(19) World Intellectual Property **Organization**

International Bureau



(43) International Publication Date 29 January 2004 (29.01.2004)

PCT

(10) International Publication Number **WO 2004/009158 A3**

(51) International Patent Classification⁷: A61M 1/16

(21) International Application Number:

PCT/US2003/022267

(22) International Filing Date: 16 July 2003 (16.07.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/397,131 19 July 2002 (19.07.2002)

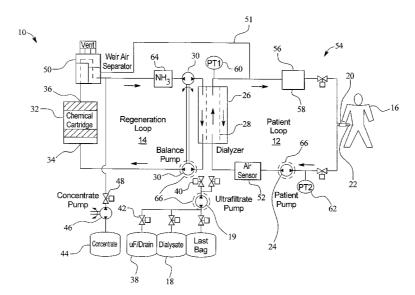
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- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: SYSTEMS AND METHODS FOR PERFORMING PERITONEAL DIALYSIS



(57) Abstract: In a peritoneal dialysis embodiment of the present invention, spent dialysate from the patient's peritoneal cavity passes, along a patient loop, through a dialyzer having a membrane that separates waste components from the spent dialysate, wherein the patient loop returns fresh dialysate to the patient's peritoneal cavity. The waste components are carried away in a second regeneration loop to a regeneration unit or sorbent cartridge, which absorbs the waste components. The regeneration unit removes undesirable components in the dialysate that were removed from the patient loop by the dialyzer, for example, excess water (ultrafiltrate or UF), toxins and metabolic wastes. Desirable components can be added to the dialysate by the system, such as glucose and electrolytes. The additives assist in maintaining the proper osmotic gradients in the patient to perform dialysis and provide the necessary compounds to the patient.



WO 2004/009158 A3



Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report: $$8\ \rm{April}\ 2004$

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.

In ational Application No PCT/US 03/22267

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61M1/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 $\begin{tabular}{ll} Minimum documentation searched (classification system followed by classification symbols) \\ IPC 7 & A61M & G01N \\ \end{tabular}$

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 DOCUME	ENTS CONSIDERED TO BE RELEVANT				
Category °	Citation of document, with Indication, where appropriate, of the rel	evant nassanes	Relevant to claim No.		
Category	Challett of document, with mulcation, where appropriate, or the re-	Relevant to claim No.			
Х	US 4 269 708 A (BONOMINI VITTORI 26 May 1981 (1981-05-26)	1-5,13, 14,16,			
Υ	column 4, line 50 - column 5, li figures 1,3	24-26 6-12,15, 17,20-23			
х	US 4 684 460 A (ISSAUTIER GERALD 4 August 1987 (1987-08-04)	1-5,13, 16,18, 19,26			
	column 3, line 36 - column 6, li figure 1	ne 9;	19,20		
Х	FR 2 154 983 A (THOMSON CSF) 18 May 1973 (1973-05-18)		1,2,4,5, 7,13,16, 18,26		
	page 2, line 10 - page 3, line 3 1	0; figure	16,20		
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X Furth	er documents are listed in the continuation of box C.	X Patent family members are listed in	n annex.		
° Special cat	egories of cited documents :	UTS lake also were to deliber of the attraction			
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	NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Böttcher, S			

Intentional Application No PCT/US 03/22267

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	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 213 859 A (BERG GERRIT H VAN DEN ET AL) 22 July 1980 (1980-07-22) column 6, line 44 - column 7, line 20; figure 1	1,2,4-7, 13,14,26
Υ	DE 31 10 128 A (FRAUNHOFER GES FORSCHUNG) 23 September 1982 (1982-09-23) page 22, line 12 - page 24, line 21; figure 2	6-10,12
Υ	US 4 464 172 A (LICHTENSTEIN ERIC S) 7 August 1984 (1984-08-07) column 21, line 10 - line 16	11,20
Y	US 5 522 998 A (POLASCHEGG HANS-DIETRICH) 4 June 1996 (1996-06-04) abstract	15
Υ	WO 02/30489 A (BAXTER INT) 18 April 2002 (2002-04-18) abstract	17
Υ	US 4 137 168 A (PERROT ERWIN) 30 January 1979 (1979-01-30) column 5, line 58 - line 63	21-23
Υ	US 3 669 880 A (MARANTZ LAURENCE B ET AL) 13 June 1972 (1972-06-13) column 3, line 34 - line 42; figure 1	21
P,X	WO 03/041764 A (BAXTER INT) 22 May 2003 (2003-05-22) the whole document	1-26
P,Y	US 2003/113931 A1 (WARIAR RAMESH ET AL) 19 June 2003 (2003-06-19) abstract	20
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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 40-61 because they relate to subject matter not required to be searched by this Authority, namely: Rule 39.1(iv) PCT - Method for treatment of the human or animal body by
therapy
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
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3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
see additional sheet
1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1 - 26
Remark on Protest The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/, 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-26

Dialysis system with a membrane device, two fluid loops each including a pump, a medical fluid regenerator and a pump controller

2. claims: 27-34

A disposable dialysis cassette comprising a flexible membrane covering a patient pump chamber and a regeneration pump chamber, and connecting means

3. claims: 35-39

Dialysis therapy device comprising a housing with a patient pump actuator and a regeneration pump actuator

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 40-61

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT Information on patent family members

Intentional Application No
PCT/US 03/22267

			PC1/03	03/2226/
Patent document cited in search report	Publication date		Patent family member(s)	Publication date
US 4269708	A 26-05-1981	IT AU DE EP FR	1174707 B 4671879 A 2964594 D1 0005266 A2 2424743 A1	01-07-1987 08-11-1979 03-03-1983 14-11-1979 30-11-1979
US 4684460	A 04-08-1987	FR EP JP	2574664 A1 0187109 A1 61143074 A	20-06-1986 09-07-1986 30-06-1986
FR 2154983	A 18-05-1973	FR	2154983 A5	18-05-1973
US 4213859	A 22-07-1980	NL DE FR GB JP JP JP US	7703937 A 2815811 A1 2387045 A1 1603444 A 1603445 A 1613307 C 2033389 B 53126797 A 4542015 A	16-10-1978 19-10-1978 10-11-1978 25-11-1981 25-11-1981 15-08-1991 26-07-1990 06-11-1978 17-09-1985
DE 3110128	A 23-09-1982	DE	3110128 A1	23-09-1982
US 4464172	A 07-08-1984	US AU DE EP JP WO	4370983 A 5999380 A 3068781 D1 0027470 A1 56500993 T 8002376 A1	01-02-1983 20-11-1980 06-09-1984 29-04-1981 23-07-1981 13-11-1980
US 5522998	A 04-06-1996	DE EP JP	4308586 C1 0615760 A1 7051361 A	11-05-1994 21-09-1994 28-02-1995
WO 0230489	A 18-04-2002	AU CA EP TW WO	1182002 A 2425501 A1 1324787 A2 510804 B 0230489 A2	22-04-2002 18-04-2002 09-07-2003 21-11-2002 18-04-2002
US 4137168	A 30-01-1979	DE GB IT JP US	2644584 A1 1556134 A 1084789 B 53043997 A 4351731 A	06-04-1978 21-11-1979 28-05-1985 20-04-1978 28-09-1982
US 3669880	A 13-06-1972	AT BE CA CH DK DK ES FI FR GB	322727 B 752534 A1 964205 A1 548778 A 2032061 A1 190978 A 138930 B 381171 A1 51432 B 2051445 A5 1316355 A	10-06-1975 01-12-1970 11-03-1975 15-05-1974 14-01-1971 02-05-1978 20-11-1978 01-12-1972 30-09-1976 02-04-1971 09-05-1973

Information on patent family members

In ational Application No
PCT/US 03/22267

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
US 3669880 A		IL JP LU NO NO SE SU ZA	34762 A 51015360 B 61228 A1 7009608 A ,1 126830 B 127487 B 380436 B 504455 A3 7004188 A	14-01-1974 15-05-1976 25-09-1970 8, 04-01-1971 02-04-1973 02-07-1973 10-11-1975 25-02-1976 24-02-1971
WO 03041764 A	22-05-2003	US WO	2003105424 A1 03041764 A1	05-06-2003 22-05-2003
US 2003113931 A1	19-06-2003	WO	03052393 A1	26-06-2003