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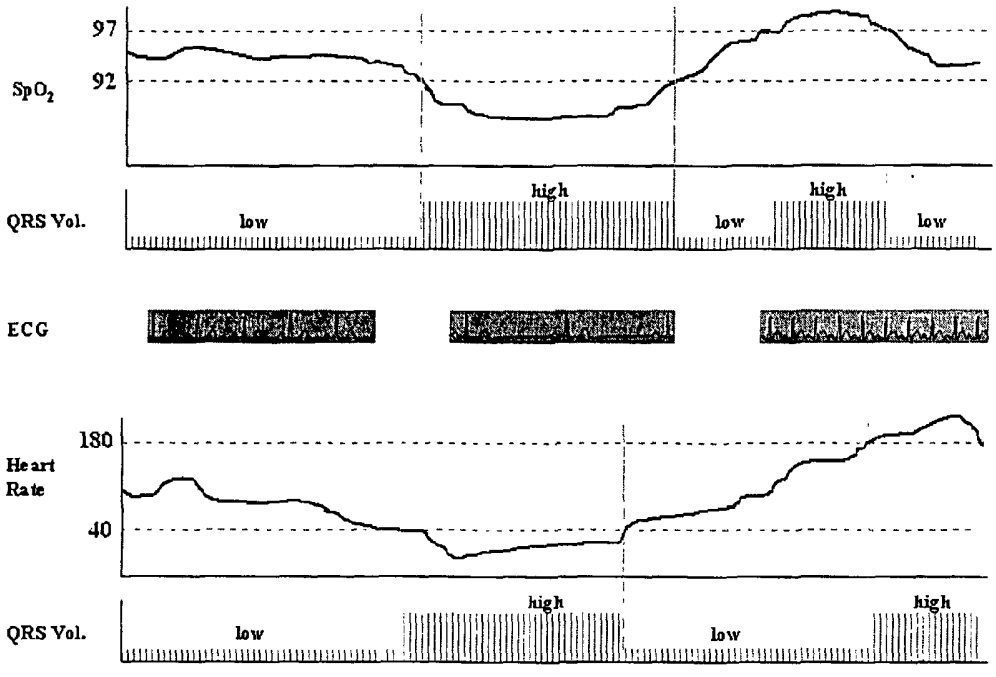
(54) Title: ALARM ACTIVATED ACOUSTIC MEASURING SIGNALS FOR PATIENT MONITORING



(57) Abstract: A system and a method for monitoring a physiological parameter of a patient providing a measurement-modulated acoustic signal (7) after/when a measurement value of the monitored physiological parameter exceeds an alarm limit.

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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.

Alarm activated acoustic measuring signals for patient monitoring

The present invention relates to a patient system and method for monitoring a physiological parameter of a patient.

In today's patient monitoring systems, one of the most important tasks is to monitor condition and/or status of a patient, and to alarm medical staff in case that one or more monitored physiological parameters of the patient exceed pre-defined upper and/or lower alarm limits. These alarm limits may either be set manually, e.g. by medical staff, or can be set automatically, e.g. at start of a measurement or on user request. Each alarm limit may be set as fixed limit and/or can be based upon one or more current values of the physiological parameter of the patient e.g. determined by the patient monitoring system.

Various methods for determining alarm limits are disclosed e.g. in US-A-4,994,790,

US-A-5,226,416, or EP-A-909551. Generally speaking, one or more limit values are determined based upon a starting value e.g. by adding or subtracting parameters specific offset values to or from these starting value, or by multiplying the starting value with a parameter specific factor.

When exceeding alarm limits, the patient monitoring system usually provides an acoustic signal for alerting the medical staff. However, it has been proved that erroneous alarming (i.e. unnecessary or faulty alarming) might lead to a situation wherein the medical staff simply switches off the acoustic alarming in order not to be bothered or confused by such kind of erroneous alarms. It is clear that such kind of situations have to be avoided since otherwise a patient's critical condition might not be noticed after alarms have been switched off.

A problem different from the erroneous alarming but which might lead to the same situation of switched off acoustic alarms, is the omnipresence of acoustic signals in particular from different patient monitoring systems. Particularly in intensive care environments with a plurality of different patient monitoring systems also for a plurality of different patients, it has been found that acoustic signals might be perceived as being

disturbing for medical staff as well as for the patients. This in particular when there are several different acoustic signals at the same time. In such environments, it has been found that either the volume of acoustic signals will be reduced to a very low value, or the acoustic signals might even be switched off entirely, thus leading to the same situation as described above wherein a critical situation of a patient might not be noticed.

The problem has even become worse in recent years with the introduction of patient monitoring systems wherein a measuring signal indicative of a patient's physiological parameter is modulated on an acoustic signal. Examples for such measurement-modulated acoustic signals are: The modulation of a beep tone that is issued with every heart beat with the value of the oxygen saturation of a patient, and a whistling sound that is issued with every detected breath, modulated with the respiratory rate or something similar for an invasively measured blood pressure.

While on one hand such measurement-modulated acoustic signals provide useful information in a very intuitive way, clinical staff often feels disturbed by those acoustic signals, thus leading to the aforementioned situation of unnoticed critical situations as a result of switched off or volume-reduced acoustic signals.

It is therefore an object of the present invention to avoid situations wherein clinical staff feels disturbed by acoustic signals from patient monitoring systems. The object is solved by the independent claims. Preferred embodiments are shown by the dependent claims.

According to the invention, a patient monitoring system for monitoring a physiological parameter of a patient will provide a measurement-modulated acoustic signal after/when a measurement value of the monitored physiological parameter exceeds an alarm limit. The measurement-modulated acoustic signal represents an acoustic signal with the present measurement value acoustically modulated thereonto.

The term "exceeding" an alarm limit as used herein shall generally mean that the measurement value becomes either higher than an upper limit or lower than a lower limit, dependent on the respective situation.

In one embodiment, the measurement-modulated acoustic signal will be provided at a pre-defined acoustic volume independent of previous settings for the volume before the alarm limit has been exceeded. Thus, it can be made sure that the measurement-

modulated acoustic signal will be heard even if all acoustic signals have been switched off before or reduced to a very low acoustic volume.

In a preferred embodiment, the measurement-modulated acoustic signal will be switched off or significantly reduced in volume as soon as the measurement values return to "normal condition", i.e. the measurement values do not exceed one or more given alarm limits.

In another preferred embodiment, the measurement-modulated acoustic signal will only be provided as long as alarm limits are exceeded, and will be switched off otherwise. This has the advantage that clinical staff becomes more sensible for such kind of acoustic signals, since they are only provided in critical situations.

According to another embodiment, the measurement modulated acoustic signal will be provided at a pre-defined high acoustic volume as long as and as soon as the measurement values are at an "alarm condition", i.e. the measurement values do exceed one ore more given alarm limits, and wherein the measurement modulated acoustic signal will be switched off or will be provided at a pre-defined low acoustic volume as long as and as soon as the measurement values are at an "normal condition", i.e. the measurement values do not exceed one or more given alarm limits.

The invention thus generally allows limiting acoustic signals to (real) critical situations only. Furthermore the invention replaces pure alarming signals (with the only information content that there is an alarm) by information-related signals (indicating that there is an alarm and having an information content related to the source of the alarm) provided in alarming situations. The information-related alarming signals according to the invention directly refer to the source of the alarming situation by immediately providing acoustically coded information about the reason of the alarming situation. While pure alarming signals only indicate that there is an alarming situation without providing further information about the source or the nature of the alarm situation, the alarming as provided by the invention allows to directly and intuitively perceiving the nature and source causing the alarming situation. Thus, immediate countermeasures in order to control the alarming situations can be initiated without loosing important time for figuring out what has been the reason for the alarming state. Precious time can thus be saved that might be decisive in critical health situations. Since the measurement-modulated acoustic signal according to the invention is switched off or at least significantly reduced in volume at normal conditions, the noise strain of patients and medical staff is reduced or avoided.

It is clear that the invention can be partly or entirely embodied or supported by one or more suitable software programs, which can be stored on or otherwise provided by any kind of data carrier, and which might be executed in or by any suitable data processing unit.

Other objects and many of the attendant advantages of the present invention will be readily appreciated and become better understood by reference to the following detailed description when considering in connection with the accompanied drawings. Features that are substantially or functionally equal or similar will be referred to with the same reference sign(s).

Fig. 1 shows a graph of an exemplary time course of a patients ECG with SpO2 and Heart Rate,

Fig. 2 shows a table wherein the frequency of a beep tone is assigned to the SpO2 value,

Fig. 3 shows a schematic view of a system according to the invention.

Fig. 1 shows how the volume of the QRS beep is linked to either the violation of an SpO2 or Heart Rate Alarm Limit. the QRS beep is a tone that is issued every time a heartbeat is detected in the ECG signal of a patient. The Heart Rate is measured in beats per minute. A usual monitoring system permanently provides an acoustic signal, namely a beep tone, with every heart beat or QRS. This acoustic signal is preferably modulated with the SpO2 value. Therefore a patient monitor can be configured so that the frequency of the beep tone depends on the currently measured SpO2 value, e.g. defined as follows:

F=662HZ/(2^[1/24)(100-%SPO2)].

Fig. 2 shows examples of audible frequencies for SpO2 values of 100, 76 and 52%.

A usual monitoring system provides this insofar measurement-modulated acoustic signal always at the same acoustic volume. Normal alarming behavior of such a usual patient monitor is that if a parameter, e.g. Spo2 or Heart Rate, violates an upper limit (e.g. SpO2: 97, Heart Rate: 180) or lower limit (e.g. SpO2: 92, Heart Rate: 40) a special

alarm tone is issued. This special alarm tone is significantly different from the usual normal beep tone of the measurement-modulated acoustic signal. If the alarm system is configured to latching alarms the alarm tone even sounds beyond the limit violation until it has been manually acknowledged by pressing a silence button. Also, in case of an alarm it is very helpful to hear the QRS beep modulated with SpO2 value.

With the present invention there is significantly less sound or no sound at all being heard in clinical environment if e.g. an Spo2 or a heart rate are within their set limits. But if an alarm occurs the volume of the QRS sound is turned on (or increased) as long as the alarm exists or in case of latching alarms until it is acknowledged manually. This means that in case of an alarm the clinical operator gets all the information needed by his attention being pulled to a sound that is familiar to him and that conveys all the information needed. The information conveyed in this case is: the variation in the SpO2 value and the heart rate. Just listening to the changes of the QRS beep the clinical operator would know immediately what is going on. An additional special alarm sound that is the same for all parameters and thus needs visual verification on a patient monitor display would not be necessary.

With the present invention a Heart Rate alarm can be announced the same way by issuing a QRS beep that has no frequency modulated sound. The same logic then applies to arrhythmia alarms that do not particularly announce the violation of an alarm limit but irregularities in the Heart Rate. As long as a Heart Rate is regular it is just an unnecessary background noise that only then becomes vital and needs to be heard if it becomes irregular.

If the present invention is used to alarm on both parameters it is still clear from the signal which parameter of the two is in alarm. If both parameters are in alarm at the same time only the combined tones as for SpO2 would be used.

The present invention can be extended to other parameters than SpO2 and Heart Rate e.g. for Respiratory signals. In this a typical respiratory sound triggered by each breath would be turned on only in case of an alarm.

The technical implementation of the present invention comprises according to fig. 3 an ECG unit 1 providing a QRS trigger signal 2 at normal condition and additionally a heart rate alarm signal 3 at alarm condition. The ECG unit 1 sends the QRS trigger signal 2 to a QRS beep generator 4 provided for generating beep tone signals 5 with different frequencies depending from a current SpO2 value. The QRS beep generator 4 is connected to a loudspeaker unit 6 provided for generating acoustic signals 7 according to the incoming beep one signals 5 of the QRS beep generator 4.

The ECG unit 1 sends the heart rate alarm signal 3 to an alarm unit 8, if the monitored heart rate exceeds an alarm limit, e.g. if the heart rate violates an upper or lower limit or if the heart rate becomes irregular. In case of a heart rate alarm the alarm unit 8 generates an alarm trigger in form of a heart rate alarm signal 9 and sends it to the QRS beep generator 4.

The monitoring system according to the invention comprises also a SpO2 unit 10 providing a SpO2 value signal 11 at normal condition and additionally a SpO2 alarm signal 12 at alarm condition. The SpO2 unit 10 sends the SpO2 value signal 11 to the QRS beep generator 4 modulating the QRS signal 2 of the ECG unit 1 with the SpO2 value alarm signal 11.

The SpO2 unit 2 sends the SpO2 alarm signal 12 to the alarm unit 8, if the monitored SpO2 value exceeds an alarm limit, e.g. if the SpO2 value violates an upper or lower limit or if the SpO2 value becomes irregular. In case of a SpO2 value alarm the alarm unit 8 generates an alarm trigger in form of a Spo2 value alarm signal 13 and sends it to the QRS beep generator 4.

The monitoring system or method according to the invention works as follows:

At normal conditions, e.g. the heart rate and the SpO2 values do not exceed its alarm limits, the ECG unit 1 only sends the QRS trigger signal 2 to the QRS beep generator 4. Also the SpO2 unit 10 only sends the SpO2 value signal 11 to the QRS beep generator 4. As long as the monitored parameters (SpO2 and heart rate) are regular the QRS beep generator 4 generates the QRS beep tone signal 5, i.e. a SpO2 modulated heart rate signal, with a very low acoustic volume and sends it to the loudspeaker 6 generating the corresponding acoustic signal 7. In another embodiment of the invention the QRS beep generator does not generate any QRS beep tone signals 5 at all as soon as the conditions are normal, therefore the loudspeaker 6 is quiet. Therefore at normal conditions there is no disturbing noise in the clinical environment of the monitoring system.

In alarm condition, e.g. if the SpO2 value violates an alarm limit, the SpO2 unit 10 sends the SpO2 alarm signal 12 to the alarm unit 8 which generates the SpO2 value alarm signal 13. As soon as the QRS beep generator 4 receives this SpO2 value alarm signal 13, the QRS beep generator 4 generates a corresponding QRS beep tone signal 5 and sends it to the loudspeaker 6 generating the corresponding acoustic signal 7. This acoustic signal 7 preferably will be provided at a pre-defined acoustic volume which is independent of previous settings for the volume before the alarm limit has been exceeded. If the QRS beep generator 4 provides at normal condition a QRS beep tone signal 5 with a small acoustic

volume, the QRS beep tone signal 5 at alarm condition has a significantly louder acoustic volume. Therefore at alarm condition the medical staff gets information-related acoustic alarming signals which directly refer to the source of the alarming situation by immediately providing acoustically coded information about the reason of the alarming situation.

The monitoring system and the monitoring method according to the present invention can be partly or entirely embodied or supported by at least one software program, which is executed in or by a conventional monitoring system.

In contrast to the invention a conventional monitoring system needs a direct connection 14 between the alarm unit 8 and the loudspeaker 6. Therefore the alarm unit 8 of a conventional system generates an alarm tone signal and sends it to the loudspeaker 6 if one of the monitored parameters violates one of the alarm limits. At a conventional system this alarm signal can replace or overlay the normal signal which is at normal condition permanently generated by QRS beep generator 4 and loudspeaker 6. Although the direct connection 14 is depicted in the embodiment of fig. 3, the monitoring system according to the invention does not need this direct connection 14. The direct connection 14 is only depicted to illustrate, that the invention can be partly or entirely embodied in a conventional monitoring system.

CLAIMS:

1. A patient monitoring system for monitoring a physiological parameter of a patient, the system provides a measurement-modulated acoustic signal (7) characterizing the present measurement value of the monitored physiological parameter after/when the measurement value of the monitored physiological parameter exceeds an alarm limit.

2. The system of claim 1, wherein the measurement-modulated acoustic signal (7) is provided at a pre-defined acoustic volume independent of previous settings for the volume before the alarm limit has been exceeded.

3. The system according to claim 1 or 2, wherein the measurement-modulated acoustic signal (7) is switched off or significantly reduced in volume as soon as the measurement values return to normal condition, i.e. the measurement values do not exceed one or more given alarm limits.

4. The system according to any one of the claims 1 to 3, wherein the measurement-modulated acoustic signal (7) is only provided as long as alarm limits are exceeded, and is switched off otherwise.

5. The system according to any one of the claims 1 to 4, wherein the measurement-modulated acoustic signal (7) is provided at a pre-defined high acoustic volume as long as and as soon as the measurement values are at an alarm condition, i.e. the measurement values do exceed one ore more given alarm limits, and wherein the measurement-modulated acoustic signal (7) is switched off or is provided at a pre-defined low acoustic volume as long as and as soon as the measurement values are at a normal condition, i.e. the measurement values do not exceed one or more given alarm limits.

6. A method for monitoring a physiological parameter of a patient providing a measurement-modulated acoustic signal (7) after/when a measurement value of the monitored physiological parameter exceeds an alarm limit.

7. The method of claim 6, wherein the measurement-modulated acoustic signal (7) is provided at a pre-defined acoustic volume independent of previous settings for the volume before the alarm limit has been exceeded.

8. The method according to claim 6 or 7, wherein the measurement-modulated acoustic signal (7) is switched off or significantly reduced in volume as soon as the measurement values return to normal condition, i.e. the measurement values do not exceed one or more given alarm limits.

9. The method according to any one of the claims 6 to 8, wherein the measurement-modulated acoustic signal (7) is only provided as long as alarm limits are exceeded, and is switched off otherwise.

10. The method according to any one of the claims 6 to 9, wherein the measurement-modulated acoustic signal (7) is provided at a pre-defined high acoustic volume as long as and as soon as the measurement values are at an alarm condition, i.e. the measurement values do exceed one ore more given alarm limits, and wherein the measurement-modulated acoustic signal (7) is switched off or is provided at a pre-defined low acoustic volume as long as and as soon as the measurement values are at a normal condition, i.e. the measurement values do not exceed one ore more given alarm limits.

11. A software program or product, preferably stored on a data carrier, for executing the method of any of the claims 6 to 10 when run on a data processing system such as a computer.

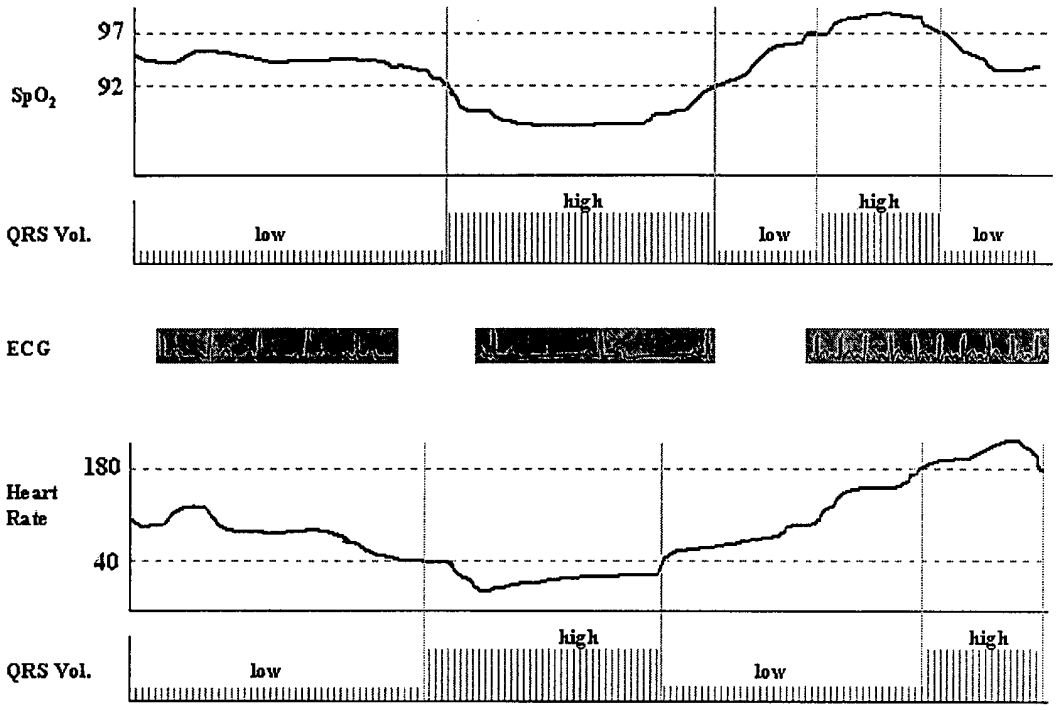

Fig. 1

SpO2	100-%SpO2->x	x/24->y	2^y->z	662Hz/z -> f
100%	0	0	1	662.0Hz
76%	24	1	2	662Hz/2 -> 331.0Hz
52%	28	2	4	662Hz/4 -> 165.5Hz

Fig. 2

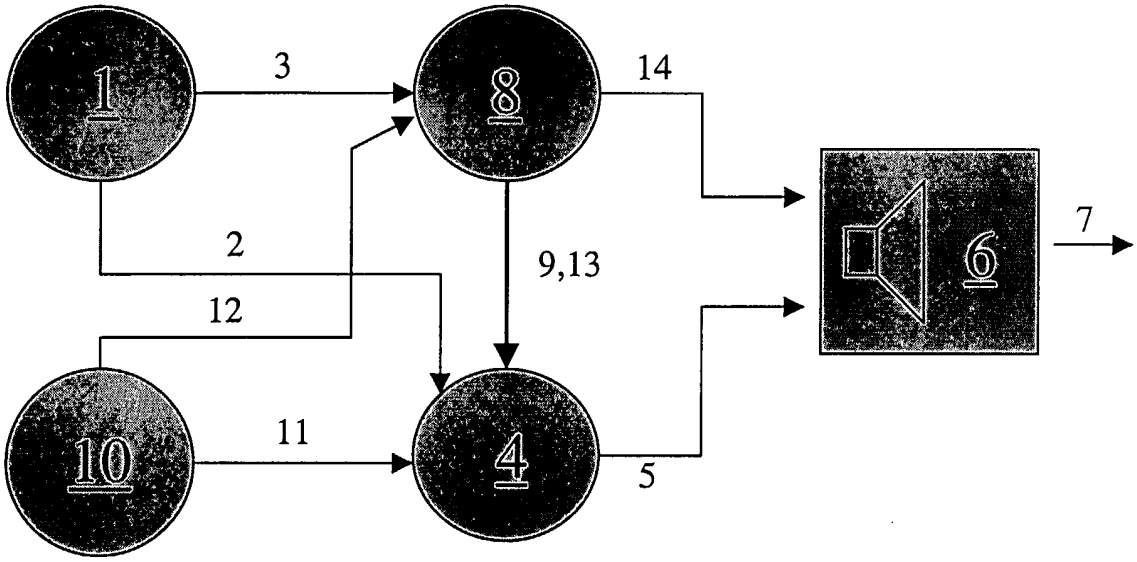

Fig. 3

INTERNATIONAL SEARCH REPORT

Internat application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/0245 A61B5/04 A61B5/00

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 7 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)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 730 140 A (FITCH WILLIAM TECUMSEH S) 24 March 1998 (1998-03-24) column 8, line 45 - line 57 column 12, line 50 - line 62 column 13, line 21 - line 40	1-11
X	US 4 653 498 A (NEW JR WILLIAM ET AL) 31 March 1987 (1987-03-31) column 11, line 17 -column 12, line 5	1,2,6,7, 11
X	US 3 841 315 A (KOPP K) 15 October 1974 (1974-10-15) column 6, line 19 - line 31	1,3,4,6, 8,9

☐ Further documents are listed in the continuation of box C.

☒ 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 February 2003	26/02/2003

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	Manschot, J

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internatic pplication No
PCT/IB 02/04310

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
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