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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 April 2019 (18.04.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/071291 A1

(51) International Patent Classification:
A61B 5/00 (2006.01)

(21) International Application Number:
PCT/AU2018/000197

(22) International Filing Date:
15 October 2018 (15.10.2018)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2017904161 13 October 2017 (13.10.2017) AU

(71) Applicant: **BIOANALYTICS HOLDINGS PTY LTD** [AU/AU]; 602/566 St Kilda Road, Melbourne, VIC 3004 (AU).

(72) Inventors: **SASSE, Anthony**; 602/566 St Kilda Road, Melbourne, VIC 3004 (AU). **JONES, Cyril**; 602/566 St Kilda Road, Melbourne, VIC 3004 (AU). **RATTEN, Stephen**; 602/566 St Kilda Road, Melbourne, VIC 3004 (AU). **MORGAN, Owen**; 602/566 St Kilda Road, Melbourne, VIC 3004 (AU).

(74) Agent: **MORCOM, Norman, Bruce**; Morcom Pernat, Suite 17, 5a Hartnett Close, Mulgrave, VIC 3170 (AU).

(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, JO, 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,

(54) Title: IMPROVEMENTS RELATING TO SLEEP MONITORING

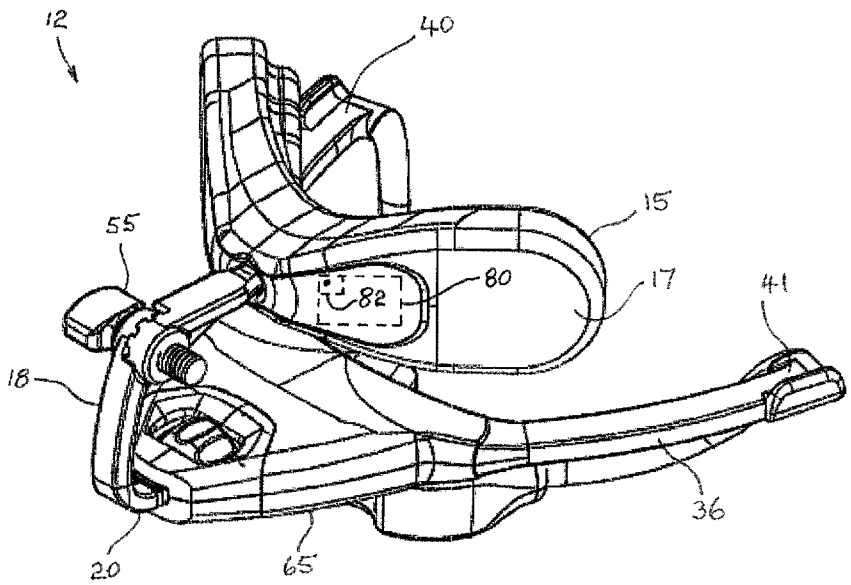


Fig. 4

(57) Abstract: A method of monitoring the status of a body of a person during sleep, said method comprising: - retaining in or adjacent the mouth or nose of said person an electronic detector which detects indications of the state of said body, - wirelessly transmitting a first data stream representing said indications to a data receiving means, - transmitting said first data stream from said data receiving means to a data processing means, - processing said first data stream within said data processing means to produce a second data stream representing said indications, or conclusion drawn from said indications, and - displaying a visual representation of said indications or conclusions.

[Continued on next page]

WO 2019/071291 A1

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

Published:

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

Improvements Relating to Sleep Monitoring

Technical Field

This invention concerns a method and apparatus for use in monitoring the status of a person while they are asleep. In addition to its more general application, the invention is particularly adapted to use with an intraoral mandibular advancement device for treatment of obstructive sleep apnea.

Background

There is a need for a low cost and convenient to use means by which the status of the body of a person can be monitored during sleep in order to record and/or provide an alert that a period of diminished breathing is underway.

Sleep apnea is a major concern for many people. The two major types of sleep apnea are Obstructive Sleep Apnea (OSA) and Central Sleep Apnea (CSA). In order to treat OSA, many different types of devices have been proposed, and are in use, for advancing the mandible of a person during sleep in order to provide a clearer airway. It has proven difficult to provide confirmation that such devices work and are efficacious in delivering the benefits claimed for them. An aim of the present invention is to provide means by which such confirmation may be achieved.

The principles of a particularly effective mandibular advancement device are described in international patent publication no. WO2006/072147. Some particularly preferred embodiments of the present invention preferably utilize a device of that general type.

However, the present invention may otherwise be used, by way of other embodiments, in testing for, and monitoring of CSA where, rather than obstruction of the airway, the issue is a diminished stability in the body's feedback mechanisms that control respiration.

The present invention may also be used for monitoring the status of a person who, while not suffering from sleep apnea, may benefit from their condition being monitored while unwell or following surgery.

Summary of Invention

Accordingly, in one aspect the invention provides a method of monitoring the status of a body of a person during sleep, said method comprising:

- retaining in or adjacent the mouth or nose of said person an electronic detector which detects indications of the state of said body,
- wirelessly transmitting a first data stream representing said indications to a data receiving means,
- transmitting said first data stream from said data receiving means to a data processing means,
- processing said first data stream within said data processing means to produce a second data stream representing said indications, or conclusion drawn from said indications, and
- displaying a visual representation of said indications or conclusions.

Preferably said second data stream is transmitted wirelessly from said data processing means to a remote location. Preferably said wireless transmission of said first data stream occurs while said person is asleep and said data receiving means is adjacent said person.

Preferably for said person a single smartphone comprises:

- said data receiving means,
- said data processing means, and
- a means by which said transmission of the second data stream is made to said remote location.

The visual representation of said indications or conclusions may be displayed on said smartphone.

The remote location may comprise a computer facility which analyses corresponding said second data streams received from multiple smartphones.

Said electronic detector may be retained in position by a device bearing on the teeth and/or gingiva of said person. Said electronic detector may be retained by or within an intraoral mandibular advancement device being worn by said person.

Alternatively, said electronic detector may be mounted in a housing which is retained in position by adhesion or adhesive tape onto the face of the person.

Alternatively, said electronic detector may be mounted in a housing which is retained in position by a strap extending around the head of the person.

In another aspect the invention provides a device for wearing by a person during sleep for the purpose of monitoring the status of said person's sleep, said device comprising:

- a first portion adapted to be retained within the person's mouth,
- a second portion adapted to detect, from outside said body, indications of the state of said body, and
- means for wirelessly transmitting a first data stream representing said detected indications to a data receiving means located adjacent said sleeping person.

Preferably said data processing means is a smartphone.

Preferably the device comprises an intraoral mandibular advancement device adapted to be worn by said person.

Preferably said second portion adapted to detect indications of the state of said body comprises an electronic detector of airflow, audio and acceleration. It may also be adapted to detect indications of one or more of electro-musculogram data, electro-osculogram data, electro-encephalogram data and percent of saturated oxygen.

Said wireless transmission means is preferably a Bluetooth transmitter.

In another aspect the invention provides apparatus for monitoring the status of a body of a person during sleep, said apparatus comprising:

- a device according to any one of claims 6 to 15, and
- a mobile smartphone including:
  - said data receiving means,
  - a data processing means for receiving said first data stream from said data receiving means, processing said first data stream to produce a second data stream representing said status, or an indication of said status, data, or conclusions drawn from said indications, and
  - means for transmitting from said data processing means to a remote location said second data stream representing said indications and/or an interpretation of, or conclusion drawn from, said indications.

Preferably said data processing means comprises software loaded into said smartphone.

Brief Description of Drawings

In order that the invention may be more fully understood there will now be described, by way of example only, preferred embodiments and other elements of the invention with reference to the accompanying drawings where:

Figure 1 is a schematic of an apparatus and system according to a first embodiment of the invention;

Figure 2 is a schematic of an apparatus and system according to a second embodiment of the invention;

Figure 3 is a schematic of an apparatus and system according to a third embodiment of the invention;

Figure 4 is a perspective view of a mandibular advancement device forming part of the apparatus in Figure 1;

Figure 5 is a side view of the device in Figure 4;

Figure 6 is a plan view of the device in Figure 4;

Figure 7 is a frontal view of the device in Figure 4;

Figure 8 is a flowchart showing the operation of the software in an SCDA module in the system illustrated in Figure 3;

Figure 9 is a flowchart showing the operation of the software in a smartphone in the system illustrated in Figure 3; and

Figure 10 is a flowchart showing the operation of the software in a central data collection computer facility in the system illustrated in Figure 3.

With respect to the different embodiments of the invention, features which have equivalent function in each embodiment are identified by numerals which are one hundred different from the numerals identifying equivalent features in another embodiment.

Description of Embodiments

Referring to Figure 1, the first embodiment of the invention utilizes apparatus 110 incorporating a mandibular advancement device 112 the same as the device 12 shown in Figures 4 to 7.

As shown in Figures 4 to 7, the mandibular advancement device 12 incorporates a curved anterior maxillary abutment portion 15 mounted to an intraoral body portion 65 via an extraoral member portion 18. An arm 20 on the extraoral member 18 engages into the intraoral body portion 65. The effective length of the arm 20 is manually adjustable by the action of an adjustment wheel 60 whose central bore 61 is threadedly engaged with a thread 62 on the arm 20. The effective height of the extraoral member 18 can be adjusted by the angularly adjustable extraoral adjustment means 55 which adjusts the angle subtended by the articulation in the middle of the extraoral member 18.

The generally banana-shaped anterior mandibular abutment 25 is connected to the body portion 65 by connecting members 30 and 31. The intraoral posterior maxillary abutments 40 and 41 are connected to the intraoral body portion 65 by respective arms 35 and 36. In use the abutment surfaces 40 and 41 make contact with portion of the

maxillary surface and that contact resists rotation of the device induced by the forces applied to the mandibular abutment surface 25 and the anterior maxillary abutment surface 15.

The concave surface 16 of the anterior maxillary abutment 15 is an elastomeric material that is shaped to fit comfortably upon the soft tissue and skin covering the user's sub-nasal maxillary bone. The anterior mandibular abutment 25 has a convex anterior face 26 which in use pushes on the user's gingiva covering their mandible. This arrangement allows the orthotic device to be applied to patients who have lost one or more of their anterior mandibular teeth. By abutting the gingiva covering the mandible, the anterior mandibular abutment surface 26 avoids or minimizes any undesirable movement of mandibular teeth over time.

An electronic module 80, specifically a sleep data collection and analysis module (hereinafter referred to as an SDCA module) is embedded within (or alternatively may be clipped over) the convex anterior face 17 of the maxillary abutment 15 at a region directly below the user's nose. A rechargeable electric battery 84 is also embedded within the concave face of the maxillary abutment 15 in order to provide an electric power source for the SDCA module 80. The battery 84, and much of the module 80, lie within cavities beneath the surface of the face 17 so their positions are indicated as dashed outlines.

The module 80 includes an electronic chip or chips on a printed circuit board (hereinafter referred to collectively as an SDCA detector system) 82 which acts as an electronic detector of the desired conditions. The device 12 is worn by the user during periods of sleep in order that relevant data may be collected by the SDCA detector system. The SDCA detector system includes two nasal and one oral sensors. The SDCA detector system is positioned so its exposed sensors are contacted by air passing into and out of the user's nose and/or mouth. The SDCA detector system detects acceleration of the user's upper lip, ambient audio and airflow past the sensors, stores that information, and transmits the data to a smartphone placed adjacent the user by means of a Bluetooth LE data link in near real time. An app loaded by the user into the smartphone processes the data and displays the results on the phone's screen.

Referring to Figure 1, concerning the first embodiment of the invention, when the user arises after sleep, they take off the mandibular advancement device 112 and place it on a base unit 114 which inductively charges the battery 84 after each night's sleep. The base unit 114 is powered from a USB charger 122. The base unit 114 is a docking station for the device 112 when the device 80 is not in use, and is configured to keep the device 112 clean and dust free. The base unit 114 has a region where relevant portions of the device 112 are soaked in an appropriate sterilizing fluid.

The user's smartphone 178 downloads the collected data from the SDCA module 80, which remains on the device 112. The SDCA module communicates with the smartphone 178 via a Bluetooth connection in order to upload the collected data from the SDCA module 80 while the user is wearing the device. The user's smartphone 178, placed near the sleeping user, is used to collect the data transmitted by the SDCA and to analyse the data to show the user the effectiveness of the device 112 for at least the previous sleep period or for other sleep periods as required. That analysis is performed by an app previously loaded by the user into the smartphone. The smartphone thus functions as a data processing means. There is accordingly a step of wirelessly transmitting a first data stream from the SDCA module 80 to a receiving means within the phone 178 after which, within the phone, the first data stream is transmitted to a data processing means where the data received is processed.

Referring to Figure 2, the apparatus 210 for the second embodiment is mostly the same as that described above for the first embodiment. A first main difference is that the SDCA module 280 has additional detection and recording functions when compared with the SDCA module 180 in Figure 1. The SDCA module 280 in Figure 2 records electro-musculogram (EMG) data, electro-osculogram (EOG) data, electro-encephalogram (EEG) data and percent of saturated oxygen (SA02) data in addition to the basic standard measurements of airflow, audio and acceleration recorded by the module 180 used in the first embodiment.

The second main difference is that the the smartphone 278 can upload the data to a suitable external repository 279 via the internet 281. Optionally the external repository

279 includes a central data analysis server which collects the data uploaded from multiple devices for appropriate health monitoring.

The electronics used in the base unit 214 are the same as the electronics used in the base unit 114.

By providing users with devices with different SDCA options, using different anterior maxillary abutment pads for the different SDCA options, the mandibular advancement device can be easily manufactured in a variety of versions. Pads for anterior maxillary abutment portions 15 can be easily interchanged. Even after purchase, a user can upgrade the product they have by purchasing an alternative version of the pad and thus change the mandibular advancement device to an enhanced version.

The invention provides higher level functions to a conventional mandibular advancement device which enhances its value and utility, so making it more attractive to users. The invention also provides confirmation of the effectiveness of the mandibular advancement device in assisting sleep behavior.

The apparatus 310 in the system illustrated by Figure 3 also provides for a local data collection on the user's home computer 377 as well as uploading to a global data collection database 379. The apparatus 310 also differs from the apparatus 210 (in Figure 2) in that the base unit 214 is not used. Instead the SDCA module 380 is charged directly from the charger 322.

In relation to the operations indicated by, and generally self-explanatory from, the flowcharts in Figures 8 to 10, the following additional features are noted.

- All the data generated by the SDCA module 80 is stored in the module until it is able to be uploaded to the next component in the data collection/transmission chain.
- If the memory of the SDCA module 80, base module or smartphone are at capacity, the oldest data is discarded in favour of any new uploads of sleep data.

- The smartphone stores at least ten overnight data sets before needing to upload the data to the external repository 179.
- The smartphone stores all data sets uploaded from the SDCA until the smartphone memory is nearly exhausted.
- The user may elect to delete any or all data sets from the smartphone.
- The user is able to peruse a list of data sets and determine which they may wish to delete.
- The system utilizes data encryption between the SDCA module, the base unit and any attached smartphones.
- The system allows a clinician to log in remotely and view the the sleep behavior of a patient in near real time.

Alternative embodiments of the invention do not utilize a mandibular advancement device in order to retain the SDCA module and its battery power supply. Instead a component similar to the curved anterior maxillary abutment provides a housing and may be held beneath the user's nose by adhesive tape or by an elastic strap around the user's head. This could be used for sleep analysis of people who do not suffer from OSA and those who would be unacceptably disturbed by sleeping while a foreign object is in their mouth.

Whilst the above description includes the preferred embodiments of the invention, it is to be understood that many variations, alterations, modifications and/or additions may be introduced into the constructions and arrangements of parts previously described without departing from the essential features or the spirit or ambit of the invention.

For example, the smartphone could be replaced by an alternative data processing means which has a suitable wireless data input such as Bluetooth LE. Its data output means (if present) may be wired or wireless.

It will be also understood that where the word "comprise", and variations such as "comprises" and "comprising", are used in this specification, unless the context

requires otherwise such use is intended to imply the inclusion of a stated feature or features but is not to be taken as excluding the presence of other feature or features.

The reference to any prior art in this specification is not, and should not be taken as, an acknowledgment or any form of suggestion that such prior art forms part of the common general knowledge.

Claims

1. A method of monitoring the status of a body of a person during sleep, said method comprising:

- retaining in or adjacent the mouth or nose of said person an electronic detector which detects indications of the state of said body,
- wirelessly transmitting a first data stream representing said indications to a data receiving means,
- transmitting said first data stream from said data receiving means to a data processing means,
- processing said first data stream within said data processing means to produce a second data stream representing said indications, or conclusion drawn from said indications, and
- displaying a visual representation of said indications or conclusions.

2. The method according to claim 1 comprising wirelessly transmitting said second data stream from said data processing means to a remote location.

3. The method according to claim 1 wherein said wireless transmission of said first data stream occurs while said person is asleep and said data receiving means is adjacent said person.

4. The method according to any one of claims 1 to 3 wherein for said person a single smartphone comprises:

- said data receiving means,
- said data processing means, and
- a means by which said transmission of the second data stream is made to said remote location.

5. The method according to claim 4 wherein said visual representation of said indications or conclusions is displayed on said smartphone.

6. The method according to claim 4 or 5 wherein said remote location comprises a computer facility which analyses corresponding said second data streams received from multiple smartphones.

7. The method according to any one of claims 1 to 6 wherein said electronic detector is retained in position by a device bearing on the teeth and/or gingiva of said person.

8. The method according to claim 7 wherein said electronic detector is retained by or within an intraoral mandibular advancement device worn by said person.

9. The method according to any one of claims 1 to 6 wherein said electronic detector is mounted in a housing which is retained in position by adhesion or adhesive tape onto the face of the person.

10. The method according to any one of claims 1 to 6 wherein said electronic detector is mounted in a housing which is retained in position by a strap extending around the head of said person.

11. A device for wearing by a person during sleep for the purpose of monitoring the status of said person's sleep, said device comprising:

- a first portion adapted to be retained within the person's mouth,
- a second portion adapted to detect, from outside said body, indications of the state of said body, and
- means for wirelessly transmitting a first data stream representing said detected indications to a data receiving means located adjacent said sleeping person.

12. The device according to claim 11 comprising an intraoral mandibular advancement device adapted to be worn by said person.

13. The device according to claim 11 or 12 wherein said second portion is adapted to detect indications of the state of said body comprises an electronic detector of airflow, audio and acceleration.

14. The device according to claim 13 wherein said second portion is adapted to detect indications of one or more of electro-musculogram data, electro-osculogram data, electro-encephalogram data and percent of saturated oxygen.

15. The device according to any one of claims 11 to 14 wherein said wireless transmission means is a Bluetooth transmitter.

16. Apparatus for monitoring the status of a body of a person during sleep, said apparatus comprising:

- a device according to any one of claims 6 to 15, and
- a mobile smartphone including:
  - said data receiving means,
  - a data processing means for receiving said first data stream from said data receiving means, processing said first data stream to produce a second data stream representing said status, or an indication of said status, data, or conclusions drawn from said indications, and
  - means for transmitting from said data processing means to a remote location said second data stream representing said indications and/or an interpretation of, or conclusion drawn from, said indications.

17. The apparatus according to claim 16 wherein said data processing means comprises software loaded into said smartphone.

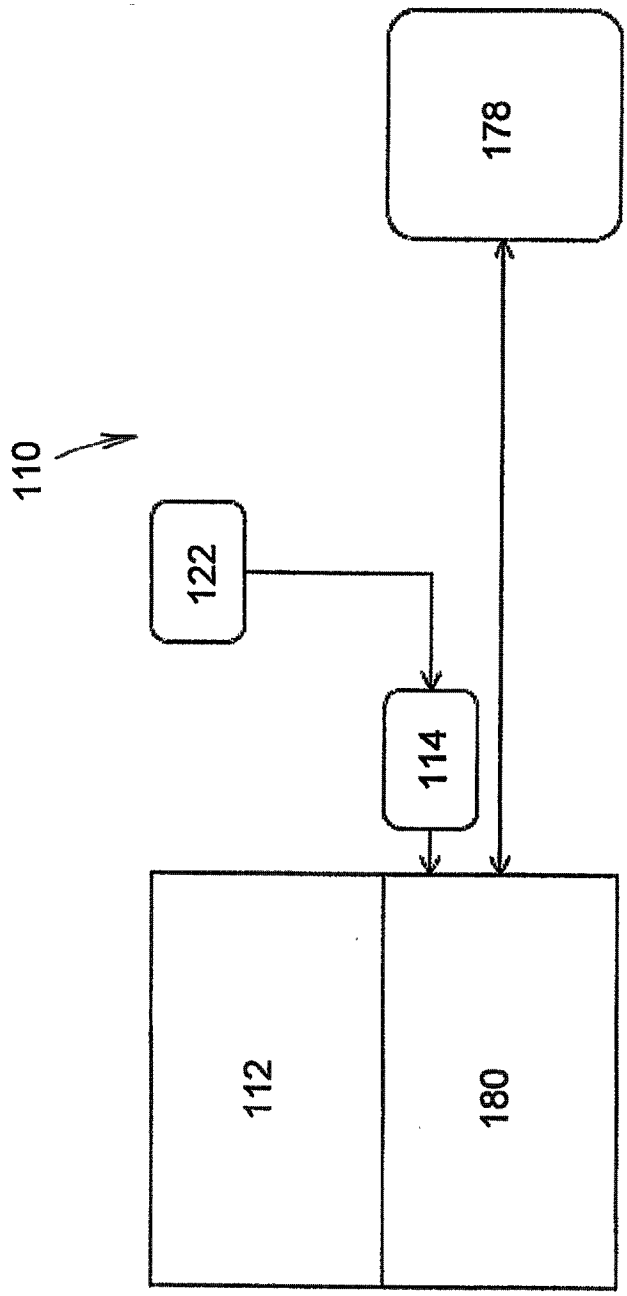


Fig. 1

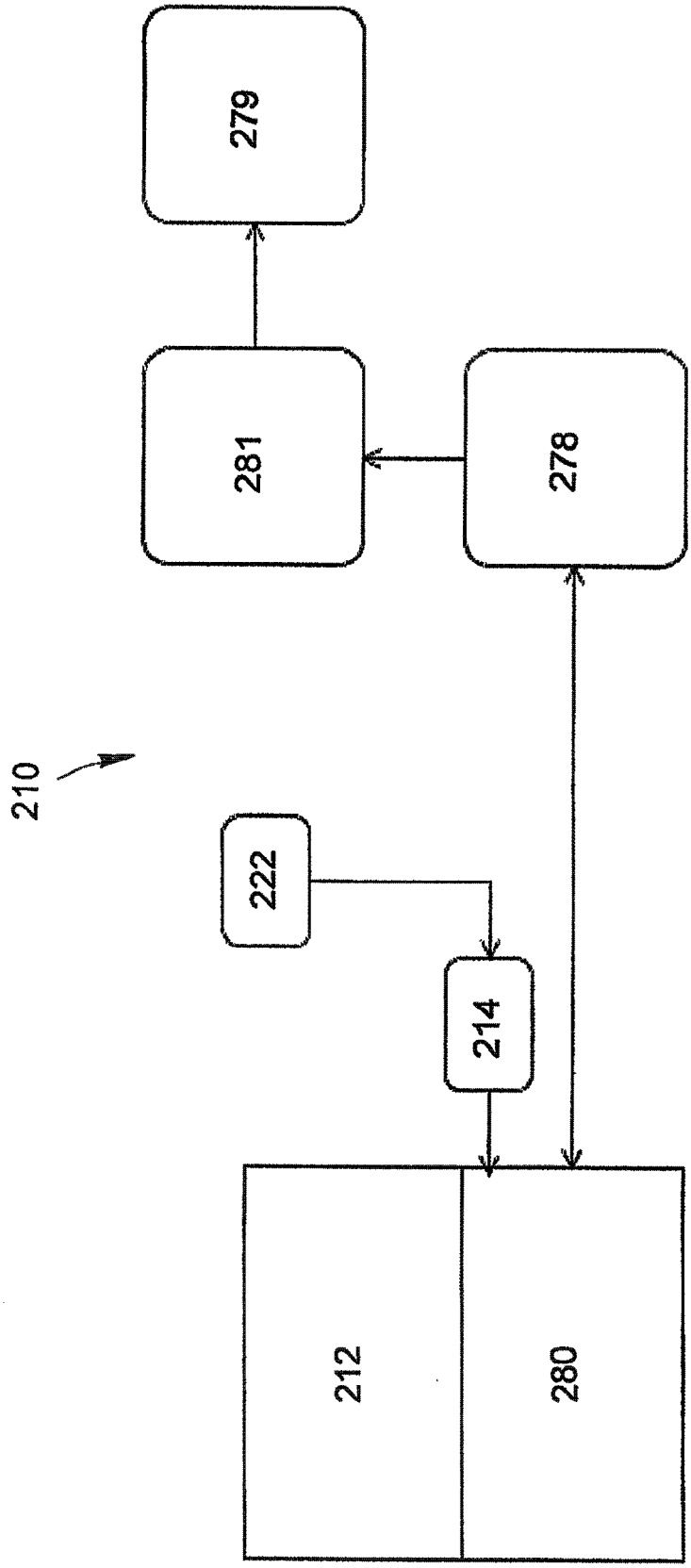


Fig. 2

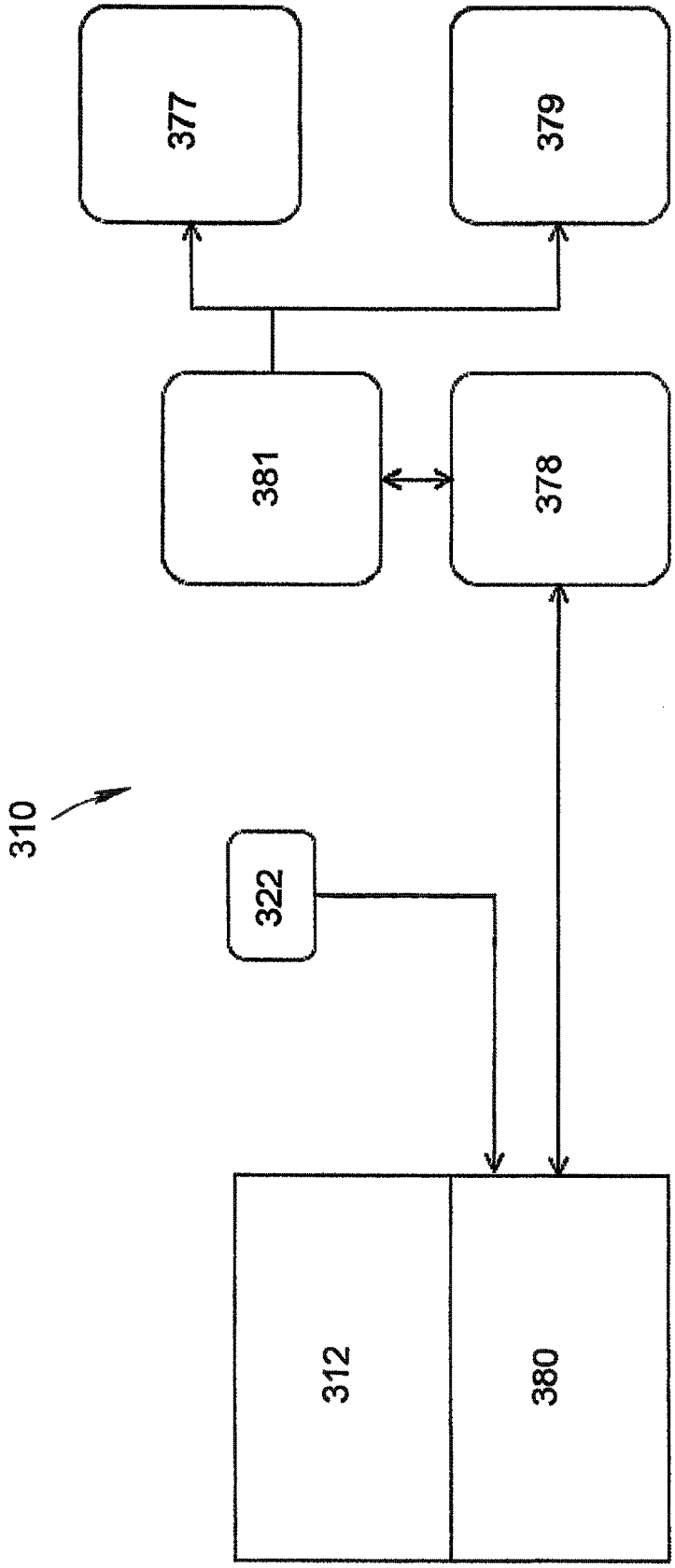


Fig. 3

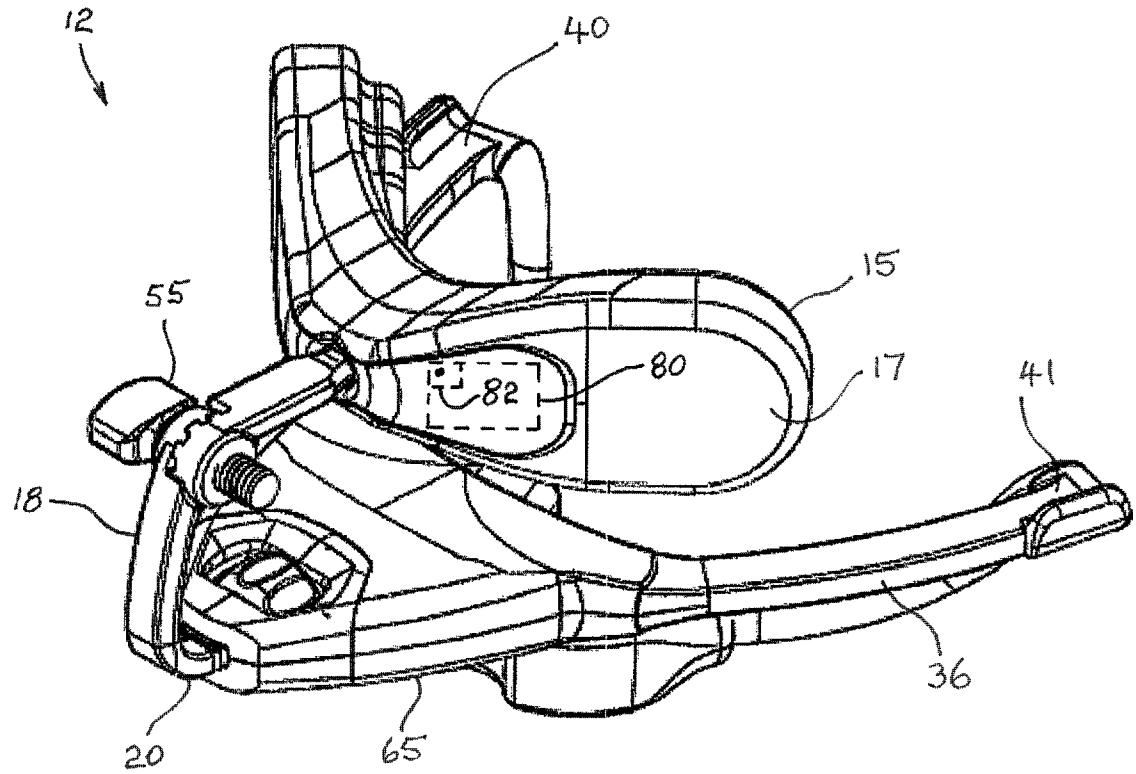


Fig. 4

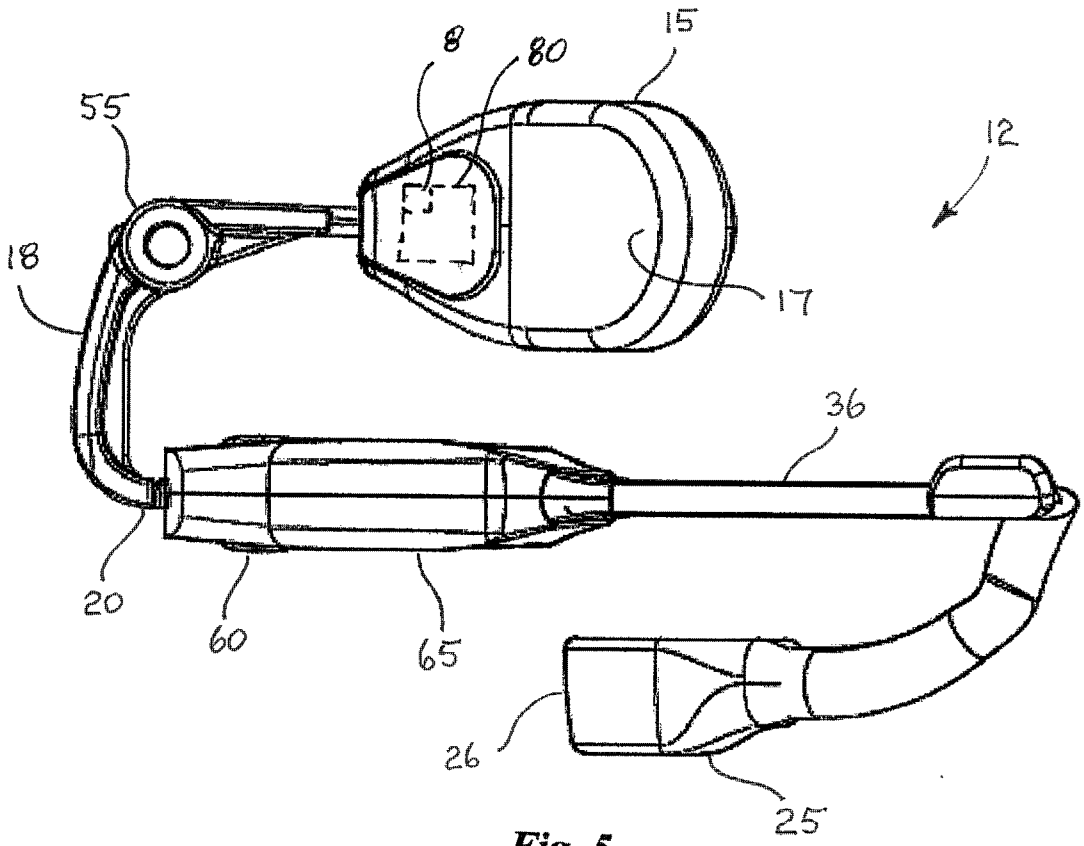


Fig. 5

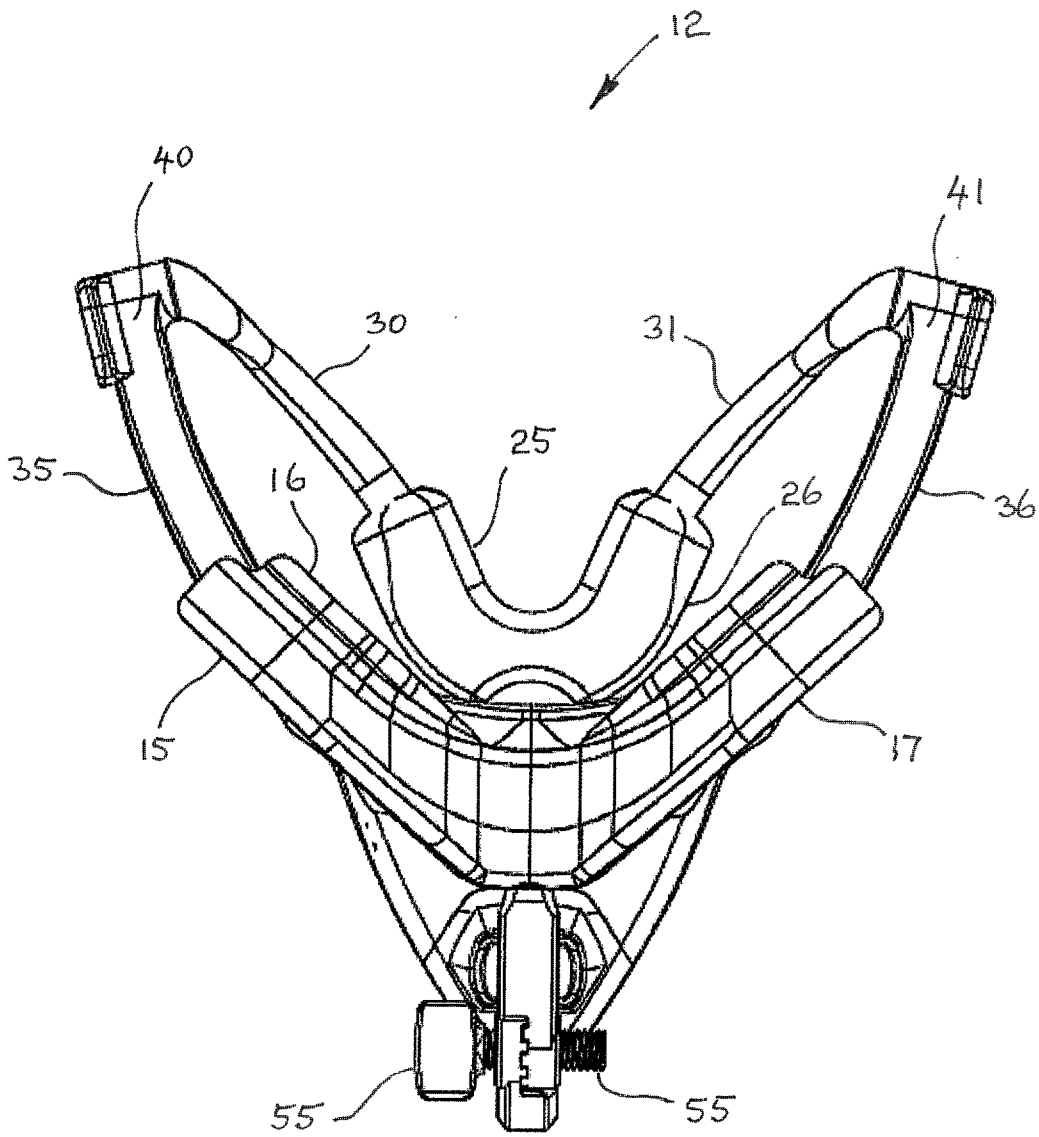


Fig. 6

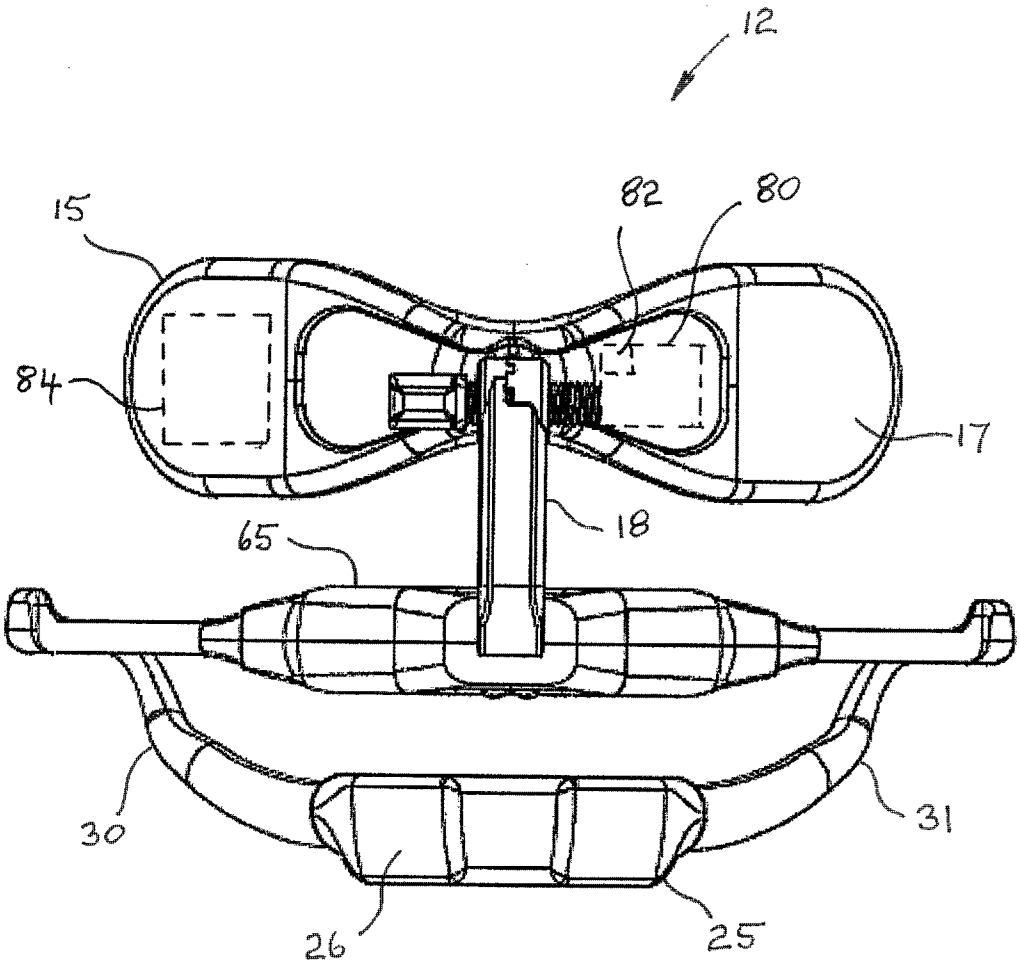


Fig. 7

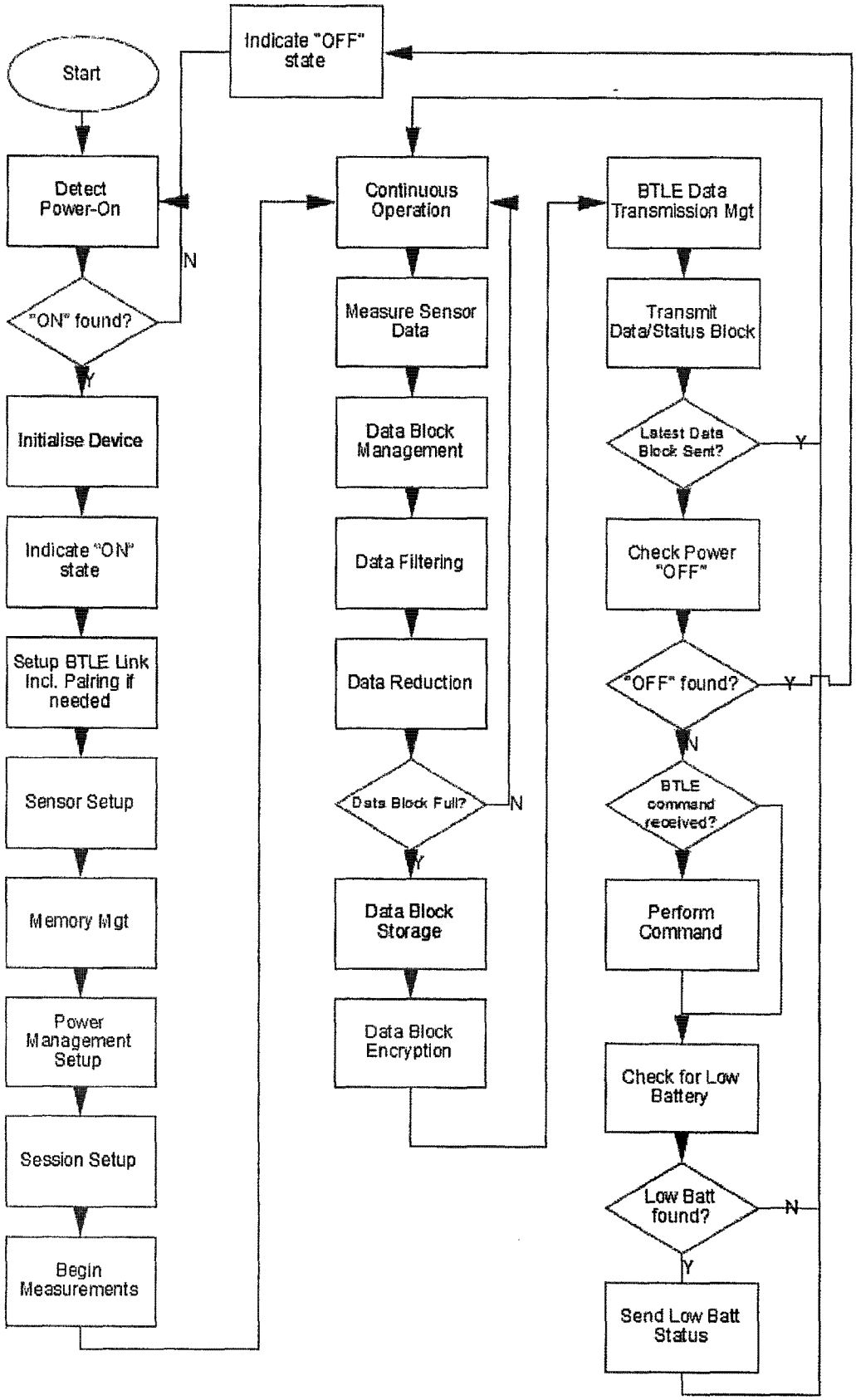

Start
Indicate "OFF" state
Detect Power-On
"ON" found?
N
Y
Initialise Device
Indicate "ON" state
Setup BTLE Link Incl. Pairing if needed
Sensor Setup
Memory Mgt
Power Management Setup
Session Setup
Begin Measurements
Continuous Operation
Measure Sensor Data
Data Block Management
Data Filtering
Data Reduction
Data Block Full?
N
Y
Data Block Storage
Data Block Encryption
BTLE Data Transmission Mgt
Transmit Data/Status Block
Latest Data Block Sent?
Y
Check Power "OFF"
"OFF" found?
Y
N
BTLE command received?
Perform Command
Check for Low Battery
Low Batt found?
N
Y
Send Low Batt Status

Fig. 8

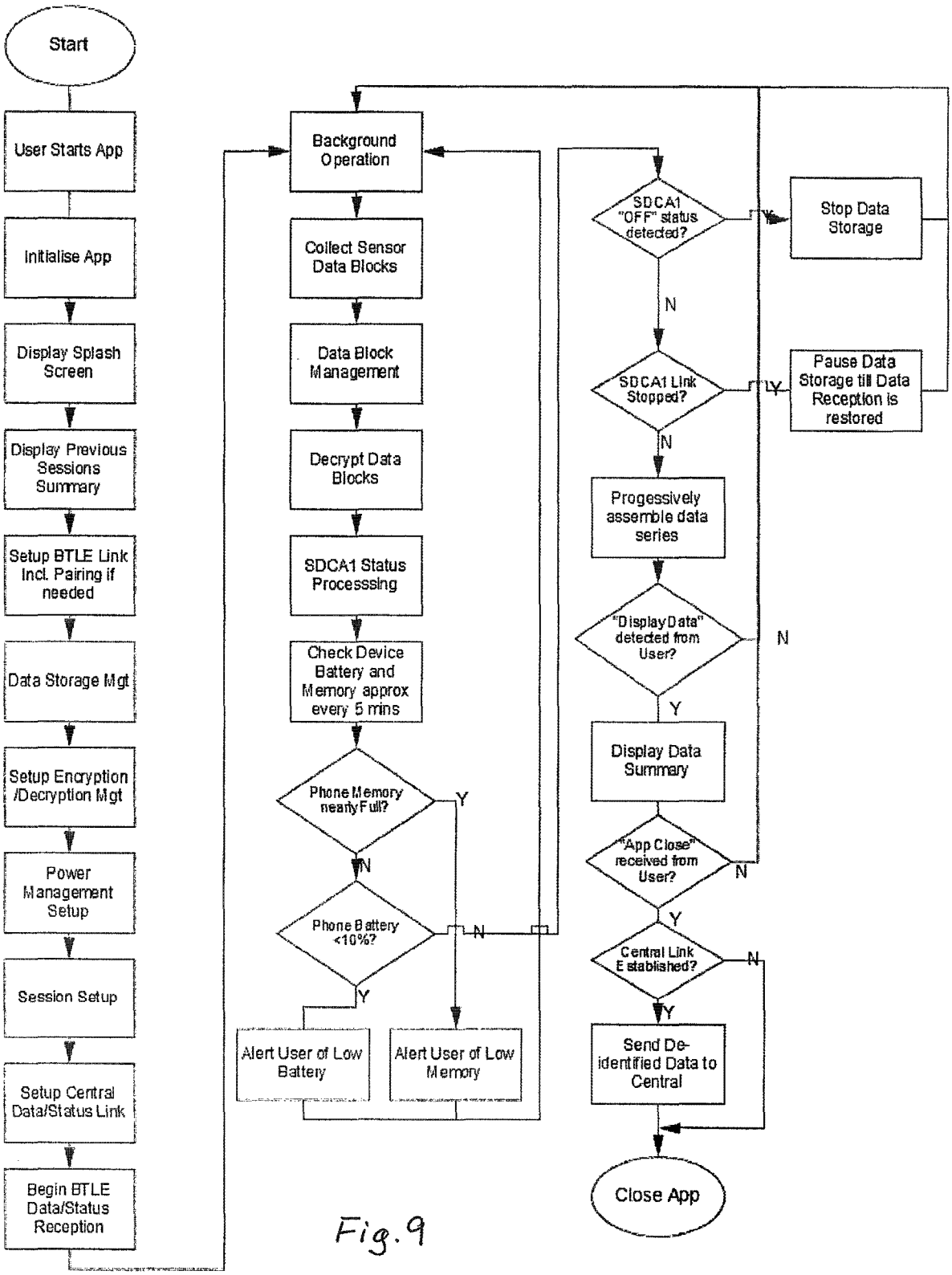

Start
User Starts App
Initialise App
Display Splash Screen
Display Previous Sessions Summary
Setup BTLE Link Incl. Pairing if needed
Data Storage Mgt
Setup Encryption /Decryption Mgt
Power Management Setup
Session Setup
Setup Central Data/Status Link
Begin BTLE Data/Status Reception
Background Operation
Collect Sensor Data Blocks
Data Block Management
Decrypt Data Blocks
SDCA1 Status Processsing
Check Device Battery and Memory approx every 5 mins
Phone Memory nearly Full?
Y
N
Phone Battery <10%?
N
Y
Alert User of Low Battery
Alert User of Low Memory
SDCA1 "OFF" status detected?
Y
Stop Data Storage
N
SDCA1 Link Stopped?
Y
Pause Data Storage till Data Reception is restored
N
Progessively assemble data series
"Display Data" detected from User?
N
Y
Display Data Summary
"App Close" received from User?
N
Y
Central Link Established?
N
Y
Send De-identified Data to Central
Close App

Fig. 9

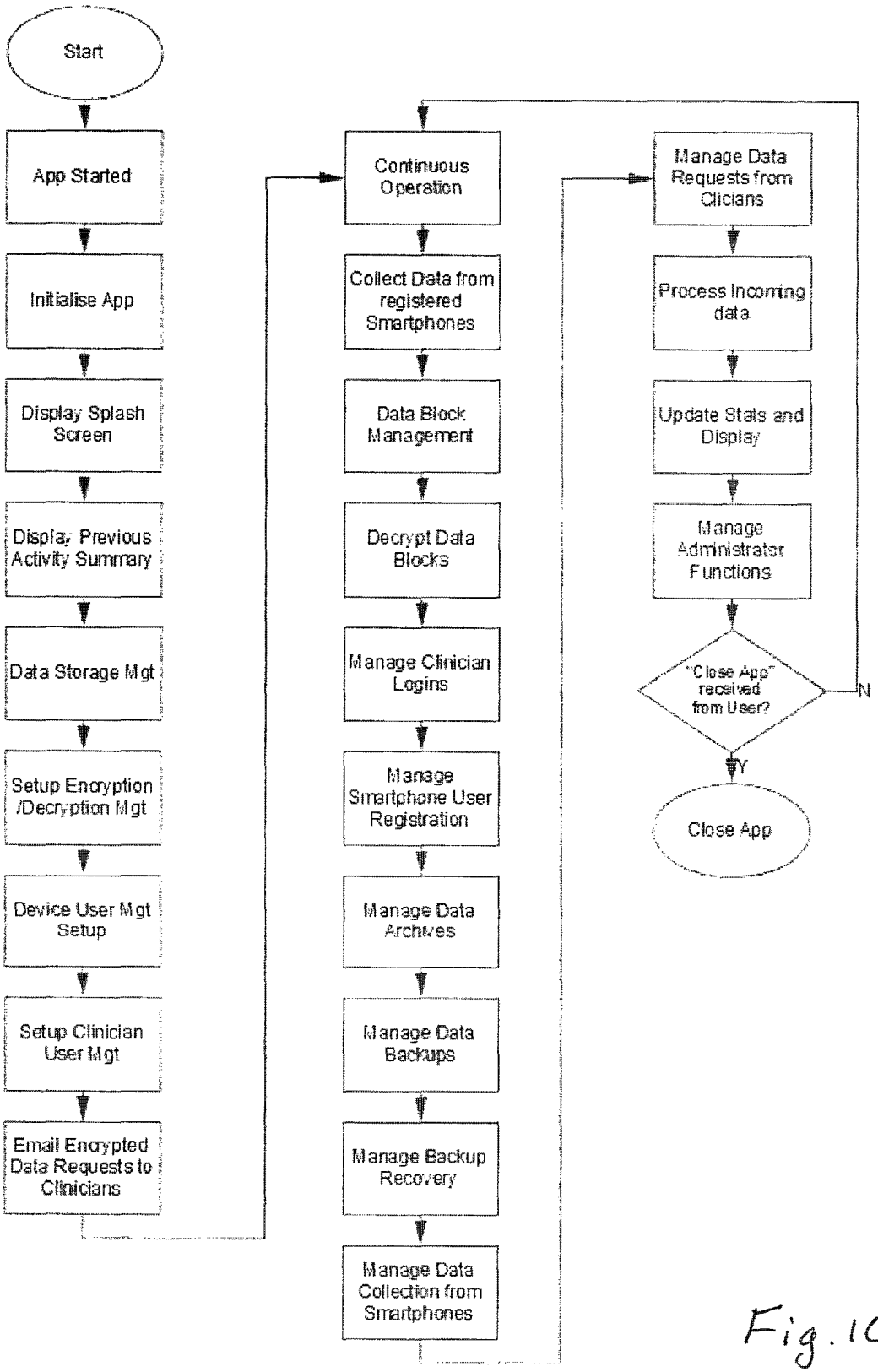

Start
App Started
Initialise App
Display Splash Screen
Display Previous Activity Summary
Data Storage Mgt
Setup Encryption /Decryption Mgt
Device User Mgt Setup
Setup Clinician User Mgt
Email Encrypted Data Requests to Clinicians
Continuous Operation
Collect Data from registered Smartphones
Data Block Management
Decrypt Data Blocks
Manage Clinician Logins
Manage Smartphone User Registration
Manage Data Archives
Manage Data Backups
Manage Backup Recovery
Manage Data Collection from Smartphones
Manage Data Requests from Clicians
Process Incoming data
Update Stats and Display
Manage Administrator Functions
"Close App" received from User?
N
Y
Close App

Fig. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2018/000197

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/00 (2006.01)

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)

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)

PATENW: IPC/CPC symbols: A61B5/4806, A61B5/0826, A61B5/002, A61B5/0022, A61B5/6812, A61B5/682, A61B5/6831, A61B5/6832, A61F5/566, A61B5/113, A61B2562/0219, A61B2562/0204, A61B5/087, A61B5/0476, A61B5/0488, A61B5/0496, A61B5/14551; keywords: smartphone, display, visual, see, show, mandibular advancement, sleep, monitor, mouth, oral, nose, nasal, wireless, strap, band, harness and like terms. Espacenet/Google Patents: sleep, monitor, wireless, position, smartphone and like terms. Applicant(s)/Inventor(s) name searched in internal databases provided by IP Australia and Espacenet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[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
24 December 2018	24 December 2018

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
Email address: pct@ipaustralia.gov.au

Authorised officer

Harish Ramachandran
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No. +61262832396

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2018/000197**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2014/0114165 A1 (DREAMSCAPE MEDICAL LLC) 24 April 2014 [0041], [0068]-[0078], [0087], claim 1, figs. 12-15	1-17
A	WO 2015/187949 A1 (GIRIDHARAGOPALAN) 10 December 2015 whole document	1-17
A	US 2017/0020391 A1 (JOHNSON & JOHNSON VISION CARE, INC.) 26 January 2017 whole document	1-17
P,X	WO 2017/218947 A1 (ALIGN TECHNOLOGY, INC.) 21 December 2017 [006], [0011], [0018], [0021], [00124], [00138], [00141], [00196], [00208], [00214], [00249], [00258], [00260], [00277], [00285], [00287], figs.1a, 15	1-5, 7-8, 11-17

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2018/000197**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
US 2014/0114165 A1	24 April 2014	US 2014114165 A1	24 Apr 2014
		EP 2911578 A2	02 Sep 2015
		JP 2015533580 A	26 Nov 2015
		JP 6387352 B2	05 Sep 2018
		US 2017020434 A1	26 Jan 2017
		WO 2014066666 A2	01 May 2014
WO 2015/187949 A1	10 December 2015	WO 2015187949 A1	10 Dec 2015
		EP 3151792 A1	12 Apr 2017
		US 2017196727 A1	13 Jul 2017
US 2017/0020391 A1	26 January 2017	US 2017020391 A1	26 Jan 2017
		AU 2016206322 A1	09 Feb 2017
		AU 2016206323 A1	09 Feb 2017
		AU 2016206324 A1	09 Feb 2017
		AU 2016206355 A1	09 Feb 2017
		AU 2016206356 A1	09 Feb 2017
		AU 2016206357 A1	09 Feb 2017
		AU 2016206358 A1	09 Feb 2017
		AU 2016206361 A1	09 Feb 2017
		AU 2016206363 A1	09 Feb 2017
		AU 2016206364 A1	09 Feb 2017
		BR 102016017043 A2	31 Jan 2017
		BR 102016017059 A2	31 Jan 2017
		BR 102016017066 A2	31 Jan 2017
		BR 102016017071 A2	31 Jan 2017
		BR 102016017073 A2	31 Jan 2017
		BR 102016017078 A2	31 Jan 2017
		BR 102016017091 A2	31 Jan 2017
		BR 102016017109 A2	31 Jan 2017
		BR 102016017114 A2	31 Jan 2017
		BR 102016017120 A2	31 Jan 2017
		CA 2936860 A1	24 Jan 2017
		CA 2936861 A1	24 Jan 2017
		CA 2936864 A1	24 Jan 2017
		CA 2936880 A1	24 Jan 2017
		CA 2936881 A1	24 Jan 2017

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2018/000197**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
		CA 2936882 A1	24 Jan 2017
		CA 2936889 A1	24 Jan 2017
		CA 2936890 A1	24 Jan 2017
		CA 2936891 A1	24 Jan 2017
		CA 2936892 A1	24 Jan 2017
		CN 106361271 A	01 Feb 2017
		CN 106361272 A	01 Feb 2017
		CN 106361273 A	01 Feb 2017
		CN 106361274 A	01 Feb 2017
		CN 106361275 A	01 Feb 2017
		CN 106361302 A	01 Feb 2017
		CN 106361355 A	01 Feb 2017
		CN 106372379 A	01 Feb 2017
		CN 106372380 A	01 Feb 2017
		CN 106375367 A	01 Feb 2017
		EP 3120754 A1	25 Jan 2017
		EP 3120755 A1	25 Jan 2017
		EP 3120756 A1	25 Jan 2017
		EP 3120757 A1	25 Jan 2017
		EP 3120758 A1	25 Jan 2017
		EP 3120759 A1	25 Jan 2017
		EP 3120760 A1	25 Jan 2017
		EP 3120761 A1	25 Jan 2017
		EP 3130281 A2	15 Feb 2017
		EP 3130282 A2	15 Feb 2017
		HK 1232098 A1	05 Jan 2018
		HK 1232099 A1	05 Jan 2018
		HK 1232100 A1	05 Jan 2018
		HK 1232101 A1	05 Jan 2018
		HK 1232102 A1	05 Jan 2018
		HK 1232103 A1	05 Jan 2018
		HK 1232104 A1	05 Jan 2018
		HK 1232105 A1	05 Jan 2018
		JP 2017023747 A	02 Feb 2017
		JP 2017023748 A	02 Feb 2017
		JP 2017023749 A	02 Feb 2017

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2018/000197**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
		JP 2017023750 A	02 Feb 2017
		JP 2017023751 A	02 Feb 2017
		JP 2017027603 A	02 Feb 2017
		JP 2017029715 A	09 Feb 2017
		JP 2017029716 A	09 Feb 2017
		JP 2017035466 A	16 Feb 2017
		JP 2017042601 A	02 Mar 2017
		KR 20170012155 A	02 Feb 2017
		KR 20170012156 A	02 Feb 2017
		KR 20170012157 A	02 Feb 2017
		KR 20170012158 A	02 Feb 2017
		KR 20170012159 A	02 Feb 2017
		KR 20170012160 A	02 Feb 2017
		KR 20170012162 A	02 Feb 2017
		KR 20170012163 A	02 Feb 2017
		KR 20170012165 A	02 Feb 2017
		KR 20170012166 A	02 Feb 2017
		RU 2016130073 A	25 Jan 2018
		RU 2016130076 A	26 Jan 2018
		RU 2016130077 A	26 Jan 2018
		RU 2016130079 A	26 Jan 2018
		RU 2016130081 A	25 Jan 2018
		RU 2016130082 A	25 Jan 2018
		RU 2016130083 A	25 Jan 2018
		RU 2016130084 A	26 Jan 2018
		RU 2016130086 A	25 Jan 2018
		RU 2016130088 A	25 Jan 2018
		SG 10201606062Y A	27 Feb 2017
		SG 10201606064Q A	27 Feb 2017
		SG 10201606067X A	27 Feb 2017
		SG 10201606069S A	27 Feb 2017
		SG 10201606072U A	27 Feb 2017
		SG 10201606073P A	27 Feb 2017
		SG 10201606074Y A	27 Feb 2017
		SG 10201606076S A	27 Feb 2017
		SG 10201606079V A	27 Feb 2017

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2018/000197**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
		SG 10201606081V A	27 Feb 2017
		TW 201717844 A	01 Jun 2017
		TW 201717851 A	01 Jun 2017
		TW 201717852 A	01 Jun 2017
		TW 201719466 A	01 Jun 2017
		TW 201719467 A	01 Jun 2017
		TW 201719479 A	01 Jun 2017
		TW 201719587 A	01 Jun 2017
		TW 201719588 A	01 Jun 2017
		TW 201720204 A	01 Jun 2017
		TW 201726049 A	01 Aug 2017
		US 2017020390 A1	26 Jan 2017
		US 2017020431 A1	26 Jan 2017
		US 2017020440 A1	26 Jan 2017
		US 2017020441 A1	26 Jan 2017
		US 2017020442 A1	26 Jan 2017
		US 2017024530 A1	26 Jan 2017
		US 2017024555 A1	26 Jan 2017
		US 2017024771 A1	26 Jan 2017
		US 2017026790 A1	26 Jan 2017
		US 2017119287 A1	04 May 2017
		WO 2018130938 A1	19 Jul 2018
WO 2017/218947 A1	21 December 2017	WO 2017218947 A1	21 Dec 2017
		CN 107518952 A	29 Dec 2017
		US 2018000563 A1	04 Jan 2018

End of Annex

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.