Diagnostic Laryngeal Mechanosensor Stimulator

Published date: Feb. 5, 2015

Technology description

Device Novelty

A feedback controlled pressure output system designed to precisely deliver air stimuli toupper aero digestive tractmucosa for the evaluation of dysphagia, laryngopharyngeal reflux, aspiration potential, and obstructive sleep apnea therapy compliance.

Background

Dysphagia and aspiration are common in the elderly, hospitalized and post-surgical patients with acute changes in levels of consciousness from anesthesia during surgery.Early identification of dysphagia and aspiration risk is critical to avoid adverse health consequences such as aspiration pneumonia, respiratory disabilities, and related morbidity, as well as death. It is equally important to avoid unnecessary gastrostomy (tube) feeding of patients since it increases the length of stay and significantly hinders the quality of life of the already debilitated patients.

Of all the diagnostic tests available for identification of dysphagia, endoscopic laryngeal sensory testing is found to be an accurate predictor of laryngopharyngeal sensation (LPS).In this technique, LPS integrity is defined by the threshold at which the laryngeal adductor reflex (LAR) is triggered in response to air pulse stimuli. Previously, Pentax AP-4000 air pulse stimulator was commercially available to produce the air pulse required for testing. However, Pentax AP-4000 suffered from major limitations such as sterilization inability, stimulus pressure instability, patient response measurement inability, limited control over stimulus duration and output range, and loud audible noise with testing. This instrument has been discontinued and not being sold, thus creating a vacuum for an alternate solution.

Invention

Researchers at the University of Toledo have developed a reliable laryngeal mechanoreceptor stimulator (LMS) that overcomes the deficiencies of the models reliably delivering stimuli by leveraging an embedded control system. The core idea was to create a design that was robust to hospital environments and could both consistently deliver results while being easy to use.By coupling two different stimuli, more reliable determination of the mechanoreceptor function is achieved.It permits separation of upper aero digestive tract dysfunction into sensory and mechanical components allowing for the easy identification of the point of maximal therapeutic benefit of medical reflux therapy.The device is a software controlled device that is briefly placed within the pharynx or larynx without anesthesia or sedation for the rapid assessment of the upper aero digestive tract sensory function. This

instrument uses extremely precise sterile stimuli in a feedback controlled system to control its output and for safety.
This device is designed to be significantly more accurate and safer for patients than previously available products, highly modular for easy future modifications and delivers diagnostic information not previously available. The device will allow for a more robust understanding of upper aero digestive tract mechanosensory function.As such, when used appropriately, it will assist clinicians identify the appropriateness of oral intake, medicinal and swallowing therapeutic interventions, the effectiveness of anti-reflux medical therapy and the appropriateness of CPAP therapy.
The novelupper aero digestive tractstimulator possesses great advantages over the inferior, outdated and discontinued Pentax AP-4000 air pulse stimulator. Major features and associated advantages of our device include:

Application area

As a diagnostic and/or measurement tool to be used to assess laryngeal function in regards to swallowing and speech functioning.
Further applications of the device include determination of mechanosensory involvement in various pathologies of the head and neck. Progressions of diseases such as neurodegenerative conditions or neuralgia can be monitored over time noninvasively during a routine clinic visit using the LMS device. The modular design of the patent allows for additional modifications to be easily made which will allow the device to remain current with the state of medicine.

Advantages

·A simple, intuitive wireless interface for clinicians permits unparalleled ease of use
·Upper aero digestive tractfunction monitoring provides clinicians with unmatched diagnostic accuracy
·Feedback control provides higher accuracy, faster ramp time (time from power on to use) and more robustness (compatibility with patients)
·The output is not dependent upon the visual detection of the vocal cord closure (laryngeal adductor reflex arc)
·Redundant safety systems preclude inappropriate stimuli from being delivered to patients
·All patient contact components can be easily sterilized eliminating the introduction of potentially infectious material into a patient’ supper aero digestive tract(throat)
·Highly modular, wireless and digital design allows for easy implementation of additional signal inputs and outputs in the future

Institution

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