific patient and in the case of multiple data entries obtained from a patient over time, said data entries are plotted on a curve to indicate the extent and speed of recovery from dysphagia by comparing the slope of the curve with other control sensory response data obtained from other patients who exhibited recovery from dysphagia.

An aspect of the present invention provides a device for diagnosing dysphagia, the device comprising: a catheter for oral or nasal insertion into a patient, the catheter comprising an elongate body having at least one electrode mounted on or about the elongate body, said at least one electrode configured to receive a variable electrical current for applying electrical stimulation to the patient's oropharynx, and a control unit comprising an electrical current generator, a non-volatile memory for storing patient sensory response data and control sensory response data, means for recording the patient's sensory response to the applied electrical stimulation and a processor for comparing the patient's sensory response to a control sensory response and determining whether the patient is suffering from dysphagia and/or monitoring the patient's recovery from dysphagia.

Another aspect of the present invention provides a device for diagnosing and/or treating dysphagia, the device comprising: a control unit, and a catheter for oral or nasal insertion into a patient, and wherein the catheter comprises a nasal gastrointestinal feeding tube and a sleeve selectively movable relative to the feeding tube, the sleeve having at least one electrode mounted thereon, said at least one electrode configured to receive a variable electrical current for applying electrical stimulation to the patient's oropharynx, and a control unit comprising an electrical current generator, a non-volatile memory for storing patient sensory response data and control sensory response data, means for recording the patient's sensory response to the applied electrical stimulation and a processor for comparing the patient's sensory response to a control sensory response and determining whether the patient is suffering from dysphagia and/or monitoring the patient's recovery from dysphagia.

Another aspect of the present invention provides a method of diagnosing dysphagia, the method comprising: i) applying an electrical current of between 1mA and 50mA to a patient's oropharynx; ii) increasing the current incrementally; iii) obtaining patient sensory feedback

after each incremental increase in current; iv) comparing the patient's sensory response with a control sensory response; and v) determining whether the patient is suffering from dysphagia and/or monitoring the patient's recovery from dysphagia.

Devices and methods of the present invention enable a medical professional to make a diagnosis of dysphagia and/or monitor a patient's recovery from dysphagia. Over time, patient's suffering from dysphagia may show signs of clinical improvement whether as a result of treatment, such as pharyngeal electrical stimulation, or through spontaneous recovery. The applicant has observed that an improvement in swallowing ability, i.e. an improvement in the patient's clinical condition, broadly corresponds to a reduction in the patient's sensory response, i.e. the patient's sensory threshold is lower. During treatment a patient would be expected to exhibit a reducing sensory threshold and this trend would be indicative of a corresponding improvement in swallowing function. The same trend would be observable in patient's who have not received treatment but whose clinical condition has spontaneously improved.

FIGURES

Aspects of the invention will now be described by way of reference to the following figures:

Figure 1 shows a first embodiment of a device according to the present invention;

Figure 2 shows a second embodiment of a device according to the present invention;

Figures 3a, 3b and 3c show a third embodiment of a device according to the present invention;

Figure 4 shows sensory threshold levels in treated and untreated subjects over three consecutive days whereby the treated group also improved their swallow function;

DESCRIPTION

Figure 1 shows a device (10) for diagnosing dysphagia. The device (10) comprises a control unit (12) and a catheter (14). The control unit (12) comprises a variable electric current generating means for delivering electrical current to the catheter (14). The control unit (12) further comprises a non-volatile memory for storing patient sensory response data and/or control sensory response data and a processing means for comparing and/or processing patient sensory response data against said control sensory response data to make a diagnostic determination of whether a patient is suffering from dysphagia and/or monitoring the patient's recovery from dysphagia.

The catheter (14) has a at least one electrode (16,18) mounted thereon. The at least one electrode (16,18) is electrically connected to the variable electric current generating means of the control unit (12). The catheter (14) may be single use or re-usable.

In embodiments of the invention described with reference to figure 1, the device (10) may be configured to provide Pharyngeal Electrical Stimulation (PES) and to provide a recommendation for further treatment based on patient sensory response.

Figure 2 shows a device (100) for diagnosing dysphagia and for providing nutrition. The device (100) comprises a control unit (102) and a catheter (104). The control unit (102) comprises a variable electric current generating means for delivering electrical current to the catheter (104). The control unit (102) further comprises a non-volatile memory for storing patient sensory response data and/or control sensory response data and a processing means for comparing and/or processing patient sensory response data against control sensory response data to make a diagnostic determination of whether a patient is suffering from dysphagia and/or to monitor the patient's recovery from dysphagia.

The catheter (104) comprises a NG feeding tube (108) and a sleeve (110) selectively movable relative to the NG feeding tube (108). The sleeve (110) carries at least one electrode (112,114) and wiring connecting the at least one electrode (112,114) to the control unit (102).

Each of the devices (10, 100) of figures 1 and 2 are either provided with a rechargeable battery (not shown) or are electrically connectable to a power source, or both. Each device (10, 100) is also provided with a power selector (20, 118) to turn the device (10, 100) on/off and a control means (22, 116) to select the level of current to be delivered to the at least one electrode (18, 112). In some embodiments a graphical display is provided to visually identify to a medical professional that a patient is suffering from dysphagia and/or to indicate a change in the patient's clinical condition. In other embodiments a speaker is provided to audibly identify to a medical professional that a patient is suffering from dysphagia and/or to indicate a change in the patient's clinical condition. In other embodiments the device (10, 100) is equipped with wireless communications technology to transmit information relating to diagnosis and treatment to a server, network or independent device such as smartphone, tablet or laptop. The wireless communications technology could be WIFI, Bluetooth or GSM, for example, but is not limited thereto.

Each device (10, 100) has a diagnostic mode for diagnosing whether a patient is suffering from dysphagia and/or for monitoring a change in the patient's clinical condition. The control unit (12, 102) collects patient sensory response data and stores said data against a specific patient record in the non-volatile memory of the device (10, 100). The control unit (12, 102) can therefore compare instantaneous patient sensory response data against control sensory response data to monitor a patient's response to PES over time to determine whether or not further PES is required.

The device (10, 100) is turned on by activation of the power selector (20, 116). The control means (22, 116) is used to select the current level and is typically set to a current level that is not detectable by a patient, i.e. 1mA. The catheter is inserted orally or nasally into the patient and the at least one electrode (16,18,112,114) is aligned with the patient's oropharynx.

The control means (22, 116) is used to activate the at least one electrode (14, 112) and impart the 1mA electrical current into the patient's tissue. The control means (22, 116) is then used to increase the electrical current in 1mA increments up to a maximum of 50mA. After each increment the patient will be requested to confirm whether they can sense the electric current or not. If the patient cannot sense the electric current it will be increased by a further 1mA. If the patient can sense the electric current the current level will be recorded as patient sensory response data.

When using the device (10, 100), the patient sensory data will be saved in the non-volatile memory against that individual patient's record. In certain embodiments the non-volatile memory is integral to the device (10, 100) and data contained therein is uploaded to a remote server either wirelessly or by plugging the device (10, 100) into a separate device connected to a server. Such a device (10, 100) can also store patient data uploaded thereto from a server or other device. Such data can be used by the device (10, 100) to compare patient sensory response data against control sensory response data. Such comparison is used by the device (10, 100) to diagnose dysphagia by comparing patient sensory response data to control sensory response data. The device (10,100) can be used to monitor unassisted recovery from dysphagia and recovery as a result of PES.

Figure 3 shows a device (200) for applying electrical stimulation to a patient's oropharynx. The device (200) comprises a re-usable probe (202), as detailed in figure 3a, and a disposable sleeve (204), as detailed in figure 3b. The re-usable probe (202) comprises a tubular body (206), which may be rigid, semi-rigid or flexible, and a pair of terminally located electrodes (208,210). Conducting wires (212,214) are connected between each electrode (208,210) and an electrical current generator (not shown).

The disposable sleeve (204) comprises a hollow tubular body (216) closed at one end. The closed end of the tubular body includes one or more areas (218,220) that are capable of

conducting an electric current from the electrodes (208, 210) through the sheath in the direction of the longitudinal axis of the device (200).

In use, as shown in figure 3c, the probe (202) is inserted into the sleeve (204) so that the pair of electrodes (208,210) are aligned and substantially in contact with the one or more conductive areas (218,220) of the sleeve (204).

Studies

Studies were conducted in two patient groups; a treatment arm and a control arm. Each patient in the treatment arm received a stimulation level that is specifically tailored to their treatment needs. This level is determined through first establishing their sensory threshold and thereafter their tolerance level (the highest level of applied stimulation the patient can tolerate for the treatment period). A suitable stimulation level is then derived from these two parameters.

A randomised controlled trial of PES in the control arm consisting of 30 subjects with dysphagia and a tracheotomy was performed to assess whether treatment resulted in sufficient restoration of safe swallowing to allow the tracheotomy cannula to be removed. As part of this study the threshold and tolerance levels of subjects in both the treatment and control arms were recorded.

Figure 4 shows the initial and subsequent mean threshold levels for the treatment (Stimulation) arm and the control (Sham) arms. It can be seen that whilst the initial sensory threshold levels were similar, over the course of treatment the sensory threshold levels in the group receiving stimulation decreased whilst those not receiving stimulation actually increased.

This data suggests that decreasing sensory threshold levels are linked to swallowing recovery and that the trend in sensory level over time may also be indicative of the extent to which the subject is responding to treatment.

CLAIMS

1. A device for diagnosing dysphagia, the device comprising:

a catheter for oral or nasal insertion into a patient, the catheter comprising an elongate body having at least one electrode mounted on or about the elongate body, said at least one electrode configured to receive a variable electrical current for applying electrical stimulation to the patient's oropharynx, and

a control unit comprising an electrical current generator, a non-volatile memory for storing patient sensory response data and control sensory response data, means for recording the patient's sensory response to the applied electrical stimulation and a processor for comparing the patient's sensory response to a control sensory response stored in the non-volatile memory and determining whether the patient is suffering from dysphagia and/or monitoring the patient's recovery from dysphagia.

2. A device for diagnosing and/or treating dysphagia, the device comprising:

a catheter for oral or nasal insertion into a patient, the catheter comprising a nasal gastrointestinal feeding tube and a sleeve selectively movable relative to the feeding tube, the sleeve having at least one electrode mounted thereon, said at least one electrode configured to receive a variable electrical current for applying electrical stimulation to the patient's oropharynx, and

a control unit comprising an electrical current generator, a non-volatile memory for storing patient sensory response data and control sensory response data, means for recording the patient's sensory response to the applied electrical stimulation and a processor for comparing the patient's sensory response to a control sensory response stored in the non-volatile memory and determining whether the patient is suffering from dysphagia and/or monitoring the patient's recovery from dysphagia.

3. A device substantially as described with reference to, and/or as shown in, the drawings.

4. A method of diagnosing dysphagia, the method comprising: i) applying an electrical current of between 1mA and 50mA to a patient's oropharynx; ii) increasing the current incrementally; iii) obtaining patient sensory feedback after each incremental increase in current; iv) comparing the patient's sensory response with a control sensory response; and v) determining whether the patient is suffering from dysphagia.

5. A method of monitoring recovery from dysphagia, the method comprising: i) applying an electrical current of between 1mA and 50mA to a patient's oropharynx; ii) increasing the current incrementally; iii) obtaining patient sensory feedback after each incremental increase in current; iv) comparing the patient's sensory response with a control sensory response; and v) monitoring the patient's recovery from dysphagia.

6. A catheter comprising:

a probe comprising an elongate body having at least one electrode mounted thereon; and

a sleeve comprising a hollow elongate body formed from a non-conductive material and configured to receive the probe, and at least one conductive area which, in use, is aligned with the at least one electrode to enable electrical current from the at least one electrode to pass through the at least one conductive area.

7. A catheter according to claim 6, wherein the at least one electrode is terminally located on the probe.

8. A catheter according to claim 7, wherein the at least one conductive area of the sleeve directs electrical current from the at least one electrode in the direction of the longitudinal axis of the catheter.

9. A catheter according to any of claims 6 to 8, wherein the probe is reusable and the sleeve is disposable.

10. A catheter substantially as described with reference to, and/or as shown in, figure 3.

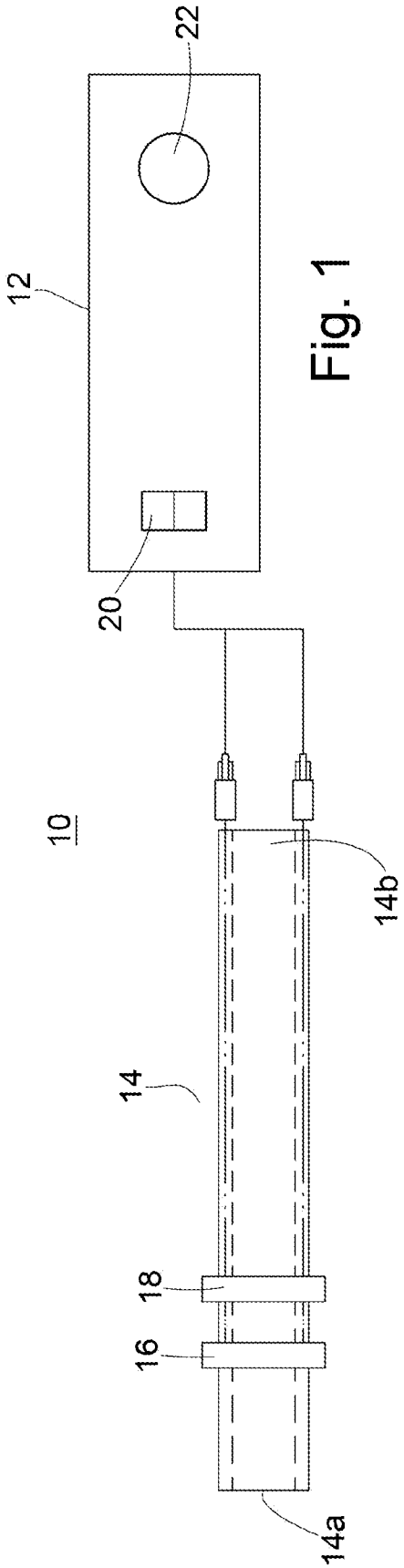


Fig. 1

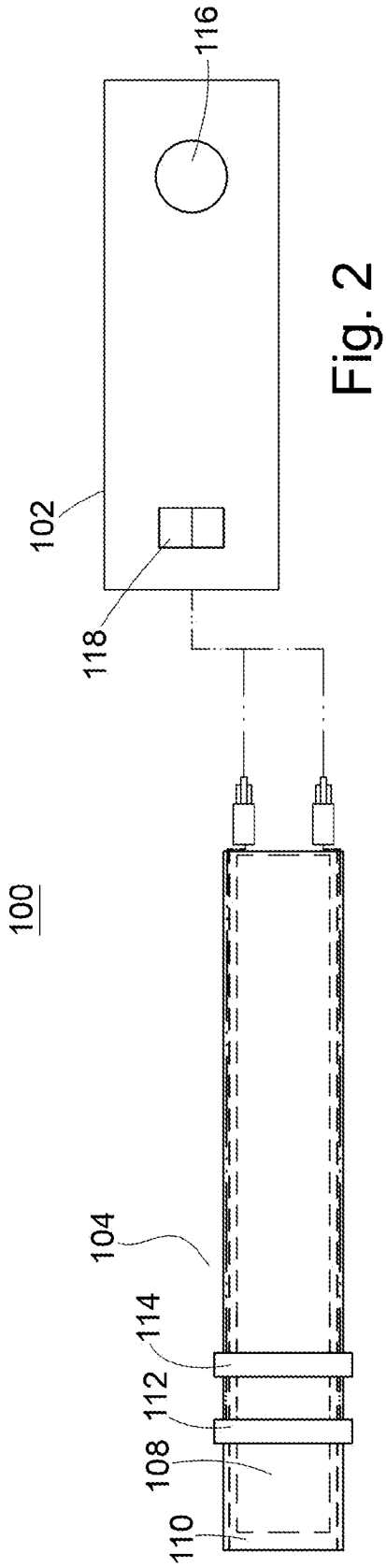
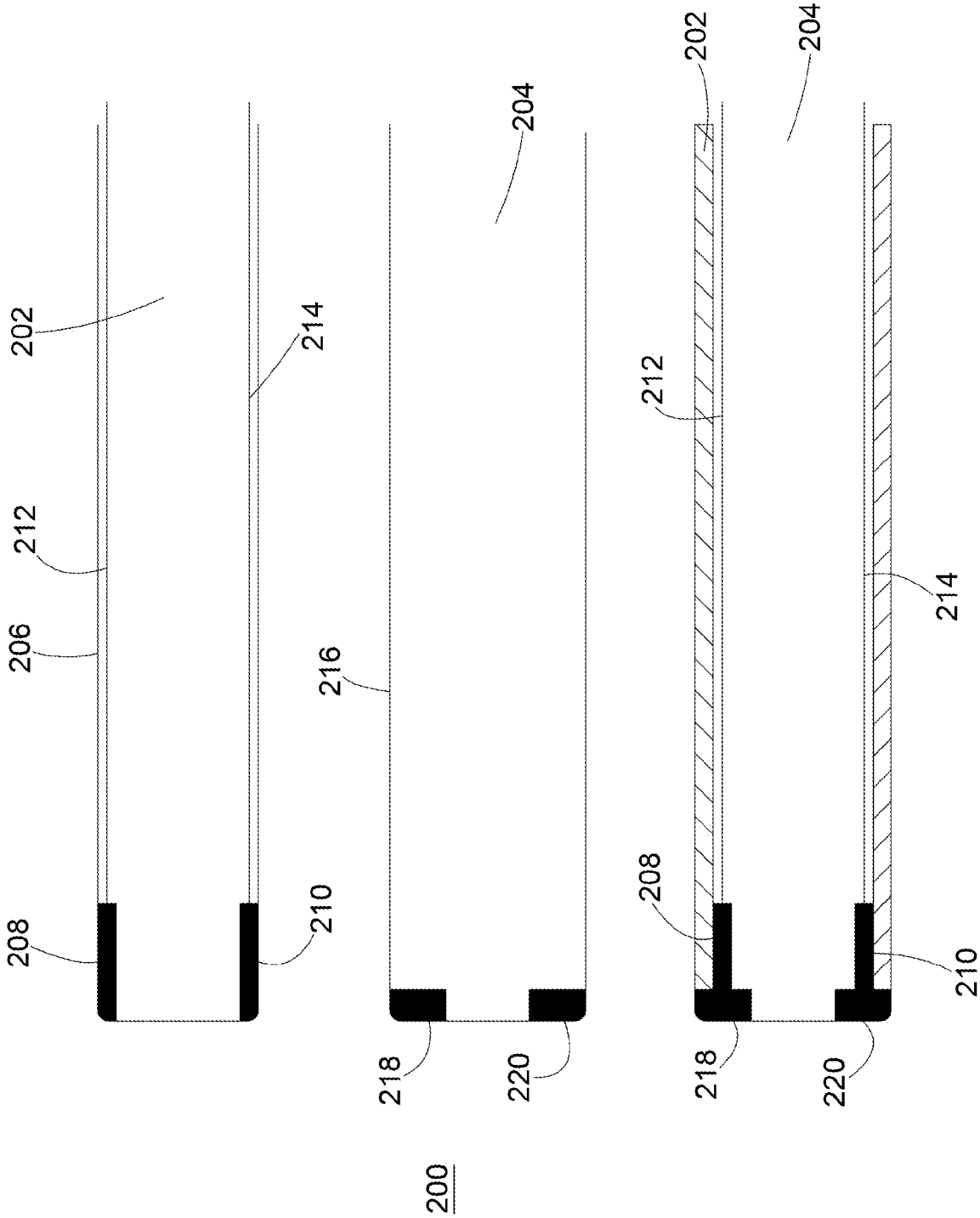


Fig. 2

Fig. 3a

Fig. 3b

Fig. 3c



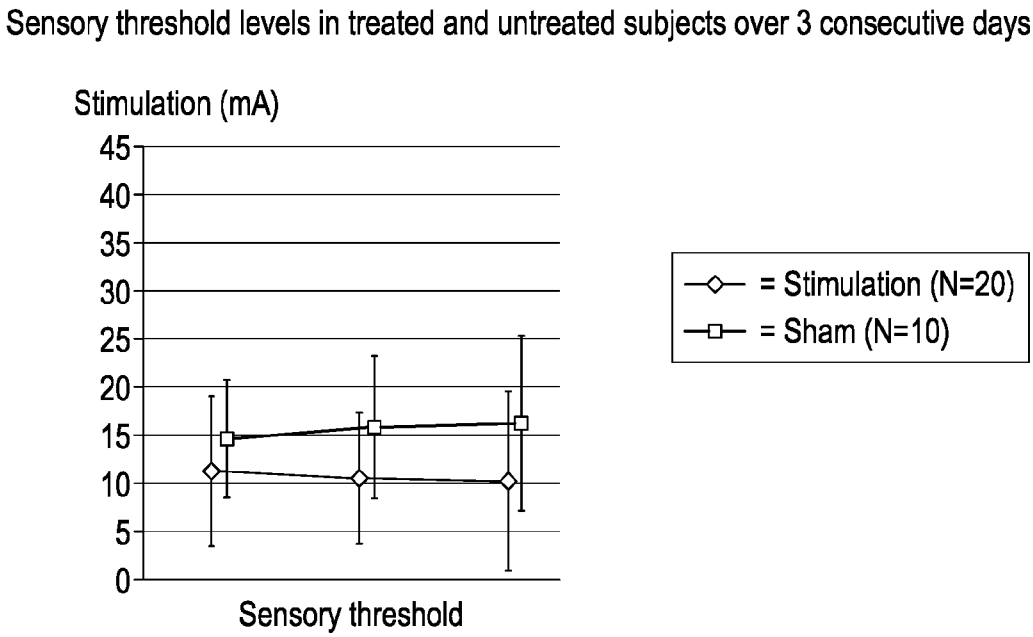

Sensory threshold levels in treated and untreated subjects over 3 consecutive days
Stimulation (mA)
45
40
35
30
25
20
15
10
5
0
Sensory threshold
= Stimulation (N=20)
= Sham (N=10)

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2016/052389

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61J15/00 A61N1/05
ADD. A61N1/36

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 A61J A61N

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 2 693 968 A1 (PHAGENESIS LTD [GB]) 12 February 2014 (2014-02-12) abstract paragraph [0020] - paragraph [0041] paragraph [0084] - paragraph [0122] figures 1-8 -----	1-3,10
Y	US 2013/197321 A1 (WILSON WILLARD [US]) 1 August 2013 (2013-08-01) paragraph [0235] paragraph [0304] - paragraph [0331] figures 15-17 -----	1-3,10

☐ Further documents are listed in the continuation of Box C.

☒ 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	Date of mailing of the international search report
2 November 2016	12/01/2017

Name and mailing address of the ISA/	Authorized officer
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1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2016/052389

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 4, 5
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-3, 10

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2016/052389

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 2693968 A1	12-02-2014	AU 2012235988 A1	17-10-2013
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		EP 2693968 A1	12-02-2014
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		WO 2013113023 A1	01-08-2013

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-3, 10

   A device for improving delivery of dysphagia therapy

   ---

2. claims: 6-9

   A probe with a sleeve

Continuation of Box II.1

Claims Nos.: 4, 5

Claims 4,5 relate to a method for treatment of the human or animal body surgery/therapy, because they all comprises the step of 'i)' and 'ii)' per se involving health risks even when carried out with the required medical care and expertise. This Authority is not required to search the present application with respect to the aforementioned claim/s (Article 17(2)(b) PCT and Rule 39.1(iv) PCT). Consequently, no International Search Report and no Written Opinion (Rule 67.1 PTC in combination with Rule 43bis.1(b) PCT) have been established with respect to them.