## (19) World Intellectual Property Organization

International Bureau



# 

# (43) International Publication Date 24 December 2003 (24.12.2003)

### **PCT**

-IL

# (10) International Publication Number WO~03/105657~A2

(51) International Patent Classification<sup>7</sup>: A61B

(21) International Application Number: PCT/IL03/00397

(22) International Filing Date: 15 May 2003 (15.05.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data: 150189 12 June 2002 (12.06.2002)

(71) Applicant (for all designated States except US):
ACOUSTITECH LTD. [IL/IL]; Kinarot Technological Incubator, Zemach, 15132 D.N. Jordan Valley (IL).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SHAHAR, Menashe [IL/IL]; Moshav Korazim, 12391 South Ramat Hagolan

(IL). **KATZ, Shahar** [IL/IL]; 42 Yehuda Hanasi Street, 51583 Bnei Brak (IL). **PORAT, Yariv** [IL/IL]; 5 Harofeh Street, 34367 Haifa (IL). **HOLDSTEIN, Yehuda** [IL/IL]; 44 Hatishbi Street, 34525 Haifa (IL). **SAHAR, Ori** [IL/IL]; Moshav Korazim, 12391 South Ramat Hagolan (IL).

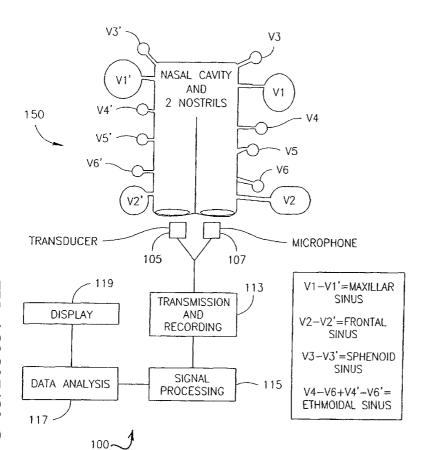
(74) Agent: JEREMY M. BEN-DAVID & CO. LTD.; Har Hotzvim Hi-Tech Park, P.O. Box 45087, 91450 Jerusalem (IL).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

#### (54) Title: ACOUSTIC DIAGNOSIS OF SINUSITIS



(57) Abstract: A system diagnosing sinusitis in a human subject including: a miniature transducer for emitting a sound signal; a miniature microphone for detecting sound signals; a transducer holder configured to contain the miniature transducer and a microphone holder configured to contain the miniature microphone, each configured to be inserted into a nostril of a human subject; signal processing apparatus for controlling sound signals emitted by the miniature transducer and for processing sound signals detected by the miniature microphone; anddata analysis apparatus analyzing the processed detected sound signals, which includes a data storage device for storing processed sound signals, baseline signals representing measurements taken on healthy and programs for data subjects, analysis.

### WO 03/105657 A2



Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

#### Published:

 without international search report and to be republished upon receipt of that report

# **Acoustic Diagnosis Of Sinusitis**

#### FIELD OF THE INVENTION

The present invention relates generally to the diagnosis of sinusitis, and in particular, wherein acoustic means is used therefor.

### **BACKGROUND OF THE INVENTION**

Rhinometry, the measurement of the nasal region, is a known field with a number of medical applications. One means of measurement employed is acoustics, using sound as the probing energy.

U.S. Patent number 5,666,960 to Fredberg, et al discloses a method and device for performing measurements of the respiratory tract. The analytical method in this patent is reflectometry. A burst of sound pulses (or a single pulse), the nature of which is not disclosed, is emitted into the nose to probe nasal morphology. The idea is to form an "acoustic image" of the nose space. The device in this patent is a tube plunged into the nose that has a loudspeaker on one end, and several microphones on the side of the tube at prescribed intervals. The tube is quite long. This device cannot show anything about the sinuses; and the medical application is exclusively about air flow and respiration.

U.S. Patent number 5,848,973 to Lane is an adaptation of the device disclosed in U.S. Patent number 5,666,960 using a novel mechanical filter to avoid contamination; and U.S. Patent number 5,902,237 to Glass is a further refinement of that same device and method, using a train of bursts triggered by the respiratory rhythm to improve the accuracy of the method. The trigger option indicates that the application is also respiration and not rhinometry.

U.S. Patent number 5,823,965 to Rasmussen employs a method similar to that disclosed in U.S. Patent number 5,666,960 to examine passages in a biological subject. Here, too, the emphasis is on flow in such passages. The patent makes no mention of sinuses or measurements thereof.

### SUMMARY OF THE INVENTION

The present invention seeks to provide a method and system for examining the system of nasal cavities in a human subject, including the nasal sinuses, particularly in order to diagnose sinusitis, using acoustic means. It is further sought that the system and method be minimally invasive and cause minimal discomfort to the subject or patient being so examined. A further objective of the present invention is to use acoustic means to provide a method and system for examining other systems of body cavities in a mammalian subject to diagnosis pathological conditions therein.

There is thus provided, in accordance with a preferred embodiment of the invention, a system for diagnosing sinusitis in a human subject including:

a miniature transducer for emitting a predetermined sound signal;

a miniature microphone for detecting sound signals;

a transducer holder configured to contain the miniature transducer and configured to be sealingly inserted into a nostril of a human subject;

a microphone holder configured to contain the miniature microphone and configured to be sealingly inserted into a nostril of a human subject;

signal processing apparatus for controlling sound signals emitted by the miniature transducer and for processing sound signals detected by the miniature microphone; and data analysis apparatus for analyzing the processed detected sound signals, which includes a data storage device for storing processed sound signals, baseline signals representing measurements taken on healthy subjects, and programs for data analysis.

The system may further include a data display device.

In accordance with a further preferred embodiment of the present invention, the system may include a second miniature transducer and a second miniature microphone and two double holders, each configured to contain both a miniature transducer and a miniature microphone and further configured to be sealingly inserted into a nostril of a human subject.

In accordance with yet a further preferred embodiment of the invention, there is provided a method of diagnosing sinusitis in a human subject, including the steps of:

externally sealing off the nostrils of a subject;

subsequent to the subject inhaling and immediately thereafter sealing his nasal cavities

internally, emitting, via a first nostril, a predetermined sound signal into the nasal cavities of the subject;

detecting, via the second nostril, sound signals from the nasal cavities of the subject in response to the emitted signal;

subsequent to the subject again inhaling and immediately thereafter sealing his nasal cavities internally, emitting, via the second nostril, a predetermined sound signal into the nasal cavities of the subject;

detecting, via the first nostril, sound signals from the nasal cavities of the subject in response to the emitted signal;

comparing the two sets of detected sound signals; and

analyzing the two sets of detected sound signals and the comparison therebetween to diagnose sinusitis in the subject.

The emitted sound signals, in either case, may be white noise sound pulses, chirp sound pulses of a particular frequency range, or some other frequency sweep in some predetermined range.

Further in accordance with a preferred embodiment of the present invention, the step of analyzing includes the step of comparing the two sets of detected sound signals with theoretically or empirically derived baseline signals representing measurements taken on a healthy subject. It further includes calculating the measured volume of the sinuses of the subject, which may be by modeling the sinuses as Helmholtz resonators.

In accordance with an alternative preferred embodiment of the present invention, there is further provided a system for diagnosing pathological conditions in body cavities in a mammalian subject including:

a sound emitter for emitting predetermined sound signals, which may be white noise sound pulses, chirp sound pulses of a particular frequency range, or some other frequency sweep in some predetermined range, into body cavities to be diagnosed;

a sound detector for detecting sound signals from the body cavities to be diagnosed; signal processing apparatus for controlling sound signals emitted by the sound emitter and for processing sound signals detected by the sound detector; and

data analysis apparatus for analyzing the processed detected sound signals, which

includes a data storage device for storing processed sound signals, baseline signals representing measurements taken on healthy subjects, and programs for data analysis. The system may further include a data display device.

In accordance with yet a further alternative embodiment of the invention, there is provided a method of diagnosing pathological conditions in body cavities, such as the lungs and their associated air passages or chambers of the heart, in a mammalian subject, including the steps of:

sealing off a set of cavities to be diagnosed;

emitting a predetermined sound signal, which may be white noise sound pulses, chirp sound pulses of a particular frequency range, or some other frequency sweep in some predetermined range, into the set of cavities to be diagnosed;

detecting sound signals from the set of cavities of the subject in response to the emitted signal;

analyzing the detected sound signals to diagnose (condition) in the subject.

Further in accordance with a further alternative embodiment of the present invention, the step of analyzing includes the step of comparing the two sets of detected sound signals with theoretically or empirically derived baseline signals representing measurements taken on a healthy subject. It further includes calculating the measured volume, which may be by modeling the set of cavities as Helmholtz resonators.

### BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more fully understood and appreciated from the following detailed description, taken in conjunction with the drawings, in which:

Figure 1 is a schematic representation of the nasal cavity, the nostrils and associated sinuses together with a block diagram of a system for diagnosing sinusitis, constructed and operative in accordance with a preferred embodiment of the present invention; and

Figure 2 is a diagrammatic representation of a method of diagnosing sinusitis in a human subject using the system of Figure 1 in accordance with a preferred embodiment of the present invention.

### DETAILED DESCRIPTION OF THE INVENTION

Referring now to Figure 1, there is shown a schematic representation of the nasal cavity, the nostrils, and associated sinuses, referred to generally as 150, together with a block diagram of a system, referred to generally as 100, for diagnosing sinusitis, constructed and operative in accordance with a preferred embodiment of the present invention. System 100 includes a miniature transducer 105 and a miniature microphone 107 for emitting and detecting, respectively, sound signals in the nasal cavities of a human subject. Transducer 105 and microphone 107 are fitted in holders (not shown) that allow them to be sealingly inserted into the nostrils of the subject. They are connected to a sound transmission and recording unit 113 which controls the sound signals emitted by transducer 105 and records sound signals detected by microphone 107. Transmission and recording unit 113 is in turn connected to signal processing unit 115 which prepares the detected signals for use by data processing and analysis unit 117 which performs data processing and analysis on processed detected sound signals. Data processing and analysis unit 117 includes a data storage device 121 for storing processed sound signals and baseline signals representing measurements taken on healthy subjects, as well as programs for data analysis, and may also have an associated display device 119 to allow an operator of the system to display results of measurements and analysis.

Alternatively, two substantially identical holders, each having fitted therein both a transducer 105 and a microphone 107, may be sealingly inserted in the nostrils of the subject, in accordance with an alternative embodiment of the present invention. Transmission and

recording unit 113 can then selectively activate a transducer 105 and microphone 107 combination to generate detected sound signals for different experimental configurations with no need to trouble the subject to rearrange transducer 105 and microphone 107 holders.

In accordance with a preferred embodiment of the present invention, Figure 2 shows in the form of a flow chart, a method of diagnosing sinusitis in a human subject using system 100 shown in Figure 1. As shown in the flowchart, the method includes the steps of:

inserting transducer 105, in its holder, into one nostril of a subject and microphone 107, in its holder, into the second nostril of the subject, thereby sealing off the nostrils of the subject;

subsequent to the subject inhaling and immediately thereafter sealing his nasal cavities internally, emitting, via transducer 105 in the first nostril of the subject, a predetermined probe sound signal into the nasal cavities 150 of the subject;

detecting, via microphone 107 in the second nostril of the subject, sound signals from the nasal cavities 150 of the subject in response to the emitted signal;

subsequent to the subject again inhaling and immediately thereafter sealing his nasal cavities internally, emitting, via transducer 105 in the second nostril of the subject, a predetermined probe sound signal into the nasal cavities 150 of the subject;

detecting, via microphone 107 in the first nostril of the subject, sound signals from the nasal cavities 150 of the subject in response to the emitted signal;

after both sets of detected sound signals are prepared, by transmission and recording unit 113 and signal processing unit 115, for analysis via data processing and analysis unit 117, comparing the two sets of detected sound signals; and

analyzing, via data processing and analysis unit 117, the two sets of detected sound signals and the comparison therebetween to diagnose sinusitis in the subject.

The second set of detected sound signals, wherein the respective sound emission and sound detection nostrils are switched, may be produced by physically switching two holders, one fitted with a transducer 105 and one fitted with a microphone 107, between the nostrils of the subject, before generating the second set of measurements. Alternatively, when two substantially identical holders, each having fitted therein both a transducer 105 and a microphone 107, are employed, transmission and recording unit 113 selectively activates a transducer 105 and microphone 107 combination to generate detected sound signals for a different desired experimental configuration with no need to trouble the subject to rearrange transducer 105 and microphone 107 holders.

The probe sound signals emitted may be sound pulses of particular frequencies or they may be white noise pulses, chirp pulses of a particular frequency range, or some other frequency sweep in some predetermined range; within the overall frequency range of 5.0 to 0.1 kHz. Pulse duration is typically 20 to 5 seconds, at a sound intensity level of 70 to 60 dBc.

By comparing the detected sound signals with baseline signals representing measurements taken on a healthy subject, which may be based on theoretical modeling of the nasal cavities 150 or on actual measurements taken on healthy subjects, the volume of the nasal cavities 150 can be calculated. In the case of the nasal cavities, the calculation is based on modeling the system of nasal cavities and sinuses as one or more Helmholtz resonators, as will be explained below. Variations in the measured volume showing reduction from the baseline volume can indicate a blockage symptomatic of sinusitis. The extent of the blockage indicates the severity of the sinusitis.

In the Helmholtz model, the nasal cavities and the sinuses are represented as a collection of connected chambers, each with a characteristic primary resonant frequency dependent on its volume, linear dimensions, and the elastic properties of its internal surfaces. The connected system will act as bandpass filters with its own characteristic frequencies. As will be understood by those familiar with the art, the relevant equations for the characteristic frequencies are given by:

$v_0 = (1/2\pi) \sqrt{(c^2 S/l_e V)}$ $v_0 = (1/\pi) \sqrt{(c^2 S/l_e V_p)}$ where:	Helmholtz resonator frequency Low and High Pass filter (multiple enclosures)
S	Area of each port in the nose
$V_p$	Partial adapter volume = adapter volume divided by n, number of ports
$ m V$ $ m l_e$ and:	Helmholtz resonator volume $\sim 1 + 0.8 \sqrt{S}$ ,
l c v	Length of port sound speed in air frequency

Returning now to Figure 1, the effective volume of the nasal cavity, the nostrils, an associated sinuses 150,  $V_E$ , may be expressed as:

$$1/V_E = 1/V_N + 1/V_{Si} + 1/V_{Si} + \cdots$$

where

V<sub>N</sub> is the volume of the nasal cavity and the nostrils and

 $V_{Si}$  and  $V_{Si'}$  are the volumes of sinus pairs Si

As will be understood by those familiar with the art, if one of a pair of sinuses or the passage thereto is blocked by sinusitis, the effective volume and hence, the resonant frequencies, will change. By performing a fast Fourier transform on the detected sound signals, the detected frequencies can be calculated and compared with expected values.

For example, in a typical adult, the frequency for the nasal cavity will be 211 Hz and for each maxillary sinus, which are normally very close in size, will be 308 Hz. Ignoring the effect of the other, smaller, sinuses, the combined system will have a characteristic frequency of 969 Hz. If one of the sinuses is blocked, the frequency will be 747 Hz. If both are blocked the system reverts to the value for the nasal cavity alone. As will be understood by those familiar with the art, frequency differences such as these are readily resolvable.

It should be noted that included in the present invention are alternative embodiments for examining other subsystems in human or other mammalian subjects, such as cattle. For example, with suitable arrangements for emitting and detecting sound signals, the lungs and their associated air passages or the heart chambers may be examined for abnormal or pathological conditions using the system and method of the present invention.

It will further be appreciated by persons skilled in the art that the scope of the present invention is not limited by what has been specifically shown and described hereinabove, merely by way of example. Rather, the scope of the present invention is defined solely by the claims, which follow.

### **CLAIMS**

1. A method of diagnosing sinusitis in a human subject, including the steps of:

externally sealing off the nostrils of a subject;

subsequent to the subject inhaling and immediately thereafter sealing his nasal cavities internally, emitting, via a first nostril, a predetermined sound signal of a predetermined frequency range into the nasal cavities of the subject;

detecting, via the second nostril, sound signals from the nasal cavities of the subject in response to the emitted signal;

subsequent to the subject again inhaling and immediately thereafter sealing his nasal cavities internally, emitting, via the second nostril, a predetermined sound signal of a predetermined frequency range into the nasal cavities of the subject;

detecting, via the first nostril, sound signals from the nasal cavities of the subject in response to the emitted signal;

comparing the two sets of detected sound signals; and

analyzing the two sets of detected sound signals and the comparison therebetween to diagnose sinusitis in the subject.

- 2. A method according to claim 1, wherein said step of emitting, via a first nostril, is emitting a white noise sound pulse.
- 3. A method according to claim 1, wherein said step of emitting, via a first nostril, is emitting a chirp sound pulse.
- 4. A method according to claim 1, wherein said step of emitting, via the second nostril, is emitting a white noise sound pulse.
- 5. A method according to claim 1, wherein said step of emitting, via the second nostril, is

emitting a chirp sound pulse.

- 6. A method according to claim 1, wherein said step of analyzing includes the step of comparing the two sets of detected sound signals with theoretically derived baseline signals representing measurements taken on a healthy subject.
- 7. A method according to claim 1, wherein said step of analyzing includes the step of comparing the two sets of detected sound signals with empirically derived baseline signals representing measurements taken on a healthy subject.
- 8. A method according to claim 1, wherein said step of analyzing includes the step of calculating the measured volume of the sinuses of the subject.
- 9. A method according to claim 8, wherein said step of calculating the measured volume includes the step of modeling the sinuses as Helmholtz resonators.
- 10. A method of diagnosing pathological conditions in body cavities in a mammalian subject, including the steps of:

sealing off a set of cavities to be diagnosed;

- emitting a predetermined sound signal of a predetermined frequency range into the set of cavities to be diagnosed;
- detecting sound signals from the set of cavities of the subject in response to the emitted signal;

analyzing the detected sound signals to diagnose (condition) in the subject.

11. A method according to claim 10, wherein said step of emitting is emitting a white noise sound pulse.

12. A method according to claim 10, wherein said step of emitting is emitting a chirp sound pulse.

- 13. A method according to claim 10, wherein the set of cavities to be diagnosed consists of the lungs and their associated air passages.
- 14. A method according to claim 10, wherein the set of cavities to be diagnosed consists of chambers of the heart.
- 15. A method according to claim 10, wherein said step of analyzing includes the step of comparing the detected sound signals with theoretically derived baseline signals representing measurements taken on a healthy subject.
- 16. A method according to claim 10, wherein said step of analyzing includes the step of comparing the detected sound signals with empirically derived baseline signals representing measurements taken on a healthy subject.
- 17. A method according to claim 10, wherein said step of analyzing includes the step of calculating the measured volume of the set of cavities of the subject.
- 18. A method according to claim 17, wherein said step of calculating the measured volume includes the step of modeling the set of cavities as Helmholtz resonators.
- 19. A system for diagnosing sinusitis in a human subject including:a miniature transducer for emitting a predetermined sound signal of a predetermined frequency range;

- a miniature microphone for detecting sound signals;
- a transducer holder configured to contain said miniature transducer and configured to be sealingly inserted into a nostril of a human subject;
- a microphone holder configured to contain said miniature microphone and configured to be sealingly inserted into a nostril of a human subject;
- signal processing apparatus for controlling sound signals emitted by said miniature transducer and for processing sound signals detected by said miniature microphone; and

data analysis apparatus for analyzing the processed detected sound signals.

- 20. A system according to claim 19, wherein said data analysis apparatus includes a data storage device for storing processed sound signals, baseline signals representing measurements taken on healthy subjects, and programs for data analysis.
- 21. A system according to claim 19, further including a data display device.
- 22. A system according to claim 19, wherein said transducer holder and said microphone holder are a single, double holder, configured to contain both said miniature transducer and said miniature microphone and further configured to be sealingly inserted into a nostril of a human subject; said system further including a second said miniature transducer, a second said miniature microphone, and two said double holders.
- 23. A system for diagnosing pathological conditions in body cavities in a mammalian subject including:
  - a sound emitter for emitting predetermined sound signals of a predetermined frequency range into body cavities to be diagnosed;
  - a sound detector for detecting sound signals from the body cavities to be diagnosed; signal processing apparatus for controlling sound signals emitted by said sound emitter

and for processing sound signals detected by said sound detector; and data analysis apparatus for analyzing the processed detected sound signals.

- 24. A system according to claim 23, wherein said data analysis apparatus includes a data storage device for storing processed sound signals, baseline signals representing measurements taken on healthy subjects, and programs for data analysis.
- 25. A system according to claim 23, further including a data display device.

1/2

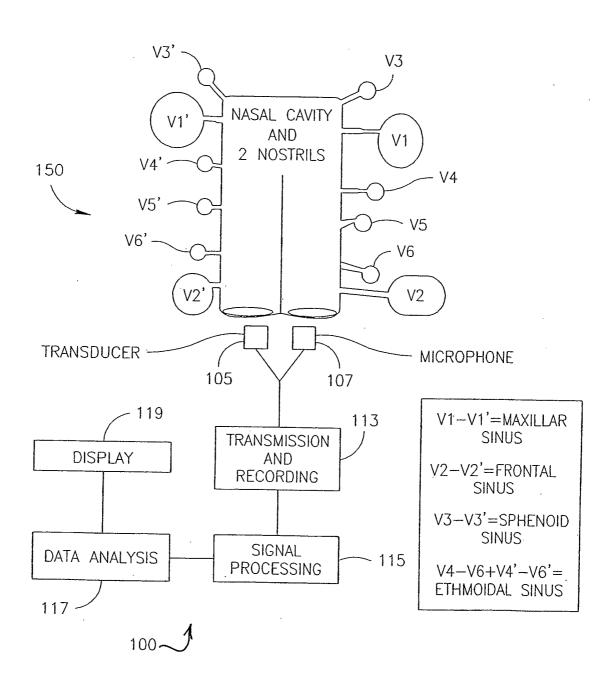


FIG.1

2/2

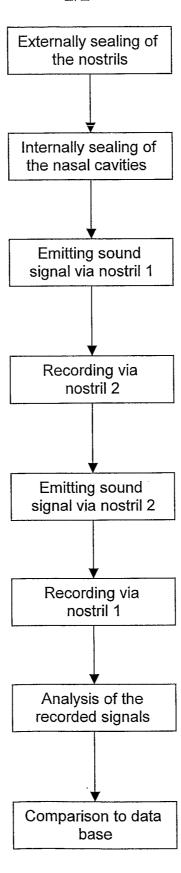


Figure 2

**SUBSTITUTE SHEET (RULE 26)**