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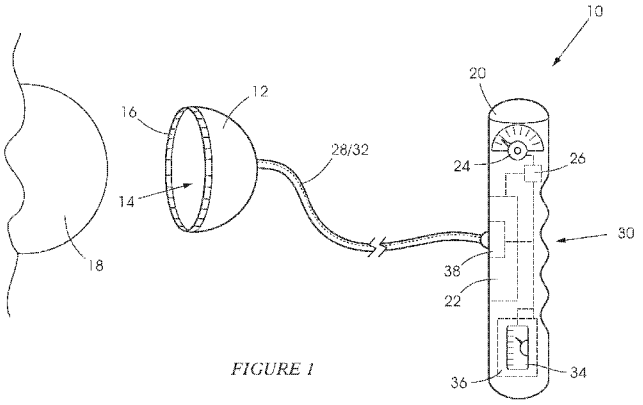

FIGURE 1

(57) Abstract: Provided is an obstetrical vacuum apparatus (10) comprising a fetal vacuum cup (12) and a housing (20) which is ergonomically sized, shaped and dimensioned for one-handed handheld operation. The housing (20) includes a negative pressure generator (22) configured to operatively generate a negative pressure or vacuum within the chamber (14), as well as a user input (24) via which a user is able to select a negative pressure value. Housing (20) also includes a controller (26) which is configured to control the generator (22) to automatically maintain the selected negative pressure value within said chamber (14). A flexible tube (28) arranges the chamber (14) in fluid communication with the negative pressure generator, with the tube (28) comprising a pulling member (32) for providing mechanical strength whilst allowing tube flexibility. The controller (26) automatically accommodates any operating pressure variations within the chamber (14) and the ergonomic housing (20) allows a user to interact with the user input and apply traction to the fetal head with a single hand.

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OBSTETRICAL VACUUM APPARATUS

TECHNICAL FIELD

[0001] This invention relates to an obstetrical vacuum apparatus for operative releasable attachment to a fetal head, and an associated obstetrical method for applying traction to a fetal head.

BACKGROUND ART

[0002] The following discussion of the background art is intended to facilitate an understanding of the present invention only. The discussion is not an acknowledgement or admission that any of the material referred to is or was part of the common general knowledge as at the priority date of the application.

[0003] The present invention lies in the field of obstetrics, in general. Currently, there are two major methods for delivering a fetus, namely the Caesarean section delivery and the vaginal delivery.

[0004] In Caesarean section deliveries, the fetus is delivered through an incision made in the uterus and a corresponding incision made in the abdomen. An upward pulling force is required in order to pull the fetus through the incisions and out of the mother. Often the force is provided by the doctor's hands directly pulling the fetus through the abdominal incision.

[0005] In vaginal deliveries, the fetus is delivered through the vaginal passage after the cervix has fully dilated and effaced.

[0006] Passing the fetus through the vaginal passage requires that the vaginal muscles be forced to stretch as the fetal head is generally much larger than the vaginal passage under normal circumstances. Some stretching force is applied to the vaginal tissues by the mother herself. The involuntary contractions of the uterus during labour push the fetus (typically the fetal head) into the vaginal passage to stretch the vaginal tissues. The stretching force of these involuntary uterine contractions is combined with the stretching force caused by voluntary contractions of the mother's abdominal muscles as the mother tries to push the fetus out of the uterus.

[0007] Often the forces described above are not strong enough or are not medically advisable to use in extracting the fetus. Supplementary force may be applied with a fetal vacuum extractor, for example, in conditions of dystocia (i.e., slow or difficult labour or delivery), uterine inertia, maternal exhaustion, maternal distress, or fetal distress .

[0008] In a conventional fetal vacuum extractor, a vacuum cup is sealed over a portion of the fetal head (e.g., the occiput) . A flexible tube connects the vacuum cup to a vacuum pump operated by a secondary operator such as a nurse. The vacuum pump allows the nurse to provide a vacuum within the vacuum cup thereby creating suction between the fetal head and the vacuum cup. As long as a sufficient vacuum is

maintained, the primary operator, such as a doctor, may pull on the vacuum cup handle thereby applying traction (i.e., a pulling, delivering force) to the fetal head.

[0009] Bodily fluids on the fetal head generally assist in making a seal between the fetal head and the vacuum cup to define a vacuum chamber. However, a vacuum so established is sometimes compromised by an imperfect seal between the fetal head and the vacuum cup. In order to minimise the chances of fetal injury, the vacuum can be intentionally lowered between contractions or when the vacuum is determined to be too strong. Therefore, the vacuum must be constantly monitored and adjusted, and must have a feature to release or lower the vacuum when necessary.

[0010] U.S. Pat. No. 6,074,399 describes an obstetric vacuum extractor comprising a suction cup, handle and a manually manoeuvred vacuum pump, which parts are delivered as one unit. This prior art vacuum extractor requires a specially configured hand pump, which leads to complicating the manufacturing process. The manufacture is further expensive, in particular when the suction device is made as a disposable item, leading to an expensive product when bought. In addition, if the seal is broken, the operator has to manually pump the device to return to the desired vacuum pressure; the pumping procedure often consumes the precious few seconds the operator has to apply traction to deliver the baby before the contraction subsides. Due to this shortcoming, a number of obstetricians opined this invention as not the most effective instrument for vacuum delivery.

[0011] Chinese Pat. No. 103860241A describes another obstetric vacuum extractor or negative pressure fetal head aspirator which is formed by connecting a silicon fetal head suction cover with a negative pressure hollow handle 2 into which a miniature direct current negative pressure pump 3 is located, along with a miniature digital negative pressure display meter 4 and a switch 5 are built. The device also includes a fine-tuning adjustor 6 by which the pump is controllable to maintain the desired pressure. Due to the design of the positions of the silicon fetal head cup and the body of the pump, the device is not appropriate for effective usage in most cases. For an effective assisted vacuum delivery, the cup has to be manoeuvrable so that it can be fitted into the tight contour of the vagina, and typically positioned at the flexion point of the fetal head. During deliveries, it is not uncommon for fetuses to face in a variety of different directions in different cases, thus an improved design is needed to enable the device to be used for effective assisted delivery of the fetuses in all cases.

[0012] As such, the Applicants have identified a shortcoming in the art for an improved obstetrical vacuum apparatus that is safe, and provides improved mobility and handling whilst being able to provide the constant and controlled negative pressure needed. A further requirement is for apparatus that may assist in mitigating complications arising from an imperfect seal with a fetal head.

[0013] As a result, the present invention seeks to propose a solution, at least in part, in amelioration of some of the shortcomings in the art.

SUMMARY OF THE INVENTION

[0014] According to a first aspect of the invention there is provided an obstetrical vacuum apparatus comprising:

a fetal vacuum cup defining at least one chamber in which a negative pressure or vacuum enables operative attachment of the cup to a fetal head;

a housing having a negative pressure generator configured to operatively generate such negative pressure or vacuum within the chamber, a user input via which a user is able to select a negative pressure value, and a controller configured to control the generator to automatically maintain the selected negative pressure value within said chamber; and

a flexible tube arranging said chamber in fluid communication with the negative pressure generator, wherein the controller automatically accommodates any operating pressure variations within the chamber, said apparatus enabling a user to apply traction to the fetal head.

[0015] It is to be appreciated that the operating pressure variations may result from a variety of external aspects, such as an imperfect seal between the vacuum cup and the fetal head, fluid leaks developing as a result of movement of the fetal head, or the like.

[0016] Preferably, the housing may be sized, shaped and dimensioned for handheld operation.

[0017] Typically, the flexible tube may have an outside diameter in the range of 5mm to 200mm.

[0018] Preferably, the flexible tube may have an outside diameter in the range of 10mm to 30mm.

[0019] Typically, the housing may define a handle which is ergonomically sized, shaped and dimensioned to facilitate hand-held operation of the apparatus.

[0020] In one example, the flexible tube may comprise a pulling member. Typically, the pulling member may comprise a cable threaded through the tube for providing mechanical strength whilst allowing tube flexibility.

[0021] Alternatively, the pulling member may comprise walls of the flexible tube having a wire or nylon braided weave for providing mechanical strength whilst allowing tube flexibility .

[0022] In an alternate example, the apparatus may comprise a separate pulling member fast at one end to the vacuum cup and a handle defined at the other end of said pulling member for operatively applying traction to the vacuum cup .

[0023] Typically, the apparatus may comprise a traction force indicator configured to indicate a value of traction applied to the pulling member. In one example, the traction force indicator may include a strain gauge.

[0024] Typically, the housing may include energising means for providing the negative pressure generator with operating energy.

[0025] In one example, the energising means may comprise a plurality of electrochemical cells for supplying electrical energy. Preferably, the electrochemical cells may be configured to be rechargeable.

[0026] In one example, the apparatus may include a negative pressure or vacuum release valve configured to release or minimise a vacuum or negative pressure within the vacuum cup chamber.

[0027] Typically, the negative pressure or vacuum release valve may be controlled by the controller.

[0028] In one example, the negative pressure generator may comprise an electromechanical pump configured to extract fluid from the chamber in the vacuum cup.

[0029] In one example, the controller may be configured to control the generator to automatically maintain the selected negative pressure value within said chamber by increasing a negative pressure generation capability of the generator to accommodate an unwanted negative pressure decrease within the chamber.

[0030] Similarly, the controller may be configured to control the generator to automatically maintain the selected negative pressure value within said chamber by decreasing a negative pressure generation capability of the generator to accommodate an unwanted negative pressure increase within the chamber.

[0031] In one example, the controller may be configured to activate the release valve to accommodate an unwanted negative pressure increase within the chamber.

[0032] According to a second aspect of the invention there is provided an obstetrical method for applying traction to a fetal head, said method comprising the steps of:

placing a fetal vacuum cup defining at least one chamber in which a negative pressure or vacuum enables operative attachment of the cup to the fetal head;

providing a housing having a negative pressure generator configured to operatively generate such negative pressure or vacuum within the chamber, a user input via which a user is able to select a negative pressure value, and a controller configured to control the generator to automatically maintain the selected negative pressure value within said chamber, as well as a flexible tube arranging said chamber in fluid communication with the negative pressure generator;

selecting a desired negative pressure value via the user input so that the controller controls the negative pressure generator to generate such a desired negative pressure within the chamber to attach the vacuum cup; and

applying traction as required to the fetal head, wherein the controller automatically accommodates any operating pressure variations within the chamber.

[0033] According to a third aspect of the invention there is provided an obstetrical method for applying traction to a fetal head, said method comprising the steps of:

providing apparatus in accordance with the first aspect of the invention;

attaching a vacuum cup of said apparatus to the fetal head; and

applying traction to the fetal head via said apparatus.

[0034] According to a fourth aspect of the invention there is provided an obstetrical vacuum apparatus comprising :

a fetal vacuum cup defining at least one chamber in which a negative pressure or vacuum enables operative attachment of the cup to a fetal head;

a housing ergonomically sized, shaped and dimensioned for one-handed handheld operation, said housing having:

(i) a negative pressure generator configured to operatively generate such negative pressure or vacuum within the chamber;

(ii) a user input via which a user is able to select a negative pressure value; and

(iii) a controller configured to control the generator to automatically maintain the selected negative pressure value within said chamber; and

a flexible tube arranging said chamber in fluid communication with the negative pressure generator, the tube comprising a pulling member providing mechanical strength whilst allowing tube flexibility;

wherein the controller automatically accommodates any operating pressure variations within the chamber and the ergonomic housing allows a user to interact with the user input and apply traction to the fetal head with a single hand .

[0035] Typically, the housing is sized, shaped and dimensioned to be easily man-portable to be easily handled, held and operated with one hand.

[0036] Preferably, the housing includes releasable attachment means configured to operatively releasably attach the housing to a leg of a patient.

[0037] Typically, the releasable attachment means is selected from a group consisting of an adhesive pad, a strap, and hook-and-loop attachment pads.

[0038] Typically, the housing defines a handle which is ergonomically sized, shaped and dimensioned to facilitate single hand-held operation of the apparatus.

[0039] Typically, the pulling member comprises a cable threaded through the tube for providing mechanical strength whilst allowing tube flexibility.

[0040] Alternatively, the pulling member comprises walls of the flexible tube having a wire or nylon braided weave for providing mechanical strength whilst allowing tube flexibility .

[0041] Alternatively, the apparatus comprises a separate pulling member fast at one end to the vacuum cup and a handle defined at the other end of said pulling member for operatively applying traction to the vacuum cup.

[0042] Typically, the apparatus comprise a traction force indicator configured to indicate a value of traction applied by the pulling member. In one example, the traction force indicator includes a strain gauge.

[0043] Typically, the housing may include energising means for providing the negative pressure generator with operating energy.

[0044] Typically, the energising means may comprise a plurality of electrochemical cells for supplying electrical energy. Preferably, the electrochemical cells may be configured to be rechargeable.

[0045] Typically, the apparatus may include a negative pressure or vacuum release valve configured to release or minimise a vacuum or negative pressure within the vacuum cup chamber .

[0046] Typically, the negative pressure or vacuum release valve may be controlled by the controller.

[0047] Typically, the negative pressure generator may comprise an electromechanical pump configured to extract fluid from the chamber in the vacuum cup.

[0048] Typically, the controller may be configured to control the generator to automatically maintain the selected negative pressure value within said chamber by increasing a negative pressure generation capability of the generator to accommodate an unwanted negative pressure decrease within the chamber.

[0049] Typically, the controller may be configured to control the generator to automatically maintain the selected negative pressure value within said chamber by decreasing a negative pressure generation capability of the generator to accommodate an unwanted negative pressure increase within the chamber.

[0050] Typically, the controller may be configured to activate the release valve to accommodate an unwanted negative pressure increase within the chamber.

[0051] Typically, the flexible tube may have an outside diameter in the range of 5mm to 200mm.

[0052] Preferably, the flexible tube may have an outside diameter in the range of 10mm to 30mm.

[0053] According to a fifth aspect of the invention, there is provided an obstetrical method for applying traction to a fetal head, said method comprising the steps of:

providing apparatus in accordance with the fourth aspect of the invention;

attaching a vacuum cup of said apparatus to the fetal head; and

applying traction to the fetal head via said apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

[0054] Further features of the present invention are more fully described in the following description of several non-limiting embodiments thereof. This description is included solely for the purposes of exemplifying the present invention. It should not be understood as a restriction on the broad summary, disclosure or description of the invention as set out above. The description will be made with reference to the accompanying drawings in which:

Figure 1 is a diagrammatic representation of an example of an obstetrical vacuum apparatus in accordance with an aspect of the invention;

Figure 2 is a diagrammatic representation of a further example of an obstetrical vacuum apparatus; and

Figure 3 is diagrammatic representation of a yet further example of an obstetrical vacuum apparatus.

DETAILED DESCRIPTION OF EMBODIMENTS

[0055] The following modes, given by way of example only, are described in order to provide a more precise understanding of the subject matter of a preferred embodiment or embodiments.

[0056] In the figures, incorporated to illustrate features of an example embodiment, like reference numerals are used to identify like parts throughout the figures.

[0057] With reference now to Figure 1 of the drawings, there is shown an example of an obstetrical vacuum apparatus 10. As discussed in the background above, the apparatus 10 is typically used in the delivery of a fetus, as is well known in the art. In the exemplified modes, a portion of a fetal head is indicated by reference numeral 18.

[0058] Accordingly, the apparatus 10 generally includes a fetal vacuum cup 12 that defines at least one chamber 14, as shown. The vacuum cup 12 also typically includes a seal 16 for assisting in establishing a fluid-tight seal between the

chamber 14 of the cup 12 and the fetal head 18. Such a seal 16 is typically of a soft material, such as silicone, rubber, a polymer material, or the like. It is to be appreciated that a negative pressure or vacuum created, made or established within the chamber 14 generally enables operative attachment of the cup 12 to the fetal head 18.

[0059] The apparatus 10 also includes a housing 20 which, in a preferred embodiment, generally has a negative pressure generator 22, a user input 24, a controller 26, a traction force indicator 34, energising means 36, and a release valve 38, as shown.

[0060] The apparatus 10 further comprises a flexible tube 28 which connects, links or arranges the vacuum cup's chamber 14 in fluid communication with the negative pressure generator 22.

[0061] As such, the negative pressure generator 22 is configured to operatively generate a negative pressure or vacuum within the chamber 14 of the cup 12. The negative pressure generator 22 typically generates a vacuum by extracting fluid, such as air, from the chamber 14 in the vacuum cup 12. Such a generator 22 may include an electro-mechanical motor or pump, as is generally known in the art. It is, however, to be appreciated that the generator 22 is preferably a small, high-powered device, as the apparatus 10 is ideally configured for mobile, hand-held operation.

[0062] The user input 24 enables a user to select a specific or desired negative pressure value and also typically enables activation or deactivation of the apparatus 10, i.e. an on/off switch. For example, depending

on obstetrical requirements, one particular negative pressure value may be appropriate under certain circumstances, with another value more appropriate under different circumstances.

[0063] A size or position of the fetal head 18 may, for example, require a specific negative pressure value, e.g. a smaller fetal head may benefit from a smaller negative pressure value, whereas a larger fetal head may require a larger negative pressure value. Similarly, a required traction force exertable via the apparatus is typically directly proportional to the selected negative pressure value. Such obstetrical practices are generally known in the art and will not be described in any particular detail herein .

[0064] In one example, the user input 24 may comprise a plurality of buttons or similar selection means, e.g. fine-tuning buttons and buttons denoting set pressure values commonly used in practice. For example, such set pressure values (with associated buttons) may include one button at 0.2kg/cm2 and one at 0.8kg/cm2. The user input 24 may also include a pressure release button, activation of which deactivates the generator 22, and/or activates a vacuum release valve 38 (described in more detail below) . The skilled addressee will appreciate that other configurations for the user input 24 may be possible, i.e. a dial, a knob, buttons, wireless selection, touchscreen input, audio input, etc .

[0065] The controller 26 is generally configured to receive such user input and to subsequently control the generator 22 in order to automatically maintain the selected

negative pressure value within the chamber 14 of the cup 12. In such a manner, the controller 26 is able to automatically accommodate any operating pressure variations within the chamber 14, whereby the apparatus 10 enables a user to apply a traction force to the fetal head 18 without having to constantly monitor and control the generated negative pressure .

[0066] It is to be appreciated that any such operating pressure variations may result from a variety of external aspects, such as an imperfect seal between the vacuum cup 12 and the fetal head 18, fluid leaks developing as a result of movement of the fetal head 18, and/or the like. It is not uncommon for the cup 12 to have an adequate seal on the fetal head 18 at one point or stage of the delivery process, only to later develop an imperfect seal during the process of delivery as traction is applied via the cup 12 to the fetal head 18.

[0067] In a preferred embodiment, the housing 20 is typically sized, shaped and dimensioned for handheld or mobile, hand-portable operation. As a result the housing 20 is configured to fit into a user's hand in an ergonomic manner, whereby the user can control the apparatus's operation, i.e. use the user input 24, as well as apply traction to the fetal head 18, all with a single hand.

[0068] In one embodiment, the housing itself 20 comprises a handle 30, as shown in Figure 1. In an alternative embodiment, as shown in Figure 2, the housing 20 defines a separate handle portion 30 which is ergonomically sized, shaped and dimensioned to facilitate hand-held operation of

the apparatus. Such differences in the housing 20 and handle 30 configurations are merely design dependent to provide different options.

[0069] The housing 20 also typically includes energising means 36 for providing the negative pressure generator 22 with operating energy. In one example, the energising means 36 may comprise a plurality of electrochemical cells for supplying electrical energy, i.e. a battery. Preferably, these electrochemical cells may be configured to be rechargeable; however this is not a limiting requirement. In an alternative embodiment, the energising means 36 may also comprise a mains-power inlet with a step-down transformer, or the like. It is to be appreciated that numerous variations of the energising means 36 are possible and will be understood by the skilled addressee.

[0070] In a preferred example, the apparatus 10 generally includes a negative pressure or vacuum release valve 38 which is configured to release, minimise or reduce a vacuum or negative pressure within the vacuum cup's chamber 14. Accordingly, such a negative pressure or vacuum release valve 38 is typically controlled by the controller 26 and/or the user. As such, the user input 24 may also be configured to control the vacuum release valve 38, e.g. so that when the apparatus is deactivated, the valve 38 is activated to release the cup 12 from the fetal head 18.

[0071] Generally, when in use, the controller 26 is configured to control the generator 22 to automatically maintain the selected negative pressure value within the chamber 14 by increasing a negative pressure generation

capability of the generator 22 in order to accommodate an unwanted negative pressure decrease within the chamber 14.

[0072] Similarly, the controller 26 is typically configured to control the generator 22 to automatically maintain the selected negative pressure value within the chamber 14 by decreasing a negative pressure generation capability of the generator 22 to accommodate an unwanted negative pressure increase within the chamber 14. Alternatively, or in addition, the controller 26 may also be configured to activate the release valve 38 to accommodate an unwanted negative pressure increase within the chamber 14.

[0073] As mentioned above, the flexible tube 28 links the housing to the cup 12. This is generally in order to arrange the generator 22 in fluid combination with the chamber 14, as well as to provide a means whereby a traction force can be applied to the cup 12 by the handle 30. However, other embodiments are possible, as will be described below.

[0074] Typically, the tube 28 has a small average outside diameter compared with conventional fetal vacuum tubes. For example, the flexible tube 28 may have an outside diameter in the range of 5mm to 200mm. Preferably the flexible tube 28 has an outside diameter in the range of 10mm to 30mm, although these ranges are to be considered non-limiting.

[0075] In one example, traction is applied to the fetal head 18 by pulling on the housing 20 which comprises a handle 30, or on a handle 30 defined on the housing 20 (Figure 2). In a further embodiment, as shown in Figure 3, the apparatus 10 may have a separate pulling member 32 fast

at one end to the vacuum cup 12 and a handle 30 defined at the other end of said pulling member 32 for operatively applying traction to the vacuum cup 12.

[0076] It is to be appreciated that the flexible tube 28 does not have to enter the cup 12 at the centre thereof, as shown. The tube 28 may enter the cup 12 anywhere practicable, dependent on design requirements. However, the pulling member 32 generally attaches to the cup 12 so that an even traction force can be applied to said cup 12, when in use, i.e. typically at the centre thereof, or the like.

[0077] In one example, the flexible tube 28 may comprise the pulling member 32. Typically, the pulling member 32 is a cable threaded through the tube 28 for providing mechanical strength whilst allowing tube flexibility. Alternatively, the pulling member 32 may comprise walls of the flexible tube 28 having a wire or nylon braided weave (not shown) for providing mechanical strength whilst allowing tube flexibility. As such, in one embodiment, a traction force may be primarily applied through the pulling member 32 (e.g., a cable) threaded through the tube 28 for preventing irreversible strain of the tube.

[0078] Typically, the apparatus 10 further comprises a traction force indicator 34 which is configured to indicate a value of a traction force applied to the pulling member 32. In one example, the traction force indicator may include a strain gauge, or the like. Such a traction force indicator 34 is helpful to a user of the device to determine how much traction force is applied to the fetal head 18. In one example, the controller 26 is configured to deactivate the

generator 22 and/or activate the release valve 38 when a predetermined traction force is reached, i.e. to avoid harm to the fetus, or the like.

[0079] In a further example, the housing 20 includes releasable attachment means 40 which is generally configured to operatively releasably attach the housing 20 to a leg of a patient (not shown) . The releasable attachment means can include an adhesive pad 40, a strap, hook-and-loop attachment pads, and/or the like. It is to be appreciated that the attachment means 40 can further facilitate ergonomic use of the apparatus 10, as the housing 20 can be releasably attached to, for example, a patient's thigh during use, so that it is conveniently within reach when needed .

[0080] As described broadly above, the present invention also particularly provides for an example of an obstetrical vacuum apparatus 10 which comprises a fetal vacuum cup 12 and a housing 20 which is ergonomically sized, shaped and dimensioned for one-handed handheld operation.

[0081] Of particular importance in this example is the housing 20, which is generally sized, shaped and dimensioned to be easily man-portable and to be easily handled, held and operated with one hand. Such ergonomics are particularly useful during a delivery, as the delivering physician only requires one hand to control and operate the apparatus, as well as to apply traction to the fetal head when necessary.

[0082] Such an example has the housing 20 including the negative pressure generator 22 configured to operatively

generate the negative pressure or vacuum within the chamber 14, as well as user input 24 via which a user is able to select a negative pressure value. Housing 20 also includes the controller 26 which is configured to control the generator 22 to automatically maintain the selected negative pressure value within said chamber 14.

[0083] This example has apparatus 10 also including the flexible tube 28 arranging the chamber 14 in fluid communication with the negative pressure generator, with the tube 28 comprising pulling member 32 for providing mechanical strength whilst allowing tube flexibility.

[0084] In this manner, the controller 26 can automatically accommodate any operating pressure variations within the chamber 14 and the ergonomic housing 20 allows a user to interact with the user input and apply traction to the fetal head with a single hand.

[0085] It is to be appreciated that the present invention also provides for an associated obstetrical method for applying traction to a fetal head, Such as method broadly comprises the steps of providing the apparatus 10 described above, attaching the vacuum cup 12 of apparatus 10 to the fetal head 18, and applying traction to the fetal head 18 via said apparatus 10, typically by means of handle 30 with pulling member 32.

[0086] The Applicant believes it advantageous that the apparatus 10 provides for a fully portable and easily operable obstetrics vacuum that is less likely to 'pop off during traction due to inadequate seal. The design of

apparatus 10 also allows it to be used for fetuses facing in any direction; minor variations may be designed for the apparatus 10 to be used in possible more difficult cases. In the absence of the known conventional vacuum pumps, the improved effectiveness in the delivery of babies by using this portable apparatus 10 can potentially reduce any long term adverse health outcomes, or even save the lives of mothers and babies.

[0087] In addition, Applicant believes it additionally advantageous that the apparatus is able to enhance the effectiveness of a safe and successful delivery which is otherwise difficult, e.g. difficulty with a malpresenting fetus when there is no electrical source or space for a conventional vacuum pump apparatus.

[0088] Optional embodiments of the present invention may also be said to broadly consist in the parts, elements and features referred to or indicated herein, individually or collectively, in any or all combinations of two or more of the parts, elements or features, and wherein specific integers are mentioned herein which have known equivalents in the art to which the invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

[0089] It is to be appreciated that reference to "one example" or "an example" of the invention is not made in an exclusive sense. Accordingly, one example may exemplify certain aspects of the invention, whilst other aspects are exemplified in a different example. These examples are intended to assist the skilled person in performing the invention and are not intended to limit the overall scope of

the invention in any way unless the context clearly indicates otherwise.

[0090] It is to be understood that the terminology employed above is for the purpose of description and should not be regarded as limiting. The described embodiment is intended to be illustrative of the invention, without limiting the scope thereof. The invention is capable of being practised with various modifications and additions as will readily occur to those skilled in the art.

[0091] Various substantially and specifically practical and useful exemplary embodiments of the claimed subject matter are described herein, textually and/or graphically, including the best mode, if any, known to the inventors for carrying out the claimed subject matter. Variations (e.g. modifications and/or enhancements) of one or more embodiments described herein might become apparent to those of ordinary skill in the art upon reading this application.

[0092] The inventor (s) expects skilled artisans to employ such variations as appropriate, and the inventor (s) intends for the claimed subject matter to be practiced other than as specifically described herein. Accordingly, as permitted by law, the claimed subject matter includes and covers all equivalents of the claimed subject matter and all improvements to the claimed subject matter. Moreover, every combination of the above described elements, activities, and all possible variations thereof are encompassed by the claimed subject matter unless otherwise clearly indicated herein, clearly and specifically disclaimed, or otherwise clearly contradicted by context.

[0093] The use of any and all examples, or exemplary language (e.g., "such as") provided herein, is intended merely to better illuminate one or more embodiments and does not pose a limitation on the scope of any claimed subject matter unless otherwise stated. No language in the specification should be construed as indicating any non-claimed subject matter as essential to the practice of the claimed subject matter.

[0094] The use of words that indicate orientation or direction of travel is not to be considered limiting. Thus, words such as "front", "back", "rear", "side", "up", down", "upper", "lower", "top", "bottom", "forwards", "backwards", "towards", "distal", "proximal", "in", "out" and synonyms, antonyms and derivatives thereof have been selected for convenience only, unless the context indicates otherwise. The inventor (s) envisage that various exemplary embodiments of the claimed subject matter can be supplied in any particular orientation and the claimed subject matter is intended to include such orientations.

[0095] The use of the terms "a", "an", "said", "the", and/or similar referents in the context of describing various embodiments (especially in the context of the claimed subject matter) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms "comprising," "having," "including," and "containing" are to be construed as open-ended terms (i.e., meaning "including, but not limited to,") unless otherwise noted.

[0096] Moreover, when any number or range is described herein, unless clearly stated otherwise, that number or range is approximate. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value and each separate sub-range defined by such separate values is incorporated into the specification as if it were individually recited herein. For example, if a range of 1 to 10 is described, that range includes all values there between, such as for example, 1.1, 2.5, 3.335, 5, 6.179, 8.9999, etc., and includes all sub-ranges there between, such as for example, 1 to 3.65, 2.8 to 8.14, 1.93 to 9, etc.

[0097] Accordingly, every portion (e.g., title, field, background, summary, description, abstract, drawing figure, etc.) of this application, other than the claims themselves, is to be regarded as illustrative in nature, and not as restrictive; and the scope of subject matter protected by any patent that issues based on this application is defined only by the claims of that patent.

CLAIMS

1. An obstetrical vacuum apparatus comprising:

a fetal vacuum cup defining at least one chamber in which a negative pressure or vacuum enables operative attachment of the cup to a fetal head;

a housing ergonomically sized, shaped and dimensioned for one-handed handheld operation, said housing having:

(i) a negative pressure generator configured to operatively generate such negative pressure or vacuum within the chamber;

(ii) a user input via which a user is able to select a negative pressure value; and

(iii) a controller configured to control the generator to automatically maintain the selected negative pressure value within said chamber; and

a flexible tube arranging said chamber in fluid communication with the negative pressure generator, the tube comprising a pulling member providing mechanical strength whilst allowing tube flexibility;

wherein the controller automatically accommodates any operating pressure variations within the chamber and the ergonomic housing allows a user to interact with the user input and apply traction to the fetal head with a single hand .

2. The obstetrical vacuum apparatus of claim 1, wherein the housing includes releasable attachment means configured to operatively releasably attach the housing to a leg of a patient .

3. The obstetrical vacuum apparatus of claim 2, wherein the releasable attachment means is selected from a group consisting of an adhesive pad, a strap, and hook-and-loop attachment pads.

4. The obstetrical vacuum apparatus of any of claims 1 to 3, wherein the housing defines a handle which is ergonomically sized, shaped and dimensioned to facilitate single hand-held operation of the apparatus.

5. The obstetrical vacuum apparatus of claim 1, wherein the pulling member comprises a cable threaded through the tube for providing mechanical strength whilst allowing tube flexibility.

6. The obstetrical vacuum apparatus of claim 1, wherein the pulling member comprises walls of the flexible tube having a wire or nylon braided weave for providing mechanical strength whilst allowing tube flexibility.

7. The obstetrical vacuum apparatus of claim 1, wherein the apparatus comprise a traction force indicator configured to indicate a value of traction applied by the pulling member.

8. The obstetrical vacuum apparatus of claim 7, wherein the traction force indicator includes a strain gauge.

9. The obstetrical vacuum apparatus of claim 1, wherein the negative pressure generator comprises an electromechanical pump configured to extract fluid from the chamber in the vacuum cup.

10. The obstetrical vacuum apparatus of claim 1, wherein the controller is configured to control the generator to automatically maintain the selected negative pressure value within said chamber by increasing a negative pressure generation capability of the generator to accommodate an unwanted negative pressure decrease within the chamber.

11. The obstetrical vacuum apparatus of claim 1, wherein the controller is configured to control the generator to automatically maintain the selected negative pressure value within said chamber by decreasing a negative pressure generation capability of the generator to accommodate an unwanted negative pressure increase within the chamber.

12. The obstetrical vacuum apparatus of claim 1, wherein the apparatus includes a negative pressure or vacuum release valve configured to release or minimise a vacuum or negative pressure within the vacuum cup chamber.

13. The obstetrical vacuum apparatus of claim 12, wherein the negative pressure or vacuum release valve is controlled by the controller.

14. The obstetrical vacuum apparatus of claim 13, wherein the controller is configured to activate the release valve to accommodate an unwanted negative pressure increase within the vacuum cup chamber.

15. The obstetrical vacuum apparatus of claim 1, wherein the flexible tube has an outside diameter in the range of 5mm to 200mm.

16. The obstetrical vacuum apparatus of claim 1, wherein the flexible tube has an outside diameter in the range of 10mm to 30mm.

17. The obstetrical vacuum apparatus of claim 1, wherein the housing includes energising means for providing the negative pressure generator with operating energy, the energising means comprise a plurality of rechargeable electrochemical cells .

18. The obstetrical vacuum apparatus of claim 1, wherein the housing is sized, shaped and dimensioned to be easily man-portable to be easily handled, held and operated with one hand .

19. An obstetrical method for applying traction to a fetal head, said method comprising the steps of:

providing apparatus in accordance with any of claims 1 to 17;

attaching a vacuum cup of said apparatus to the fetal head; and

applying traction to the fetal head via said apparatus.

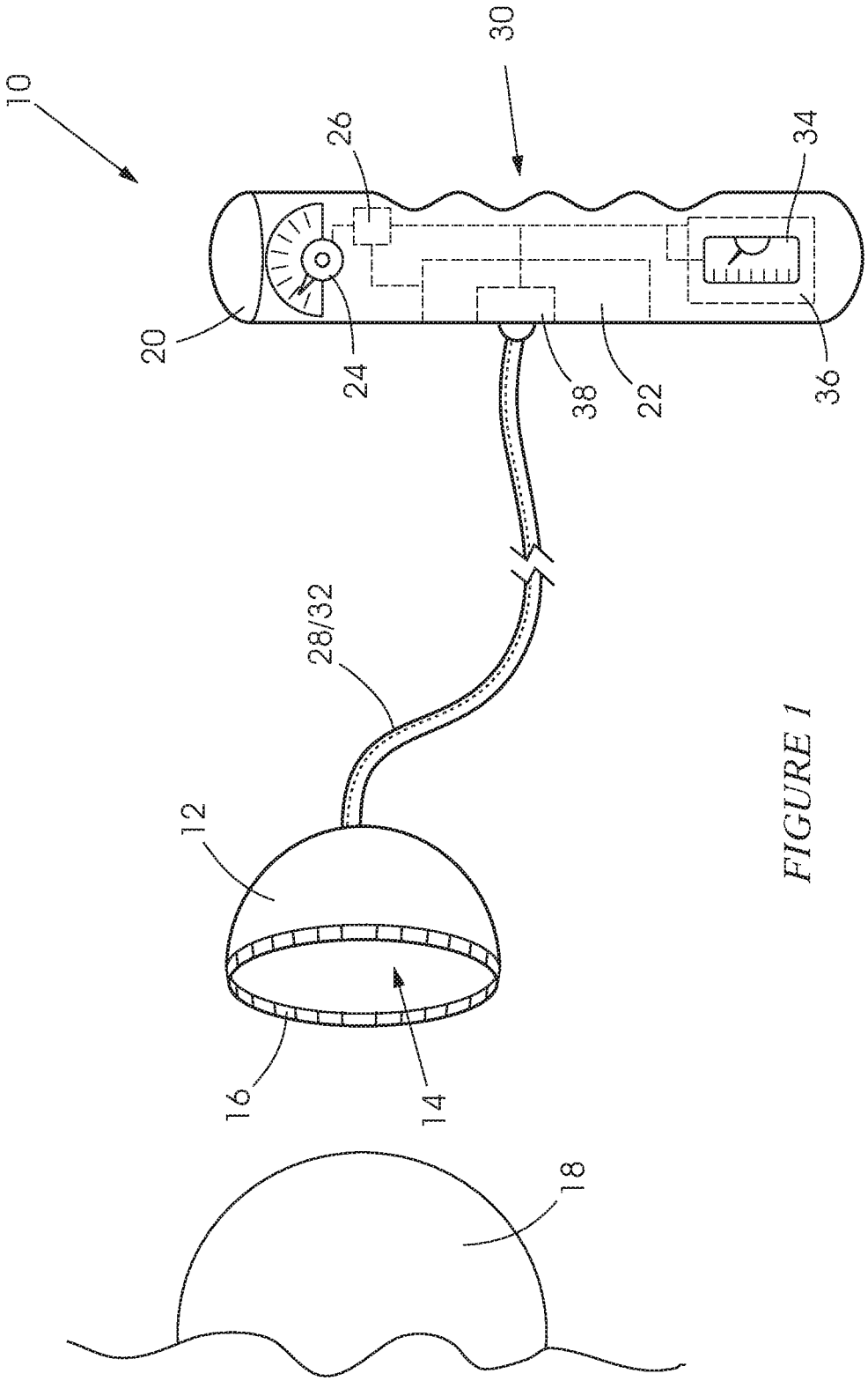

FIGURE 1

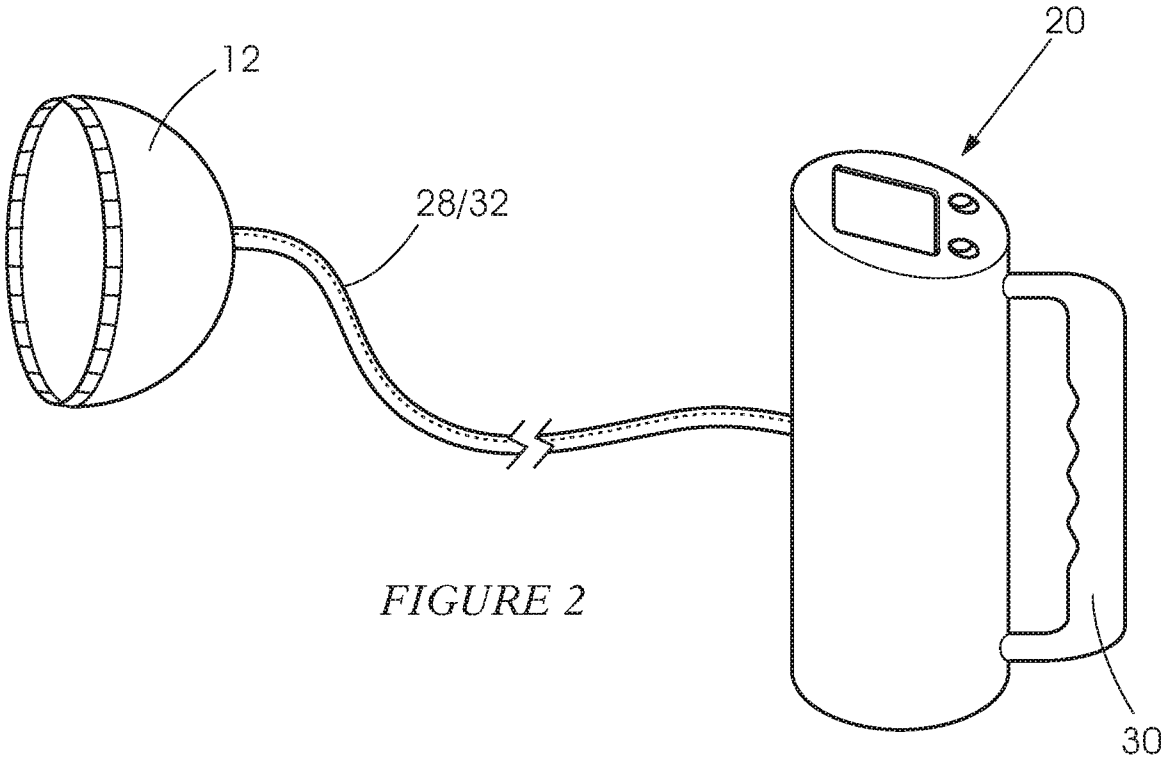

FIGURE 2

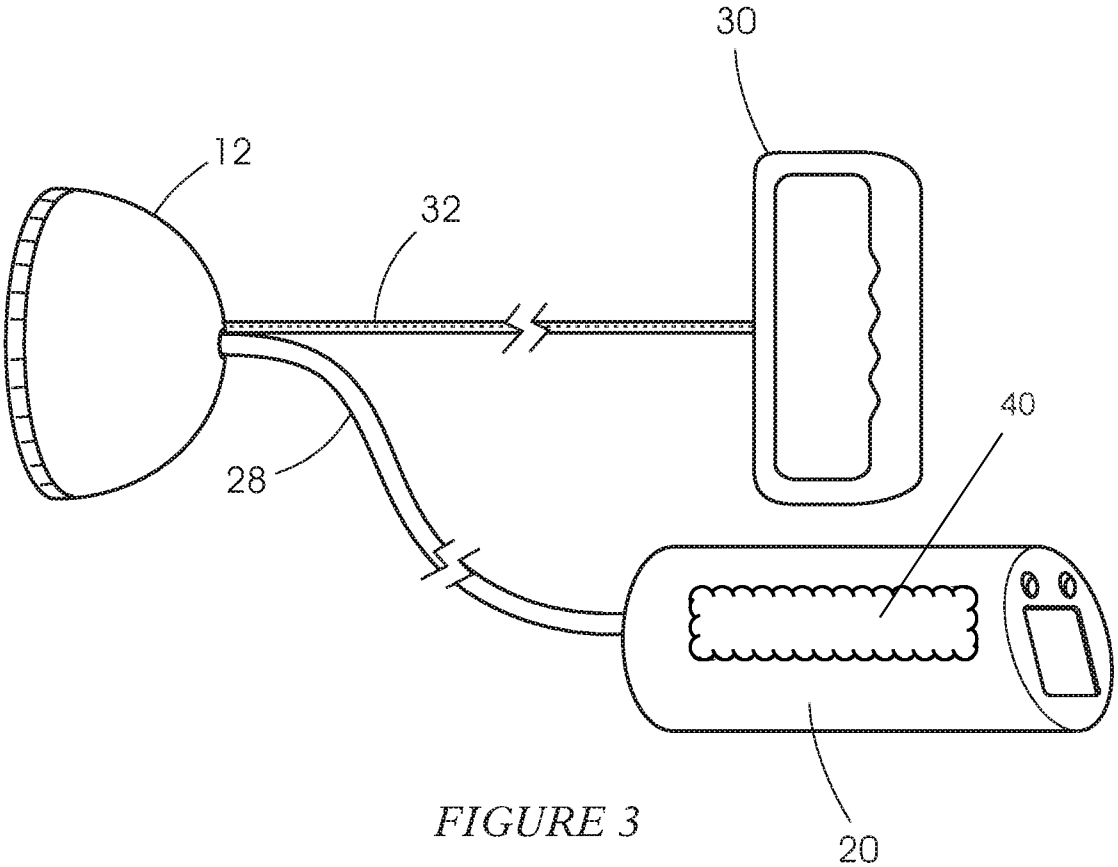

FIGURE 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2016/050928

A. CLASSIFICATION OF SUBJECT MATTER

A61B 17/42 (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)

EPODOC, TXTE: IPC and CPC: A61B17/42, A61B17/44; keywords: vacuum, suck, handheld, traction, pull (and like terms). Applicant and inventor name search.

Google Patents: keywords: obstetrical vacuum device, handheld, automatic, pressure, control (and like terms).

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
15 November 2016	15 November 2016
Name and mailing address of the ISA/AU	**Authorised** officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au	Eng **Wei** Soo AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. 0262832138

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2016/050928**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2010/01 85048 A1 (LONKY et al.) 22 July 2010 Abstract; figs. 1-3; paragraphs [0009], [003 1], [0038], [0039], [0046]-[0052], [0067], [0068], [0072]-[0079], [01 18] Abstract; figs. 1-3; paragraphs [0009], [003 1], [0038], [0039], [0046]-[0052], [0079]	1-3, 7-19 4-6
Y	US 6059795 A (WALLACE et al.) 09 May 2000 col. 3, lines 33-39; col. 11, lines 27-35	5, 6
Y	US 6468284 B1 (WALLACE) 22 October 2002 col. 4, lines 41-42; col. 5, lines 25-27	4
A	US 6074399 A (WALLACE et al.) 13 June 2000 Entire document	1-19
A	US 6361 542 B1 (DIMITRIU et al.) 26 March 2002 Entire document	1-1 9
A	US 7291 156 B1 (PERONE) 06 November 2007 Entire document	1-19
A	US 2003/0220542 A1 (BELSON et al.) 27 November 2003 Entire document	1-19

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/AU2016/050928**

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.

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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/AU2016/050928**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
		WO 9958071 A1	18 Nov 1999

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/AU2016/050928**

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Patent Document/s Cited in Search Report		Patent Family Member/s	
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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/AU2016/050928**

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**
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End of Annex

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