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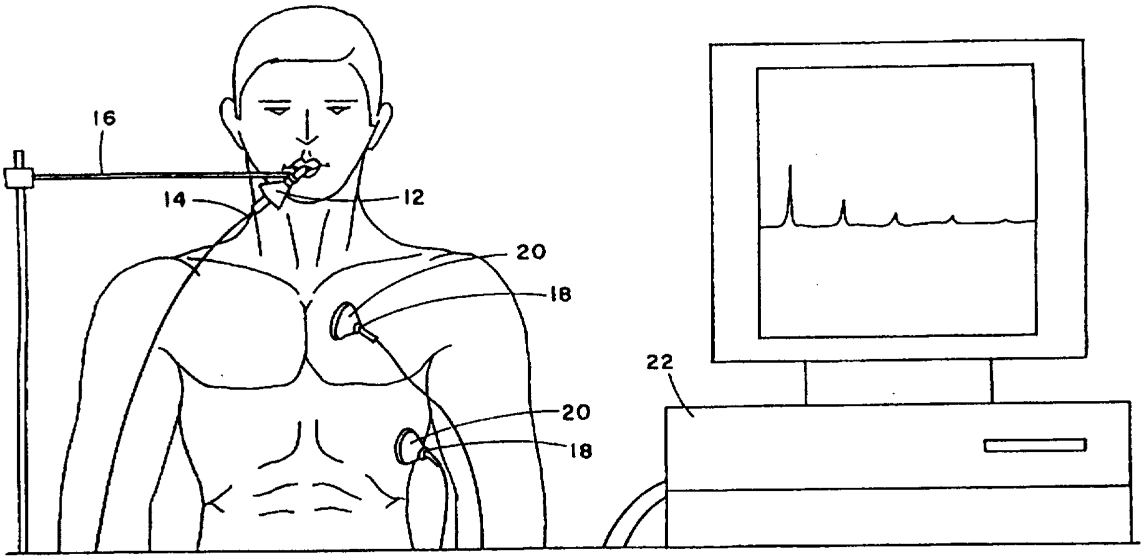
(54) Title: DIAGNOSIS OF LUNG CONDITION



(57) Abstract

A device for testing an individual in order to diagnose conditions of the respiratory system is provided. This device comprises a sound actuator which produces sound proximal to the individual's mouth. Vibrations are detected either on the skin at the thorax region or close to the site of the sound production. Signals recorded are processed, and based on these processed signals, an indication of pathological conditions of the respiratory system is provided.

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DIAGNOSIS OF LUNG CONDITION

FIELD AND BACKGROUND OF THE INVENTION

The present invention is generally in the field of medical diagnosis and concerns an apparatus and method for the diagnosis of a lung condition.

In today's medical practice, the doctor does not have available to him means which allow him a routine objective assessment of a person's lung and respiratory tract condition. Thus, after an initial physical examination of a person complaining of certain lung and respiratory problems is performed by the doctors, in case of a suspicion of a severe condition, e.g., pneumonia, cancerous growths in the lung, etc., the patient has to be sent to a medical center for the performance of an x-ray test, a CT scan and the like.

It would be highly desirable to have available to the doctor means which could be used in his clinic, which would allow him to immediately an objectively assess a person's lung condition. It is the object of the invention to provide same.

GENERAL DESCRIPTION OF THE INVENTION

In accordance with the invention it has surprisingly been found that the clinical condition of the various parts of an individual's respiratory system (lung, trachea, etc.), has an effect on vibrations recorded on the surface of the individual's skin at the thorax region, when sound is produced by a sound actuator in the individual's mouth. Thus, in accordance with the invention, such vibrations are recorded from the surface of the skin at the thorax region in order to diagnose the individual's respiratory condition. In diagnosing respiratory condition in accordance with the invention, the vibrations recorded on the thorax' skin are preferably compared to those produced directly by the actuator and recorded at its output. The sound actuator may be of a kind which is activated by the human breath, e.g. a whistle, or may be an actuator which produces sound independently, i.e. without the aid of the human breath, e.g. electrically activated.

It has further been found in accordance with the invention that some respiratory conditions have an effect on sound emitted by a breath activated actuator and recorded at its output. Accordingly, by an embodiment of the invention, the diagnosis of some respiratory conditions is based on recording sound vibrations at a breath activated actuator's output.

The present invention thus provides a device for testing an individual in order to diagnose the individual's lung condition, comprising:

(i) a sound actuator adapted for the production of sound in or at proximity to the individual's mouth;

(ii) at least one of:

- one or more first vibration detecting means adapted for recordal of vibrations on the surface of the skin at the thorax region and transduction of the recorded sound into one or more first electrical signals, and
- one or more second vibration detecting means adapted for recordal of sound at the output of said actuator;

(iii) processor means adapted to receive said one or more first and said one or more second signals and to perform a spectral analysis of each one or more first or second signals; and

(iv) output means for the provision of an indication of the spectral analysis, whereby the patient's lung condition can be assessed.

In accordance with one embodiment of the device, the sound activator is of a kind which is adapted for the production of sound by the presence of the individual's breath. In accordance with another embodiment, the sound activator is an independent device capable of sound production by an intrinsic, typically electric, mechanism.

The present invention further provides a method for testing an individual in order to diagnose the individual's respiratory tract condition. By one embodiment the method comprises:

(a) recording vibrations at a time in which the individual blows air through a sound actuator, the force of the human breath of a kind which is activated to produce sound by said vibrations being at least one of:
   - vibrations recorded on the individual's skin at the thorax region, and
   - sound vibrations of the sound emitted by said sound actuator, recorded at the actuator's output; and
(b) performing a spectral analysis of said vibrations, whereby, by means of certain spectral analysis, said condition is diagnosed.

By another embodiment, the method comprises:

(a) recording vibration on the individual's skin at the thorax region at a time sound is produced by a sound actuator held in the individual's mouth or placed in proximity of the individual's mouth; and
(b) performing a spectral analysis of said vibrations, whereby, by means of said spectral analysis, said condition is diagnosed.

In accordance with one embodiment of the invention, the spectral analysis is a power-frequency relation giving the power, i.e. the intensity of the recorded vibrations, at each frequency. In accordance with this embodiment, the power at different frequencies is compared, this comparison providing an indication of the individual's respiratory system condition.

In accordance with a specific embodiment of the invention, the diagnosis of the individual's respiratory condition is based on the simultaneous recordal of signals both from the individual's thorax and at the output of the sound actuator. For the sake of convenience, the former type of vibrations will be referred to herein at times as *"data signal"*, and the former vibrations as *"reference signal"*. The term reference signal does not signify that this signal serves only as a reference. On the contrary, at times, when using an actuator of a kind which produces sound by the force of the human mouth, this signal, as pointed out above and as will be clarified further below, may serve as a diagnosis tool by itself. In accordance with this specific embodiment, a spectral analysis of both the reference and the data signals is performed and by this analysis, and preferably by comparing the data and the reference signals to one another, the individual's respiratory condition is diagnosed. It may be appreciated that at times more than one data and more than one reference signals will be recorded and analyzed, and accordingly the apparatus of such an embodiment will comprise more than one first and more than one second vibration detecting means, respectively.

The vibration detecting means may be a microphone, particularly such having a uniform response curve throughout a wide frequency spectrum. Alternatively, the vibration detecting means may be an accelerometer, e.g. of the type customarily used in instruments designed for the detection of various lung conditions (An example of such an accelerometer used by H. Pasterkemp *et al.*, *Chest*, **96**: 1405-1412, 1989).

The invention will now be illustrated in the following non-limiting specific embodiments with occasional reference to the annexed drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic representation of a system in accordance with the invention;

Fig. 2 shows a side (a), front (b) and rear (c) view of a whistle of a kind used in experiment performed in accordance with the invention;

Fig. 3 is a block diagram of the signal processing pathway in a system in accordance with the invention;

Figs. 4-6 show a spectral analysis of both a reference and data signals from healthy individuals, using a whistle having an output frequency at about 720 Hz;

Figs. 7 and 8 show a spectral analysis from an individual which was diagnosed by an X-ray analysis to have free fluid in the bottom of his left lung. Fig. 7 shows recordings from the right lower back side and Fig. 8

results from the left lower back side. The whistle used in this experiment had a maximum frequency output at about 720 Hz;

Fig. 9 shows a spectral analysis from a woman who had a removal of a lung portion at her left side. The figure shows results from recordal at the right back side and the left back side while using a whistle having a maximal frequency output at a range of about 39–58 Hz;

Figs. 10 and 11 shows results from an individual who had some evidence for infiltration in his right lung, using a whistle having a maximal frequency output at about 720 Hz. The recordings are from the right back side (Fig. 10) and left back side (Fig. 11);

Fig. 12 shows results from an individual who had bronchopneumonia in his right lung bottom and center, a whistle having a maximal peak output at about 720 Hz was used;

Figs. 13 and 14 show results from a child suffering from pneuomonia in his left lung, using a whistle having a maximal frequency output at about 58 Hz. The recordal was made in the right back side (Fig. 13) and in the left back side (Fig. 14); and

Fig. 15 shows a spectral analysis from an old patient having a severe COPD which was tested using a whistle having a maximal frequency output at about 136 Hz.

Fig. 16 A and B show harmonic pattern of two healthy individuals, each blowing an identical high pitch sound actuator, showing the Fourier analysis of the "*reference signal*" only, harmonics are numbered from 1 to 4.

Fig. 17 A and B show harmonic patterns of two asthmatic patients, each blowing an identical high pitch sound actuator e, which is the same as in Fig. 16, showing the Fourier analysis of the "*reference signal*" only, harmonics are numbered from 1 to 4.

DESCRIPTION OF A SPECIFIC EMBODIMENT

Reference is first being made to Fig. 1 showing a system in accordance with the invention comprising a sound actuator 12 having attached thereto a microphone **14** adapted for recordal of sound emitted by sound actuator **12**; a support structure **16** holding the actuator at a level where it is immediately accessible to the mouth of an individual; a plurality of vibration detectors **18** comprising each a chest piece **20** and a microphone (not shown) contained therein. Rather than a microphone, the skin vibration detector may also comprise an accelerometer sensitive in a desirable frequency range (e.g. 20–1000 Hz). Microphone **14** and vibration detector **18** are electrically linked to computer **22** which is adapted to analyze the signal recorded by the microphone.

Fig. 2 is a more detailed representation of the sound actuator used in the experiments to be reported below. The sound actuator **12** which is a pitch–pipe of the kind used in accordions has a microphone attachment **24** for holding a microphone (not shown) and has a narrow portion which serves here as a mouth piece **26**. The sound is produced by pressing air through mouth piece **26** which then passes through reed **28** whereby sound is produced. The positioning of the microphone on attachment **24** ensures that the sound recorded by the microphone is that produced in sound actuator **12**. As will no doubt be appreciated, various other types of sound actuators may also be used in accordance with the invention.

An example of such other types of actuators is one which produces a sound without the aid of the human breath whereby the sound produced will be completely breath–free. In accordance with this embodiment the individual will hold the mouth piece of the actuator by his mouth and then the actuator will be activated to produce a sound. Such type of actuator is especially useful in cases (such as those shown in Example 7 below) when the reference signal is affected by the individual's respiratory condition. At times, the device may comprise two or more actuators, at least one being driven manually by the breath of the individual and the other driven independently, optionally triggered manually by the individual's breath.

Fig. 3 shows the signal processing pathway in a system of the invention. The analog data **30** recorded by each microphone is transmitted to and received by a audio card **32** wherein processing circuit **34** amplifies the signal, digitizes it and converts it into appropriate format for further processing. The signal may then be analyzed in real time or stored on a computer disk **36** for later processing. The analysis may be performed by a digital signal processing (DSP) program, typically a fast Fourier analysis program, running in a processor **38** and the analysis result may then be presented by output means **40**, which in the experiments reported hereinbelow were graphical representation of a power–frequency graph. However, various other types of output means may also be used, e.g. digital output giving a certain numerical value, a print–out, a screen display, and the like.

Detection of vibrations on the skin at the thorax region in a system of the invention may be performed either on the chest or on the back of the tested individual. Typically, the thorax vibration detectors **18** are placed in either one of eight regions consisting of upper left, lower left, upper right and lower right regions of either the chest or the back at the thorax of the individual. In Fig. 1, the system is shown as having four vibration detectors **18**, two on the chest (one on the upper left region and one on the lower left region), and one vibration detector on the back (only the cable leading thereto is obviously seen in this representation). However, it will be appreciated that, if desired, the system may contain less or more vibration detectors, e.g. four or eight, for simultaneous detection from part or all of the relevant regions.

For testing, the individual is requested to blow into sound actuator **12**, and the vibrations produced are then detected by detectors **18** and analyzed. By comparing the signal recorded by each of detectors **18** to one another, an indication of the respiratory system can be obtained. Furthermore, the results obtained may be normalized by comparing to the signal recorded by microphone **14**.

In the following, some examples of tests performed in accordance with the invention are described. In these tests a hand-held sound actuator was used. In the tests, two microphones were used, one for recordal of the output of sound actuator **12** and the other for recordal of vibrations at the thorax region of the tested individual. The thorax vibration detector was prepared as follows:

The membrane of a chest piece of a stethoscope was removed and the tube leading from the chest piece to the ear tips was cut at a distance of about 8 cm from the chest piece. The microphone was then inserted into the tube and for recordal, this vibration detector was hand-held on the skin of the tested individual.

The microphone used in the test was Model MKE 2™ (Sennheiser, Germany), which has a uniform gain curve at a frequency range of 20–40,000 Hz. The computer used for analyzing the signals was a personal computer with a 386™ processor equipped with a Sound Blaster™ 16 ASP card (Creative Labs Inc.). The signal was sampled simultaneously in two channels, one sampling the signal recorded from the microphone attached to the sound actuator, (*"reference signal"*) and the other sampling the signal recorded from the thorax (*"data signal"*). The sampling rate in each channel was 22 KHz at 16 bit resolution. The Sound Blaster card amplifies the signal, digitizes it and then converts it into a data file having a specified format which can then be stored in the computer's disk. The analysis of the data was performed by the DSP program – Hypersignal™ (Hyperception Inc., U.S.A.).

Results of some tests are reported in the following examples:

Example 1

Figs. 4–6 show results obtained from healthy individuals, namely such who had a healthy respiratory system. The individuals were tested using a whistle having a first outward peak at about 720 Hz. The results in the three Figs. are from different individuals (in Fig. 4 from a 55 year old male; in Fig. 5 from a 4 year old girl; and in Fig. 6 from a 40 year old male).

As can be seen, the data signal in each case had a peak at 722 Hz which is highly pronounced as compared to the reference signal. The reference signal showed a peak at about the same frequency and additional peaks at various harmonic frequencies to the original frequency. No harmonic peaks were seen for the data signal. In Fig. 6 there is also a peak at 19 Hz, but this is not a harmonic of the original frequency.

Example 2

An individual which had a severe blow at his right side which occurred two weeks before the test, which at a later stage (i.e. after performance of a test in accordance with the invention) was diagnosed by an X–ray analysis as having free fluid in the bottom of his left lung was tested by the use of a whistle of the type used in Example 1. The results obtained from recordal at the right lower back side are shown in Fig. 7 and the results obtained from recordal at the left lower back side are shown in Fig. 8. In both cases, the data signal is shown together with the reference signal recorded simultaneously.

As can be seen in Fig. 7, the main peak, at a frequency of 703–722 Hz, is higher in the reference signal as compared to the data signal. Against this, the opposite was seen in the left side, as can be seen in Fig. 8, in which the data signal at this peak is much stronger than the reference signal. Furthermore, in Fig. 8, a peak having a frequency of about 58 Hz, of an amplitude about half of that of the peak at 703 Hz, which peak is not observed at all in the records from the left side.

Example 3

Tests were carried out on a woman who was later confirmed to have had a removal of a lung portion at her left side although an X–ray picture of the woman did not provide any indication to the removal.

Fig. 9 shows results recorded from the lower back in both the right and the left sides. The sound actuator used was a whistle having a maximal frequency output at a range of about 39–58 Hz.

In the left side, a maximum peak at 97 Hz was obtained, whereas the maximum peak in the right side was at 39 Hz. It should be noted that such a high peak (97 Hz) was not seen in any of several tens of normal individuals tested.

Example 4

A slightly asthmatic individual who had a car accident about two weeks before and suffered from a fever lasting for about 10 days was tested. This individual was analyzed later by X–ray analysis, which analysis showed evidence for infiltration in his right lung. Figs. 10 and 11 show results from this individual; the data was recorded from the right lower back side and the lower left side, respectively, of the individual's thorax. The whistle which was used in this test was the same as that used in Example 1.

As can be seen from Figs. 10 and 11, the data signal showed a peak at 39 Hz slightly higher than the peak at 722 Hz. This signal signature is different than that recorded from normal individuals as can be verified when comparing to the results reported in Example 1. Furthermore, in this individual recordals made at the left side showed a high data peak at 19 Hz and almost no peak at 722 Hz. Thus, in addition to confirming the existence of the lung disorder at the right side, the results also indicated a possible disorder of the lung at the left side.

Example 5

The whistle which was used had an output with a first peak at about 722 Hz. The tested individual was later confirmed as having bronchopneumonia in the right lung, bottom and center.

The results presented in Fig. 12 show a new data peak at 19 Hz which is never pronounced to the extent or is even non–existing in a healthy lung (compare to Figs. 4–6). Furthermore, there is also a very pronounced data peak at the third harmony of the original signal (at about 2800 Hz) which is not typical in a normal lung (also compare to Figs. 4-6).

Example 6

A child, which was later confirmed (by X-ray analysis and clinical examination) as suffering from pneumonia in his left lung, was tested by the use of a whistle having a maximal frequency output at about 58 Hz. A signal was recorded from the lower back thorax region in both the right side and the left side and the results are shown in Figs. 13 and 14, respectively.

As can be seen from Fig. 13, there is a very pronounced peak at 39 Hz in the right side whereas the data signal in the left side peaked at 58 Hz. It can be seen that the peak in the right side was much more pronounced than that of the left side, (at 58 Hz) as compared to the reference signal in each case.

Example 7

An old patient having a severe COPD (chronic obstructive pulmonary disease) was tested using the same whistle as in Example 6 showing this time a maximal frequency output at 136 Hz.

Unlike recordal from a patient having a normal respiratory system, from reasons which are yet not clear, as can be seen in Fig. 15 the lung condition of this patient affected also the reference signal. As can be seen, there are a large number of reference signal peaks up to a frequency of about 500 Hz and then there are additional small peaks seen within a frequency range of 1000-1500 Hz. (marked by an arrow in the figure).

In parallel, there are also a large number of small peaks in the data signal.

Example 8

In this example a whistle of high pitch was used to to invoke a signal in four individuals, two asthmatic and two healthy, the signals being recorded and analyzed, except that the graphic output was made by a different program, for each case drawing a graph that indicates the harmonics in the frequency range between 0- 11014 Hz. . The lowest harmonic of the whistle was 2681 Hz, second harmonic 5351 Hz, third 8032 Hz, and fourth 10702 Hz. It can be seen that for asthmatic patients, in Fig. 17A and B , the pattern of harmonics is evidently different than the one of healty patients, Fig. 16A and B. Most pronounced is the relative magnitude of harmonic 2 which is low for sick patients. For the case shown in 16A it is evident that harmonic 2 is most prominent.

CLAIMS:

1. A device for testing an individual in order to diagnose the individual's respiratory system's condition, comprising:

(i) a sound actuator adapted for the production of sound in or at proximity to the individual's mouth;

(ii) at least one of:

- one or more first vibration detecting means adapted for recordal of vibrations on the surface of the skin at the thorax region and transduction of the recorded sound into one or more first electrical signals, and
- one or more second vibration detecting means adapted for recordal of sound at the output of said actuator;

(iii) processor means adapted to receive said one or more first and said one or more second signals and to perform a spectral analysis of each one or more first or second signals; and

(iv) output means for the provision of an indication of the spectral analysis, whereby the patient's lung condition can be assessed.

2. A device according to Claim 1, wherein said sound actuator is of a kind which is adapted for the production of sound by the force of the individual's breath.

3. A device according to Claim 1, wherein the sound actuator is an independent device capable of sound production by an intrinsic mechanism.

4. A device according to any one of the preceding claims, comprising one or more said first vibration detecting means and one or more said second vibration detecting means.

5. A device according to Claim 4, wherein the diagnosis involves comparing the spectral analysis of said one or more first signals to the spectral analysis of said one or more second signals.

6. A device according to any one of the preceding claims, wherein at least of said vibration detecting means is a microphone.

7. A method for testing an individual in order to diagnose the individual's respiratory tract condition, comprising:

(a) recording vibrations at a time in which the individual blows air through a sound actuator, the force of the human breath of a kind which is activated to produce sound by said vibrations being at least one of:
   - vibrations recorded on the individual's skin at the thorax region, and
   - sound vibrations of the sound emitted by said sound actuator, recorded at the actuator's output; and

(b) performing a spectral analysis of said vibrations, whereby, by means of certain spectral analysis, said condition is diagnosed.

8. A method for testing an individual in order to diagnose the individual's respiratory tract condition, comprising:

(a) recording vibration on the individual's skin at the thorax region at a time sound is produced by a sound actuator held in the individual's mouth or placed in proximity of the individual's mouth; and

(b) performing a spectral analysis of said vibrations, whereby, by means of said spectral analysis, said condition is diagnosed.

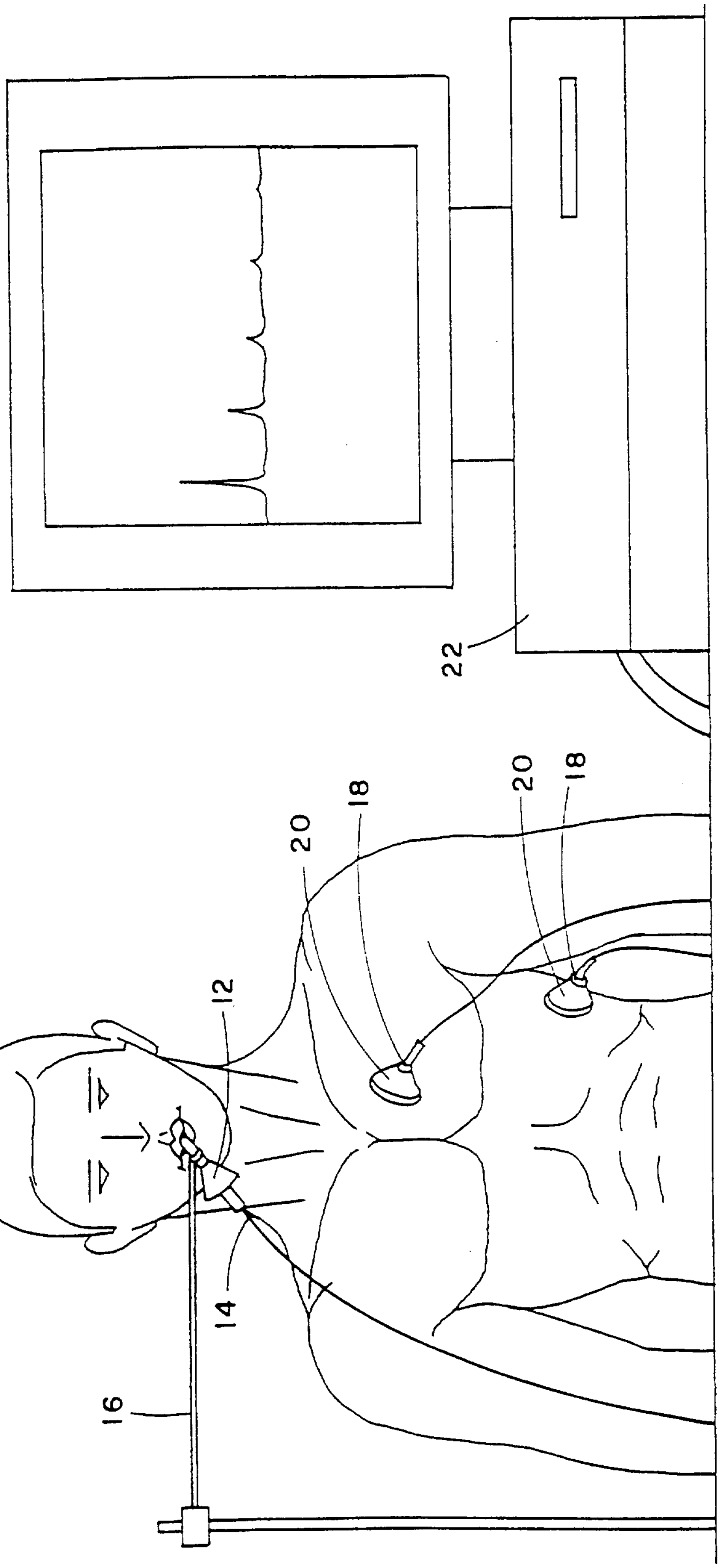

Fig. 1

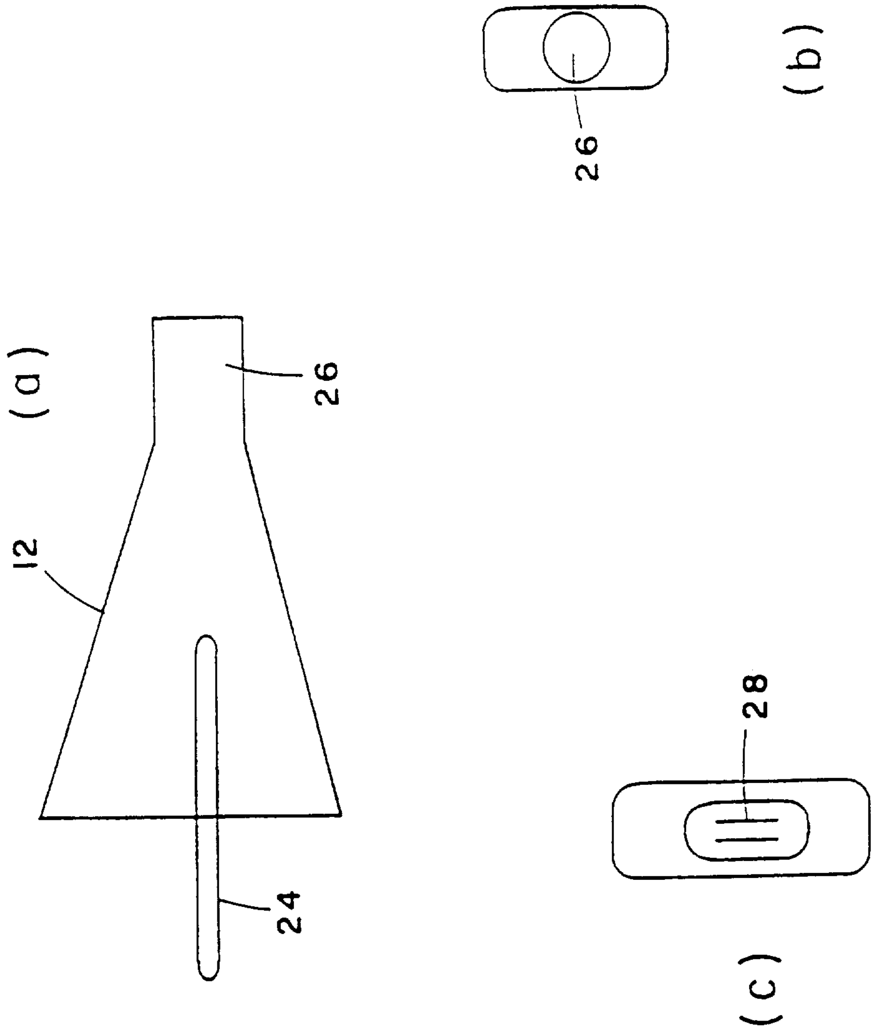

Fig. 2

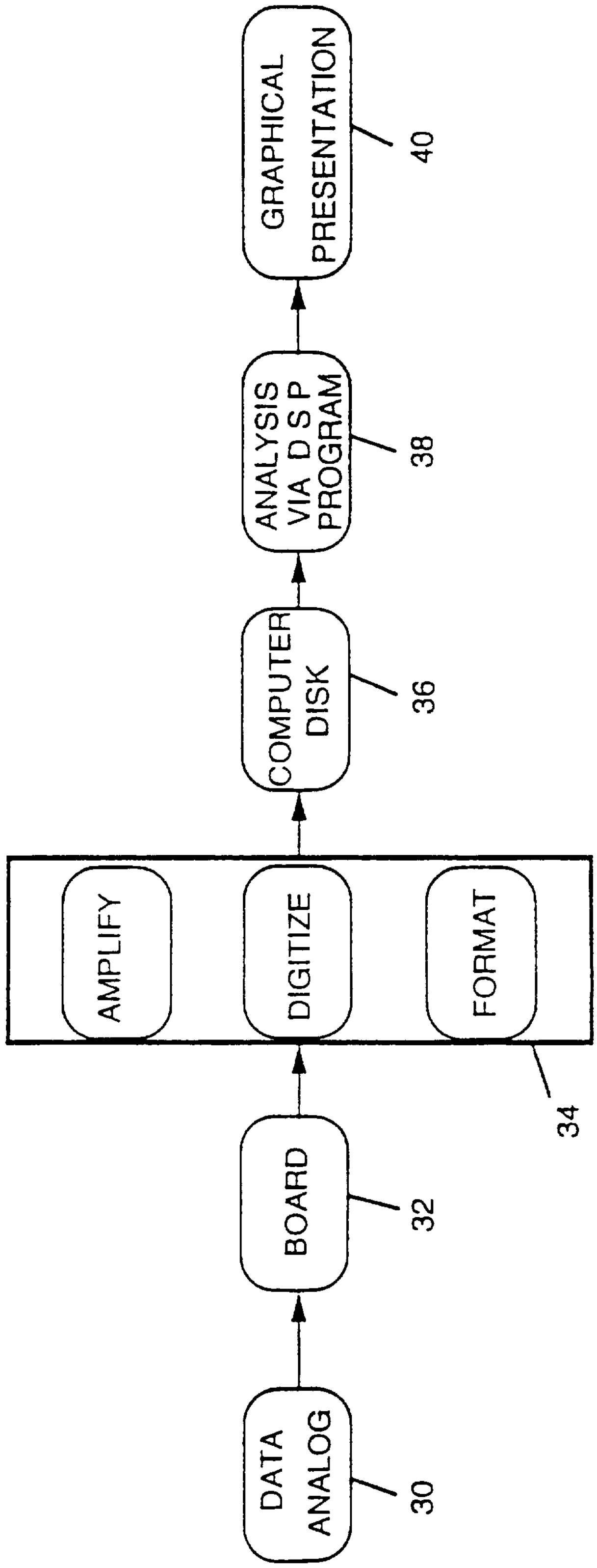
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Fig. 3

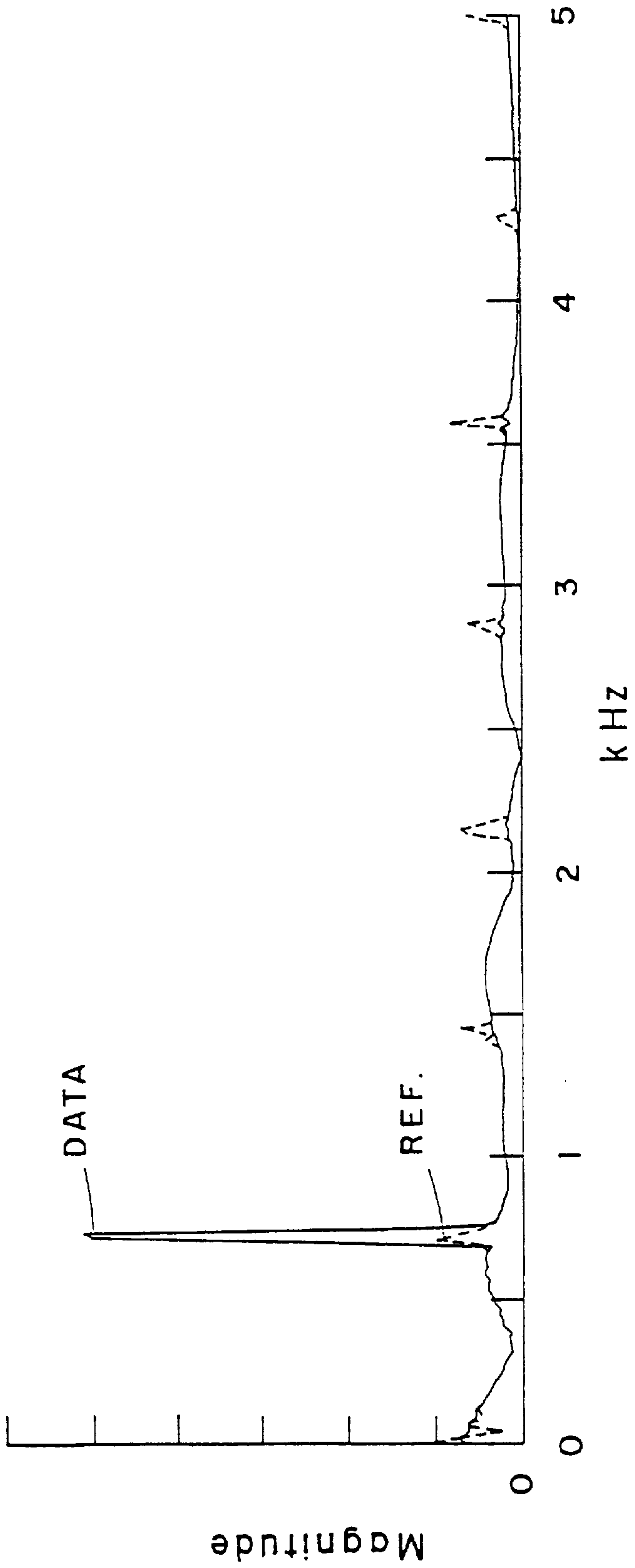

Fig. 4

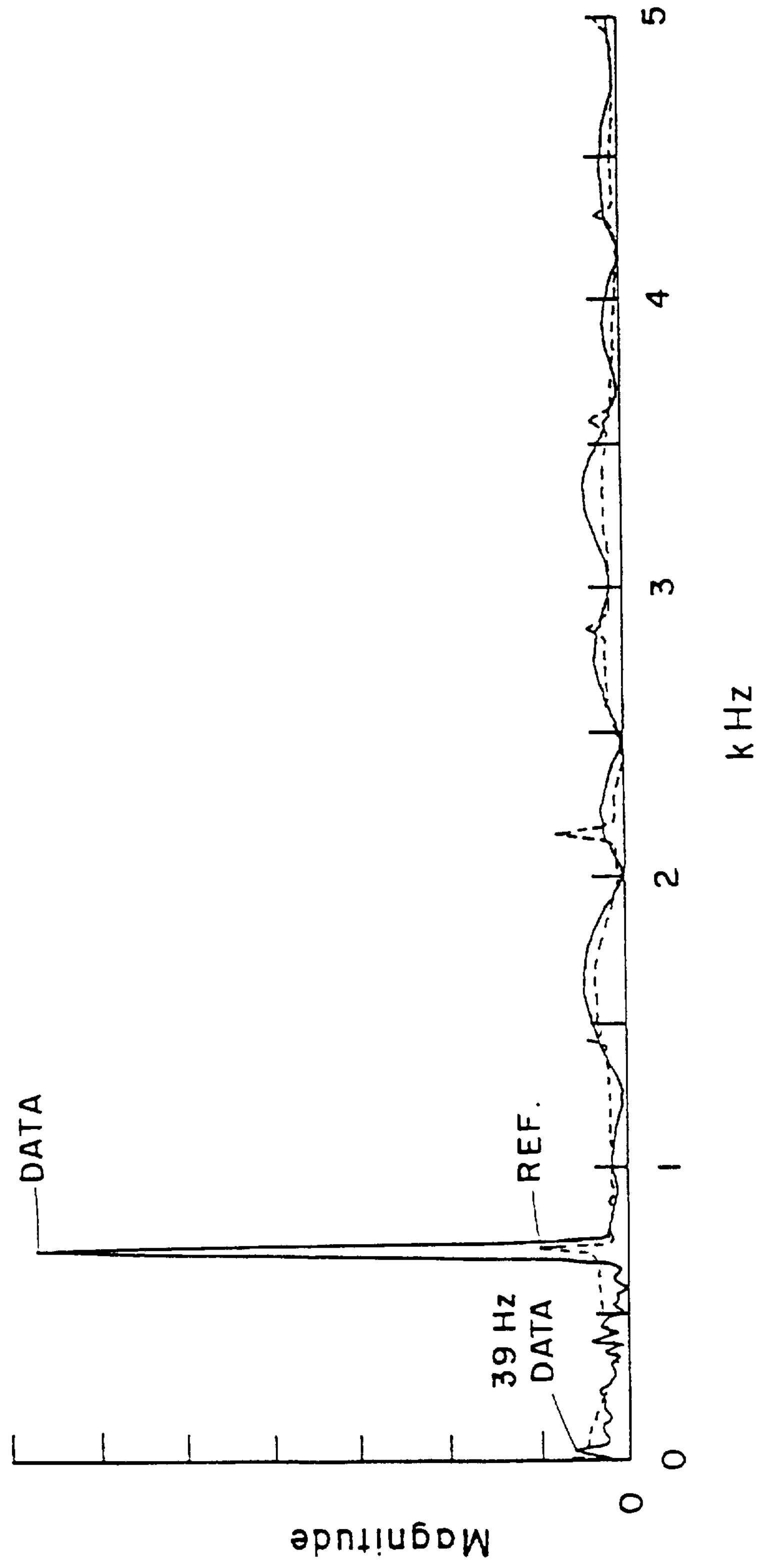

Fig. 5

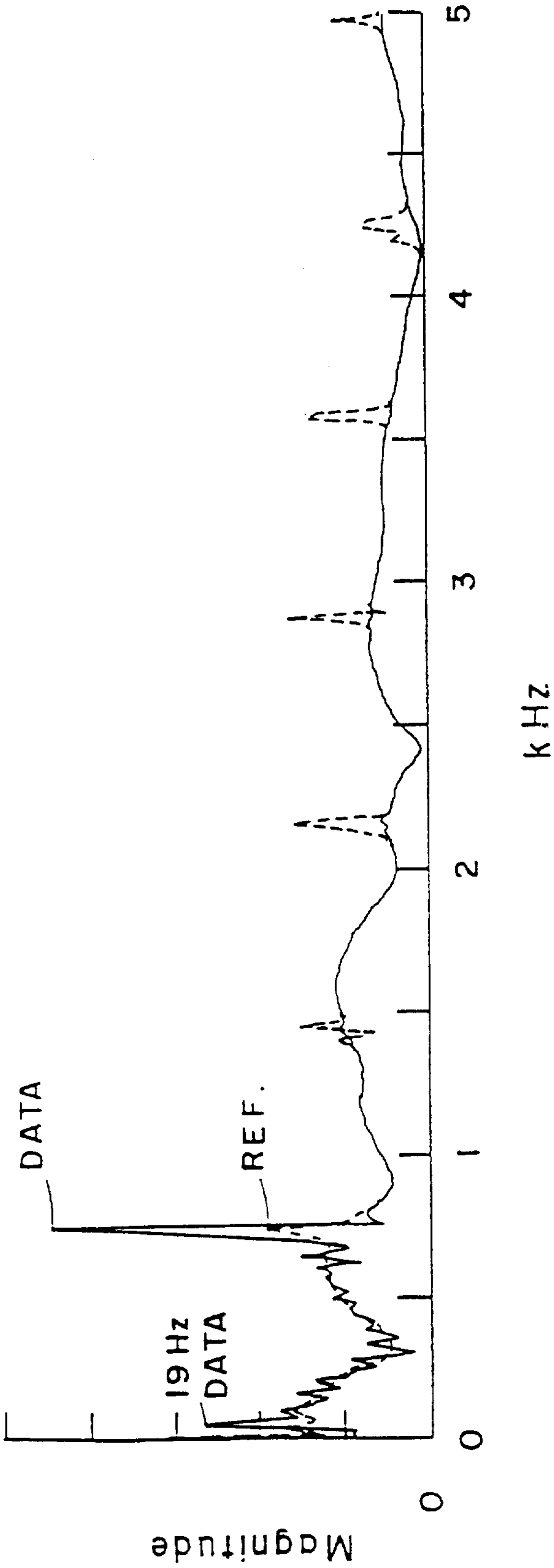

Fig. 6

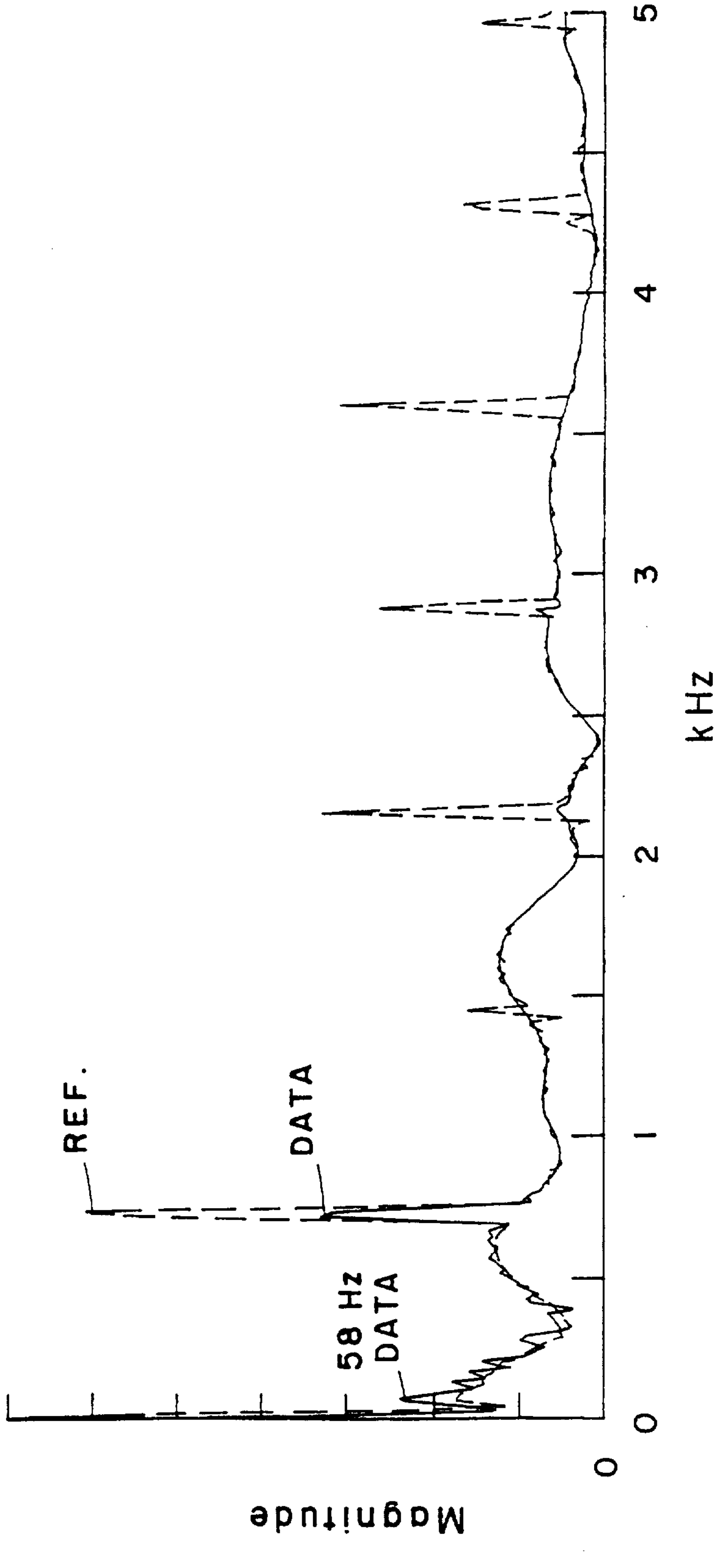

Fig. 7

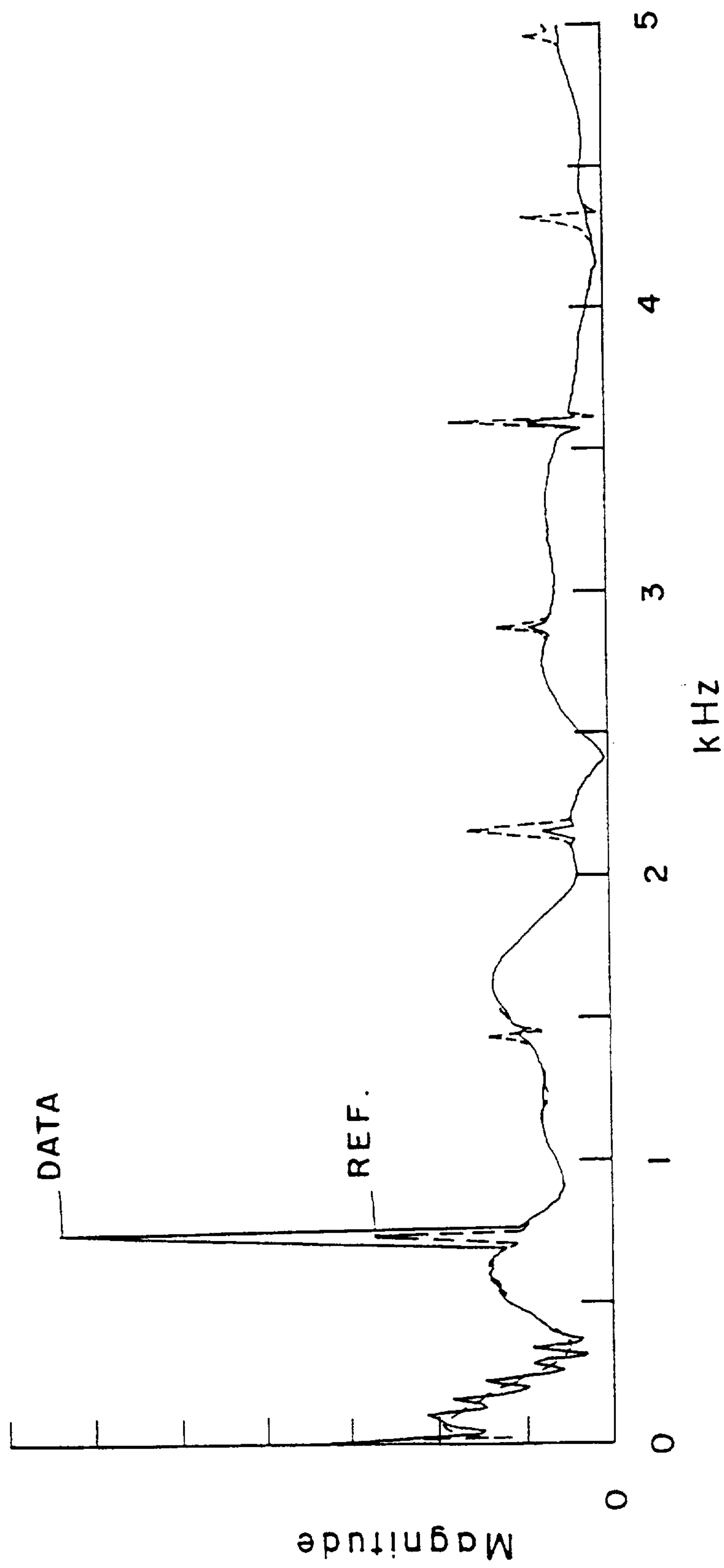

Fig. 8

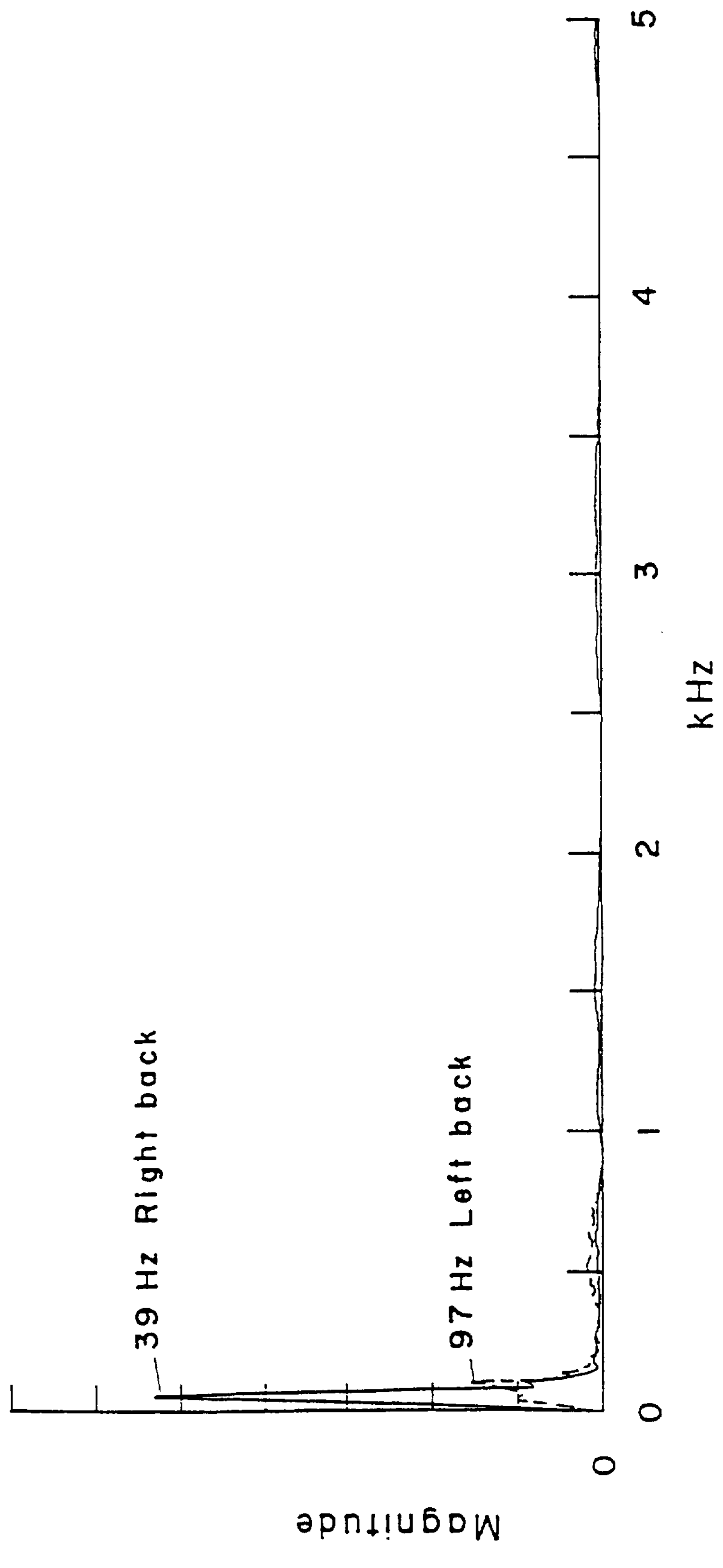

Fig. 9

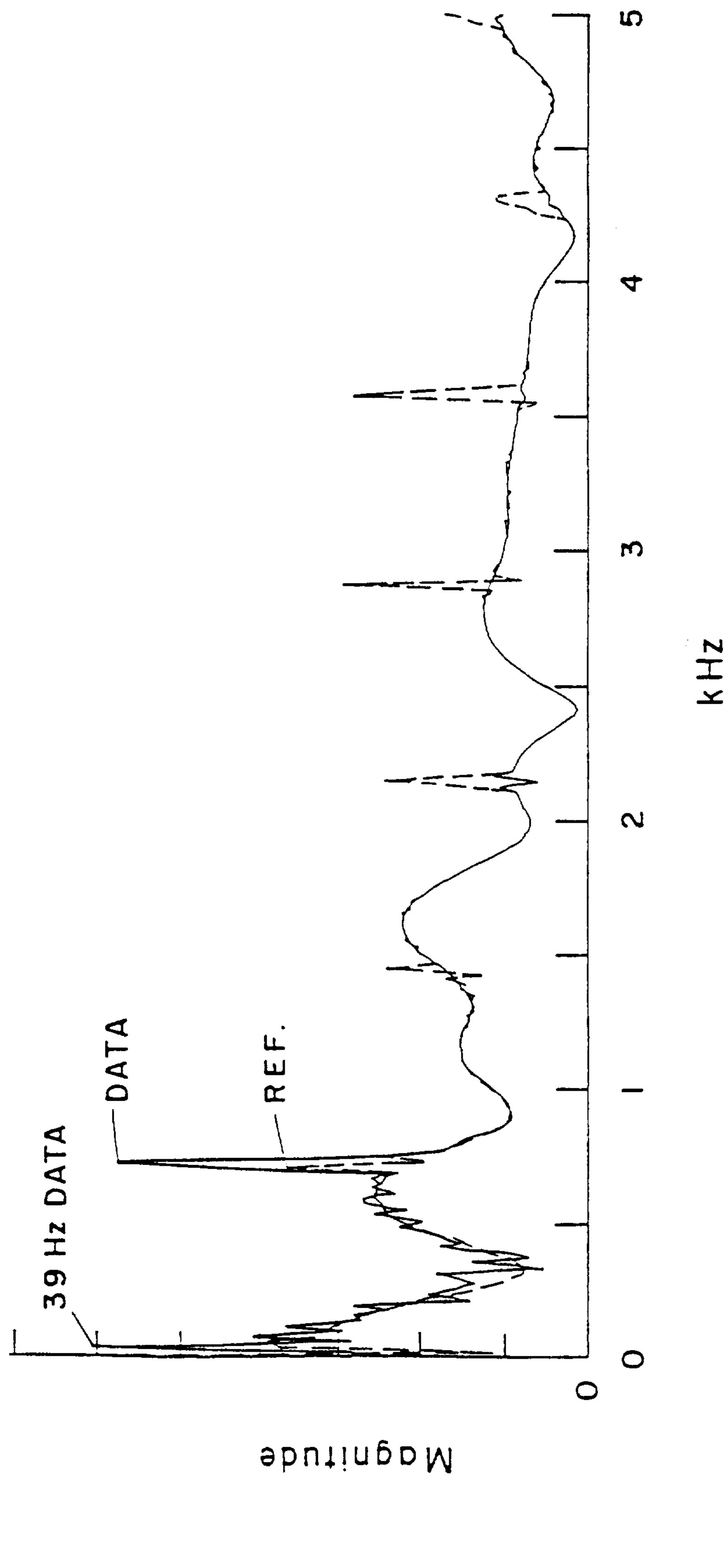

Fig. 10

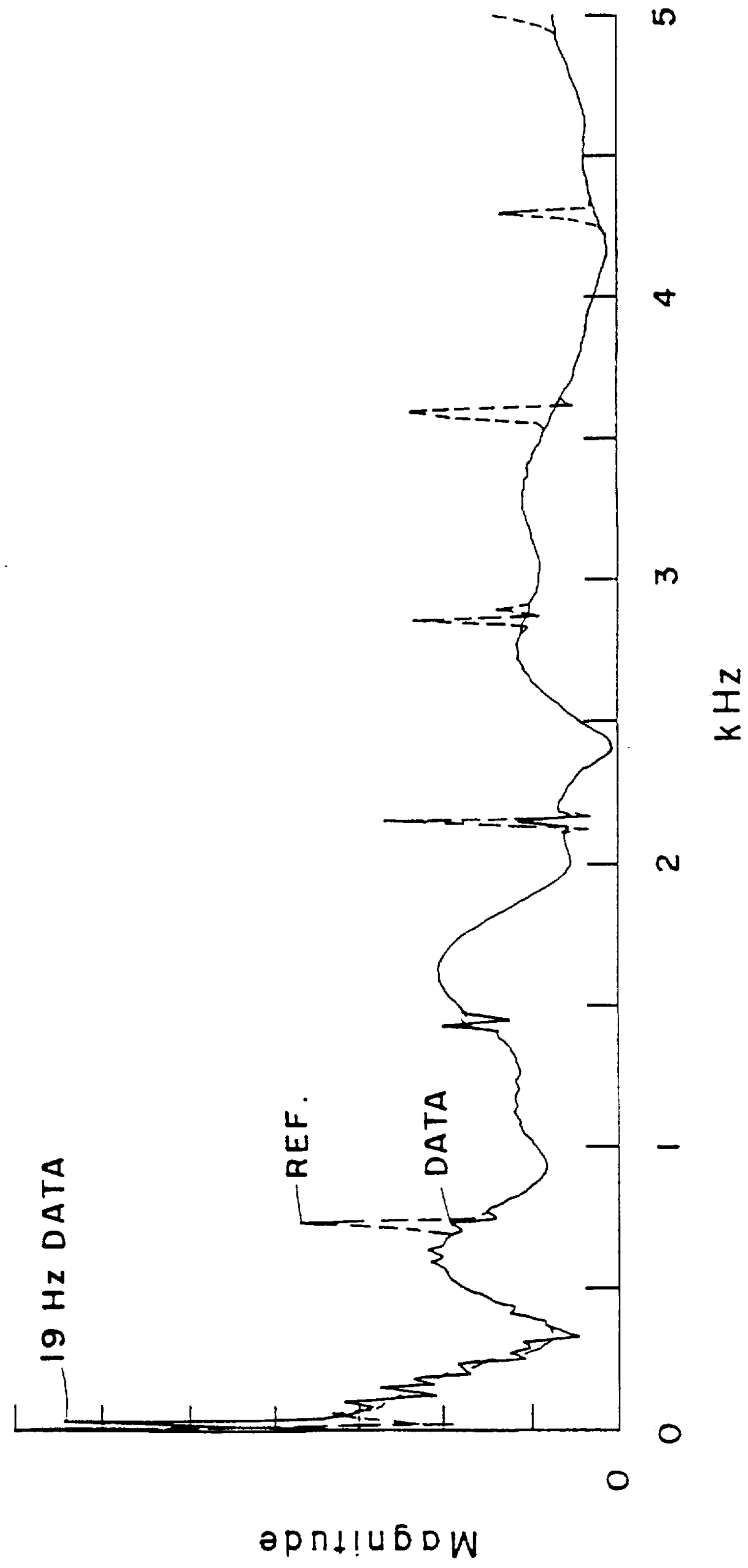

Fig. 11

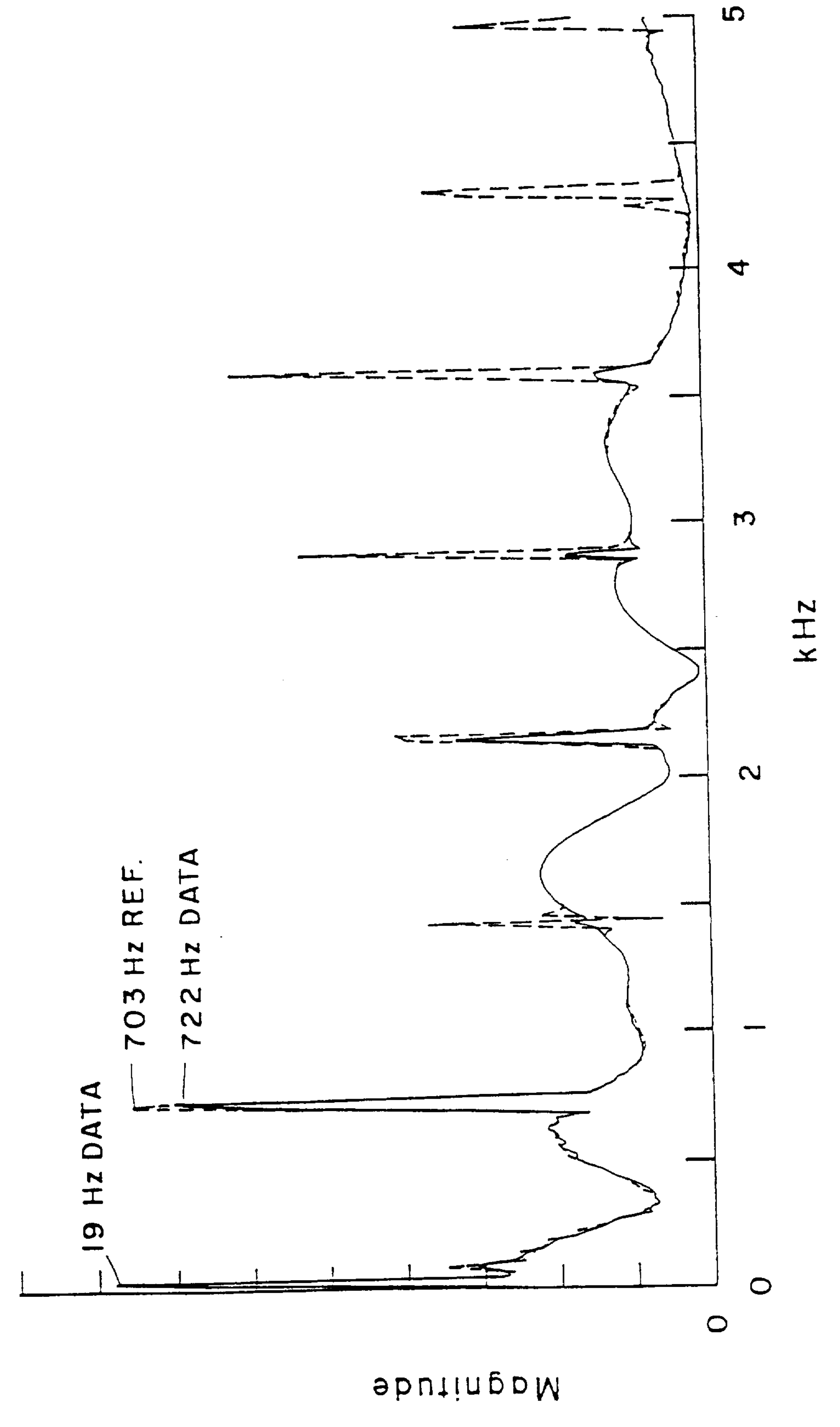

Fig.12

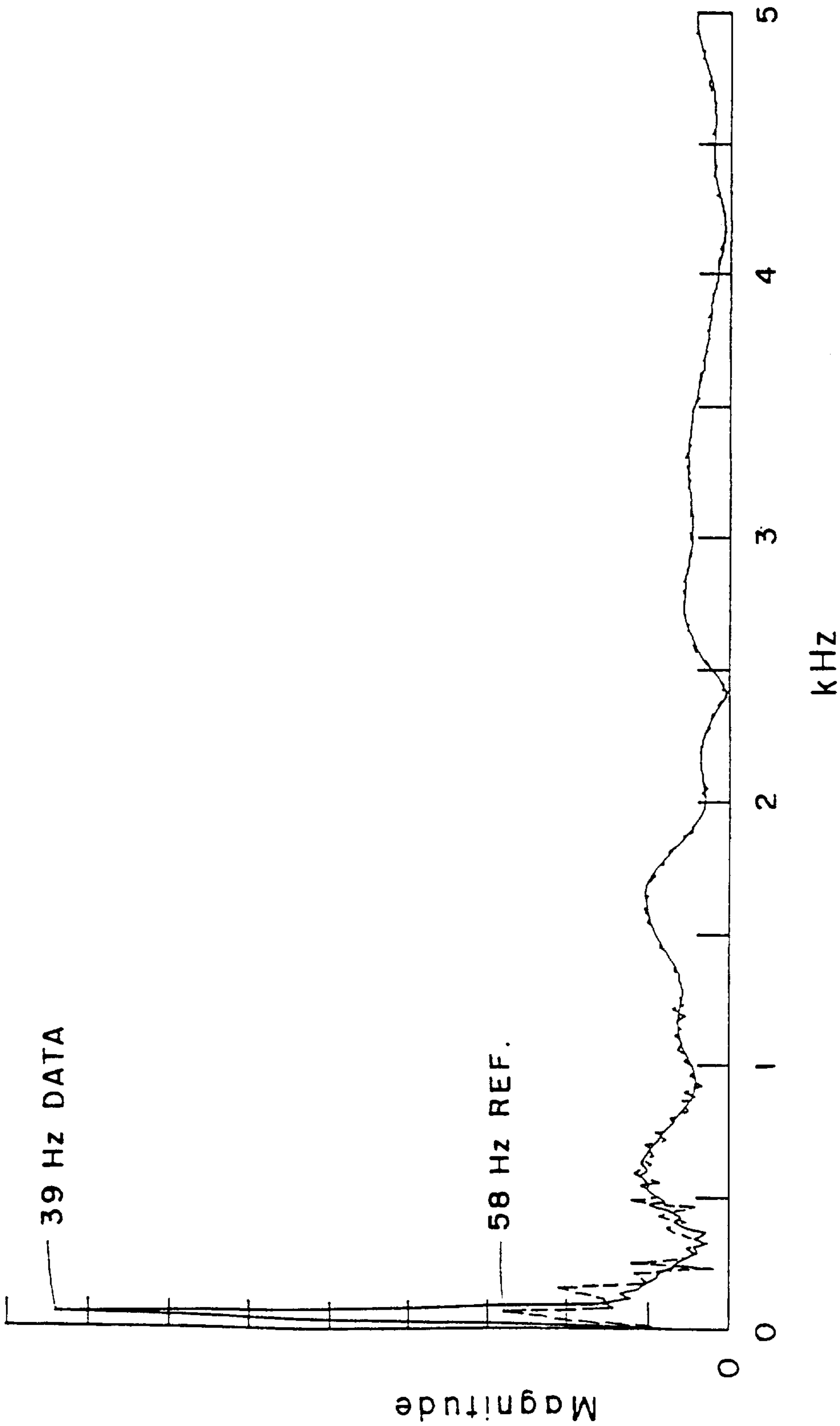

Fig. 13

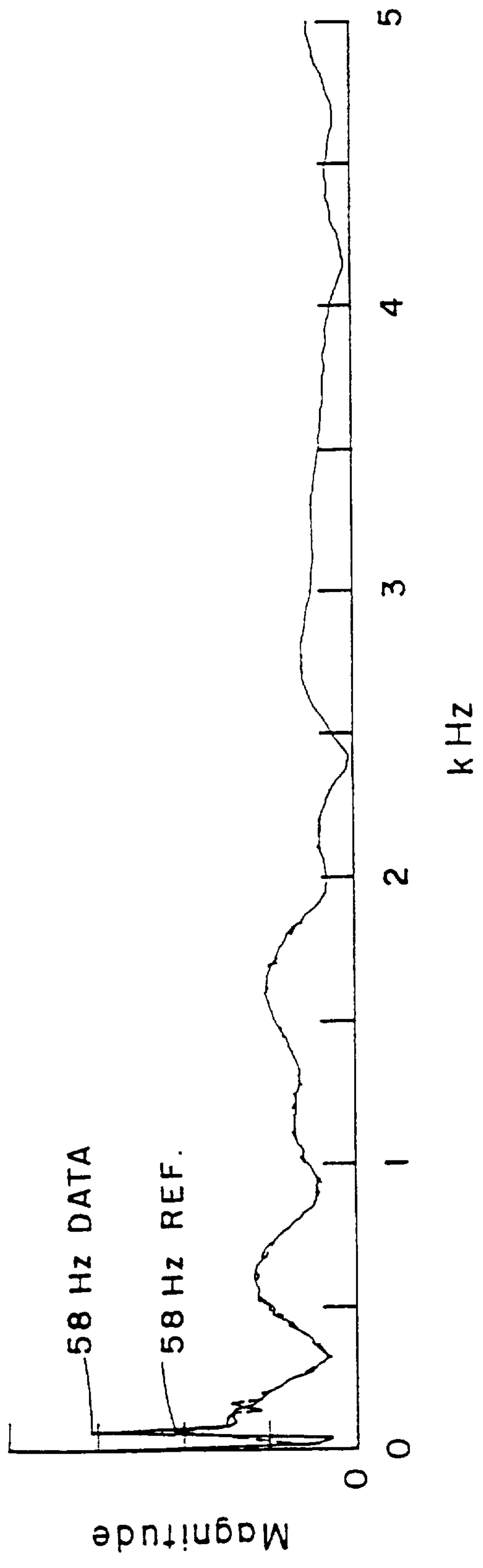

Fig. 14

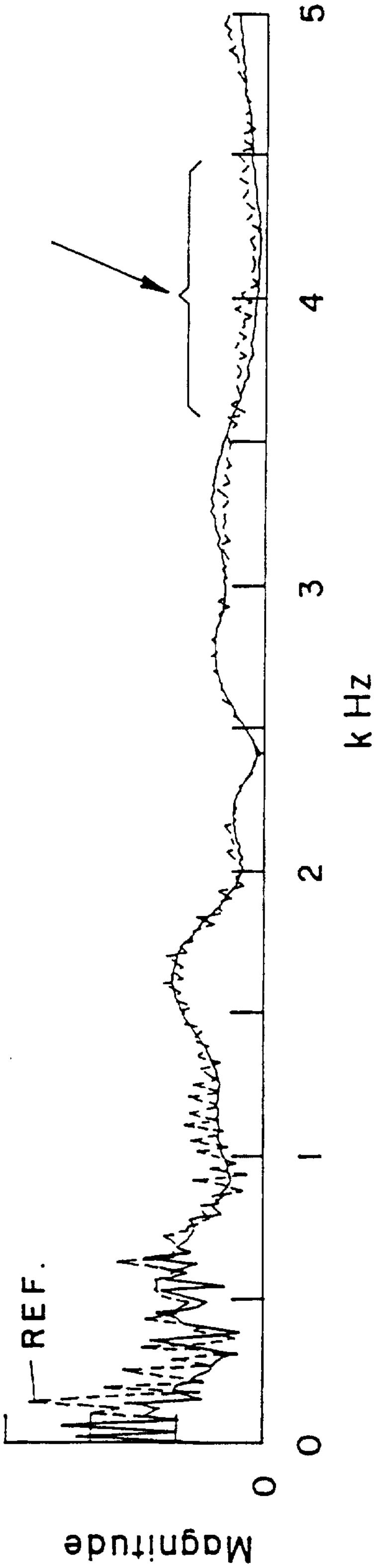

Fig. 15

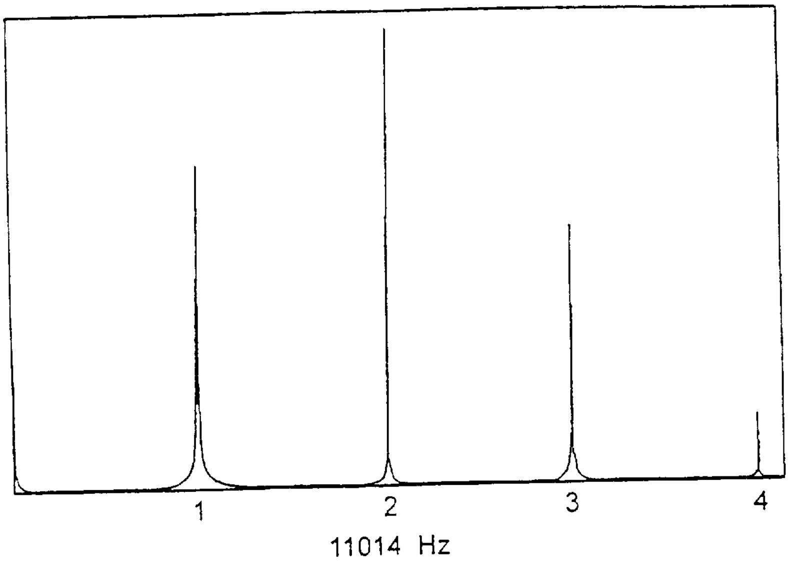

Fig. 16 A

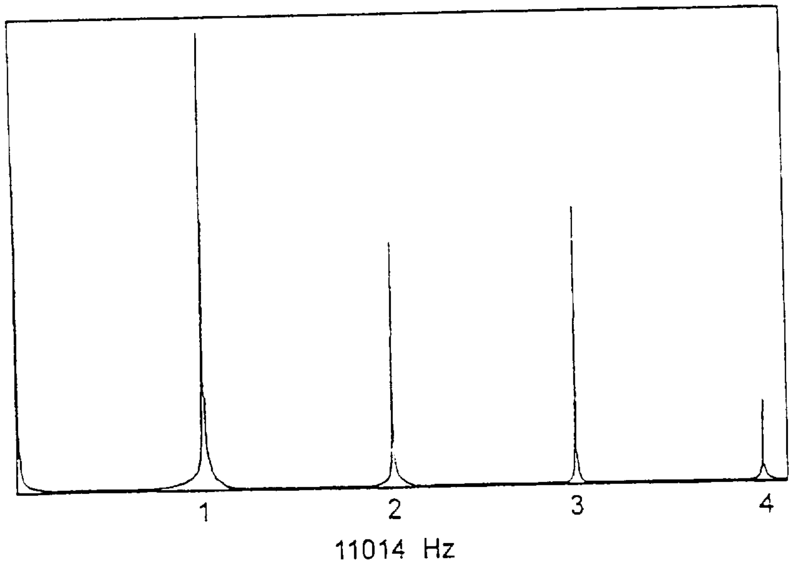

Fig. 16 B

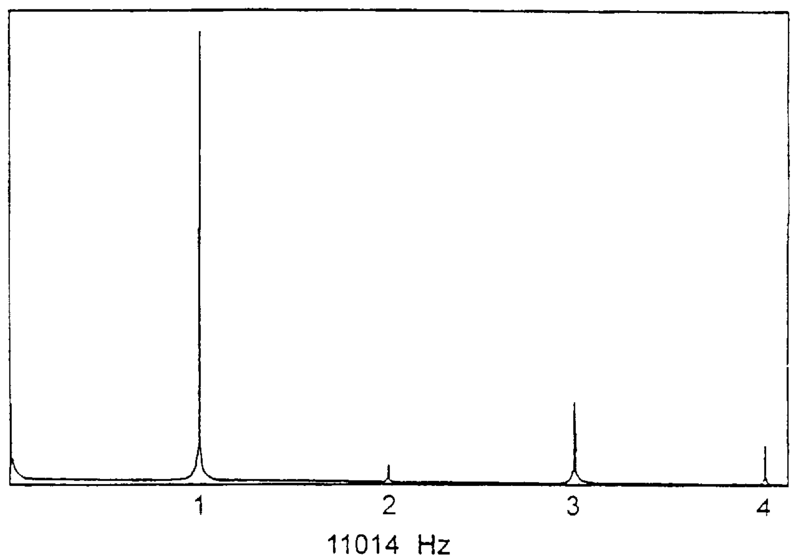

Fig. 17 A

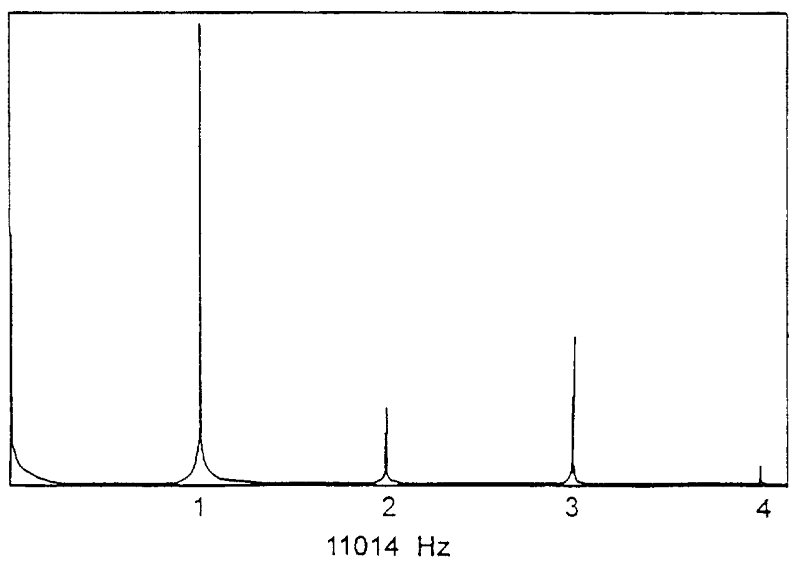

Fig. 17 B

INTERNATIONAL SEARCH REPORT

Inte .onal Application No
PCT/IL 97/00052

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B7/00 A61B5/085

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 6 A61B

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 practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 672 793 A (UNIV LIMOGES) 21 August 1992 see the whole document ---	1,3-6
X	MEDICAL AND BIOLOGICAL ENGINEERING AND COMPUTING, vol. 32, no. 5, September 1994, pages 489-494, XP000469338 WODICKA G R ET AL: "BILATERAL ASYMMETRY OF RESPIRATORY ACOUSTIC TRANSMISSION" see the whole document --- -/--	1,3-6

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
20 May 1997	29.05.1997

Name and mailing address of the ISA	Authorized officer
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	Ferrigno, A

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	MEDICAL AND BIOLOGICAL ENGINEERING , vol. 14, no. 6, November 1976, STEVENAGE GB, pages 653-659, XP002031158 M. MIYAKAWA ET AL.: "Acoustic measurement of the respiratory system - An acoustic pneumograph" see the whole document ---	1-6
Y	WO 90 04945 A (STONEMAN STEWART ALBERT THOMAS) 17 May 1990 see abstract; figure 1 -----	1-6

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL 97/00052

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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WO 9004945 A	17-05-90	EP 0396712 A GB 2225948 A,B JP 3503498 T	14-11-90 20-06-90 08-08-91