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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
19 October 2017 (19.10.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/178776 A1

(51) International Patent Classification:
A61M 16/00 (2006.01) *G06M 1/08* (2006.01)
A61M 16/08 (2006.01) *A61B 5/00* (2006.01)
A63B 23/18 (2006.01) *A61B 5/087* (2006.01)
G06M 1/22 (2006.01) *A61M 16/20* (2006.01)

(21) International Application Number:
PCT/GB2017/000032

(22) International Filing Date:
9 March 2017 (09.03.2017)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1606580.7 14 April 2016 (14.04.2016) GB

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(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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, 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,

[Continued on next page]

(54) Title: RESPIRATORY THERAPY DEVICES

(57) Abstract: A vibratory expiratory therapy device (200) includes a breath counter (100) to count the number of breaths taken by a user. The counter includes a piston (101) in a cylinder (102) that opens into the housing (2) of the device. The piston is connected to a hinged arm (106) that is rotated against the action of a spring (108) when the piston is moved during exhalation. The arm carries a pawl (112) with a free end (113) arranged to engage teeth (116) around a counter disc (117). The disc has numbers (118) around its edge that advance each time the patient exhales.

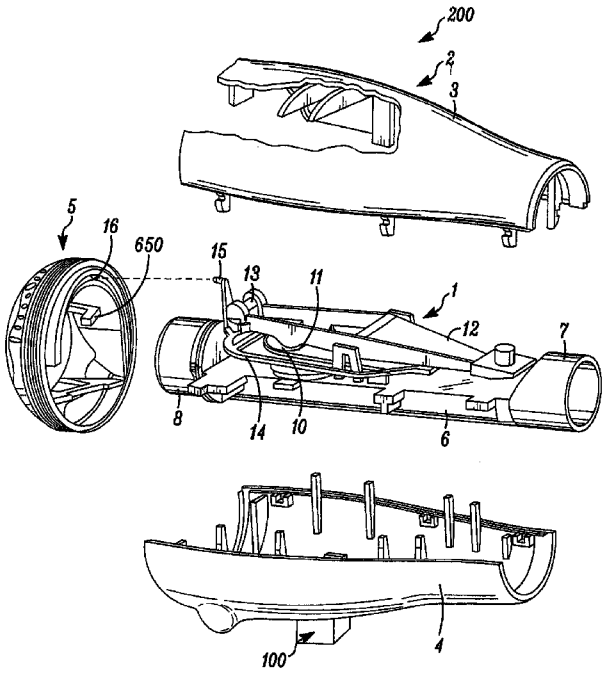

FIG. 1

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LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *as to the identity of the inventor (Rule 4.17(i))*

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *of inventorship (Rule 4.17(iv))*

Published:

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

RESPIRATORY THERAPY DEVICES

This invention relates to respiratory therapy devices of the kind arranged to produce a resistance to respiratory flow through the device

Positive expiratory pressure (PEP) devices, that is, devices that present a resistance to expiration through the device, are now widely used to help treat patients suffering from a range of respiratory impairments, such as chronic obstructive pulmonary disease, bronchitis, cystic fibrosis and atelectasis. More recently, such devices that provide an alternating resistance to flow have been found to be particularly effective. One example of such a device is sold under the trade mark Acapella (a registered trade mark of Smiths Medical) by Smiths Medical and is described in US6581598, US6776159, US7059324 and US7699054. US8534284 describes a device with an interrupter valve driven by pressurised gas delivered to the apparatus. The speed of the valve is dependent on the back pressure created by expired breaths from the patient. WO2016/092247 describes a respiratory therapy including a compliance meter having a cylinder with a piston that moves progressively along the cylinder when air is released from the cylinder on each expiratory cycle. The piston drives a flag to indicate progress of a therapy session. Other vibratory respiratory therapy devices are available, such as "Quake" manufactured by Thayer, "AeroPEP" manufactured by Monaghan, "TheraPEP" manufactured by Smiths Medical and "IPV Percussionator" manufactured by Percussionaire Corp. These devices generate vibratory positive pressures mechanically and fluctuating exhalation flows that help overcome the inertia and stiction of the sputum within the bronchi and lower passages of the lung. This enhances mucociliary clearance. Alternative apparatus such as "CoughAssist" manufactured by Philips is also available. Respiratory therapy devices can instead provide an alternating resistance to flow during inhalation.

Although respiratory therapy devices can be highly effective at treating respiratory impairments, the relief obtained is dependent on how closely the patient adheres to the

prescribed treatment regime: how regularly he uses the device and the manner in which the device is used. Patients are trained to use the devices by a clinician in a hospital but it is essential that the devices are used regularly by the patient in the prescribed manner at home where there is no clinical supervision. The problem, however, is that the patient may not use the device as prescribed when unsupervised, outside a clinical environment. The clinician is unable to determine whether any lack of improvement in the patient's condition is due to his failure to adhere to the treatment regime or other factors so this makes control of the patient's condition very difficult.

It is an object of the present invention to provide an alternative respiratory therapy device.

According to one aspect of the present invention there is provided a respiratory therapy device of the above-specified kind, characterised in that the device includes a movable member arranged to be displaced backwards and forwards during each respiratory flow cycle, that a mechanical linkage is coupled with the movable member and with a counter having numerical markings, that the linkage and counter are arranged such that the counter is advanced numerically by each respiratory cycle so as to provide a numerical indication to the user of the number of breaths taken.

The device may be arranged to produce a resistance to expiratory flow through the device. The device is preferably arranged to produce an alternating resistance to respiratory flow. The movable member may be a spring-loaded piston moved backwards and forwards along its length by pressure change in the device during each respiratory cycle. The counter may include a disc with a toothed edge that is arranged to be engaged by an arm coupled to the movable member such that the arm is pivoted by movement of the movable member and rotates the disc. The disc may be marked with numbers around its edge.

A vibratory PEP expiratory respiratory therapy device according to the present invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is an exploded view of the device;

Figure 2 shows schematically one part of the counter mechanism; and

Figure 3 shows schematically a different part of the counter mechanism.

With reference first to Figure 1, the respiratory therapy device 100 comprises a rocker assembly 1 contained within an outer housing 2 provided by an upper part 3 and a lower part 4 of substantially semi-cylindrical shape. The device is completed by an adjustable dial 5 of circular section. The outer housing 2 contains an air flow tube 6 with a breathing inlet 7 at one end and an inspiratory inlet 8 at the opposite end including a one-way valve (not shown) that allows air to flow into the air flow tube but prevents air flowing out through the inspiratory inlet. The air flow tube 6 has an outlet opening 10 with a non-linear profile that is opened and closed by a conical valve element 11 mounted on a rocker arm 12 pivoted midway along its length about a transverse axis. The air flow tube 6 and housing 2 provide a structure with which the rocker arm 12 is mounted. At its far end, remote from the breathing inlet 7, the rocker arm 12 carries an iron pin 13 that interacts with the magnetic field produced by a permanent magnet (not visible) mounted on an adjustable support frame 14. The magnet arrangement is such that, when the patient is not breathing through the device, the far end of the rocker arm 12 is held down such that its valve element 11 is also held down in sealing engagement with the outlet opening 10. A cam follower projection 15 at one end of the support frame 14 locates in a cam slot 16 in the dial 5 such that, by rotating the dial, the support frame 14, with its magnet, can be moved up or down to alter the strength of the magnetic field interacting with the iron pin 13. The dial 5 enables the frequency of operation

and the resistance to flow of air through the device to be adjusted for maximum therapeutic benefit to the user.

When the patient inhales through the breathing inlet 7 air is drawn through the inspiratory inlet 8 and along the air flow tube 6 to the breathing inlet. When the patient exhales, the one-way valve in the inspiratory inlet 8 closes, preventing any air flowing out along this path. Instead, the expiratory pressure is applied to the underside of the valve element 11 on the rocker arm 12 causing it to be lifted up out of the opening 10 against the magnetic attraction, thereby allowing air to flow out to atmosphere. The opening 10 has a non-linear profile, which causes the effective discharge area to increase as the far end of the rocker arm 12 lifts, thereby allowing the arm to fall back down and close the opening. As long as the user keeps applying sufficient expiratory pressure, the rocker arm 12 will rise and fall repeatedly as the opening 10 is opened and closed, causing a vibratory, alternating or oscillating interruption to expiratory breath flow through the device. Further information about the construction and operation of the device can be found in US6581598, although this is not essential to an understanding of the invention.

As so far described, the device is conventional.

The device differs from conventional therapy devices by the inclusion of a breath counter 100 that is arranged to indicate the number of breaths or respiratory cycles exerted by the user. The breath counter 100 is provided by a unit attached with the lower part of the housing 2 and is shown in more detail in Figures 2 and 3. The counter 100 includes a piston 101 slidable along a cylinder 102 that opens at its upper end into the interior of the housing 2 so that the piston is exposed to pressure change within the housing as the user inhales and exhales through the device. The piston 101 has a head 103 at its upper end that makes a sliding gas-tight seal with the inside of the cylinder 102. A rod 104 extends downwardly from the head 103 out of the closed lower end of the cylinder 102. At its lower end the rod 104 is hingedly coupled towards the free end 105 of a pivoted arm 106 that is pivotally mounted at

its opposite end 107. A helical tension or extension spring 108 is attached, at its lower end, with the arm 106 between its pivoted end 107 and the attachment of the piston rod 104 and, at its upper end, with a fixed component, such as a part of the housing 2. The spring 108 is arranged to apply a resilient force to pull the free end 105 of the arm 106 upwardly, that is, to pivot the arm in a clockwise direction. This has the effect of tending to pull the piston 101 upwardly, towards the housing 2 of the therapy device. Upward movement of the arm 106 is limited by engagement of the upper surface of the arm with a fixed stop 110.

The arm 106 also has a latch arm or pawl 112 (Figure 3) that extends downwardly from the arm. The pawl 112 has a free end 113 that engages one of a series of teeth 116 projecting from around the edge of a counter disc or gear 117 rotatably mounted about an axis parallel with the pivot axis of the arm 106. The teeth 116 are marked with a series of numbers 118 that increase around the disc 117. The teeth 116 are movable behind a window 119 through which the user can view the numbers 118.

Each time that the user exhales pressure within the housing 2 of the device increases. This increased pressure causes the piston 101 to be forced down the cylinder 102 against the force applied by the spring 108. As the piston 101 moves down the arm 106 is also moved down or rotated anticlockwise to the lower position shown in Figure 2 by the broken lines. This causes the free end 113 of the pawl 112 to disengage from the tooth 116 with which it was previously engaged and to move to the next tooth around the counter disc 117. When the user has finished exhaling, the pressure in the housing 2 falls back towards atmospheric pressure, thereby allowing the piston 101 to be pulled up by the spring 108. This allows the arm 106 and pawl 112 to be displaced clockwise so that its free end 113 engages and indexes around the next tooth 116 on the counter disc 117. In this way the number 118 visible in the window 119 is advanced by one count. The user can thereby check his progress through a therapy session involving a prescribed number of expiratory breaths.

If it is only necessary to be able to count a small number of breaths a single counter disc may be sufficient with the requisite number of teeth spaced around it. For larger numbers several counter discs could be ganged together, side by side, so that when one disc is advanced beyond "9" it rotates the adjacent disc by one step so that, for example "09" is advanced to "10".

The arrangement of the present invention enables a numerical count of breaths to be displayed to the user in a relatively simple and low-cost manner.

The invention is not confined to vibratory or expiratory therapy devices but could be used with inspiratory therapy devices and those without any vibratory effect.

CLAIMS

1. A respiratory therapy device (200) arranged to produce a resistance to respiratory flow through the device, characterised in that the device includes a movable member (101) arranged to be displaced backwards and forwards during each respiratory flow cycle, that a mechanical linkage (106, 112) is coupled with the movable member (101) and with a counter (100) having numerical markings (118), that the linkage and counter are arranged such that the counter (100) is advanced numerically by each respiratory cycle so as to provide a numerical indication to the user of the number of breaths taken.

2. A respiratory therapy device according to Claim 1, characterised in that the device (200) is arranged to produce a resistance to expiratory flow through the device.

3. A respiratory therapy device according to Claim 1 or 2, characterised in that device (200) is arranged to produce an alternating resistance to respiratory flow.

4. A respiratory therapy device according to any one of the preceding claims, characterised in that the movable member is a spring-loaded piston (101) moved backwards and forwards along its length by pressure change in the device during each respiratory cycle.

5. A respiratory therapy device according to any one of the preceding claims, characterised in that the counter (100) includes a disc (117) with a toothed edge (16) that is arranged to be engaged by an arm (106, 112, 113) coupled to the movable member (101) such that the arm is pivoted by movement of the movable member and rotates the disc (117).

6. A respiratory therapy device according to Claim 5, characterised in that the disc (117) is marked with numbers (118) around its edge.

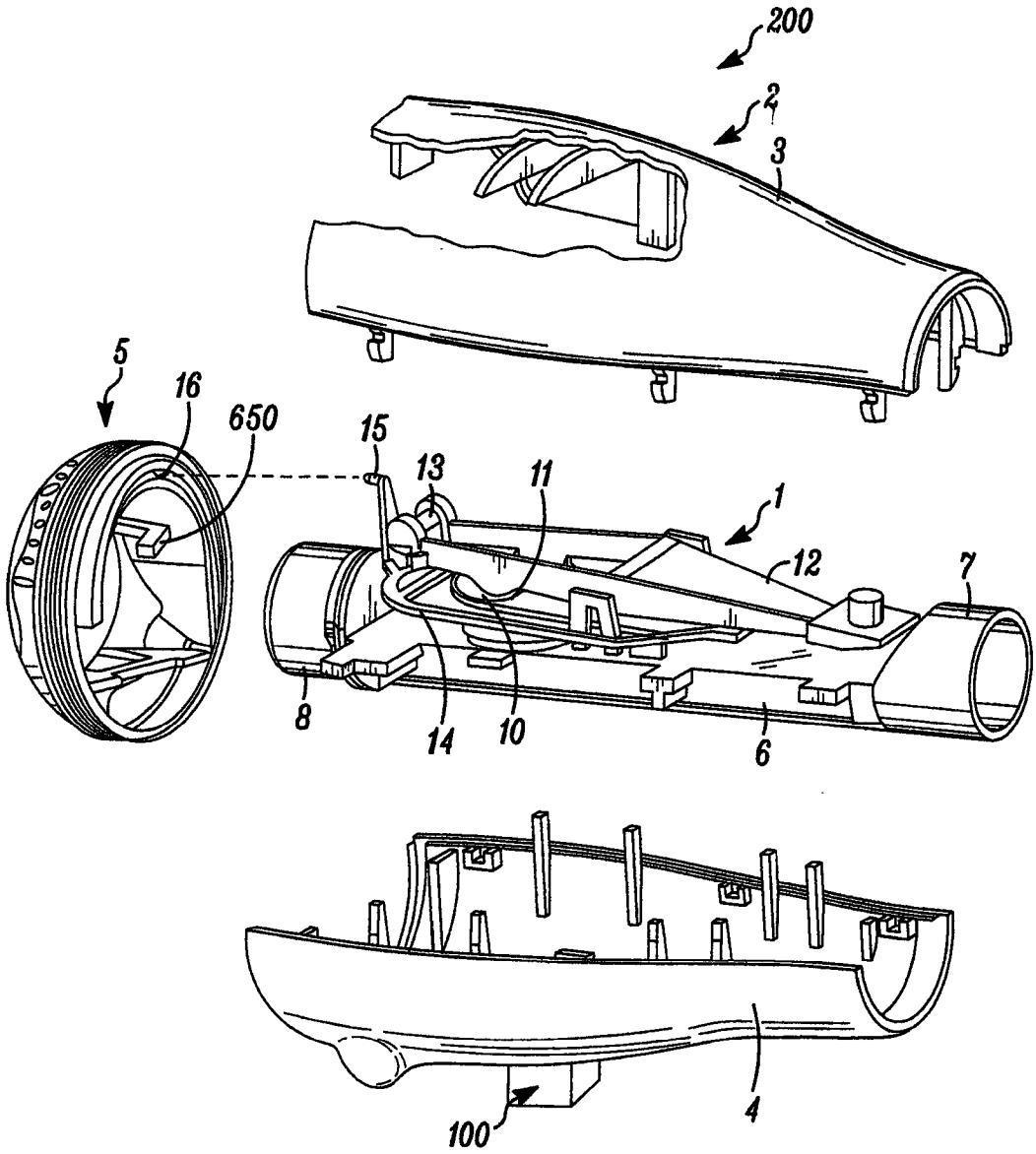

FIG. 1

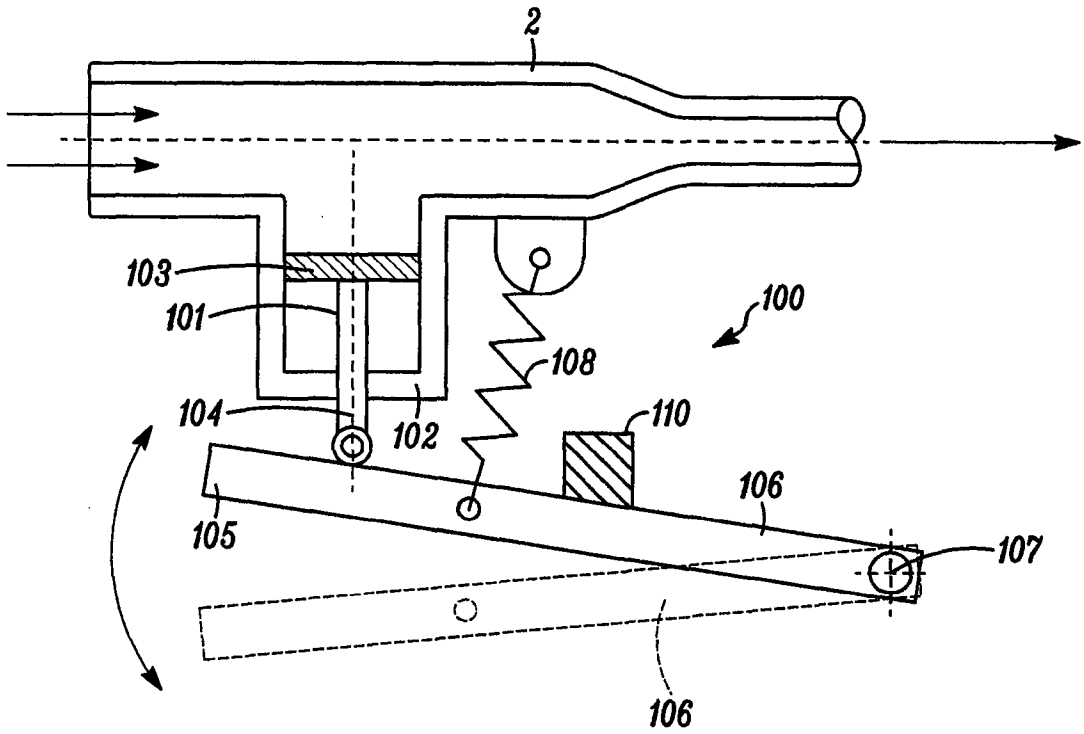

FIG. 2

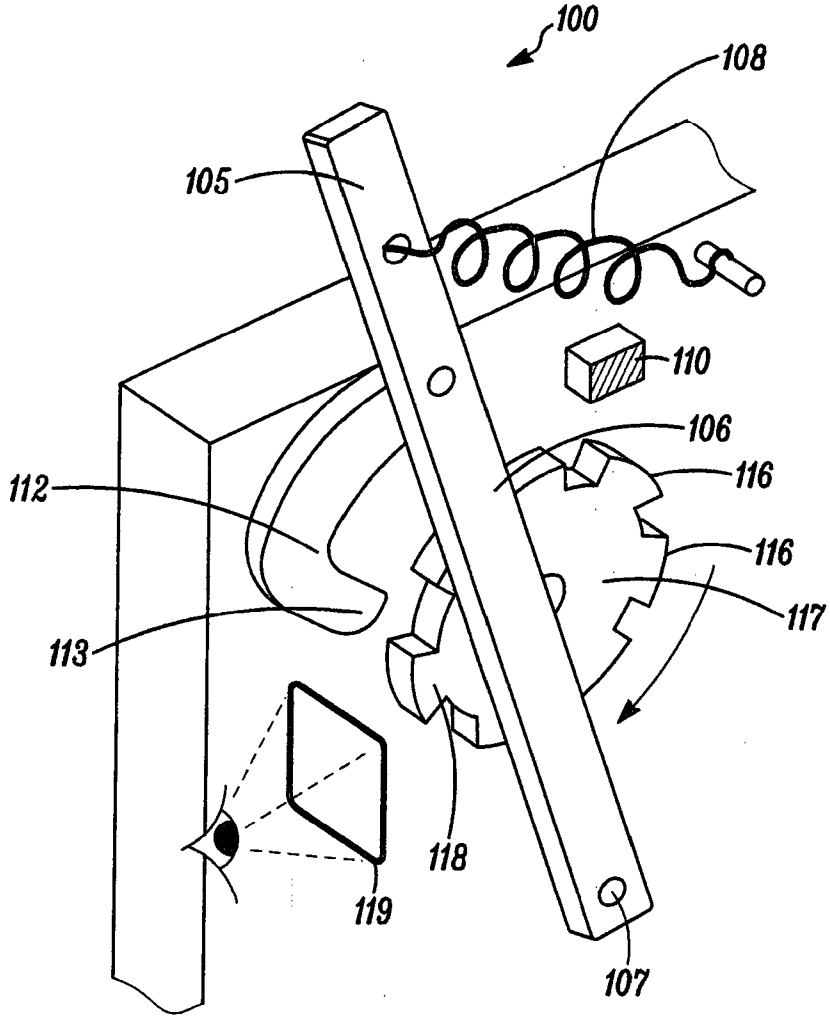

FIG. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2017/000032

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/00 A61M16/08 A63B23/18 G06M1/22 G06M1/08
ADD. A61B5/00 A61B5/087 A61M16/20

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)
A61M A63B A61B G06M

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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2013/182833 A1 (SMITHS MEDICAL INT LTD [GB]) 12 December 2013 (2013-12-12) the whole document, and especially page 6 lines 11-24, page 7 lines 6-31, and figures 1-7	1-6
A	WO 2004/096110 A2 (CHI LLC [US]; BAUMERT BETH A [US]; PROLL JANICE G [US]) 11 November 2004 (2004-11-11) the whole document, and especially page 11 line 35 to page 12 line 1, and figures 1-10	1-6
A	WO 2014/140532 A1 (UNIV SHEFFIELD HALLAM [GB]) 18 September 2014 (2014-09-18) the whole document, and especially the figures 1-6	1-6

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

☒ 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

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"O" document referring to an oral disclosure, use, exhibition or other means

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"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
28 April 2017	24/05/2017

Name and mailing address of the ISA/	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2017/000032

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2013182833 A1	12-12-2013	CN 104470591 A	25-03-2015
		EP 2858725 A1	15-04-2015
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WO 2014140532 A1	18-09-2014	GB 2512047 A	24-09-2014
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