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## **EUROPEAN PATENT APPLICATION**

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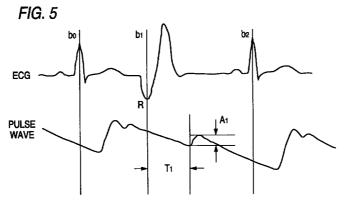
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### (54)Patient monitoring apparatus

(57)A patient monitoring apparatus includes electrocardiogram measuring means 1 for measuring electrocardiograms, pulse-wave measuring means 2 for measuring pulse waves, and a CPU 30 for processing electrocardiogram signals derived from the electrocardiogram measuring means 1 and pulse wave signals derived from the pulse-wave measuring means 2. The CPU 30 detects the amplitudes of the pulse waves corresponding to the R waves of the cardiogram and the pulse wave propagation times, and computes a ratio (Nr/N) of the heart rate N and the heart rate Nr exclusive of the heart beats of wave deficits.



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### Description

### BACKGROUND OF THE INVENTION

### Field of the Invention

**[0001]** The present invention relates to an apparatus for non-invasively monitoring changes in the heart contractions of the heart by use of electrocardiogram information and pulse-wave information.

### Related art

[0002] The non-invasive monitoring apparatus uses mainly the information of electrocardiograms, arterial oxygen saturation, blood pressure measured by the oscillometric blood-pressure measuring apparatus and the like as parameters representative of dynamic states of a patient. Of those parameters, electrocardiogram information, arterial oxygen saturation and the like may continuously be measured. In particular the electrocardiogram information is used as a parameter sensitively representing a change of a dynamic state of the patient. [0003] Thus, the electrocardiogram information has been used as the continuously monitoring parameter. An arrhythmia of the patient is monitored by use of the waveforms and heart rates on the electrocardiogram. The monitoring based on only the electrocardiogram has the following problems.

[0004] The patient monitoring apparatus can monitor an abnormality, e.g., arrhythmia, of the excitation conducting system, but cannot monitor, for example, a pulse deficit, which arises from an abnormality of the heart contraction. In the case of the pulse deficit, the heart cannot supply sufficient amounts of blood to the peripheries of the internal organs, to possibly cause serious diseases. For this reason, it is necessary to monitor the occurrence of the pulse deficit in a continuous manner. Here, the term "pulse deficit" includes two states, a first state in which the heart propels little amount of blood and a second state in which the ventricle is insufficiently filled with blood and the heart contraction is unsatisfactory.

**[0005]** Where only the electrocardiogram information for the parameter continuously and non-invasively obtained is used, there is a limit in monitoring changes in the heart contractions.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

### [0006]

Fig. 1 is a block diagram showing the conceptual arrangement of a patient monitoring apparatus constructed according to the present invention;

Fig. 2 is a block diagram showing a hardware arrangement of the patient monitoring apparatus of

Fig. 1;

Fig. 3 is a diagram showing the contents of a RAM 33 in the Fig. 2 arrangement;

Fig. 4 is a flow chart showing an operation of the patient monitoring apparatus shown in Figs. 1 and 2:

Fig. 5 is a waveform diagram showing an electrocardiogram and a pulse wave signal, processed by the Figs. 1 and 2 apparatus; and

Fig. 6 is a flow chart showing the detail of the step S6 in the Fig. 4 flow chart.

### **SUMMARY OF THE INVENTION**

**[0007]** Accordingly, an object of the present invention is to monitor changes in the heart contractions non-invasively.

[0008] Aspect of the present invention, there is provided a patient monitoring apparatus comprising: electrocardiogram measuring means for measuring electrocardiograms; pulse-wave measuring means for measuring pulse waves; pulse-wave data detecting means for detecting at least a pulse wave propagation time by use of electrocardiogram information measured by the electrocardiogram measuring means and pulse wave signals measured by the pulse-wave measuring means; and occurrence-frequency detecting means for obtaining data on a frequency of occurrence of wave deficits by use of pulse wave data detected by the pulse-wave data detecting means.

**[0009]** In the thus constructed apparatus, the occurrence-frequency detecting means obtains data on a frequency of occurrence of wave deficits by use of at least the pulse wave propagation time.

**[0010]** According to the the patient monitoring apparatus of the present invention, the pulse-wave data detecting means detects the amplitudes of pulse waves measured by the pulse-wave measuring means.

**[0011]** The apparatus of the present invention obtains data on a frequency of occurrence of wave deficits by use of at least the pulse wave propagation time and the amplitude of pulse wave.

# <u>DETAILED DESCRIPTION OF THE PREFERRED</u> <u>EMBODIMENTS</u>

[0012] An embodiment of the present invention will be described. The embodiment is a patient monitoring apparatus for monitoring changes in the heart contractions. The patient monitoring apparatus is generally made up of electrocardiogram measuring means 1, pulse-wave measuring means 2 for measuring a pulse wave, pulse-wave data detecting means 3 for detecting at least a pulse wave propagation time by use of a car-

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diographic waveform measured by the electrocardiogram measuring means 1 and a pulse wave measured by the pulse-wave measuring means 2, and occurrence-frequency detecting means 4 for obtaining data on a frequency of occurrence of pulse deficits on the basis of the pulse wave data detected by the pulse-wave data detecting means 3.

[0013] An arrangement of the patient monitoring apparatus is shown in detail in Fig. 2. The electrocardiogram measuring means 1 includes an electrocardiogram electrode 11 to be put on the chest of a patient, an amplifier 12 for amplifying a cardiogram signal derived from the electrocardiogram electrode 11, and an A/D converter 13 for converting the amplified cardiogram signal into a digital signal. The pulse-wave measuring means 2 includes a photoelectric pulse wave sensor 21 put on the finger tip of the patient, an amplifier 22 for amplifying a pulse wave signal derived from the photoelectric pulse wave sensor 21, and an A/D converter 23 for amplifying the amplified pulse wave signal into a digital signal. The output signals of the A/D converter 13 and the A/D converter 23 are input to a CPU 30.

[0014] The CPU 30 is connected to a display device 31, a ROM 32 and a RAM 33. The CPU 30 receives a cardiogram signal from the electrocardiogram measuring means 1 and a pulse wave signal from the pulsewave measuring means 2, processes those signals in predetermined rules, and displays the result of the processing on the display device 31. The ROM 32 stores programs for the process carried out by the CPU 30, and data used for the processing. The RAM 33 is used such that when the CPU 30 executes the process, writes necessary data into the RAM 33 and reads out necessary data therefrom. The contents of the RAM 33 are in part shown in Fig. 3. As shown, the RAM includes a ring buffer containing a group of pulse-amplitude storing registers Ai and a group of pulse wave propagation time storing registers Ti and its ring buffer full flag F1. Here, i = 0, 1, 2, ... N-1 (N : number of addresses of the ring buffer).

[0015] The operation of the patient monitoring apparatus will be described with reference to a flow chart shown in Fig. 4. To start a measurement, the CPU 30 initializes the registers, flag and the like (step S1); waits till an R wave appears in the electrocardiogram signal (ECG) output from the electrocardiogram measuring means 1 (step S2); when an R wave appears, it measures an amplitude of a pulse wave corresponding to an R wave of the previous complete beat in the ECG and stores the result of the measurement into the pulseamplitude storing register Ai (step S3); measures a time interval from R wave of previous ECG to the occurrence of the pulse wave corresponding to the R wave of the previous complete beat in the ECG; and stores the result of the measurement into the pulse wave propagation time storing register Ti (S4). An example of the measurement when i = 1 is shown in Fig. 5.

[0016] The CPU 30 judges whether or not the con-

tents of the ring buffer full flag F1 is 1 (1 = buffer full) (step S5), and if it is 1, it measures a ratio of the heart rate and the heart rate exclusive of the heart beats of wave deficits (step S6).

[0017] The details of the step S6 will be described with reference to Fig. 6. The CPU 30 first obtains the medium value Amed of the data Ai stored in all the pulse-amplitude storing registers Ai, and removes the data Ai of heart beats, which satisfies Ai < Amed x r (step S61). Here, r is: 0 < r < 1. This value is a preset value for removing the heart beats of small amplitudes. Then, the CPU 30 removes the data corresponding to the heart beats that was removed in the step S61, from the data Ti stored in all the pulse wave propagation time storing registers Ti, and obtains a medium value Tmed of the remaining data (step S62). The CPU 30 removes the data Ti satisfying Ti > Tmed +  $\Delta$ T (step S63). The heart beats corresponding to the data removed in the steps S61 and S62 are the heart beats of wave deficits. The CPU 30 obtains the number Nr of data left after the step S63 is processed (step S64). Subsequently, the CPU 30 computes a ratio Nr/N (where N : heart rate, and Nr: heart rate exclusive of the heart beats of the wave deficits), and displays the result of the computation on the screen of the display device 31 (step S65).

[0018] The heart beats whose amplitudes are small are removed in the step S61. The reason for this follows. In some of the wave deficits, the heart is little contracted, and therefore, some of the heart beats have extremely small amplitude. In other words, the heat beats whose amplitudes are extremely small may be considered to be those of the wave deficits.

[0019] The reason why the heart beats whose pulse wave propagation time is long is removed in the step S63 follows. In some of the wave deficits, the heart contracts, but an insufficient amount of blood is fed to the ventricle. In such a case, the blood filling of the ventricle is insufficient, and therefore a preload on the heart is small, so that a contraction force of the heart does not increase as taught by Frank-Starling's theorem. Therefore, the pre-ejection period is long, and consequently the pulse wave propagation time is also long.

[0020] Further, same effect could be enjoyed by reversing the arrangement of Steps 61 and 63. Namely, in stead of steps 61 to steps 63, The CPU 30 obtains the medium value Tmed of data Ti stored in all the pulse wave propagation time storing registers Ti, and removes the data satisfying Ti > Tmed +  $\Delta T'$ . Next, the CPU removes the data corresponding to the heart beats that was removed in step S61', from the data Ai stored in all the pulse-amplitude storing registers Ai, and obtains a medium value Amed of the remaining data. Next, it is applicable for removing data Ai satisfying Ai>Amed  $\times r'$  from remaining data Ai after proceeding step S62'. After these step, the process is the same as described before.

[0021] A case where a wave deficit occurs at the heart beat b1 is illustrated in Fig. 5. In this case, the amplitude

A1 of the pulse wave is: A1 < Amed x r (or the pulse wave propagation time Ti is: Ti < Tmed +  $\Delta$ T ), and the data of that beat is removed.

**[0022]** Following the step S6, the CPU 30 resets the ring buffer full flag F1 to "0" (step S7) (Fig. 4), and then 5 advances to the next step S8. In this step, the CPU 30 checks if i = N - 1 (i: contents of a pointer to point to the address of the ring buffer).

**[0023]** If not i = N - 1, the CPU 30 adds 1 to the pointer contents (step S9), and returns to the step S2. If i = N - 1, the CPU 30 resets the pointer contents i to 0 (step S10), sets the contents of the ring buffer full flag F1 to 1 (step S11), and returns to the step S2.

[0024] The processings of the steps S1 to S4 and S8 to S10 in Fig. 4, carried by the CPU 30, correspond to the pulse-wave data detecting means 3 in Fig. 1; and the processings of the steps S5 to S7, and S11 (Fig. 4) correspond to the occurrence-frequency detecting means 4 (Fig. 1).

**[0025]** In the present embodiment, r = 0.1, and  $\Delta T = 30$ msec. Further, the ratio of Nr/N is displayed in the embodiment. In an alternative, this ratio is compared with a preset value (= 50% in this embodiment), and if it exceeds the preset value, it is judged that the heart contraction is abnormal, and produces an alarm sound.

[0026] In the embodiment, the ratio of Nr/N is obtained every time all the data about the pulse waves of an N number of heart beats are rewritten (Fig. 4). If necessary, the step S7 in the Fig. 4 flow chart may be omitted. In this case, after the ring buffers are full, the ratio of Nr/N is obtained every time the data of one heart beat. The monitoring of the heart contractions is more exact. [0027] In the description thus far made, the wave deficit is detected and then the heart contractions are monitored on the basis of the detection result. However, the patient monitoring apparatus, like the normal monitoring apparatus, is capable of displaying electrocardiograms and pulse wave signals by use of the display device 31. A no-invasive blood pressure measuring device may be attached to the patient monitoring apparatus of the invention. When a heart contraction is abnormal, the blood pressure monitoring device is operated to quickly check a blood pressure at that time.

**[0028]** As described above, to detect the wave deficit, two check items, the amplitude of pulse wave and the pulse wave propagation time, are used. Therefore, the wave deficit detection is more exact.

[0029] In the embodiment mentioned above, the amplitude of pulse wave is compared with a preset value, and the pulse wave propagation time is also compared with a preset value. A wave deficit is detected on the basic of the comparisons the amplitude of pulse wave and pulse wave propagation time with the preset values, respectively, and the calculation of a ratio of the heart rate and the heart rate exclusive of the heart beats of wave deficits is executed. If necessary, the heart rate may be compared with the pulse wave propagation time in their variances. If a variance ratio of them exceeds a

predetermined value, it is judged that the heart contraction is abnormal.

[0030] According to the present invention, the patient monitoring apparatus in constructed incorporating the same thereinto to monitor changes in the heart contractions in a non-invasive manner. To detect changes in the heart contractions, the electrocardiograms and pulse signals, usually used for patient monitoring, are used. Therefore, there is no need of using specially designed detecting means. This leads to construction simplification of the apparatus.

[0031] According to the present invention, the amplitudes of pulse waves are additionally used for detecting changes in the heart contractions. An exact detection is secured.

### **Claims**

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1. A patient monitoring apparatus comprising:

electrocardiogram measuring means for measuring electrocardiograms;

pulse-wave measuring means for measuring pulse waves;

pulse-wave data detecting means for detecting at least a pulse wave propagation time by use of electrocardiogram information measured by said electrocardiogram measuring means and pulse wave signals measured by said pulsewave measuring means; and

occurrence-frequency detecting means for obtaining data on a frequency of occurrence of wave deficits by use of pulse wave data detected by said pulse-wave data detecting means.

- 2. The patient monitoring apparatus according to claim 1, in which said pulse-wave data detecting means detects the amplitudes of pulse waves measured by said pulse-wave measuring means.
- 3. The patient monitoring apparatus according to claim 1, in which said occurrence-frequency detecting means selects data having pulse wave propagation time within a predetermined period and obtains data on a frequency of occurrence of wave deficits by use of the data which have selected.
- 4. The patient monitoring apparatus according to claim 2, in which said occurrence-frequency detecting means selects data having pulse wave propagation time within a predetermined period and obtains data on a frequency of occurrence of wave deficits by use of the data which have selected.
- 5. A method for monitoring a patient, comprising the steps of:

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measuring electrocardiograms;

measuring pulse waves;

detecting at least a pulse wave propagation time by use of electrocardiogram and pulse wave signals measured; detecting amplitudes of the pulse wave by use

detecting amplitudes of the pulse wave by use of the pulse wave signals measured; storing the pulse wave propagation time and the amplitudes of the pulse wave measured which are synchronized as a related data; selecting data having the pulse wave propagation time within a predetermined time of period from the related data; and

obtaining a frequency of occurrence of wave deficits by use of the selected data.

6. The method for monitoring the patient as claimed in claim 5, the selecting data step includes:

selecting data having amplitude of the pulse 20 wave within a predetermined range from a plurality of data selected in preceding step.

**7.** A method for monitoring a patient, comprising the steps of:

measuring electrocardiograms;

measuring pulse waves;

detecting at least a pulse wave propagation time by use of electrocardiogram and pulse 30 wave signals measured;

detecting amplitudes of the pulse wave by use of the pulse wave signals measured;

storing the pulse wave propagation time and the amplitudes of the pulse wave measured which are synchronized as a related data; selecting data having the amplitudes of the

pulse wave within a predetermined range from the related data; and obtaining a frequency of occurrence of wave 40

8. The method for monitoring the patient as claimed in

deficits by use of the related data.

claim 7, the selecting data step includes:

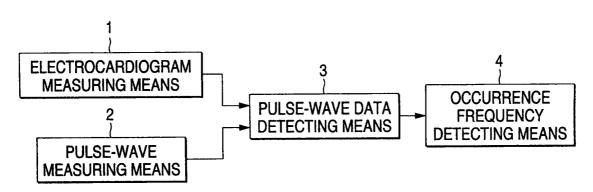
selecting data having the pulse wave propagation time within a predetermined time of period from a plurality of data selected in preceding step.

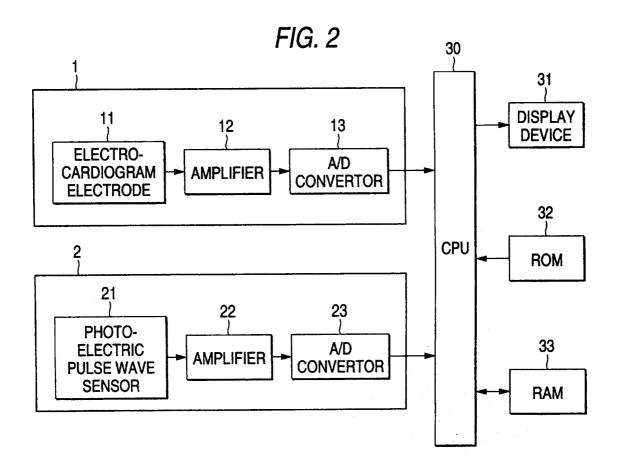
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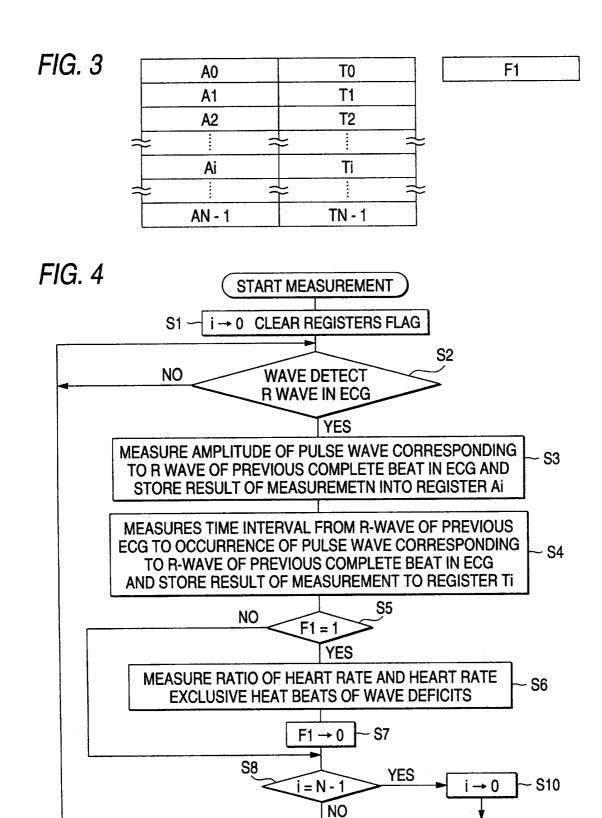
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FIG. 1





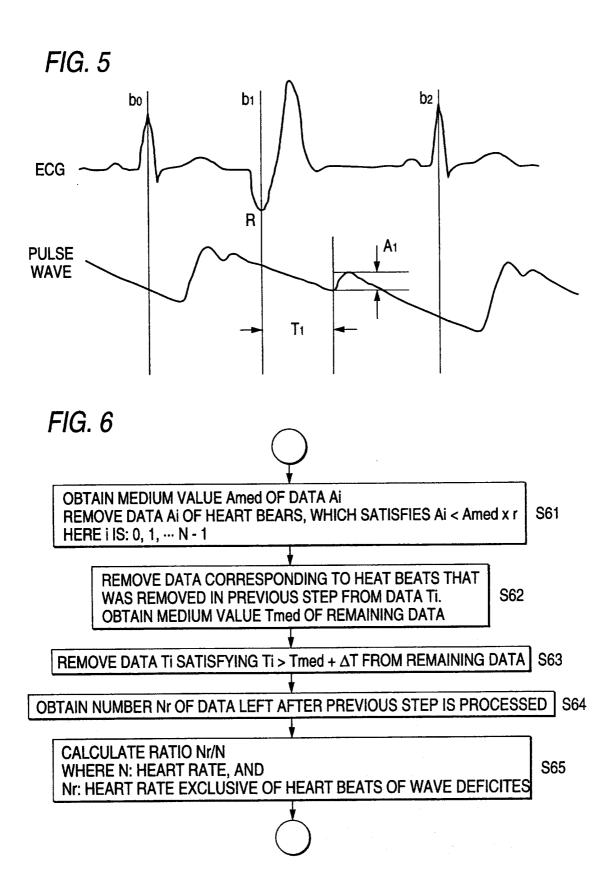


i-→i+1

S9 ~

 $F1 \rightarrow 1$ 

- S11





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### **EUROPEAN PATENT APPLICATION**

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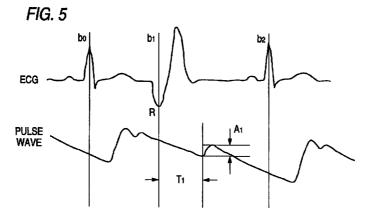
- · Sohma, Takeshi Shinjuku-ku, Tokyo (JP)
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### (54)Patient monitoring apparatus

(57)A patient monitoring apparatus includes electrocardiogram measuring means 1 for measuring electrocardiograms, pulse-wave measuring means 2 for measuring pulse waves, and a CPU 30 for processing electrocardiogram signals derived from the electrocardiogram measuring means 1 and pulse wave signals derived from the pulse-wave measuring means 2. The CPU 30 detects the amplitudes of the pulse waves corresponding to the R waves of the cardiogram and the pulse wave propagation times, and computes a ratio (Nr/N) of the heart rate N and the heart rate Nr exclusive of the heart beats of wave deficits.





## **EUROPEAN SEARCH REPORT**

Application Number

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| 23 July 1991 (1991-07-23)  * column 1, line 44 - column 2, line 42 *  * column 3, line 4 - column 4, line 25 *  * column 7, line 25 - line 33; claims; figures *  A DE 14 66 830 A (FRITZ HELLIGE & CO) 14 May 1969 (1969-05-14)  * the whole document *  A US 3 742 938 A (STERN T) 3 July 1973 (1973-07-03)  * column 3, line 15 - line 45 *  * column 4, line 45 - column 6, line 34; claims; figures *  Technical  A61B                                     | ategory   | Citation of document with indication of relevant passages  | , where appropriate.   | Relevant<br>to claim   | CLASSIFICATION OF THE APPLICATION (Int.CI.6) |
|---|---|--|--|--|--|
| 14 May 1969 (1969-05-14) * the whole document *   A US 3 742 938 A (STERN T) 3 July 1973 (1973-07-03) * column 3, line 15 - line 45 * * column 4, line 45 - column 6, line 34; claims; figures *  TECHNICAL SEARCHED  A61B  | k<br>   | 23 July 1991 (1991-07-23<br>* column 1, line 44 - co<br>* column 3, line 4 - col<br>* column 7, line 25 - li                   | s)<br>Numn 2, line 42<br>umn 4, line 25 *                                  | *  | A61B5/0285                                   |
| 3 July 1973 (1973–07–03) * column 3, line 15 - line 45 * * column 4, line 45 - column 6, line 34; claims; figures *  TECHNICAL SEARCHED  A61B   | 1   | 14 May 1969 (1969-05-14)   |  | 1-8  |  |
| The present search report has been drawn up for all claims  | 3<br>  x<br>  x                                   | 3 July 1973 (1973-07-03)<br>* column 3, line 15 - li<br>* column 4, line 45 - co   | ne 45 *  | 1-8  |  |
| The present search report has been drawn up for all claims  |   |  |  |  | TECHNICAL FIELDS SEARCHED (Int.Cl.6)         |
| The present search report has been drawn up for all claims  |   |  |  |  |  |
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| Place of search Date of completion of the search Examiner   |   |  | ,  |  |  |
| THE HAGUE 20 January 2000 Manschot, J   |   | THE HAGUE  |  |  |  |
| CATEGORY OF CITED DOCUMENTS  X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure  C: theory or principle underlying the invention E: earlier patent document, but published on, or after the filling date D: document cited in the application L: document cited for other reasons A: member of the same patent family, corresponding | X : partice<br>Y : partice<br>docum<br>A : techno | ularly relevant if taken alone<br>ularly relevant if combined with another<br>nent of the same category<br>ological background | E : earlier pater<br>after the filin<br>D : document ci<br>L : document ci | at document, but pub-<br>g date<br>ted in the application<br>ted for other reasons | lished on, or                                |

## ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 98 11 4937

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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| cited in se | locument<br>arch report |      | Publication date | Pate<br>mer           | nt family<br>mber(s) | Publ | icatio<br>late |
|-------------|-------------------------|------|------------------|-----------------------|----------------------|------|----------------|
| US 5033     | 472                     | A 23 | 3-07-1991        | NONE                  |                      |      |                |
| DE 1466     | 830                     | A 14 | I-05-1969        | NONE                  |                      |      |                |
| US 3742     | :938 <i>I</i>           | A 03 | 3-07-1973        | NONE                  |                      |      |                |
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