(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 January 2011 (13.01.2011)

PCT

(10) International Publication Number
WO 2011/005165 A1

(51) International Patent Classification:
A61M 25/00 (2006.01) *H05K 3/42* (2006.01)
A61N 1/05 (2006.01)

(21) International Application Number:
PCT/SE2010/000186

(22) International Filing Date:
1 July 2010 (01.07.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0900936-6 6 July 2009 (06.07.2009) SE

(71) Applicant *(for all designated States except US)*: **CATHPRINT AB** [SE/SE]; Björnnäsvägen 21, SE-119 14 Stockholm (SE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **KÄLLBÄCK, Bengt** [SE/SE]; Norra Catalinagränd 20, SE-183 68 Täby (SE). **THOMSEN, Malin** [SE/SE]; Tomträttsvägen 10, SE-129 31 Hägersten (SE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK,

[Continued on next page]

(54) Title: CATHETER AND METHOD FOR MANUFACTURING SUCH A CATHETER

(57) Abstract: The invention relates to a catheter with at least one external electrode (6, 6a-c) arranged on the outer surface of the catheter. The external electrode is connected to a conductor (4a, b), which extends along at least part of the inside length of the catheter and is electrically connected to an internal electrode (5a, b). A hole (7, 7a, b) is arranged on the outer surface of the catheter to expose the internal electrode (5a, 5b). On the internal electrode (5a, b) a conducting plug (8) is built to fill the hole (7, 7a, b). Several plugs can be created simultaneously without individual manual treatment. The plug is typically created by electroplating, which allows the construction to be controlled electrically though the power connection at the end of the corresponding conductor, which is at the proximal end of the catheter. It provides a stable mechanical and electrical connection to the catheter's external electrodes.

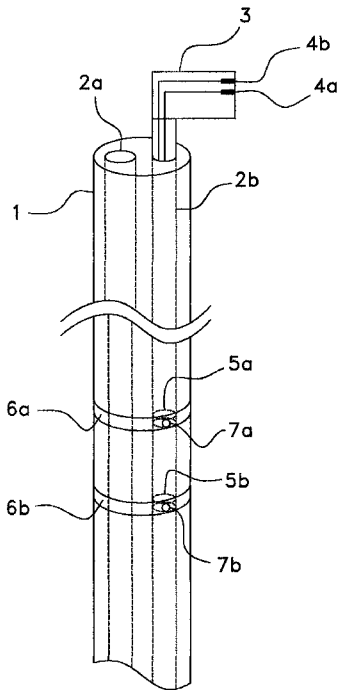

Fig. 1

WO 2011/005165 A1

SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

Catheter and method for manufacturing such a catheter

The present invention is related to a catheter and a method for manufacturing such a catheter according to the preamble of the independent claims.

Background of the invention

Catheters with electrodes that are connected to conductors, which extend along the lengths of the catheters, are known. For example, the document US6856822 describes a catheter with lumens that extend along the catheter. Electric conductors are arranged in these lumens, from each of which a hole extends orthogonally through the catheter walls to the outer surface of the catheter. Around the catheter are arranged conducting rings that act as electrodes and these are connected to the conductors inside the lumens through the holes in the catheter wall. The electrical connection between the conducting rings and the internal conductors is made with an element which fills the hole. Each such element must typically be manually created and treated individually.

One purpose of the invention is therefore to provide a catheter and a method for manufacturing such a catheter that enables the electrical connection element to be created in the catheter in a simple way.

Another purpose of the invention is to provide a catheter and a method for manufacturing such a catheter that enables the simultaneous production of multiple electrical connection elements on a catheter.

These are other purposes are achieved by a catheter and a method for manufacturing such a catheter according to the characterising portion of the independent claims.

Summary of the invention

The invention concerns a catheter with at least one external electrode 6, 6a-c arranged on the outside of the catheter. An external electrode is electrically connected to an internal conductor 4a, b, which extends along at least part of the length of the catheter and is electrically connected to an electrical conductor element, 5a, b.

Holes 7a, b are arranged on the outer surface of the catheter and extend through the catheter walls to the internal conductor element 5a, b. At the internal conductor element 5a, a conducting plug 8 is built into the hole 7, 7a, 7b. Several plugs can be created simultaneously without individual manual treatment.

Electroplating is the most advantageous method of creating this plug. This process can be monitored and controlled electrically using the connections to the conductors at the proximal catheter end. This system will make it possible to check which plugs have been created as an electric connection will signify a completed plug. In addition, this procedure results in a connection between the internal and external electrodes that is mechanically and electrically more stable than one provided by, for example, conductive epoxy.

A particularly advantageous embodiment is a catheter with at least one lumen 2b that extends along the length of the catheter in the direction in which a conductor or a conductor carrier is arranged. The conductor carrier 3 may comprise a long flexible printed circuit board rolled about its longitudinal axis, with at least one conductor printed on the flexible printed circuit board.

The invention concerns the method of manufacturing such catheters, which includes a step where the conducting plug 8 is created in the hole 7, 7a, 7b on top of the internal electrodes 5a, b, typically by electroplating.

Brief description of the drawings

Fig. 1 shows a catheter to which the invention can be applied.

Fig. 2 shows the first step in manufacturing the first embodiment of the invention.

Fig. 3 shows the second step in manufacturing the first embodiment of the invention.

Fig. 4 shows the third step in manufacturing the first embodiment of the invention.

Fig. 5 shows the first step in manufacturing the second embodiment of the invention.

Fig. 6 shows the second step in manufacturing the second embodiment of the invention.

Description of preferred embodiments

Fig. 1 shows a catheter with a design that is suitable for the application of the invention. The catheter comprises a shaft 1 of a flexible material with two lumens with circular cross-sections that run along the length of the shaft. The first lumen 2a has a larger cross-section than the other lumen 2b. The first lumen may be intended for the delivery of liquid or gas and is empty in the figure. A flexible electrical conductor carrier is inserted into the second lumen. The conductor carrier 3 is designed as a narrow, rectangular, flexible printed circuit board, which is rolled into a tube along most of its length. The rolled portion of the flexible printed circuit board is filled with an adhesive which is flexible in its hardened state. The flexible printed circuit board is the narrow tube which is inserted into the second lumen.

The flexible printed circuit board is double-sided. On the side that becomes the inner side of the tube lie conductors along the length of the board. At the upper end of the board, which extends slightly beyond the upper end of the catheter, the board is not rolled into a tube but flat. On this flat portion are conductors that can be connected electronic equipment. Each conductor measures a unique length from the end of the board, and the opposite ends connect to the internal electrodes 5a and 5b. The internal electrodes 5a, b are arranged on the other side of the double-sided board, which becomes the outer side of the tube when the board is rolled.

On the catheter are holes 7a, b which are drilled from the outer surface of the catheter through the catheter wall to the second of the two lumens to coincide with the internal electrodes. Around the circumference of the catheter are external electrodes 6a, b, which are electrically connected to the internal electrodes 5a, b via the holes. With the conventional technology, each conductor, in the form of a wire, is pulled through the catheter lumen, out the appropriate hole in the catheter wall and individually connected to a conducting ring that acted as the external electrode. With the device described above, electrical contact is achieved separately for each external and internal electrode pair in a single step. Clearly, other types of conductors may be used with the invention, but the invention is particularly beneficial in the example described here involving a conductor carrier.

The external electrodes can be used for sensing purposes or for applying electric currents for

various medical purposes. The electrodes 5a, b, 6a, b, though illustrated as annular elements in the figures, can also be designed in other shapes. The advantage of annular elements is that electrical contact is achieved regardless of how they are rotated with respect to the rest of the catheter.

Fig. 2 shows in greater detail a cross-section through a catheter in the first step in manufacturing the first embodiment of the invention. This cross-section is taken through one of the holes 7, which is visible in this figure as an opening in the otherwise circular catheter. The hole 7 extends to the second lumen 2b, which is separate from the first lumen 2a. The conductor carrier 3 is arranged in lumen 2b. The conductor carrier is round in shape and fills the most of the lumen. Around the outer surface of the conductor carrier is an internal electrode, which is exposed through the hole 7.

Fig. 3 shows the second step in manufacturing the first embodiment of the invention in which the electroplating metal has been created to make contact with the inner electrode. The metal layer is built up until the entire hole 7 has been filled, resulting in a plug 8. The plug 8 extends to the outer surface of the catheter and is electrically connected to the internal electrode.

Electroplating is carried out by immersing the catheter in an electrolyte with metal ions. Then electrical power is supplied to the conductors on the conductor carrier that are connected to the internal electrodes on which the metal plug will be built. Providing power to all conductors will result in plugs being created simultaneously on all the internal electrodes. Plugs can be created individually to achieve different metals or heights as needed by controlling the power supply to respective conductors in the electroplating process.

The plugs are naturally built from the part of the internal electrode exposed by the hole 7 and adopt the shape of the hole. The plug maintains connection with the internal electrode at all times and no connection problems can arise from a gap between the internal electrode and the plug.

Fig. 4 shows the third step in manufacturing the first embodiment of the invention. A separate metal ring 6 is placed over the catheter so that it rests on the plug 8. Since the catheter material is flexible, the ring 6 can be swaged so that its inner diameter is smaller than the outer diameter of the catheter in the unloaded state. The ring will naturally then be pressed against the plug, achieving electric contact.

In an embodiment not illustrated here, the plug is created so that it extends beyond the outer surface of the catheter. A ring 6 can be fixed in place over the plug to make a connection with the internal electrode 5, providing an indication that can be felt by touch that the ring is in position.

Fig. 5 shows the first step in manufacturing the second embodiment of the invention. The external electrode 6c, which is not a separate and removable element as is the case in the first embodiment. Instead, the ring is applied on the catheter using one of several possible methods.

A possible application method involves spray or brush painting of conducting paint, moulding or plating with metal or another conducting material. A plating method that can be used is described in EP0985333B1. This provides a layer of metal applied to the catheter in the desired shape of the electrode. Whichever application is used, the external electrode material must cover not only the outer surface of the catheter but also reach into the hole 7 to make contact with the exposed internal electrode.

The strength of the external electrode connection is limited when applied as a thin metal layer. In particular, it is possible that the joint between the internal electrode and the plug will become damaged, resulting in no electrical contact between the two elements. Another critical point is the joint between the plug and the external electrode.

Fig. 6 shows the second step in manufacturing the second embodiment of the invention. Here, a plug 8 is created in the hole according to the electroplating step in the first embodiment. The metal plug fills the hole, growing on top of the metal layer that is the internal electrode. The plug forms a continuous layer of metal elements and is connected mechanically and electrically to the internal electrode. The plug guarantees electrical connection between the external and internal electrodes. In addition, it provides improved stability and strength to prevent mechanical failure.

When the plug is created by electroplating, the external electrode is achieved in the same process by building a thicker layer of metal. After the electroplating process has been carried out for as long as it takes to achieve a stable electrical connection between the internal electrode and the deposited external electrode, the external electrode will continue grow at the same rate as the plug.

Claims

1. A catheter with at least one external electrode (6, 6a-c) arranged on its outer surface, which is connected to a conductor (4a, b) that extends along at least a part of the catheter's length on the inside of the catheter, where the external electrode (6, 6a-c) is electrically connected to an internal electrode (5a, b) attached to a conductor, and where a hole (7, 7a, b) in the catheter wall exposes the internal electrode (5a, b), **characterised in** that the conducting plug (8) in the hole (7, 7a, b), is created by electroplating.

2. A catheter according to claims 1 or 2, **characterised in** that the external electrodes (6, 6a-c) are made of individual annual elements that are electrically connected to the plugs.

3. A catheter according to any of the above claims, **characterised in** that the catheter has at least one lumen (2b) extending along the catheter's longitudinal axis, in which the conductors are arranged.

4. A catheter according to claim 4, **characterised in** that in the lumen is a conductor carrier (3) comprising a long flexible printed circuit board rolled about its longitudinal axis, with at least one conductor printed on the flexible printed circuit board.

5. A method of manufacturing a catheter, where the catheter includes at least one external electrode (6, 6a-c) on its outer surface, which is connected to a conductor that extends along the at least part of the inside length of the catheter, where an external electrode (6, 6a-c) is electrically connected to an internal electrode (5a, b) which is in turn connected to a conductor, and where a hole (7, 7a, b) in the catheter wall exposes the internal electrode (5a, 5b), **characterised in** that the plug (8) is built by electroplating in the hole (7, 7a, 7b) to connect the internal and external electrodes.

6. A method according to claim 7, **characterised in** that the plug built up when the metallic parts of the catheter are reduced in a solution with metal ions, with conductors that are electrically connected to the internal electrodes (5a, 5b).

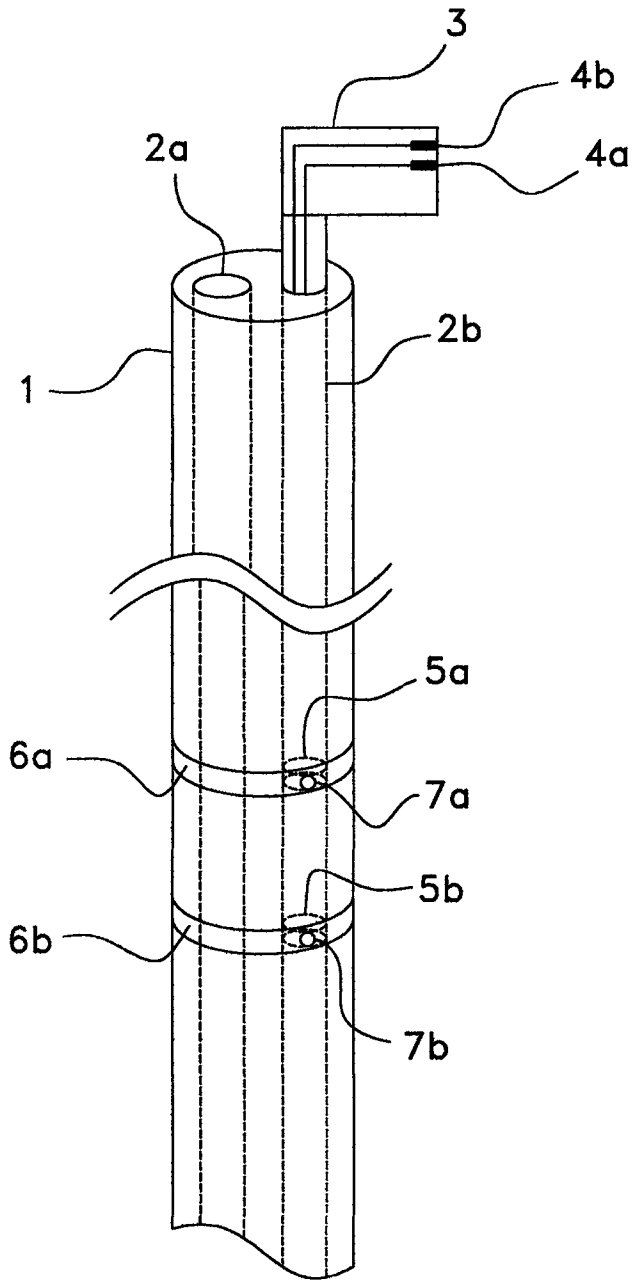

Fig. 1

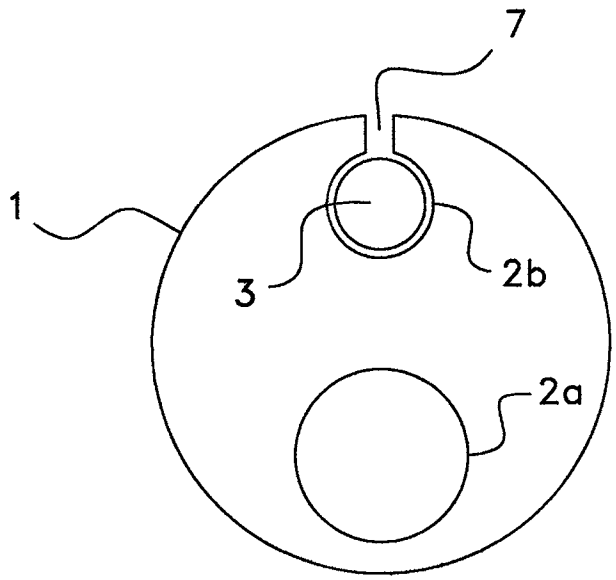

Fig. 2

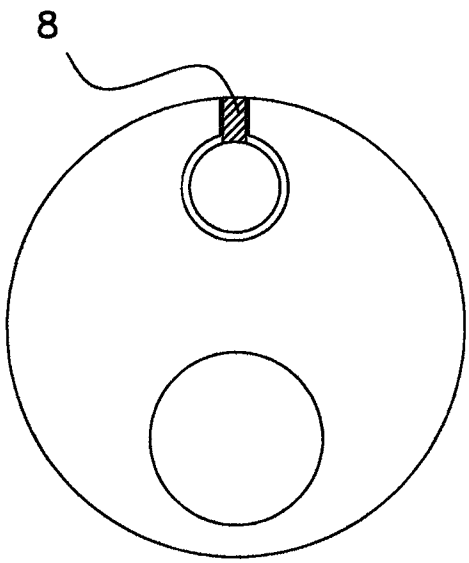

Fig. 3

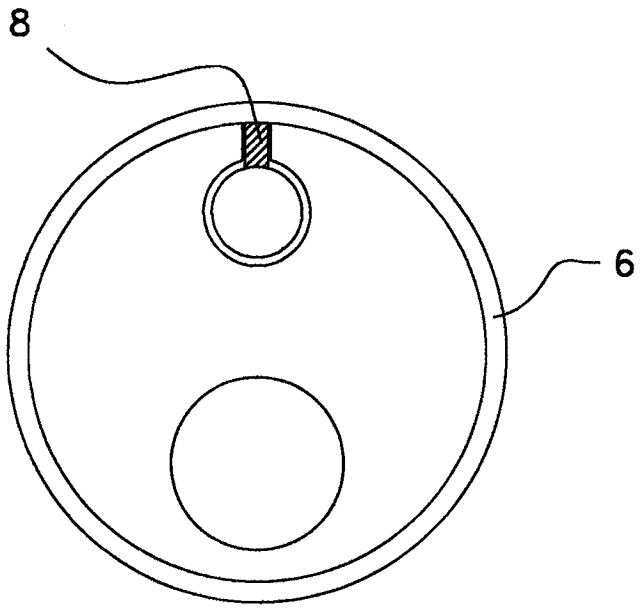

Fig. 4

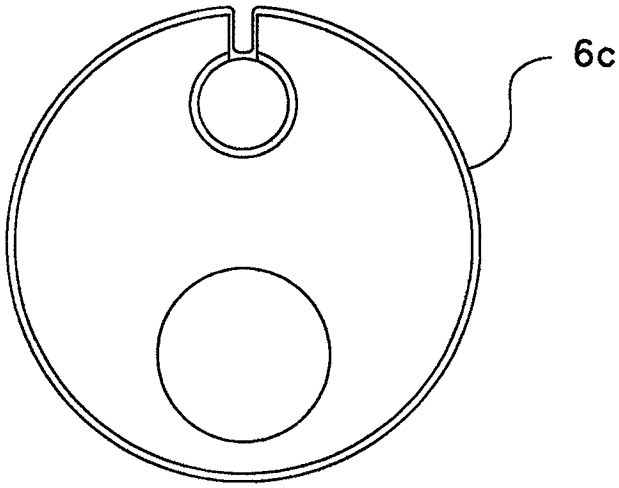

Fig. 5

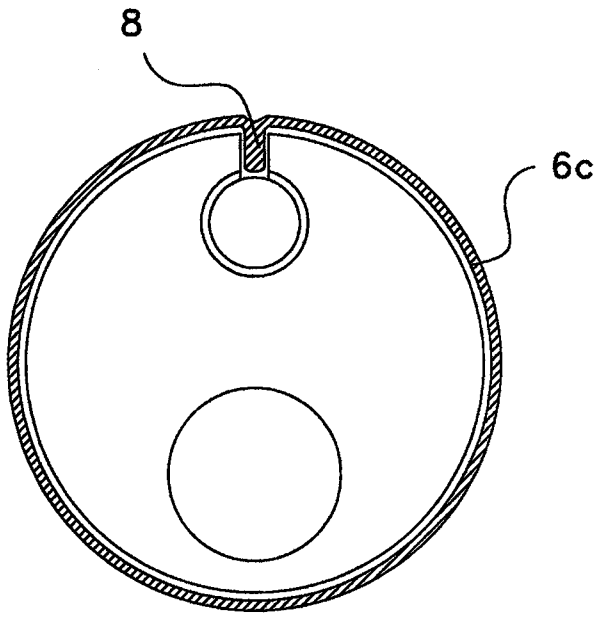

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2010/000186

A. CLASSIFICATION OF SUBJECT MATTER

IPC: see extra sheet
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: A61M, H05K, A61L, A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ, COMPENDEX, INSPEC, MEDLINE, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2007139479 A1 (HLB CATHETER AB), 6 December 2007 (06.12.2007), page 4, line 10 - line 30; page 14, line 5 - line 27, figures 1-4, abstract --	1-6
A	US 5029585 A (C.E. LIEBER ET AL), 9 July 1991 (09.07.1991), column 7, line 13 - line 21; column 8, line 16 - line 21, figures 3,5, abstract --	1-6
A	US 6024702 A (A.A. IVERSEN), 15 February 2000 (15.02.2000), column 2, line 30 - line 36; column 2, line 51 - column 3, line 10; column 5, line 7 - line 15, figure 8, abstract --	1-6

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"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 documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 Sept 2010	13 -09- 2010
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Mika Silfver / MRo Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE2010/000186

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9834446 A1 (CUPTRONIC AB), 6 August 1998 (06.08.1998), figures 1,2, abstract ---	1-6
A	US 20050038320 A1 (D.J. HARTWICK), 17 February 2005 (17.02.2005), figures 1b,2, paragraph (0103) ---	1-6
A	US 4762135 A (P.D. VAN DER PUIJE ET AL), 9 August 1988 (09.08.1988), figure 1, abstract ---	1-6
A	US 3568660 A (N.A. CRITES ET AL), 9 March 1971 (09.03.1971), column 4, line 72 - column 5, line 9, figure 9, abstract ---	1-6
A	US 5433742 A (A. WILLIS), 18 July 1995 (18.07.1995), column 5, line 39 - column 6, line 3; column 6, line 22 - line 27, figures 2-5, abstract --- --------	1-6

International patent classification (IPC)

A61M 25/00 (2006.01)
A61N 1/05 (2006.01)
H05K 3/42 (2006.01)

Download your patent documents at www.prv.se
The cited patent documents can be downloaded:

- From "Cited documents" found under our online services at www.prv.se (English version)
- From "Anförda dokument" found under "e-tjänster" at www.prv.se (Swedish version)

Use the application number as username. The password is **JXFENSOYBQ**.

Paper copies can be ordered at a cost of 50 SEK per copy from PRV InterPat (telephone number 08-782 28 85).

Cited literature, if any, will be enclosed in paper form.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/SE2010/000186

WO	2007139479	A1	06/12/2007	EP	2032201	A	11/03/2009
				JP	2009538682	T	12/11/2009
				US	20090143651	A	04/06/2009
US	5029585	A	09/07/1991	NONE			
US	6024702	A	15/02/2000	NONE			
WO	9834446	A1	06/08/1998	AT	373411	T	15/09/2007
				AU	5888798	A	25/08/1998
				DE	69838420	D,T	03/07/2008
				DK	0985333	T	21/01/2008
				EP	0985333	A,B	12/09/2007
				SE	0985333	T3	
				ES	2293674	T	16/03/2008
				JP	2001509213	T	10/07/2001
				PT	985333	E	17/12/2007
				SE	508280	C	21/09/1998
				SE	9700307	A,L	01/08/1998
US	20050038320	A1	17/02/2005	NONE			
US	4762135	A	09/08/1988	CA	1240784	A	16/08/1988
US	3568660	A	09/03/1971	NONE			
US	5433742	A	18/07/1995	AU	1178595	A	06/06/1995
				WO	9513844	A	26/05/1995