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(54) **HANDHELD PORTABLE IMPULSE OSCILLOMETER**

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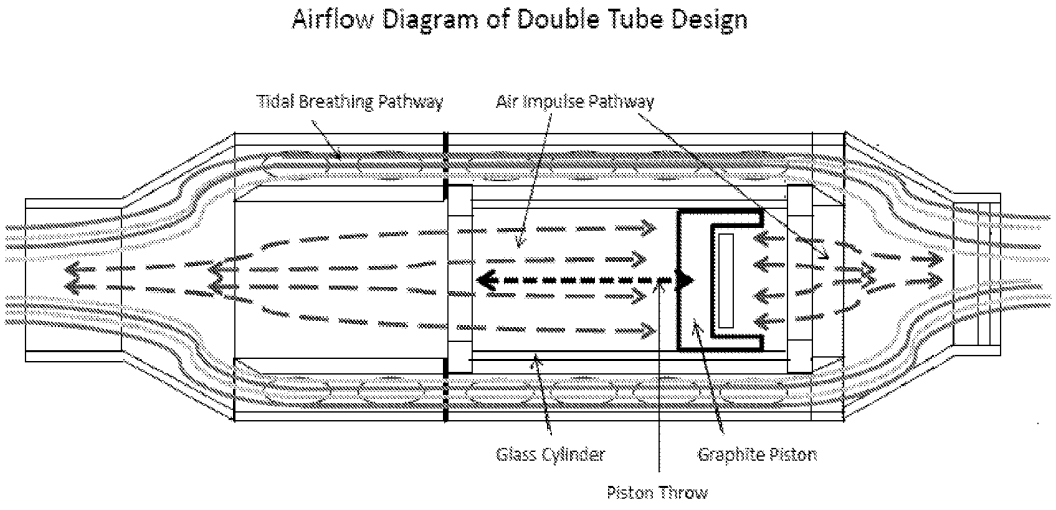
| ***H02J 50/10*** | (2006.01) |
| ***A61B 5/097*** | (2006.01) |
| ***A61B 5/00*** | (2006.01) |

(52) **U.S. Cl.**

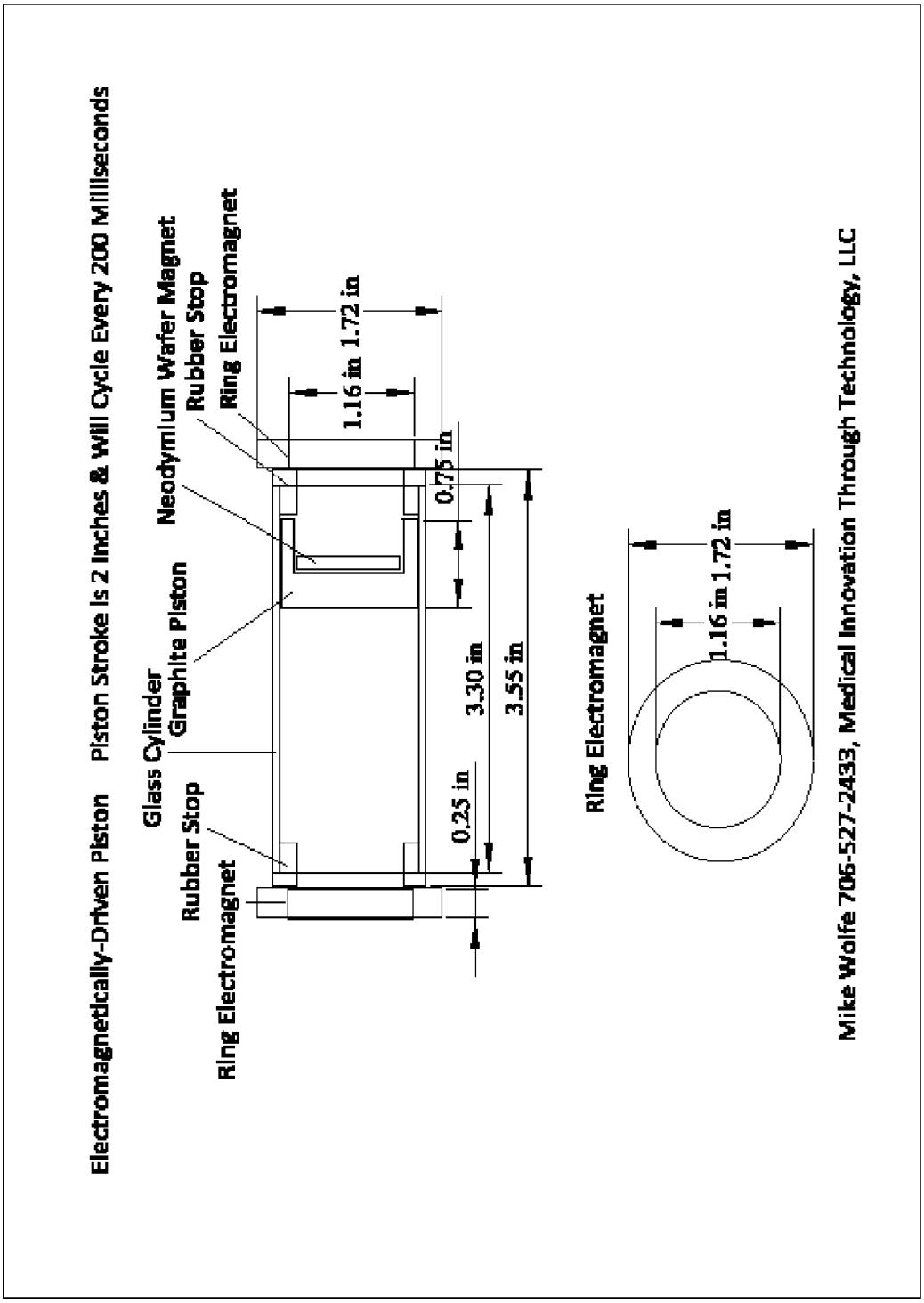
CPC ..... ***A61B 5/085*** (2013.01); ***A61B 5/097*** (2013.01); ***A61B 5/742*** (2013.01); ***A61B 5/0022*** (2013.01); ***H02J 7/025*** (2013.01); ***H02J 50/10*** (2016.02); ***H02J 7/0054*** (2013.01); *A61B 2562/0247* (2013.01); *A61B 2560/0431* (2013.01); *A61B 2560/0425* (2013.01); *A61B 2560/0214* (2013.01); *A61B 2560/0252* (2013.01); *A61B 2560/0257* (2013.01)

(57) **ABSTRACT**

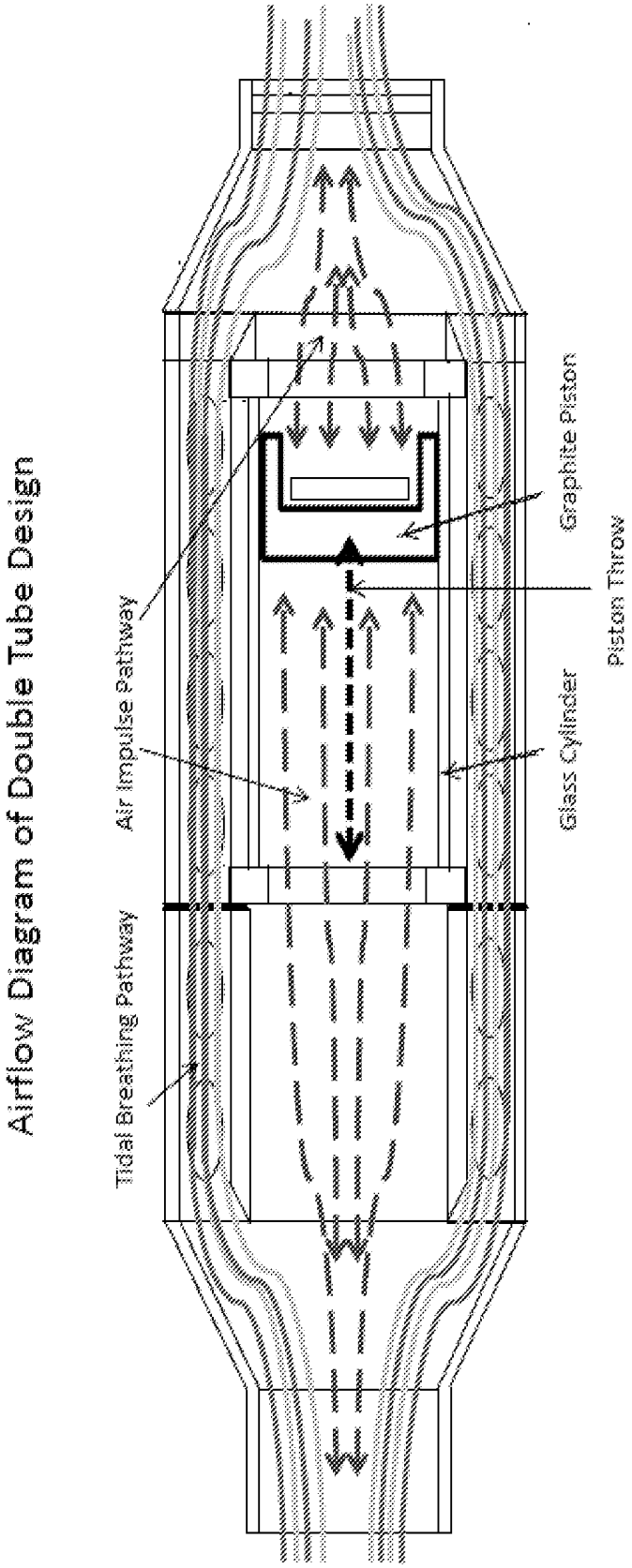
A multitude of clinical research studies have validated the superiority of impulse oscillometry (IOS) over spirometry because it is far more sensitive in the detection of pulmonary diseases and since it is effort-independent, it can be successfully used in children as young as six-months old. By miniaturizing the IOS to be a hand-held and portable device, the present invention takes IOS technology out of the exclusive environments of the research lab and specialty Pulmonology office. Also by advancing the technology, the manufacturing cost is greatly reduced thereby making the device affordable and available to the average primary care physician for use in their office. In addition, as the present invention becomes available as a home-use device, it will significantly improve the home management of complex respiratory diseases, i.e., Asthma and COPD. The present invention, being a miniaturized and electromagnetically piston-driven IOS, is truly unique in its concept and technology.



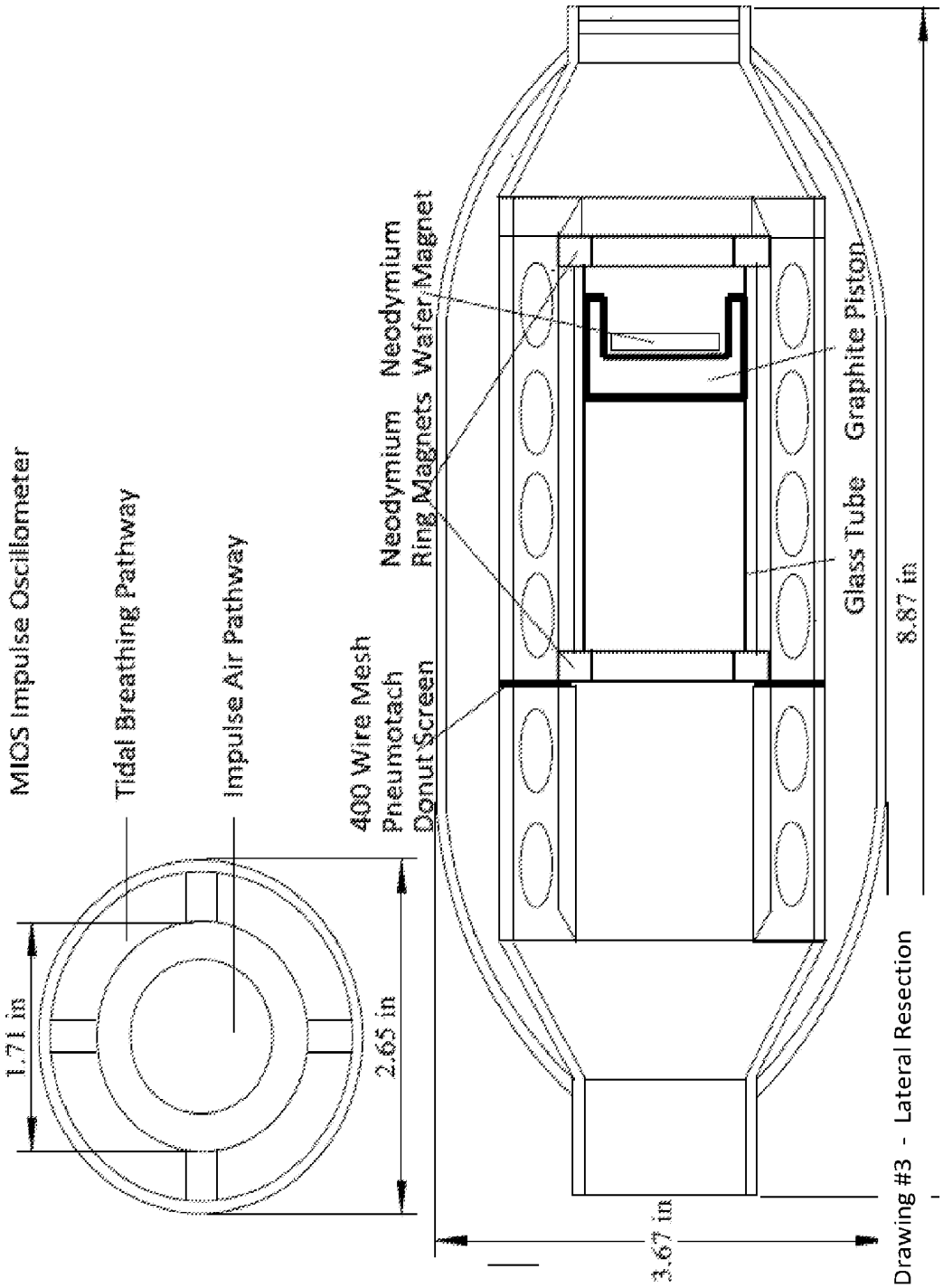

Air Flow Diagram

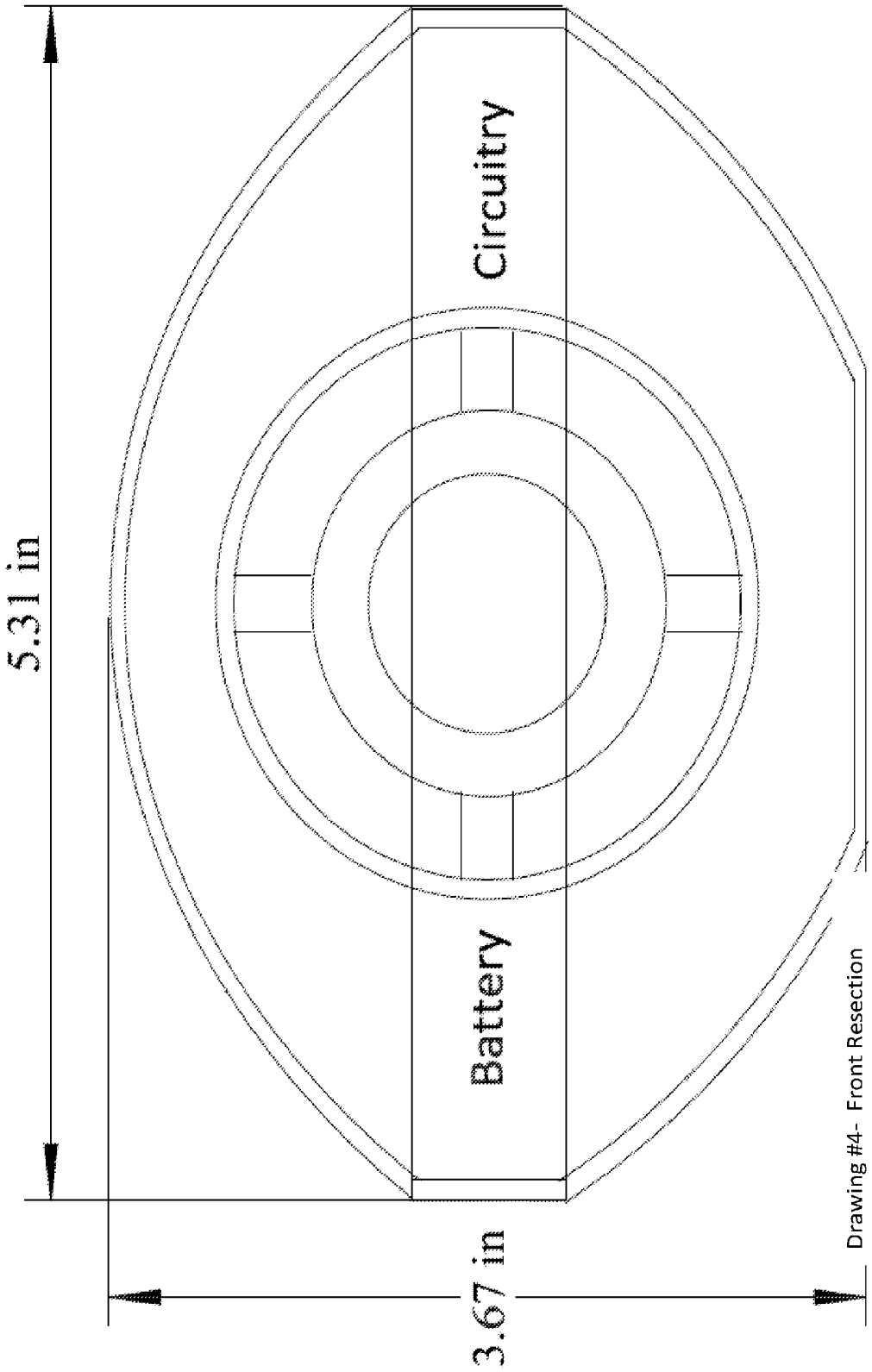


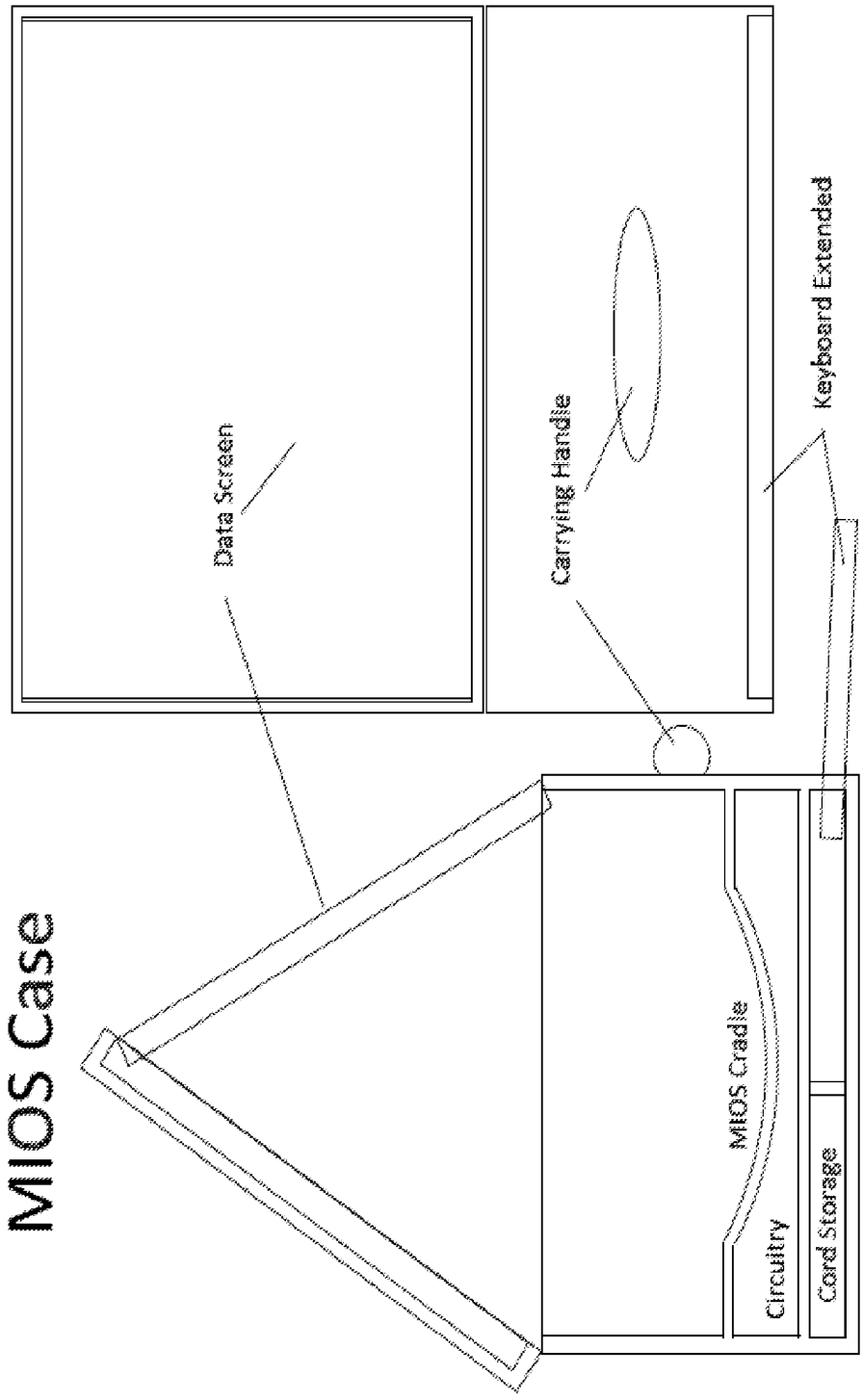

Drawing # 1 - Piston Detail



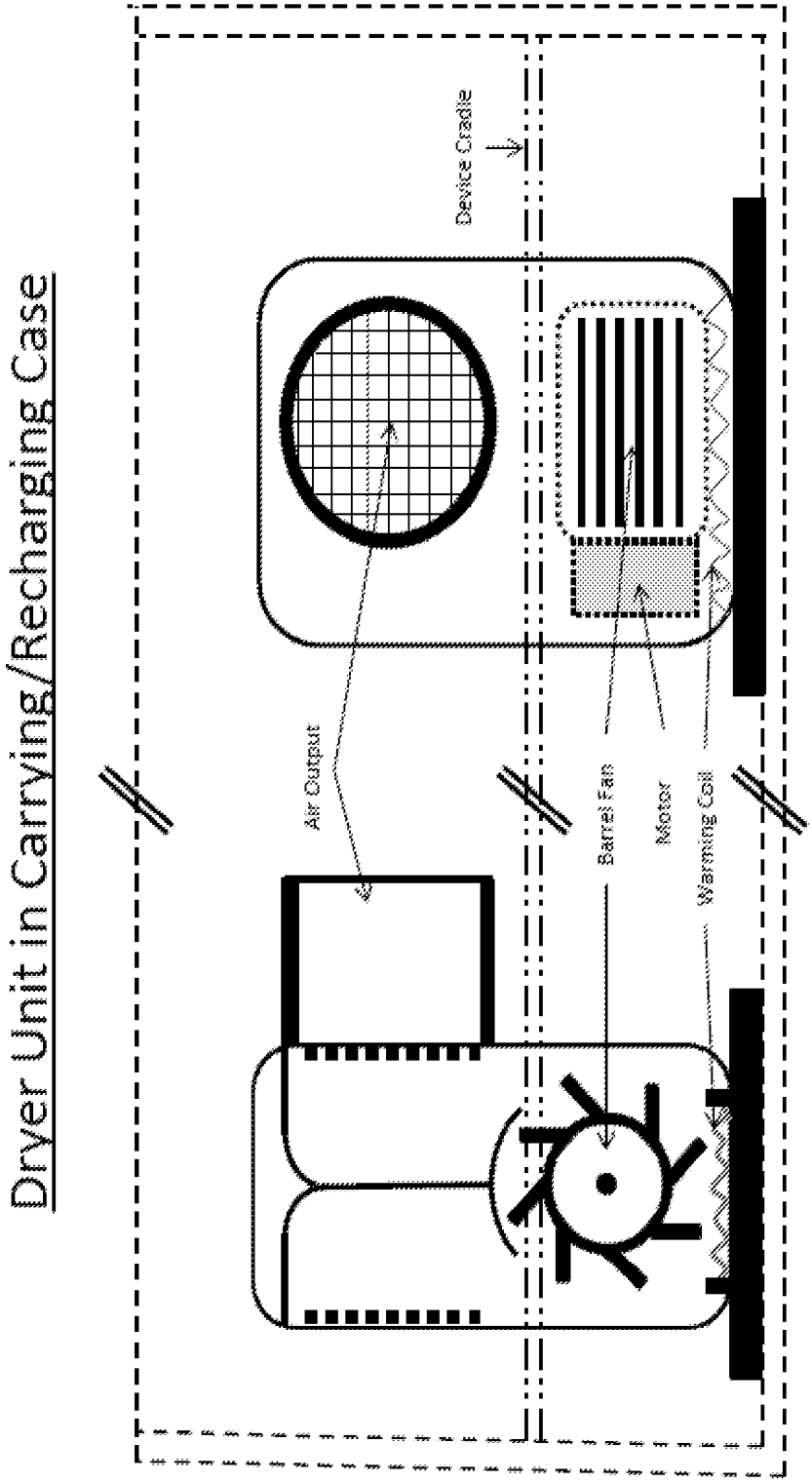

Drawing #2 - Air Flow Diagram


MIOS Impulse Oscillometer
Tidal Breathing Pathway
Impulse Air Pathway
400 Wire Mesh
Pneumotach
Donut Screen
Neodymium
Ring Magnets
Neodymium
Wafer Magnet
Glass Tube
Graphite Piston
1.71 in
2.65 in
3.67 in
8.87 in
Drawing #3 - Lateral Resection


Circuitry
Battery
5.31 in
3.67 in
Drawing #4- Front Resection




Drawing #5 - Carrying Case




Drawing # 6 - Dryer Unit

# HANDHELD PORTABLE IMPULSE OSCILLOMETER

**[0001]** The present device is a miniaturized handheld portable impulse oscillometer (IOS) device designed to assess and analyze lung functions for the diagnosis and treatment of the full range of pulmonary diseases. IOS is an accepted pulmonary functions test (PFT) and is widely used in pulmonary medicine. The present device is a Class II medical device.

## CROSS-REFERENCE TO RELATED APPLICATIONS

**[0002]** (1) *Impulse Oscillometry: Interpretation and Practical Application*, Chest Journal, September 2014, Volume 146, No. 3, Dr. Burton Lesnick, et al.

**[0003]** (2) 2004 *Global Burden of Asthma Report*, Global Initiative for Asthma (GINA), Sponsored by the National Heart, Lung, and Blood Institute, NIH and the World Health Organization (WHO).

**[0004]** (3) (2013). "Asthma's Impact on the Nation (2012)." 2014, from http://www.cdc.gov/asthma/impacts_nation/default.htm?s_cid=tw_DrCP274,

**[0005]** (4) Erika G Meraz, Homer Nazeran, Carlos D Ramos, Pat Nava, Bill Diong and Michael D Goldman, *Analysis of Impulse Oscillometric Measures of Lung Function and Respiratory System Model Parameters In Small Airway-Impaired and Healthy Children Over a 2-Year Period*, U.S. National Institute of Environmental Health Sciences (NIEHS—S11 ES013339—Pilot 1 PI: HN), NIH.

**[0006]** (5) 2012; *Peripheral Airway Impairment Measured by Oscillometry Predicts Loss of Asthma Control in Children*. Yxin Shi, M S, Anna S. Aledia, B S, Stanley P. Galant, M D, Steven C. Goerge, M D, PhD, Jun. 6, 2012 NIH www.jacionline.org article S0091/6749%2901544-8/full text.

**[0007]** (6) PMCID: PMC381359 NIHMSID: NIHMS 509309—*Invasive Testing of Lung Function and Inflammation in Pediatric Patients With Acute Asthma Exacerbations*. Ann Allergy Asthma Immunol. Author manuscript; available in PMC Jul. 23, 2012. Published in final edited form as: Ann Allergy Asthma Immunol. March 2011; 106(3): 191-199. Published online Jan. 6, 2011. doi: 10.1016/j.anai.2010.11.011

**[0008]** (7) 2012 NIH sponsored study: *Impulse Oscillometry in the Evaluation of the Airways in Children*, Hirsh D. Komarow, MD., Laboratory of Infectious Diseases, NIAID, NIH.

**[0009]** (8) Lappas, A. ( ) Forced oscillations in applied respiratory physiology. Pneumon, 26.

**[0010]** (9) Carefusion. Technical Specifications for Impulse Oscillometry. Available at: http://www.carefusion.com/pdf/Respiratory/Pulmonary_Function_Testing/MasterScreen_IOS_Specifications. Accessed Feb. 13, 2014.

**[0011]** (10) Abou-atme Y S, Chedid N, Melis M, Zawawi K H. Clinical measurement of normal maximum mouth opening in children. Cranio. 2008; 26(3):191-6.

**[0012]** (11) Fang Y, Ma G, Lou N, Liao W, Wang D. Preoperative Maximal Oxygen Uptake and Exercise-induced Changes in Pulse Oximetry Predict Early Postoperative Respiratory Complications in Lung Cancer Patients. Scand J Surg. 2014

**[0013]** (12) Behrakis P, Lappas A, Tzortzi A. Forced Oscillations in Applied Respiratory Physiology. JAMA. December 2013; No 4 Vol 26:327-345.

**[0014]** (13) Non-Heated Pneumotachometer. (2014, Jan. 1). Non-Heated Pneumotachometer. Retrieved Apr. 1, 2014, from http://www.harvardapparatus.com/webapp/wcs/stores/servlet/haisku3_10001_11051_41149-1_HAI_ProductDetail_n_37840_37841_37844

**[0015]** (14) Rothenberg, M. ( ). Measurement of Airflow in Speech. Journal of Speech and Hearing Research, 20, 155-176.

## STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

**[0016]** Not Applicable

## REFERENCE TO A "SEQUENCE LISTING"

**[0017]** Not Applicable

## BACKGROUND OF THE INVENTION

**[0018]** (1) Field of the Invention

Classifications

U.S. Classification 600/538, 417/415

International Classification F041335/04, A61B5/085, A61B5/087

Cooperative Classification A61B5/097

**[0019]** (2) Description of Related Art

| Cited Patents | Filing Date | Publication Date | Applicant | Title |
|---|---|---|---|---|
| U.S. Pat. No. 8,449,474 B2 | Jun. 28, 2006 | May 28, 2013 | Scireq Sc Res Eq | Self-actuated cylinder and Oscillation spirometer |
| U.S. Pat. No. 5,856,745 | Feb. 14, 1997 | Jan. 5, 1999 | Caterpillar Inc. | Hydraulic cylinder end Member arrangement for a piston position sensing system |
| U.S. Pat. No. 8,641,637 B2 | Feb. 4, 2013 | | Sly | Method of measuring an acoustic impedance of a respiratory system . . . |
| U.S. Pat. No. 5,318,038 | Jun. 7, 1994 | | Jackson | Infant respiratory impedance measuring apparatus . . . |
| EP 0616792 B1 | Jun. 3, 1998 | | Dipl-Ing | Oscillometric determination of the airway impedance, . . . |
| U.S. Pat. No. 8,100,836 | Jan. 24, 2012 | | Diong | Augmented RIC model of respiratory systems . . . |
| U.S. Pat. No. 7,325,545 | Feb. 5, 2008 | | Dellaca | System & method of automatic detection of the expiratory flow limitation. |
| U.S. Pat. No. 7,402,139 | Jul. 22, 2008 | | Ganshorn | Appliance for the oscillometric analysis of the impedance of the respiratory tract. |

## BRIEF SUMMARY OF THE INVENTION

**[0020]** The current impulse oscillometers on the market are large medical devices, are very expensive, and are mainly found in specialized PFT clinics or research laboratories. The present device is handheld, portable, low cost, and is intended for the primary care provider and for home use by the patient.

## BRIEF DESCRIPTION OF DRAWINGS

**[0021]** (1) Piston Detail—Provides specifics of the piston cylinder and the relation of the ring-shaped electromagnets with drive the piston.

**[0022]** (2) Airflow Diagram—Describes the air impulse tube which houses the piston cylinder and is surrounding by the tidal airflow tube. Arrows illustrate laminar air flow.

**[0023]** (3) Lateral Resection—Illustrates the positioning of the double tube (air impulse tube and tidal breathing tube) within the overall handheld portable impulse oscillometer.

**[0024]** (4) Front Resection—Shows the double tube from the front of the device.

**[0025]** (5) Carrying Case—Case shows the positioning of the device cradled for transportation, relation with the dryer unit, and the location of the data screen and pullout key board.

**[0026]** (6) Dryer Unit—Blows warmed air though the double tube after use to remove any humidity present.

## DETAILED DESCRIPTION OF THE INVENTION

**[0027]** Impulse oscillometry (IOS) measures the amount of inflammation occurring within the central airways and within the peripheral airways of the lungs including the alveoli or small air sacs located at the very ends of the bronchial tubes. By emitting low frequency air impulses into the lungs, the air impulses travel throughout the small airways, and this is the main location where inflammation occurs. While spirometry depends on the patient taking an extreme deep breath and then forcibly exhaling as hard as they can to measure total lung volume, the action only measures complications within the central airways. Spirometry is considered a patient dependent test because the success of the test depends on how hard the patient is willing or is able to participate. Impulse oscillometry is termed a patient independent test because all the patient does is breath normally (tidal breathing) through the device. The gentle low frequency air impulses travel throughout the patient's central and peripheral airways measuring the amount of swelling or resistance as the impulse penetrates the lungs, and then measures the amount of elasticity, or reactance, as the impulses bounce back to the IOS.

**[0028]** Tidal breathing is achieved by a unique double-tube system whereby the patient's normally breathing passes through a measured sized tube that routes the air around a central tube. There is a measured opening in the tube at the opposite end from the mouthpiece that creates a small amount of pressure within the tidal breathing tube, but that is hardly noticeable to the patient. The terminal resistor allows pressure to build up in the tube before releasing out of the device by series of holes hole at the end of the device with a diameter totally approximately 7.87 mm. This provides a resistance of 0.1 kPaS/L within the device. The inner tube contains the device that generates the air impulse, and this central location of the air impulse tube allows for the optimal projection of the air impulse into the patient's lungs.

**[0029]** The mechanical core of the present invention is an electromagnetically-driven piston that generates measured air impulses into the lungs of the patient. The piston contains a disk-shaped neodymium permanent magnet within an indentation in piston and it's oscillations displace 40 mL of air in the cylinder in 40 ms. The piston is pushed and pulled by two ring-shaped opposite pole electromagnets. The electromagnets are located on the ends of a tube (d=1.25", L=3.5") containing the magnetically driven piston. By alternating the polarities of the electromagnets at 5 Hz, the piston is moved from one end of the cylinder to the other. The electromagnets are adjusted to the desired strength to power the piston with quick pulses to generate the necessary air impulse sent into the lungs. The current system uses N48 neodymium disk magnets (H=1/16 in D=7/8 in). The current electromagnets are 1.75" outside diameter×1.0" inside diameter×0.75" thick. The volume displacement, speed of impulse, and frequency are aligned with the current clinical impulse oscillometry system. The device is designed to work with the piston parallel to the ground, but can effectively function at a 90 degree angle. This negates the majority of gravitational effects.

**[0030]** Surrounding the air impulse tube and constructed within the tidal breathing tube is the pneumotachometer system that measures the differential pressures of resistance and reactance via digital pressure sensors being located on both sides of the pneumotach resistive screen. The airflow is converted into a proportional signal based on pressure differences on either side of the screen. This stainless steel 400 wire screen is a low resistive screen that ensures a linear signal for all flow rates. The wire screen has a wire diameter of 0.001 in and the resistance across the screen is between 2.34 cmH2O*s/L and 2.83 cmH2O*s/L. The digital differential pressure sensors currently connect to the device with crush-resistant silicone rubber tubing with an outer diameter of 0.25 in. The sensors are soldered to a PCB board and powered by a 5V supply voltage on the Arduino. The PCB board is connected onto the breadboard. The output of each pressure sensor is then converted into digital data and exported to analysis software. Analysis is first used to convert the data from pressure difference to flow rate by taking advantage of the linear relationship between pressure difference and laminar flow. The flow data is then compared to the raw pressure data from the backpressure sensor. The ratio of the FFT of the pressure to the FFT of the flow rate at 5 Hz is the primary output of the device.

**[0031]** Output data is transmitted from the IOS device via Bluetooth to circuitry within the carrying case, and is then re-transmitted to a secure and encrypted cloud server where the analysis is completed. Interpreted results are transmitted back to the patient's smartphone and displayed in a manner consistent with the patient's age and preferred language. Results are also transmitted to the patient's primary care provider for storage in their electronic medical record.

**[0032]** The handheld portable portion of the device is intended for the ease of use by the patient and the provider. It works in tandem with its carrying case since the carrying case houses additional circuitry, an additional battery pack, memory and communication systems, and in certain models, a data screen and pullout keyboard. This allows the IOS device itself to be as light weight and conveniently portable as possible. The IOS device has a communications range of

approximately fifty yards from its carrying case. The carrying case also incorporates a dryer unit that automatically turns on and blows warmed air through the double air tubes to remove any humidity that may have accumulated during patient use. This occurs each time the IOS device is re-docked into its cradle within the carrying case.

**[0033]** The carrying case contains a battery pack that powers the electronics within the carrying case and also has a power cord to plug into an AC power source. The carrying case re-charges the IOS device via matching inductive magnetic units placed in the bottom of the IOS device and within the cradle of the carrying case. The IOS device is automatically recharged each time it is inserted into its docking station. The rechargeable battery pack within the IOS device is rated to last for two hours of continuous use, for four hours of intermittent use, and for twelve hours of occasional use. This provides for a high degree of portability and flexibility in how it is used.

**[0034]** To properly perform impulse oscillometry, the patient must utilize a nose clip to close off the nose, and hold the cheeks firmly so they do not vibrate when exposed to the air impulses of the IOS. Since the present invention is intended to be handheld and portable, allowing to patient to perform the test by them self, a unique cheek holder has been developed to fit over the mouth piece and hold the cheeks firmly, but gently, in place while the procedure is being performed. Disposable mouth pieces and disposable bio-filters are supplied separately for the procedure. These must have an external diameter of 32.4 mm and be able to extend 10 mm into the front end of the device.

**1**- The present invention generates air impulses by an electromagnetically driven piston, that is contained within a glass cylinder of the appropriate length and diameter to generate the required air impulse, that contains a piston with an indentation to hold a permanent magnet that is the appropriate size and strength to facilitate the required attraction and repulsion required to work in combination with two ring-shaped electromagnets placed at opposite ends of the cylinder, that are wired via electronic circuitry to reverse the polarity of the ring-shaped electromagnets at a speed necessary to cause the piston to oscillate at the required speed necessary for the proper functioning of the device.

**2**- The present invention contains a unique double-tube arrangement that is comprised of an air impulse tube that houses the electromagnet piston designed to project the air impulse straight into the patient's mouth and trachea, and the air impulse tube is surrounded completely by the tidal breathing tube into which the patient breathes naturally during the period of the test, and since the tidal breathing tube is properly sized in concert with the mouthpiece, there is minimal airflow resistance through the tidal breathing tube, even when considering the additional resistance created by the fine wire mesh pneumotachometer screen placed within the tidal breathing tube in a donut shape around the impulse tube to measure the impedance and reactance of the air pressure as it moves into and out of the patient's lungs and is measured on both sides of the screen by digital differential pressure sensors.

**3**- The present invention contains longitudinal vanes within the tidal breathing tube that keep the air impulse tube centered and secured, and since the vanes contain openings along the full length of the vanes, they allow for equalization of air pressure around the entirety of tidal breathing tube which increases the accuracy of the impedance and reactance pressure measurements recorded and analyzed by the device.

**4**- The present invention is currently shaped as noted in the drawings and is the result of extensive ideation studies on the best ergonomic shape for a handheld miniaturized impulse oscillometer, but it is noted that this unique shape will be modified as this present invention is adapted to a broader range of uses, being the present invention is constructed of high impact plastic and whereby the upper portion of the device is constructed of opaque plastic allowing for the internal insertion of various colors of LED lights that signal to the patient different phases of the test's operation and the status of the test analysis, and this is complimented by a series of colored LED lights situated on the top of the device to signal to the patient when the test is beginning and when an adequate test sample has been obtained.

**5**- The present device incorporates a unique carrying case made of high impact plastic in which to not only house the device during transport, but to also provide space for a multitude of additional circuitry in the lower section, a battery recharging station within the device's cradle, a source of battery back-up power in the lower section, a dryer unit (to be detailed in a later claim), control switches, wireless communications equipment that allows the IOS device to be utilized within fifty yards of the carrying case, an storage compartment for an AC power cord, and a storage compartment for a printer connection and printer cable if wireless communications is disrupted, and in some versions, a flip out electrical data screen and a pull out keyboard for data entry.

**6**- The present invention utilizes the circuitry for inductive magnetic re-charging between the IOS device and the carrying case whereby the inductive magnetic recharging units are positioned within the base of the cradle section of the carrying case and the bottom surface of the IOS device in order to eliminate an opening in the cases of each component which may create a breach in the water proof element of either component, and in which the inductive magnetic re-charging unit is automatically engaged whenever the IOS device is returned to its location in the cradle within the carrying case, and the united is timed to return the IOS device to full re-charge status, and this source of electrical power is provided by the battery supply contained within the carrying case and/or is supplied directly by a source of AC electricity when the carrying case is plugged into an AC power source.

**7**- The present invention contains a re-chargeable battery system within the IOS device that is sized in power to supply the IOS device for continuous independent operations for two hours, intermittent operations for six hours, and occasional operations for a minimum of 24 hours without requiring re-charging, and the battery pack is uniquely shaped to fit with the IOS device and maintain a proportional balance within the IOS device.

**8**- The present invention contains a re-chargeable battery system within the carrying case that is sized in power to supply the carrying case for continuous independent operations for four hours, intermittent operations for twelve hours, and occasional operations for a minimum of 48 hours without requiring re-charging, and the battery pack is uniquely shaped to fit with the base of the carrying case and maintain a proportional balance within the carrying case.

**9**- The present invention contains carefully sized and shaped circuit boards whereby the circuitry is arranged in the most efficient manner and the boards housing the circuitry are divided and stacked within the available space within the IOS device to allow for the smallest amount of space possible.

**10**- The present invention contains carefully sized and shaped circuit boards whereby the circuitry is arranged in the most efficient manner and the boards housing the circuitry are divided and stacked within the available space within the carrying case to allow for the smallest amount of space possible.

**11**- The present invention communicates its data via Bluetooth circuitry between the IOS device and the carrying case in which base pressure measurement data is analyzed and stored in its internal memory circuits, and is then transmitted wirelessly to both Android and iPhone based smartphones for further interpretation of the results to the patient for their use, but the data is also automatically transmitted wireless to a secure cloud server where it is stored in a secured and encrypted database by a unique patient number where the data undergoes further analysis for ongoing comparison to thousands of other data reports before the interpreted analysis is re-transmitted back to the patient via their smartphone or to their provider's computer system and displayed in a manner in which is best understood by the patient and/or their provider, and because this mass data is analyzed and trended in a consolidated database, it can report major criteria and trends in the diagnosis and effective management of respiratory diseases.

**12**- The present invention incorporates a specially developed and re-usable cheek piece that fits around the front air tube of the IOS device in front of the disposable biofilter and mouthpiece to allow for hands free cheek support because it is constructed of sturdy but flexible plastic approximately ⅛ inches thick, two inches wide, and approximately six inches long and gently curved on both ends toward the patient's face in such a manner to gently, but firmly, hold the patient's cheeks in place and to prevent their vibration when subjected to the impulses of air emanating from the impulse oscillometer eliminating the need for either the patient or a second person from having to hold the patient's cheeks in place.

**13**- The present invention contains an electrical dryer unit in the base of the carrying case designed to blow warm dry air through the double tubes of the IOS device to dissipate any humidity accumulated through patient use automatically each time the IOS device is returned to its cradle and the mouthpiece of the IOS device is inserted into the dryer unit causing the dryer unit to turn on and run for a set amount of time, and this is facilitated by the dryer unit being constructed of high impact plastic and containing a small electrical motor carefully sized to rotate a small barrel fan at such a speed to blow a specific amount of air that is slightly warmed by a small electric coil heater located in the base of the dryer unit.

**14**- The present invention contains circuitry within the carrying case which, when the device is turned on, automatically measures the current temperature, humidity, and barometric pressure being experienced in that location at that time and analyzes those readings as to their impact upon the impulse oscillometric readings to be taken by the IOS device, and causes the those readings to be incorporated into the calculations and also being reported separately as a part of the internal calibration conducted by the unit each time the present invention is used.

* * * * *

| | | | |
|---|---|---|---|
| 专利名称(译) | 手持式便携式脉冲示波器 | | |
| 公开(公告)号 | US20160345860A1 | 公开(公告)日 | 2016-12-01 |
| 申请号 | US15/168152 | 申请日 | 2016-05-30 |
| [标]申请(专利权)人(译) | 沃尔夫米迦勒W<br>WOLFE KATHERINE C | | |
| 申请(专利权)人(译) | 沃尔夫，MICHAEL W.<br>沃尔夫，KATHERINE C. | | |
| 当前申请(专利权)人(译) | 沃尔夫，MICHAEL W.<br>沃尔夫，KATHERINE C. | | |
| [标]发明人 | WOLFE MICHAEL W<br>WOLFE KATHERINE C | | |
| 发明人 | WOLFE, MICHAEL W.<br>WOLFE, KATHERINE C. | | |
| IPC分类号 | A61B5/085 H02J7/00 H02J7/02 H02J50/10 A61B5/097 A61B5/00 | | |
| CPC分类号 | A61B5/085 A61B5/097 A61B5/742 A61B5/0022 H02J7/025 H02J50/10 A61B2560/0257 A61B2562/0247 A61B2560/0431 A61B2560/0425 A61B2560/0214 A61B2560/0252 H02J7/0054 G16H40/67 | | |
| 优先权 | 62/168854 2015-05-31 US | | |
| 其他公开文献 | US10492711 | | |
| 外部链接 | Espacenet USPTO | | |


摘要(译)

大量的临床研究已经验证了脉搏示波测量（IOS）在肺量计上的优越性，因为它在肺部疾病的检测中更加灵敏，并且由于其是努力独立的，它可以成功地用于儿童，个月。通过将IOS小型化为手持和便携式设备，本发明将IOS技术从研究实验室和专业肺病办公室的独有环境中采用。此外，通过推进该技术，大大降低了制造成本，从而使得该装置是负担得起的并且对于普通初级保健医生可用于在他们的办公室中使用。此外，由于本发明可用作家用装置，它将显着改善复杂呼吸道疾病，即哮喘和COPD的家庭管理。本发明是一种小型化和电磁活塞驱动的IOS，其概念和技术是真正独特的。