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A DEVICE FOR REFLECTOMETRIC EXAMINATION AND
MEASUREMENT OF CAVITIES

The present invention relates to a device for reflectometric examination and measurement of cavities of the kind which includes an acoustic signal generator, a hose with a distal end to be introduced via an entrance to the cavity to be examined, at least one transducer connected to the signal generator for transmission of an activation signal from the signal generator to the hose, at least another transducer connected to the hose for reception of response signals from the cavity and a computer adapted for analysis of the response signal in relation to the excitation signal sent to the cavity.

For examination and measurement of blockings, deformations, movements etc. in various human and animal cavities, e.g. pharynx, larynx and other air and eating passages, arteries etc. various methods are known.

In catheter examinations, balloonangioplasty etc. it is known to use a probe in the shape of a hose of flexible material.

Another method is based on measurement of reflection (reflectometry) using an acoustic, transient excitation signal which, through a hose and through the patient's mouth, is sent into the air passages of the patient, cf. e.g. US-A-4.326.416.

Another method based on the use of a non-transient excitation signal - random or pseudorandom signal - is used in an equipment manufactured by the applicant firm, under the commercial designation SRE 2000 and SRE 2000 PC.

Especially in connection with examination of movements in the air passages and examination of stertorous respiration mainly pressure transducers,

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placed in or on catheters to be introduced in nose or mouth, have so far been used. This allows for measurement of pressure variations, constrictions etc. in nose and throat.

5 A drawback in this technique is to be seen in that the measurement probe must include a relatively large number of closely located pressure transducers connected to a corresponding apparatus which offers the possibility, on a screen with a sufficient resolution, to
10 determine the position of and pressure at each examined spot.

Known techniques also include endoscopy by which optical examinations are made of nose, pharynx and other internal organs. However, these examinations have a
15 certain number of limitations, including the clarity and size of the optical image, the size of the catheter and specially the lack of catheter flexibility which makes the catheter unsuitable for examination of e.g. stertorous respiration.

20 CT and MRI scannings have been tried, but involve long periods of measurement which do not give useful measurements and no dynamic measurements at all.

By using acoustic reflectometry of the above mentioned kind, it is known that it is possible to
25 measure cross-sectional areas in the air passages as a function of the distance from the transducer used for emission the excitation signal, cf. the above patent US-A-4.326.416 or an article: "Airway geometry by analysis of acoustic pulse response measurements" by Andrew C.
30 Jackson et al. in J. Appl. Physiology, 43(3): 525-536, 1977.

Direct measurement limits measurements of cross modes, i.e. cross resonance, and of the adjacent cavities, which, to a large extent, limits the use of such direct
35 measurements having large differences in the cross-

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sectional areas as a function of the distance from the signal source.

Especially when examining stertorous respiration the use of direct measurements is hampered by the transient or continuous sound influence, necessary for the measurements, which affects the sleep state or awakens the patient during the examination phase itself, and also causes measurement errors because of noise from the measurement microphone and a measurement error due to the very large cavity made up by the mouth and throat.

The invention aims at remedying the above mentioned disadvantages and in order to do so a device of the type mentioned in the introduction is according to the invention characterized in that the hose is adapted, seen from the signaling transducer, so as to be introduced in the cavity in question with its distal end placed past the zone to be examined, that it consists of a thin-walled, soft, flexible plastics or elastomere material and that, at its proximal end, it is equipped with said at least one transducer connected with said signal generator, which transducer is adapted to transform an activation signal from the signal generator to an excitation signal which can transmit through the hose and cause a response signal back to the transducer due to a deformation, if any, of the hose wall.

The invention is based on the recognition that humans have many spots where a contracted or pathological change or obstruction in the air passages, urinary system etc. can be difficult to determine, locate and measure with the above mentioned known technique, among other things because of the common cross resonance in the large or small surrounding cavities at the spot which is to be examined and that it is particularly suitable to use a very flexible hose, whose wall can be



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made to abut the side wall in question of the passage or can be deformed by some change e.g. a constriction at the spot in question. By this, the measurement equipment can only "see", so to speak, the interior of the hose and clearly measure the least deformation in the inner cross-sectional area of the hose as a function of the distance from the spot in the hose where the excitation signal is emitted on to the spot or spots where a deformation or deformations appear and where the response signal comes from.

According to a particular appropriate embodiment of the invention the device can be characterized in that the hose has a longitudinal, axially centred lumen surrounded by a ring-shaped wall and around the ring-shaped wall a number of spaced, longitudinal canals separated from each other by means of essentially radial partitions.

By combining reflectometric measurements made inside the lumen of the hose and the peripheral canals or chambers it is possible with much greater sensibility to determine the position/measure the areas in the hose which due to some local change or obstruction in the passage in question (air passage, urinary system etc.) are compressed, as well as the degree of compression.

Upon insertion of the hose it is possible, with or without positive or negative compressive force in the lumen of the hose and/or the canals, by measuring the inner cross-sectional areas of the hose as a function of the distance to determine the areas which are the most narrow or compress the hose locally.

In this way it is possible, in balloon examinations and freeing of arteries in case of arteriosclerosis, to check the distension (cross-sectional area/longitudinal distance) of the balloon at the end of a catheter concurrently with the inflation of the balloon.

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The invention is explained in detail hereinbelow with reference to the schematical drawings where

fig. 1 shows a block diagram of the basic layout of the device according to the invention,

5 fig. 2 a perspective drawing of part of the hose according to the invention, at the spot where the measurement is made,

fig. 3 a perspective drawing of part of the hose in another embodiment of the invention,

10 fig. 4 a sectional view of the hose according to fig. 3 in a sectional plane at right angles to the axis of the hose,

fig. 5 illustrates the placing of a hose according to the invention in the upper air passages with a
15 patient being examined for tongue-fallback,

fig. 6 illustrates the placing of a hose according to the invention in the upper air passages with a patient being examined for stertorous respiration, and

fig. 7 shows a diagram of a hose with a balloon for
20 a catheter examination in an artery.

Fig. 1 shows the basic layout of the device according to the invention.

At 1 there is shown a hose the design of which will be explained below. At its proximal end A the hose
25 1 of a manner known per se, not illustrated, is connected to auxiliary equipment used for inserting the hose in e.g. the air passages of a patient, e.g. through the mouth or the nostrils, or in the urinary system or an artery. At B is shown the distal end of the hose
30 which after insertion of the hose will be present in the cavity of the patient who undergoes an examination.

At 2 is shown an electronic signal generator adapted to give an activation signal to a transducer 3 connected to the hose 1. The signal generator 2 delivers
35 the same signal to a signal analysis processor 4. At 5



is shown a transducer connected to the hose 1. When an excitation signal is transferred from the signal generator 2, via the transducer 3, to the interior of the hose 1, this signal will propagate in the hose, on
5 to the distal end of the hose, from where a response signal is sent back and received by the transducer 5 and therefrom led to the signal analysis processor 4.

The signal analysis processor 4 is connected to a computer 6 by means of which it is possible, on a screen
10 7 to present an image which illustrates the results of the examination and measurements made.

The transducer 3 can be an arbitrary type known per se, e.g. an electromagnetic transducer, an electrostatic transducer, a piezo-electric transducer etc. Its task
15 is to transform the electronic signal from the signal generator 2 to an excitation signal in the interior of the hose 1.

The transducer 5 can also be of the above mentioned arbitrary type, e.g. a microphone, the purpose of which
20 is to receive an acoustic response signal from the distal end of the hose and to transform this response signal to an electric signal which is led to the signal analysis processor 4.

The excitation signal can be a transient signal in
25 the low frequency band, as known from e.g. the above US-A-4.326.416 or from the Jackson article. It can also be a non-transient excitation signal - a random or pseudo-random signal, as used in the above mentioned equipment SRE 2000 og SRE 2000 PC.

30 The invention is a very important contribution to determination of the exact position of the obstruction and to measure when and for how long the obstruction will last. It is thus possible to connect an alarm system to the measurement equipment which gives an alarm



when the probe has been compressed for a certain fixed period.

The analysis itself of the response signal in relation to the excitation signal belongs to a technique 5 known per se.

Fig. 2 shows part of the hose 1 in the hose zone B. The characteristic of the hose according to the invention is that, at least in its B zone at the distal end it is thin-walled. The hose according to fig. 2 is 10 a simple hose, i.e. a hose with only one lumen 19.

If the hose 1, as will be explained later, locally, i.e. in the mentioned B zone, is exposed to an external mechanical influence (as indicated at the arrow F), due to a constriction in the air passage, the oesophagus or 15 an artery of the patient, the reduction of the cross-section of the hose in said B zone will consequently bring about a modification of the response signal, a modification which can be seen in the picture analysis and on the screen. This modification expresses the 20 change that might be present in the patient, e.g. a constriction.

Fig. 3 shows a further embodiment of hose according to the invention. The hose 10 has a central lumen 11 and three peripheral circular canals or chambers 12, 13, and 25 14. Such a hose can be made by extrusion of a soft plastics material or elastomere. The outer diameter of the hose can vary from e.g. 1 mm to e.g. 3-4 mm, according to the intended use. The wall 15 around the central lumen 11 is continuous in the longitudinal 30 direction of the hose and it separates the lumen 11 from the three peripheral chambers 12, 13, 14. The chambers themselves which are also continuous in the longitudinal direction of the hose are separated from each other by means of radial partitions 16, 17, 18.



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Fig. 4 shows a cross-sectional view of the hose in a plane at right angles to the axis of the hose.

A transducer 20 has been introduced from the outside through the outer chamber 12 and through the wall 15 so that the response signal receiving end 21 of the transducer 20 is located in the lumen 11.

Fig. 4 also shows two transducers 22, 23, which are introduced from the outside into the outer wall of the hose 11 and whose response signal receiving ends 24, 25 respectively are located in a peripheral chamber, e.g. chamber 14.

While the sectional view in fig. 4 shows the two transducers placed in the sectional plane (the plane of the diagram) it should be understood that they do not need be it and that e.g. transducers 23 can be placed axially staggered from the transducer 22.

Fig. 5 illustrates the use of the hose in order to determine the position of and measure the so-called "tongue-fallback" with a patient, i.e. the situation where the patient's tongue narrows the upper air passages.

Here the hose has been introduced through the nostrils and into the air passage. Part of the hose is compressed by the rear end of the tongue in the zone D.

Fig. 6 illustrates the use of the hose in order to determine the position of and measure the outbreak of vibrations in the soft palate (velum palatum).

Fig. 6 shows the situation illustrated in Fig. 5 as well as the situation where said soft parts of the palate compress the hose in the E zone.

The mode of operation of the device according to the invention will be explained below.

It should be recalled, as mentioned in the preamble of the specification, that it is possible with the measurement technique known from US-A-4.326.416 and from

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the Jackson article and the one used in the known measurement equipment of the applicant firm, to determine the cross-sectional area of a cavity as a function of the distance from the excitation signal giving
5 transducer to the measurement spot.

While the known technique has the disadvantage that the measurements can be disturbed by crossmodes (i.e. cross resonances) which e.g. is the case in examinations of the air passages and the lungs with a patient, the
10 technique according to the invention has the essential advantage that it is the inner cavity of the hose which constitutes the proper measurement cavity which, should the occasion arise, can be modified by e.g. a constriction in the passage in which the hose has been introduced.
15 The construction of the hose excludes the outbreak of cross resonances as in the known technique. If the hose, which as mentioned has thin, flexible walls, is affected locally by a constriction, one or more of the outer chambers 12, 13, 14 and/or the central canal
20 (lumen 19, Fig. 2, or lumen 11, Fig. 3) is affected mechanically by this constriction which can be measured immediately by the measurement equipment.

Supposing that the hose has the form shown in fig. 3 and 4 and that it has been introduced in the patient's
25 air passage as shown in fig. 5. The mechanical compression force from e.g. the rear end of the tongue on the hose can e.g. influence one of the outer chambers, e.g. the outer chamber 14, which can be ascertained electronically in the measurement equipment or perhaps also
30 the second and third outer chamber.

The invention therefore offers the possibility to get a "differentiated" positioning and measurement of the cross sectional area in the zone in question as a function of the distance from the excitation signal
35 giving transducer in question to the zone in question.



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If it is only the outer chamber 14, as mentioned in the previous paragraph, which in a patient's air passage is influenced by e.g. the rear end of the tongue, only the transducer(s) belonging to the chamber 5 14 will react.

Fig. 6 illustrates as already mentioned the situation where a patient is to be examined for vibrations in the soft parts of the palate, i.e. typically stertorous respiration. The vibrations in the E zone 10 will influence at least one of the outer chambers of the hose and the measurement equipment can carry out the positioning and measurement.

Another field of particular medical/surgical interest for the invention is examinations of constrictions, i.e. calcification or other pathologic disorders 15 tions, e.g. at the heart.

Fig. 7 shows another embodiment of the hose according to the invention, made for this kind of examination.

20 The distal end of the hose 31 is in a manner known per se (normal catheter technique for freeing arteries) formed as an inflatable balloon 32. It can be inflated by pressure feed through longitudinal canals (not shown) in the outer wall of the hose. Between the balloon 32 25 and the distal end of the hose there is, in a manner known per se, a number of openings 33 which are to ensure blood passage and at some distance away from the balloon 32 in the direction towards the proximal end of the hose there are outlets (not shown) for the cir- 30 culating blood.

In the case where it is medically/surgically advisable temporarily to disconnect the blood circulation through the hose in order to measure and/or widen, it is possible to use a hose which does not have

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a canal for circulating blood, i.e. having neither openings 33 nor matching outlets.

Upon introduction of the hose it is possible, in the above mentioned way, to position and measure the 5 constriction or the calcification and the widening, if any.

Within the scope of the invention it is possible to make a hose without the above mentioned balloon and manufacture the hose so that it has, at its distal end, 10 i.e. where the balloon otherwise would be placed, a considerably thinner and/or considerably more flexible outer wall. Within the scope of the invention the hose can be formed near its proximal end with means (not shown) so as to establish a negative or positive 15 pressure e.g. of fluid in the lumen and/or in each chamber. Such a positive pressure will bring about a dilation of said thinner and/or more flexible part of the hose at the distal end. Whether the hose has a balloon or not, whether it is inflated or not and 20 whether one or more chambers are compressed by the constriction in the vein, the measurement equipment will give a picture of the situation in the area in question.

A description of a hose has been given above with one single lumen or with one central lumen and periphe- 25 ral chambers, but it is within the scope of the invention to allow for a hose with two axial canals or a central lumen and two, four or e.g. five peripheral chambers.

Obviously medical/surgical considerations decide 30 the choice of the inner and outer dimensions of the hose which is the reason why the hose is manufactured in different sizes (and lengths too), while the measurement equipment decides the upper frequency limit, if a transient signal is used, as well as the other physical 35 parametres.

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If the hose according to the invention is to be used for examination of the breathing organs, the needed supply of air or gas to the patient can take place through the inlet of the hose (A in fig. 1) and through
5 a canal to the openings 33 (fig. 7) at the distal end of the hose. In that case the response signal which comes from e.g. one or several of the peripheral chambers, can be separated electronically in the measuring equipment from the response signal coming from
10 the lungs, due to the difference in the signal transit time.

A particular example of the use of the invention has already been mentioned.

Exact examinations of persons, whose air passages
15 are blocked during their sleep and who can be described as having stertorous respiration, are naturally very difficult and through the ages many failed corrective operations have been made on these patients.

The invention is a very important contribution to
20 determine the exact position of the blocking and to measure when and for how long the blocking will last. It will therefore be possible to connect an alarm system to the measuring equipment which gives an alarm when the probe has been compressed for a certain fixed periode
25 of time.

To day a pulsoxymeter (instrument measuring the concentration of oxygen in blood) is connected during these examinations. An alarm is therefore activated when the concentration reaches certain predetermined limits.

30 It is not the stertorous respiration itself which is a risk, but the period during which the patient does not breathe because of a blocking.

This is the reason why equipment which acoustically registers the stertorous respiration does not activate
35 an alarm with sufficient security, as the non-occurence

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of a "snoring-sound" is either due to a quiet, steady respiration with a low regular flow, which is all right, or the air passages are blocked for a long time. This is where the risk is.

5 In order to stress the importance of the invention it is significant that the under-supply of oxygen to the lungs for such a long time considerably increases the risk of brain damages and thrombosis, especially for older overweight persons.

10 An internal measurement has the advantage that the patient during the measurements is not awakened by the excitation signal and at the same time the measurements are not influenced to a large extent by the high tones sound spectrum of the snoring sounds.

15 The measurement probe itself is very easy to introduce ambulatory into the patient's nose before the night, in cooperation with a doctor or a nurse.

A correct "tightening" through the nose happens automatically due to the reflectory swallowing and a
20 connection (transducer/microphone part) at the end which projects out of the nose can be made without problems.

A synchronization of the area measurements with the snoring sound is easy to make either by means of an external microphone e.g. one of the transducers 22, 23,
25 fig. 4 or by using the low frequency signal received through the measurement microphone.

It should also be noted that the measurement equipment (hardware/software) which adequately makes the measurements in each chamber and during the measurements
30 changes the static pressure in each chamber can also concurrently give information about the elasticity of the tissue giving counter-pressure to the surface of the chambers.

By establishing a pressure in the hose and a
35 concurrent supply of acoustic energy in the infrasound



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band up to 200 Hz in the lumen and the chambers and a synchronization of this infrasound signal with the acoustic rhinometry (reflectometric) measurements, it is possible to get valuable information about the elasticity in the walls to which the hosewall establishes a contact during the various pressure conditions.

Considering that these kinds of transducers e.g. a piezoelectric transducer function in both directions, i.e. that an electric voltage is applied in order to give a pressure signal or receive a pressure signal and give an electric signal, it is obvious that instead of two transducers 3, 5 in fig. 1 it is in principle possible to use one single transducer, in which case the signal generator 2 from an electronic point of view should be designed in such a way that, when operated from the analysis unit 4 and the computer 6, it firstly gives a transient signal and then transfers the response signal to the analysis unit. If a random or a pseudo-random signal is used as excitation signal, emitted continuously in the measurement period, two separate transducers will be used, as shown in fig. 1.

It should also be added that the invention also offers the possibility of making prostata, uterus examinations etc.

Finally, it should be mentioned that the invention also offers a possibility to make reflectometric examinations of other cavities, e.g. current control of the cavity in an item manufactured by extrusion, as the technique according to the invention makes it possible to closely monitor the extrusion parameters in order e.g. to obtain a constant thickness of walls in the item, which could e.g. be a hose.

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C L A I M S

1. A device for reflectometric examination and measurement of cavities and of the kind which includes an acoustic signal generatorsystem, a hose with a distal
5 end to be introduced via an intrance to the cavity to be examined, at least one transducer connected to the signal generator for transmission of an activation signal from the signal generator to the hose, at least another transducer connected to the hose for reception
10 of response signals from the cavity and a computer adapted for analysis of the response signal in relation to the excitation signal sent to the cavity, characterized in that the hose (1,10) is adapted, seen from the signaling transducer, so as to be introduced in the
15 cavity in question with its distal end placed past the zone to be examined, that it consists of a thin-walled, soft, flexible plastics or elastomere material and that, at its proximal end, it is equipped with said at least one transducer (3) connected with said signal generator
20 (2), which transducer is adapted to transform an activation signal from the signal generator to an excitation signal which can transmit through the hose and cause a response signal back to the transducer, due to a deformation, if any, of the hose wall.
- 25 2. A device according to claim 1, characterized in that the hose (1) has one longitudinal, axially centred lumen (19).
3. A device according to claim 1, characterized in that the hose (1) has two longitudinal lumens separated
30 from each other by a diametral partition.
4. A device according to claim 1, characterized in that the hose (10) has a longitudinal, axially centred lumen (11) surrounded by a ring-shaped wall (15) and around the ring-shaped wall (15) a number of spaced,
35 longitudinal canals (12, 13, 14) separated from each ot-





her by means of essentially radial partitions (16, 17, 18).

5. A device according to claim 4, characterized in that the hose (1) has three longitudinal canals (12, 13, 14) which seen in a sectional view at right angles to the longitudinal axis of the hose (1) are essentially shaded in circular arc and that there is essentially equal angular distance between the partitions (16, 17, 18).

10 6. A device according to any of the preceding claims, characterized in that the proximal end (A) of the hose (1) is so adapted as to be connected to auxiliary equipment used for inserting the hose (1) in the cavity in question.

15 7. A device according to any of the preceding claims, characterized in that the hose (1) at its proximal end has means so as to establish a negative or positive pressure, in relation to the environment, in the lumen or lumens and/or in each chamber.

20 8. A device according to any of the preceding claims, characterized in that the proximal end of the hose (1) is adapted for mounting said transducer or transducers in order to transfer an activation signal from said signal generator to the lumen and/or the 25 lumens and/or the canals.

9. A device according to any of the preceding claims characterized in that the hose (1) over at least part of its length and preferably at its distal end has at least one zone (B) of increased outer wall flexibility. 30 ty.

10. A device according to claim 9, characterized in that said zone (B) of increased outer wall flexibility is created by the outer wall having a locally thinner wall thickness.



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11. A device according to claim 9, characterized in that said zone (B) of increased outer wall flexibility is created by a local change in the nature of the outer wall material.

5 12. A device according to any of the preceding claims, characterized in that the hose also has a longitudinal canal for blood circulation from blood inlet openings (33) at the distal end of the hose to a blood outlet at a certain distance from the distal end.

10 13. A device according to any of the claims 1-11 and for examination of the air passages, characterized in that the hose also has a longitudinal canal for venting the air passages during the examination performed.



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