PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6:

A61B 5/00, 5/09, 5/024, 5/083

(11) International Publication Number:

WO 98/53732

A1

(43) International Publication Date:

3 December 1998 (03.12.98)

(21) International Application Number:

PCT/IT97/00197

(22) International Filing Date:

31 July 1997 (31.07.97)

(30) Priority Data:

RM97A000314

27 May 1997 (27.05.97)

Published

With international search report.

(81) Designated States: JP, US, European patent (AT, BE, CH, DE,

DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

(71) Applicant (for all designated States except US): COSMED S.R.L. [IT/IT]; Via dei Piani di Monte Savello, 37, I-00040 Pavona di Albano (IT).

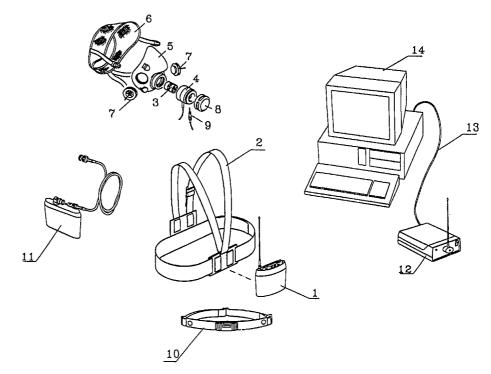
(72) Inventor; and (75) Inventor/Applicant (for US only): BRUGNOLI, Paolo [IT/IT]: Viale della Vittoria, 21, I-00122 Roma (IT).

(74) Agent: MASCIOLI, Alessandro; Via Urbana, 20, I-00184 Roma (IT).

(54) Title: PORTABLE SYSTEM WITH TELEMETRIC DATA TRANSMISSION FOR THE MEASUREMENT OF METABOLIC **PARAMETERS**

(57) Abstract

The portable system for the measurement of the metabolic parameters of an individual or athlete or patient, in real conditions of physical activity with "breath by breath" technique is composed by a portable unit (1) of reduced weight and dimensions, fixed to the body by means of an anatomic harness (2) during the test, comprising a turbine flowmeter (3-4-8) applied at the mouth through an anatomic face mask (6-7-8), a heart rate monitor belt (10), a rechargeable battery (11) for supplying the system and a receiver unit (12) that, connected to a personal computer (14) by RS232 connection (13), allows to receive and display in real time the measurement on the The portable unit is screen. mainly composed by a fast CO-2 analyzer, an intrinsically slow oxygen analyzer, whose output



signal is elaborated in order to obtain a response time short enough to allow the accurate measurements on a "breath by breath" basis, a microprocessor, a memory for data storage, a UHF transmitter, an LCD display and a keyboard. The receiver unit contains mainly a UHF receiver module and an interface for the connection to the personal computer. The flowmeter is composed by a bidirectional turbine (3) and by an optoelectronic reader that, based on the infrared interruption technique, detect the rotations of a blade and consequently the volumes ventilated by the individual.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	ĹŨ	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	ТĴ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
ВJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM	Cameroon		Republic of Korea	\mathbf{PL}	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
\mathbf{CZ}	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

PORTABLE SYSTEM WITH TELEMETRIC DATA TRANSMISSION FOR THE MEASUREMENT OF METABOLIC PARAMETERS

The present invention consists of a portable system for the "breath by breath" measurement of the metabolic parameters of an individual, with telemetric data transmission and storage of results for further analysis.

It is known that, nowadays, the analysis of the metabolic response of an individual is usually performed in laboratories using statitionary equipment able to measure mainly the following parameters: oxygen uptake (VO₂), carbon dioxide production (VCO₂), respiratory quotient (RQ=VCO₂/VO₂), ventilation (VE) and heart rate (HR).

These equipments allow to carry out exercise tests making the individual performing a physical activity using an ergometer (cycle or treadmill...).

The major limitation of the previous mentioned methodology is related to the fact that most of the activities (sports and non), such as for instance ski, tennis, the daily job or the drive of a wheelchair, cannot be correctly simulated in the lab.

Up to some years ago, portable systems for metabolic tests were not available; the device described in the U.S. Patent No. 4,658,832 (BRUGNOLI), of 21 April 1987, was the first system with limited dimensions introduced in the market.

During the last years, however, the measurement techniques of the metabolic parameters used by the stationary systems has been interested by an evolution, turning from the "mixing chamber" methodology to the "breath by breath" technique.

The first one, as it is well known, provides the results as an average of the all breaths carried out in a consistent time interval (typically 30 seconds), while the second one provides results for each breath of the individual.

The "breath by breath" analysis is described in detail in the following publications:

- Beaver, Wasserman, Whipp, JAP. 34(1): 128-132, 1973: "On line computer analysis and breath by breath graphical display of exercise function tests";
- Sue, Hansen, Blais, Wasserman, JAP. 49(3): 456-461, 1980: "Measurement and analysis of gas exchange, using a programmable calculator";
- Wasserman et al. 1994: "Principles of exercise testing and interpretation", 2nd edition.

The origin of the two previous mentioned techniques is related to a technological limitation: the measurement of the oxygen uptake (VO₂) and carbon dioxide production (VCO₂) in correspondence of each breath, requires the use of two gas analyzers with a response time lower than 200 milliseconds. When such analyzers are not available, it is possible to mix the expired air in a "mixing chamber" in order to average the concentrations of the two gases (O₂ and CO₂) making the fluctuations so slow as to be accurately detected by the slow response time analyzers.

The "mixing chamber" analysis has however some great limitations:

- it does not allow the detection of fast variations of the metabolic functions following sudden changes in the workload;
- it does not allow to analyze the gas exchange correspondent to each breath, but only related to the average of several breaths;
- it does not allow the measurement of some important parameters such as FetCO₂ or VD/Vt.

Nowadays, although some portable systems for the measurements of metabolic parameters in real conditions are already available, no one of those is able to provide measurements with the "breath by breath" technique.

The main reason for this lack is that oxygen analyzers with a fast response time (tr < 200 msec) with dimensions and power consumption compatible with the requirements of a portable system, are not available.

The aim of the present invention is to provide a portable system for the monitoring of the metabolic parameters of an individual (oxygen uptake, carbon dioxide production, ventilation and heart rate), in real conditions, without affecting significantly the physical performance, using the "breath by breath" technique.

The system according to the present invention will be described more in detail hereinbelow, according to the enclosed drawings in which a preferred embodiment is shown.

Fig. 1 shows an axonometric view and a partially exploded view of the main components of the system according to the present invention.

Fig. 2 shows the block diagram of the electronic circuitry.

Fig. 3 shows a graph of the output of the oxygen sensor, following a step solicitation, before and after the numerical elaboration of the signal.

The enclosed figures show a portable system for the measurement "breath by breath" of the metabolic parameters of an individual, with telemetric data transmission and storage for further analysis, consisting of:

- a portable unit 1, transported by the individual during the test, fixed to an anatomic harness 2 incorporating a pump that samples continuously a fraction of the expired breath through a sampling line 9 connected near the mouth, bringing the gas into the analyzer (O₂ and CO₂) to provide the measurement of the oxygen and carbon dioxide concentrations; electrical signals coming from a turbine flowmeter 3-4-8 are elaborated to provide the measurement of the volumes of air ventilated by the individual; a detector circuit that receives the magnetic pulses transmitted by a heart monitor belt 10 to provide the heart rate; all the acquired signals are elaborated by the microprocessor incorporated in the portable unit and transmitted to a receiver unit 12 or stored in an internal non volatile memory and transferred afterwards to a personal computer 14 for the analysis of the results; the portable unit 1 is powered by means of a rechargeable battery 11 fixed to the rear side of the harness in order to balance the weights;
- a flowmeter 3-4-8, manufactured so that the ventilated air passing through a turbine 3, composed by two elycoidal conveyors which impress a rotation on it, proportional for its intensity to the flow and for its spin to the direction of the breath (inspiration/expiration); a blade, free to rotate on an axis parallel to the flow and perpendicular to the conveyors, assumes a rotation, whose spin and intensity are measurable through the interruptions of the rays transmitted by three infrared diode emitters, and received by as many receiving phototransistors; the pulsed signals coming from

the optoelectronic reader 4 are acquired by the portable unit and elaborated; an aerodynamic cover 8, fixed to the front side of the flowmeter, is intended to avoid that, when the individual is moving during the test, the measurement of the ventilation is affected by the air entering the flowmeter;

- a face mask 5-6-7, connected to the flowmeter, manufactured with antiallergenic material, provided with two inspiratory valves 7, whose task is to reduce the inspiratory resistance and to help the elimination of the sweat from the face, is fixed to the individual by means of an anatomic head cap 6;
- a battery unit 11 that supplies the portable unit 1, fixed to the rear side of the harness 2 so that the weights are balanced;
- a heart monitor belt 10, provided with two electrodes to detect the electrical signals generated by the heart on the skin of the individual, incorporating an electronic circuit that amplifies the signals and transforms them into magnetic pulses corresponding to each beat; these pulses can be detected by the portable unit 1 wireless:
- a receiver unit 12 that receives the results of the measurements transmitted by the portable unit via telemetric communication; this data, although transmitted, are however stored in the non volatile memory of the portable unit and can be transferred to the personal computer 14 once the test is completed.

The main functions of the system can be described referring to the block diagram of fig. 2:

- the expired gas of the individual is sampled by the line 9 connected at the output of the flowmeter 3-4; a miniaturized pump 15 provides the necessary depression to let the gas sample pass through the oxygen 16 and carbon dioxide 17 analyzers, connected in series in the pneumatic circuit; the output signals (O₂ and CO₂) are converted in numeric format and elaborated;
- pulses coming from the flowmeter 3-4 are counted in order to obtain the measurement of the volume, and their width is measured for the flow calculation; since the pulses are distributed on three different lines, corresponding to the three couples of infrared emitters/receivers, determining the order by which those are detected, it is possible to provide the versus of the individual's breath (inspiration/expiration);

- a detector probe 18, consisting of a coll and conditioning circuit, detects the magnetic pulses transmitted by the heart rate belt 10 and provides electrical pulses which, counted by the microprocessor, allow the calculation of the heart rate;
- all the operating procedures carried out during the normal use of the system (calibration, configuration, test execution...) are managed activating the keys of the keyboard 19 and controlling the messages prompted by the LCD display 21 or through the commands sent by the personal computer 14 via RS232, if eventually connected;
- the results of the measurements of the test are stored in a non volatile memory (flash memory) and in the meantime transmitted through the on board transmitter 20 to the receiver unit 12, connected to the personal computer 14 to allow the operator to control in real time the metabolic response of the individual under test;
- the calculations used to obtain from the acquired signals (flow, O₂, CO₂ and HR) the main metabolic parameters (VO₂, VCO₂, RQ...), are the same described in literature, however the particular elaboration of the oxygen concentration signal represents a particularity of the present invention.

As formerly discussed, the response time of O_2 and CO_2 analyzers must be lower than 200 msec, for correctly carrying out correctly the measurement with the "breath by breath" technique. The CO_2 analyzer 17, based on the infrared absorption technology, is fast enough to meet the specification.

The oxygen analyzer 16 instead, is a galvanic fuel cell and has an intrinsic response time of about 800 msec. The numeric elaboration performed on the O_2 concentration signal allows to "speed up" the dynamic response so as to obtain a response time lower than 130 msec.

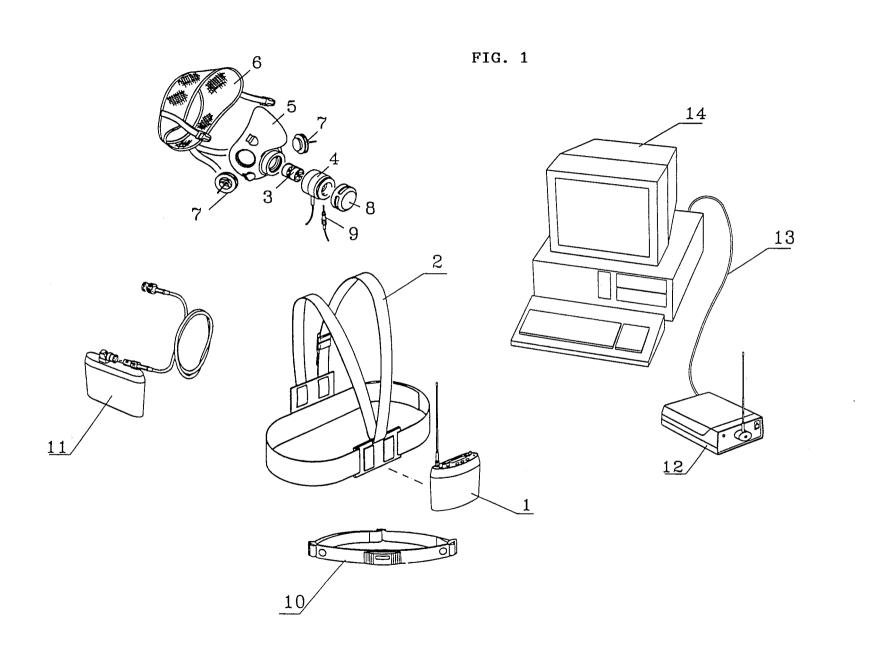
The graph of figure 3 shows the output signal of the oxygen sensor 16 following a step solicitation (obtained by suddenly turning the sampling line from room air to a calibration gas) before and after the elaboration; from the above mentioned plot it is possible to verify that the combination of the low response oxygen sensor plus the numeric elaboration completely meets the requirements of the portable breath by breath metabolic system.

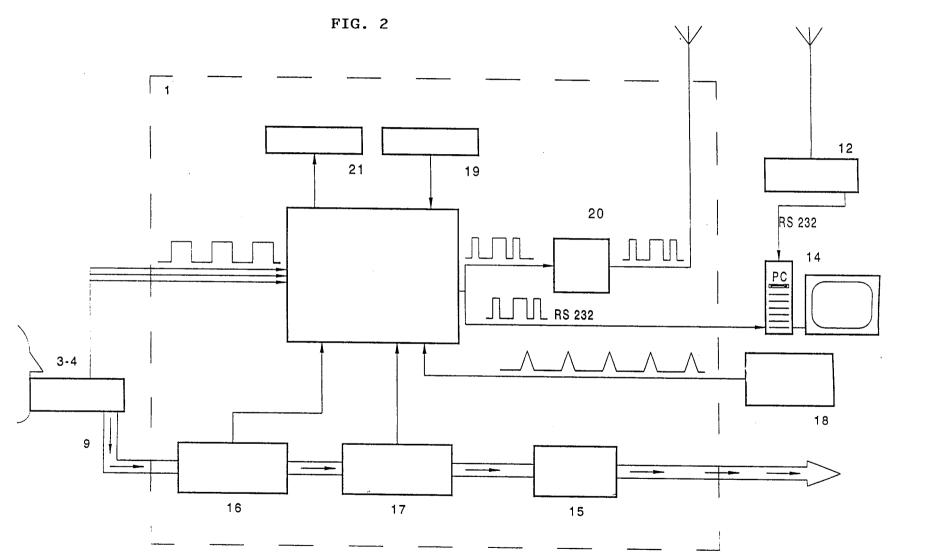
CLAIMS

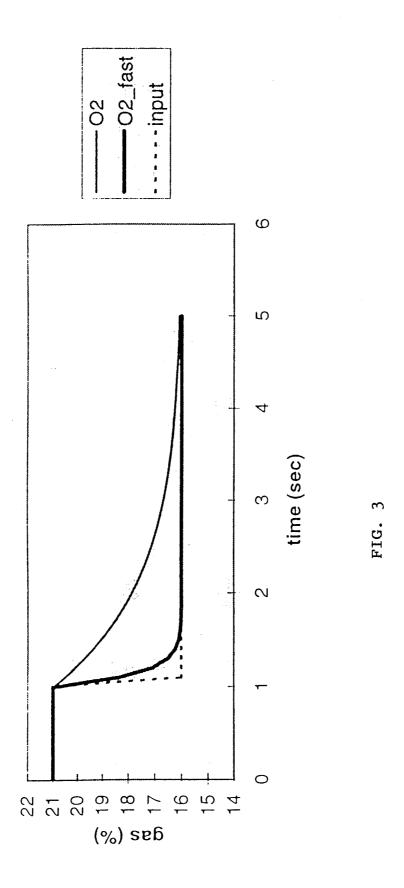
- 1. A portable system for the measurement "breath by breath" of the metabolic parameters of an individual, with telemetric data transmission and storage for afterwards analysis, characterized in:
- a portable unit (1), transported by the individual during the test fixed to an anatomic harness (2) provided with an internal pump that samples continuously a fraction of the expired breath through a sapling line (9) connected near the mouth, bringing the gas into the analyzer (O₂ and CO₂) to provide the measurement of the oxygen and carbon dioxide concentrations while electrical signals coming from a turbine flowmeter (3-4-8) are elaborated to provide the measurement of the volumes of air ventilated by the individual; a detector circuit that receives the magnetic pulses transmitted by a heart monitor belt (10) to provide the heart rate; all the acquired signals are elaborated by the microprocessor incorporated in the portable unit (1) and transmitted to a receiver unit (12) or stored in an internal non volatile memory and transferred after the test to a personal computer (14) for the analysis of the results;
- a flowmeter (3-4-8), manufactured so that the ventilated air passing through a turbine (3) composed by two elycoidal conveyors which impress a rotation on it, proportional for its intensity to the flow and for its spin to the direction of the breath (inspiration/expiration); a blade, free to rotate on an axis parallel to the flow and perpendicular to the conveyors, assumes a rotation, whose spin and intensity are measurable through the interruptions of the rays transmitted by three infrared diode emitters, and received by as many receiving phototransistors; the pulsed signals coming from the optoelectronic reader (4) are acquired by the portable unit and elaborated; an aerodynamic cover (8), fixed to the front side of the flowmeter, is intended to avoid that, when the individual is moving during the test, the measurement of the ventilation is affected by the air entering the flowmeter;
- a face mask (5-6-7), connected to the flowmeter, manufactured with antiallergenic material, provided with two inspiratory valves (7), whose task is to reduce the inspiratory resistance and to help the elimination of the sweat from the face, is fixed to the individual by means of an anatomic head cap (6);
- a battery unit (11) that supplies the portable unit (1), fixed to the rear side of the harness (2) so that the weights are balanced;

- a heart monitor belt (10), provided with two electrodes to detect the electrical signals generated by the heart on the skin of the individual, and an electronic circuit that amplifies the signals and transforms them into magnetic pulses corresponding to each beat; these pulses can be detected by the portable unit (1) wireless;
- a receiver unit (12) that receives the results of the measurements transmitted by the portable unit via telemetric communication; this data, although transmitted, are however stored in the non volatile memory of the portable unit and can be transferred to the personal computer (14) once the test is completed.
- 2. A portable system according to claim 1, characterized in that the expired gas of the individual is sampled by the line (9) connected to the output of the flowmeter (3-4), while a miniaturized pump (15) provides for the necessary depression to let the gas samples pass through the oxygen (16) and carbon dioxide (17) analyzers in series, in the pneumatic circuit, which continuously detect concentrations of O₂ and CO₂, while the output signals are converted in numeric format and elaborated by the microprocessor.
- 3. A portable system according to claim 1, characterized in that the pulses coming from the flowmeter (3-4) are counted in order to obtain the measurement of the volume, and their width is measured for the flow calculation; since the pulses are distributed on three different lines, corresponding to the three couples of infrared emitter/receiver, determining the order by which those are detected, it is possible to provide the versus of the individual's breath (inspiration/expiration).
- 4. A portable system according to claim 1, characterized in that a detector probe (18), consisting of a coll and conditioning circuit, detects the magnetic pulses transmitted by the heart rate belt (10), and provides electrical pulses which, counted by the microprocessor, allow the calculation of the heart rate.
- 5. A portable system according to claim 1, characterized in that all operating procedures carried out during the normal use of the system (calibration, configuration, test execution...) are managed by activating the keys of the keyboard (19) and controlling the messages prompted by the LCD display (21) or through the commands sent by the personal computer (14) via RS232, if eventually connected.

- 6. A portable system according to claim 1, characterized in that the results of the measurements of the test are stored in a non volatile memory (flash memory), and in the meantime transmitted through the on board transmitter (20) to the receiver unit (12), connected to the personal computer (14) to allow the operator to control in real time the metabolic response of the individual under test.
- 7. A portable system according to claim 1, characterized in that the elaboration of the oxygen concentration signal, coming from a slow response time analyzer, allows to "speed up" the dynamic response so as to obtain a response time lower than 130 msec.







INTERNATIONAL SEARCH REPORT

Internal Application No PCT/IT 97/00197

. CLASSIFICATION OF SUBJECT MATTER PC 6 A61B5/00 A61E A61B5/09 A61B5/024 A61B5/083 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. Α EP 0 196 396 A (COSMED) 8 October 1986 1,2,5,6 cited in the application see the whole document DE 14 66 834 A (F.HEILLIGE) 27 March 1969 Α 1,2 see the whole document NL 6 615 576 A (MIJNHARDT) 6 May 1968 Α 1,3 see page 3, line 16 - line 24; claim 1 GB 2 258 587 A (POLAR ELECTRO OY) 10 Α 1,4 February 1993 see page 3, line 9 - line 16 Α FR 2 604 888 A (ATESYS) 15 April 1988 see the whole document Further documents are listed in the continuation of box C. Patent family members are listed in annex. ° Special categories of cited documents : "T" later document published after the international filing date or priority date and not in conflict with the application but "A" document defining the general state of the art which is not cited to understand the principle or theory underlying the considered to be of particular relevance invention "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to filing date "L" document which may throw doubts on priority claim(s) or involve an inventive step when the document is taken alone which is cited to establish the publication date of another citation or other special reason (as specified) "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such docu-"O" document referring to an oral disclosure, use, exhibition or ments, such combination being obvious to a person skilled "P" document published prior to the international filing date but later than the priority date claimed in the art. "&" document member of the same patent family Date of the actual completion of theinternational search Date of mailing of the international search report 11 February 1998 18/02/1998 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 Lemercier, D

1

INTERNATIONAL SEARCH REPORT

Inter mal Application No
PCT/IT 97/00197

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT								
Category 3	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.						
1	EP 0 369 506 A (MIJNHARDT) 23 May 1990 see column 3, line 31 - column 5, line 42	1						
	EP 0 760 224 A (CITIZEN) 5 March 1997 see column 7, line 25 - line 33	1						

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter: nal Application No PCT/IT 97/00197

			į '	
Patent document cited in search repo	-	Publication date	Patent family member(s)	Publication date
EP 196396	Α	08-10-86	US 4658832 A	21-04-87
DE 1466834	Α	27-03-69	NONE	
NL 6615576	Α	06-05-68	NONE	
GB 2258587	A	10-02-93	DE 4223657 A FR 2681493 A HK 30696 A US 5486818 A	28-01-93 19-03-93 01-03-96 23-01-96
FR 2604888	A	15-04-88	NONE	
EP 369506	Α	23-05-90	NL 8802809 A AT 111213 T DE 68918051 D DE 68918051 T JP 2259426 A US 5003828 A	01-06-90 15-09-94 13-10-94 13-04-95 22-10-90 02-04-91
EP 760224	 А	05-03-97	 WO 9629005 A	 26-09-96