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SUCTION SEQUENCES FOR A BREASTPUMP

This application is a continuation-in-part of U.S. Patent Application No. 09/476,076, filed December 30, 1999, which claims the benefit of U.S. Provisional Application No. 60/170,070, filed December 10, 1999.

FIELD OF THE INVENTION

This invention relates to breastpumps for drawing breastmilk, and particularly to a motorized, such as electrically driven, breastpump.

BACKGROUND OF THE INVENTION

Breastpumps for use by nursing mothers are well known. They allow the nursing woman to express the breastmilk as necessary or convenient, and further provide collection of the breastmilk for later use. For some mothers, breastpumps may be a necessity, such as when the child has suckling problems, or if the mother has problems with excessive or deficient milk production, or soreness, deformation or injury of the mammilla.

Manual breastpumps are commonplace, primarily because they are relatively inexpensive and easy to transport. Being manually driven, however, stroke rate and suction pressure produced can be uneven, and operating the pump can ultimately be tiring.

Electrically-driven breastpumps are also commonplace. They may be of a substantially large size of a non-portable or semi-portable type, typically including a vacuum pump which has an electric motor that plugs into standard house current. Advantages of this type of pump are ready controllability and regulation of the vacuum, and the ability to pump both breasts at once. That is, the nursing woman has both hands free to hold two breastpump shields in place for pumping of both breasts at the same time.

Battery-driven breastpumps have also been developed. These breastpumps have the advantages of controllability and regulation of the vacuum, as well as being easily carried. Such a battery-driven portable breastpump is described in U.S. 4,964,851, for example. This breastpump, sold under the name MINIELECTRIC by Medela, Inc., is lightweight and achieves good vacuum (i.e., negative pressure)

regulation in preferred limits, for example, between about 30 and about 300 mmHg. The LACTINA breastpump sold by Medela, Inc. is also another type of breast pump which may be driven by battery as well as house current. It is generally disclosed in U.S. Patent No. 5,007,899.

Electrically driven motorized breastpumps have almost universally been developed with a single type of "cycle" for a given pump. That is, the driving mechanism for generating the vacuum (negative pressure) to be applied at the breast in the more sophisticated pumps is geared to a particular sequence, or curve, of negative pressure increase (i.e., increasing suction), and then release. This is often aimed at reproducing in some sense the suckling action of an infant, for instance. Breastpumping can cover a range of different conditions, however, such as where the mother's nipples are sore for some reason, there is a state of significant engorgement, some nipple stimulation may be particularly desired, ejection and relaxation may be of particular interest, it may be desired to increase milk production, and so on.

Some breastpumps provide the user with the ability to vary the amount of vacuum being applied, as well as the speed of the pumping action (i.e., number of cycles per minute). In some instances in the prior art, speed and vacuum level may influence each other, such that as speed increases so does the vacuum level. The basic "curve" remains fixed, however, and the user must adapt as best she can to making variations within that particular curve built into the machine, which typically has been generalized for the overall population of users.

SUMMARY OF THE INVENTION

It is a principal objective of the present invention to provide a breastpump which can be programmed to generate, among other things, a plurality of differing milk expression (extraction) sequences, or curves. To this end, the invention in one form is a breastpump comprising a breastshield having a portion within which a woman's breast is received for the expression of milk. A source of vacuum is in communication with the breastshield. There is a mechanism for operating the source of vacuum according to a first sequence, and a controller for operating the source of vacuum according to a second sequence.

The controller can have a preset program for the second sequence which is a milk ejection sequence, for example. Preferably, the breastpump has a plurality of different programs for the controller wherein each program has a different sequence.

In one embodiment of the invention, a motorized pump (e.g., compressed air, battery and/or house current) is provided with a microprocessor-based controller. Cards, with memory "chips," containing different suction curves adapted for varying conditions and objectives are included for programming the controller in this embodiment. A user selects a desired program, and that card is then read by a mechanism providing input to the controller. It should be noted that while suction curves are generally addressed in the first instance herein, the milk expression sequences may also include a positive pressure aspect. The programming could also be provided via other media, including discs, CDs, infrared data transfer, electronic feed (e.g., an Internet connection), and so forth.

A significant, and heretofore unavailable advantage realized by the present invention is the ready ability to modify the breastpump suction action to a variety of desired conditions, and provide this ability to the end-user. An attendant advantage is that, as the science of breastpumping continues to make advances, new and improved suction curves and sequences can be made available on further cards, or other program-inputting means.

Yet another attendant advantage is that the programmable pump can also record data relating to its use and operation. That data could be stored, for instance, and then retrieved as by downloading through an Internet connection, magnetic recording (disk or card), and the like. This data retrieval would be useful in medical research, for updating the pump with new data, for monitoring usage, just for some instances.

Further, a program could be made of a particular infant's suckling pattern. That program could then be used to operate the pump, and then varied over time as the infant grows.

In yet another aspect of the invention, an improved breastpump is provided which has a pre-programmed milk ejection sequence. The ejection sequence is most advantageously made available through a button or the like provided on the breastpump used to actuate the sequence.

The present invention in another significant aspect has as an objective to provide a breastpump with one or more novel suction sequences which are considered to produce advantageous particularized results. Such sequences include, but are not limited to: a suction method (e.g., program or curve) for a sore nipple condition; a

suction method for increased milk production; an improved suction method in general; and a method for nipple stimulation.

A method for operating a breastpump for a sore nipple condition according to the present invention comprises varying the amount of vacuum within a range of from about 20 mmHg (the least vacuum) to about 250 mmHg (the greatest vacuum) while simultaneously varying the overall suction cycle from about 25 cycles/min. at the least vacuum to about 40 cycles/min. at the greatest vacuum, such that for a lower vacuum applied there is an increase in the number of cycles. In general, this program is intended to provide a lower peak vacuum over a longer cycle.

A method for operating a breastpump to yield an increase in milk output according to the present invention comprises operating the pump at a rapid cyclical rate on the order of about 120 cycles/min., with a negative pressure in the range of about 40 mmHg to about 220 mmHg. This method may further include a pause after each period of vacuum application, such as applying cycles of vacuum for about ten seconds, with then a two second pause at atmospheric pressure.

A method for operating a breastpump according to yet another aspect of the invention comprises varying the vacuum within a range of about 30 mmHg (the least vacuum) to about 300 mmHg (the greatest vacuum), while simultaneously varying the overall suction cycle from about 47 cycles/min. at the greatest vacuum to about 78 cycles/min. at the least vacuum, such that for a lower vacuum applied there is an increase in the number of cycles, with a cycle following a curve which initially builds to a peak negative pressure, then smoothly starts a pressure increase (less negative) along an initial slope but then slows the pressure increase briefly, before continuing on essentially said initial slope for the negative pressure release.

These and other features and advantages of the present invention will be further understood and appreciated when considered in relation to the following detailed description of embodiments of the invention, taken in conjunction with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front perspective view of a breastpump assembly made in accordance with aspects of the present invention;

FIG. 2 is a side elevational view of the breastpump of FIG. 1;

FIG. 3 is a rear perspective view of the breastpump of FIG. 1;

FIG. 4 is a perspective view of the breastpump of FIG. 1 looking at the bottom;

FIG. 5 is a top view of the breastpump of FIG. 1 with a cover removed revealing diaphragm pumps;

FIG. 6 is an enlarged side view of the breastpump of FIG. 1 adjacent the bottom highlighting the program card insert slot;

FIG. 7 is a bottom perspective view of the breastpump of FIG. 1 showing battery arrangement;

FIG. 8 is a somewhat exploded assembly view of the major components of the breastpump of FIGS. 1 through 5, with a modified top cover for the diaphragm pump assembly;

FIG. 9 is a diagrammatic representation of the interaction of various components with the controller;

FIG. 10 is a schematic-type representation of a data storage and retrieval process that can be effected in accordance with the present invention;

FIGS. 11 through 14 are various methods (curves) for operating the breastpump to differing ends;

FIG. 15 is a front perspective view of another embodiment of a breastpump assembly made in accordance with aspects of the invention;

FIG. 16 is a rear perspective view of the FIG. 15 embodiment;

FIG. 17 is a somewhat exploded assembly view of the major components of yet another breastpump made in accordance with the present invention;

FIG. 18 is an enlarged front perspective view of the motor drive of the breastpump of FIG. 17;

FIG. 19 is a view similar to that of FIG. 18 but from a top perspective;

FIG. 20 is an enlarged assembly view of the diaphragm pump mechanism;

FIG. 21(a) is a cross-sectional view of the assembled diaphragm pump of FIG. 20;

FIG. 21(b) is an elevational view of the assembled diaphragm pump of FIG. 20;

FIG. 21(c) is a top view of the assembled diaphragm pump of FIG. 20;

FIG. 22 is a sectional view of the assembled breastpump of FIG. 17 taken through the middle of the breastpump along its long lateral axis (side to side) looking rearwardly;

FIG. 23 is a sectional view similar to that of FIG. 22 taken along a plane forwardly of that of FIG. 22;

FIG. 24 is a sectional view similar to that of FIG. 22 taken along a plane behind the electric motor looking back to front;

FIG. 25 is a graph depicting a method (vacuum cycle) for operating a breastpump to elicit milk expression; and

FIG. 26 is a graph depicting a method (vacuum cycle) for operating a breastpump to elicit a milk ejection reflex.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The Breastpump Assembly

Referring to FIGS. 1 through 7 initially, a breastpump assembly of the present invention in one form has an aesthetically pleasing and compact design. The housing for the major components of the assembly is a casing 10 made of a rigid high impact plastic. As shown, it has a generally ellipsoidal cross-section along its vertical axis, yielding a pleasing smooth curving look to the casing exterior. The casing 10 is closed at its upper end by an upper housing part 11, to which is affixed a carrying handle 12.

In this first embodiment, carrying handle 12 has a pair of cradles 15 formed in opposite ends thereof. These cradles 15 are adapted to receive and support the funnel portions 16 of respective breastshields 17. These breastshields 17 (sometimes referred to themselves as breastpumps) are of the type shown and described in U.S. Patent No. 4,964,851 and 4,929,229, for instance. Further detail regarding the breastshields 17 may be obtained through reference to those patents, but will be omitted herein since the inventive features in point in this application are not contingent upon the breastshield being used, so long as it is suitable to the task of milk expression.

In general, however, the breastshields 17 have the aforementioned funnel portion 16 which communicates with conduit structure connecting to a container (bottle) 18. This particular breastshield 17 is adapted for both manual as well as

motorized pumping. It has a collar 20 to which a manually-driven piston pump (not shown) is screw-threaded for attachment and use in one mode of operation. When an electrically operated vacuum pump is to be employed, there is a port provided inside of the collar 20 which is in communication with the funnel portion, and to which a tube from the vacuum pump is releasably connected to convey vacuum to the breastshield. Again, such detail is well known, and can be gleaned from the foregoing patents, among other public sources. In operation in either mode, the widened (conical) portion of the breastshield 17 is placed on the breast for drawing vacuum within the shield, and thereby drawing milk through a pulling force applied to the breast. Milk drawn from the breast is collected in the bottle 18.

FIGS. 15 and 16 show a modified exterior for the breastpump 10′ (prime numbers being used herein to refer to similar but modified parts). In this version the breastshields 17 are not cradled by the handle 12′, but instead are carried in a holder 26 mounted to the back of the unit.

--The Drive Motor

Referring to FIG. 8 initially, casing 10 has a drive unit 25 mounted therein. There are, of course, any number of drives that may be used for diaphragm pumps such as those used in the instant embodiment. Indeed, the type of pump (diaphragm, piston, etc.) is not necessarily significant to certain aspects of the present invention. The driving mechanism for the breastpump shown for the embodiment in point, however, is a linear drive for the diaphragm pumps consisting of a reduction drive arrangement and a 12 V DC-motor 28.

It will be noted that the FIG. 8 embodiment is substantially the same as that of FIGS. 1 through 7, except for a modified cover for the upper housing, which here includes the rigid shells 24 for the diaphragms 34 as part of the cover 35. The diaphragm pumps 30 will be further described hereafter.

FIG. 17 shows yet another version of a breastpump of the present invention substantially the same as that of FIGS. 1 through 8, except with a modified cover 35″ and shell 24″ for the diaphragm pump 30. The breastshield holder of the FIGS. 15 and 16 embodiment has also been slightly modified. It is with respect to this FIG. 17 embodiment that the majority of the interior detail of the breastpump will be further understood.

Turning now to FIGS. 18, 19 and 22 through 24 in particular, the reduction gearing contains belts 27a, 27b and 27c. Power is transferred from the shaft 29 of motor 28 to belt 27a. Belt 27a is received in a channel of wheel 51, which is mounted to the drive chassis 62 on rotatable shaft 52. Shaft 52 is fixed to rotate with wheel 51. A freewheel 53 is mounted on a shaft 54 fixed to the chassis 62 to freely rotate, and engages the outside of belt 27a, producing more surface engagement by the belt 27a with wheel 51.

Shaft 52 has a small toothed gear 55 mounted thereon. Belt 27b is toothed, and engages the gear 55. Toothed belt 27b furthermore engages a larger toothed gear 56 fixed to rotating shaft 57 (FIGS. 22 and 24). Part of gear 56 is small toothed gear portion 58. Belt 27c, which is also toothed, engages gear 58 as well as toothed gear 59. Gear 59 is fixedly mounted to rotating shaft 70. Fixed at each end of shaft 70 are small toothed gears 71a, 71b. Toothed belts 72a, 72b respectively engage gears 71a, 71b and freely rotating toothed gears 73a, 73b.

Diaphragm pusher (push/pull) shafts 74a, 74b are respectively clamped to belts 72a, 72b at one end. The other end engages the interior of a respective diaphragm membrane member 34 (FIG. 22, and also see FIGS. 20 and 21(a)). Here, a screw engagement with the shafts 74a, 74b was used, with a threaded nut-like element 37 mounted in a reinforced central area of membrane 36 (again, the diaphragm pumps 30 are described in more detail below). Both of the pusher shafts 74a, 74b move in tandem as driven by respective belts 72a, 72b.

Accordingly, as motor drive shaft 29 turns, belt 27a rotates shaft 52 via wheel 51. Belt 27b is in turn thereby driven off of smaller gear 55, causing rotation of shaft 57, which in turn rotates larger gear 56 and its smaller part 58, to thereby turn shaft 70 via belt 27c which couples gear part 58 with larger gear 59. This transfers the motion via gears 71a, 71b to belts 72a, 72b, imparting a linear movement to the pusher shafts 74a, 74b. A forward and then backward stroke is generated, through reversal of the motor shaft 29 direction. Reduction gearing is thus obtained as desired through appropriate selection of the various gears/wheels noted above.

The location of the shafts 74a, 74b along the path of travel, as well as the length of the stroke, is measured by position sensing mechanism 78, which can be of any standard and well known variety. This sensing mechanism 78 uses a toothed

wheel 78a mounted to the shaft 29 of motor 28, which is registered by counter 78b. Signals generated by the counter 78b are processed by the cpu of the breastpump.

A negative pressure, or vacuum, is generated in a pair of diaphragm pumps 30. Each diaphragm pump has a flexible membrane 34 mounted in the upper housing 11 assembled with a respective rigid shell 24 (and see FIGS. 20 and 21(a) through 21(c) described further below). The membrane and shell are in substantially airtight engagement. When the membrane 34 is pulled away from the shell 24, a vacuum is generated in the space between the shell interior and the membrane, which can be accessed through outlet port 31 formed on the shell, to which a tube 32 is connected to communicate the vacuum to a respective breastshield 17.

Power is provided either through ordinary house current via power cord 38, or electrochemical battery 39, such as a pair of 6V, 1.2Ah lead-acid type rechargeable batteries. Power cord 38 is provided on a wrap-around mount conveniently located for storage in a well in the bottom of the lower housing part 13. FIG. 7 shows wells 41 formed within the lower housing 13 through which the batteries 40 are inserted into receptacles formed within the casing 10, having covers 42 for the wells. FIG. 7 omits the detail of the wrap mount 40, for clarity.

–The Single Switch Inversely Controlling Vacuum and Rate

An on-off switch or knob 45 (and see FIG. 9) is provided on the casing, which can be rotary or push-button to that end. It is nonetheless rotary and push-button in this embodiment since it also acts to control the amount of vacuum being applied. As the knob 45 is rotated, a signal is generated which increases or decreases the level of vacuum (suction force) to be applied, depending on which way the knob is turned. In this embodiment, as the suction force is increased, the cycle (rate) is decreased. That is, the rate and force are inversely related. This is considered to have a beneficial effect. The knob is pushed in for on and off.

–The Function Indicator

Additionally visible from the exterior of the casing 10 is a LCD display 48, a milk ejection button 49, and a program card slot 50 (the ejection sequence and programmable aspects will also be discussed in more detail below). Milk-let down button 49 is used to activate a pre-programmed suction sequence (embodied in components to be hereinafter described) particularly adapted for ejection and

stimulate the milk ejection reflex. The slot 50 provides the interface access for programming cards used with the breastpump of this invention.

The display 48 provides visual indications of various functions of the pump. This could include, for example, the type of sequence then programmed, the level of suction force, the battery condition, and so forth.

--The Diaphragm Protective Covers

In this embodiment, the two diaphragm pumps 30 are in a well formed in the top of the casing 10. A cover 35 (also 35′ and 35″ (again, primed numbers being substantially similar to their un-primed counterparts)) is provided which fits over the well and is generally flush with the upper housing part 11. The outlets 31 extend through relieved areas in the cover 35, for example, for easy access in use.

It may be noted that the shells 24 are shown formed in the cover of the embodiment of FIG. 8. The FIG. 17 embodiment has the shells 24 mounted in a removable manner in the upper housing, as through a snap fit or interference engagement, such as shown in the embodiment of FIGS. 20 and 21(a) through 21(c), to allow easier access for cleaning or replacing the membranes of the pumping mechanism, and for cleaning the shells themselves (which are provided with grips 33 to these ends).

In the FIG. 17 embodiment, diaphragm member or membrane 34, which may be made of any suitably durable flexible and durable fluid-impervious material (to be airtight), such as silicone with a Shore A hardness in the range of 30 to 70, is molded around its perimeter to a rigid plastic collar 85. Collar 85 has a plurality of depending anchor posts 86 with outboard flanges formed thereon, which engage with the inside lip of the respective well in the upper housing part 11 within which the collar 85 is received to snap-fit the membrane 34 in place.

Prophylactic (protective) disposable/cleanable covers 36 are additionally and advantageously provided, which form-fit over the diaphragms 34 and isolate them from air and other fluid from the breastshields. The covers 36, which can be made of the same material as the membranes but thinner, are likewise fluid-impervious.

Referring to FIGS. 20 and 21(a) through 21(c) in particular, each of the covers 36 has an upturned cuff 87 which forms an annular well around the perimeter of the cover 36. A pair of circumferential beads 88 and 89, which are slightly offset vertically from each other, are formed along the bottom area of the annular well.

Uppermost bead 88 engages in an annular rim channel 90 formed along the bottom outside of shell 24', for a substantially airtight engagement between the protective cover 36 and the shell.

An interior channel 93 is formed within the interior bottom of the cover 36 by a bead 91 and shoulder 92, which each run circumferentially around the cover. This interior channel 93 is received on a slightly protruding edge or rim on the collar 85 of the membrane 34. An airtight fit is thus provided between the protective cover 36 and the membrane 34, which also serves to releasably fix the shell 24 in place over the membrane 34, and complete the diaphragm pump 30.

Note also that a one-way valve 95 is provided in the membrane 34, which communicates with the possible space that may form between the membrane 34 and overlying cover 36. This valve permits any entrapped air therebetween to be exhausted, such as if the first stroke on start-up happens to be toward the shell 24, with the protective cover 36 thereafter then following the movement of the diaphragm 34 to which it will generally be in facial engagement.

The Programmable Aspects

One significant aspect of the present invention is the ability to program the breastpump with different types of suction sequences, or cycles as they are sometimes referred to herein. With reference to FIG. 9, for instance, the breastpump utilizes a microprocessor-based system indicated at 60 which is provided user input through a plurality of "chip" cards 61. Each chip card contains one or more predetermined programs recorded on an EEPROM. For example, each card could contain a specific type of sequence along with a milk ejection sequence.

An EEPROM microcontroller of the type MB90562 may be used, for one example, or the Atmel 2-wire EEPROM chipcard microcontroller AT24C164 for another. These provide about 16K of memory, which is considered presently sufficient.

The programs (some examples of which are described hereafter) are recorded in a conventional manner, and would be provided to the mother ready to use. The programmed chip card is inserted into the slot 50 in the back of the casing 10, where it engages an interface to the microprocessor. The particular program on the selected chip card 61 is then communicated to the microprocessor 60. Microprocessor 60 is integrated with the drive unit 25 to effect operation of the drive unit in accordance

with the selected program, drawing upon either the AC power source as converted via standard technology to DC (indicated at 68 in FIG. 9), or from the battery source 39. The microprocessor 60 can also control power management.

Suction force (e.g., the amount of negative pressure generated) will typically also be adjustable by the user via operation of the rotary control knob 45, as noted above. A pre-set range for the suction force will nonetheless ordinarily be provided in the program as an initial setting, for adjustment by the user thereafter via the knob 45.

One embodiment contemplated provides a milk ejection sequence (milk ejection reflex) that can be engaged without need of a chip card for the same. The milk ejection sequence (described below) is pre-programmed in the microprocessor 60, or may otherwise be wired into the circuitry in a manner to override the then-existing operating program. When the mother desires to engage this sequence, she presses the button 49, which produces and sends an electrical signal, as to the microprocessor 60. The ejection program is then effected.

It will be readily understood that a chip card 61 is but one way to program the microprocessor 60. Other input means could be used, such as more dedicated buttons like button 49, each set to actuate a given sequence pre-programmed into the microprocessor 60. A numeric pad could be provided to input a code. The programs could be provided through an electronic data link, such as a modem, or optically, or otherwise.

Data can also be recorded by the microprocessor for downloading or transfer to the chip card. Data could also be directly recorded on the chip card. For instance, it is contemplated that the suckling action of a particular child could be recorded and reduced to a sequence. That sequence could then be programmed into the pump, and the mother would then have a suckling action from the pump very reminiscent of her own child.

Referring now to FIG. 10, the chip card 61a with breastpump operation data thereon is then read (downloaded) at a "card station" 75, shown here as a card reader 76 linked to a computer 77. The computer 77 is used to transfer the data to one of a variety of available media, such as CD, floppy disk, etc. for physical transfer to a research or data monitoring facility, here indicated at 80. The data could also simply be transferred via modem through an Internet interface.

The New Expression Methods (Cycles)

It can thus be seen that a variety of different suction cycles or sequences can now be provided with the same breastpump equipment. An example of the kind of methods that such cycle could represent comprises FIGS. 11 through 15.

FIG. 11, for instance, is what is referred to by Medela, Inc. as the "Standard Classic Program". This is a method for operating a breastpump that has been developed which is considered to provide a general optimal suction curve reminiscent of an infant's normal suckling, such as provided by the 015 "CLASSIC" breastpump sold by Medela, Inc. As indicated in the graph of FIG. 11, negative pressure is along the y-axis (in millimeters of mercury) and time (in seconds) along the x-axis. In this particular method, the cycles are fixed at about 47 per minute; the amount of suction is generally adjustable between about 100 to about 250 mmHg.

FIG. 12 illustrates what can be termed as a new "Sore Nipple Program" method. In comparison to FIG. 11, it will be seen that the lower end of the vacuum range is reduced to about 20 mmHg, and the overall suction cycle is extended in duration, i.e., from a low of about 25 cycles/min. to about 40. For a lower vacuum applied in this program, there is an increase in the number of cycles. In general, however, there is a slower and gentler suction compared with the "CLASSIC" program of FIG. 11.

FIG. 13 shows a new method for operating a breastpump which is considered to yield an increase in milk output. This is a program that might be applied between regular pump sessions several times a day. In this method, the breastpump is operated at a rapid cyclical rate on the order of about 120 cycles/min., preferably with a pause after a period of vacuum application; here, 10 seconds of vacuum, then a 2 second pause. The negative pressure is in the range of about 50 to about 150 mmHg. Note the detail in the inset of FIG. 13 showing the rapidity and steep slopes of the vacuum application.

What has been termed a new "Superior Program" for operating a breastpump is illustrated in FIG. 14. A vacuum range of about 100 to about 250 mmHg has been chosen, with cycles ranging from about 47 to about 78 per minute. The cycle rate and the vacuum are tied, such that as, for instance, the cycles decrease, the amount of vacuum increases, i.e., there is an inverse relationship. It will be noted that this program differs from the "CLASSIC" program above in part through a sequence that

initially reaches a peak negative pressure, then smoothly starts a pressure increase (less negative) along a similar (although opposite) slope to that of the negative pressure build-up, but then slows the pressure increase briefly, before continuing on essentially the initial slope for the negative pressure release. A milk ejection sequence is also incorporated in this "Superior Program," and utilizes a vacuum range of about 40 to about 220 mmHg, with cycles ranging between about 80 to about 160 per minute and preferably at about 120 cycles per minute.

--Mathematical Expressions of The Cycles

A preferred embodiment of a vacuum cycle for the purpose of eliciting milk expression by generating a cyclical pressure change with a breastpump is shown in FIG. 25. What is shown is a range of vacuum operation of the breastpump from a minimum curve A to a maximum curve B. As will be discussed below, both extremes of operation defined by curves A and B include identical or nearly identical curve envelopes. In other words, while the amplitude and cycle duration of vacuum produced by the breastpump may be varied anywhere between the limits described by curves A and B, the envelope (the shape) of the vacuum curve over time does not change, that is, the overall pattern of the vacuum values produced over time in the breastpump does not change regardless of the amplitude. Therefore, a single mathematical expression may be used to describe the envelope of the expression cycle, which may be varied in duration and amplitude as shown.

The duration of the expression cycle shown in FIG. 25 varies from 0.61 to 0.95 seconds from curves A to B. The amplitude of the minimum cycle A varies from 0 mmHg to about –36 mmHg and the maximum cycle B from 0 mmHg to about –297 mmHg. The duration of the cycle varies in proportion to the peak vacuum generated.

The expression cycle is optimized for milk expression from a mother's breast. As discussed above, FIG. 25 includes two separate curves that generally define the boundaries of a range of expression curves lying within having the same envelope or overall shape or pattern. A first curve A, which pressure varies from 0 mmHg (atmospheric) to about –36 mmHg (vacuum) shows the vacuum generated during the cycle and in particular, a lower limit for the effective expression of breast milk with the curve envelope described. A second curve B, which ranges in pressure from 0 mmHg to about –297 mmHg represents the highest limit of the vacuum generated for the effective expression of breast milk. It can be seen that the minimum and

maximum curves A, B differ in amplitude and cycle duration but share a common envelope, shape or pattern.

The envelope of the curves may be described by defining separate adjacent portions or segments of the curves. Generally, a first segment S1, includes a major portion having an essentially linear negative slope leading to a peak vacuum point P. A second segment, S2, includes a major portion having an essentially linear positive slope after the peak vacuum point P. A flat rest segment R follows segment S2, characterized by no change in vacuum. The rest segment R is a portion of the curve having no change in pressure at a time in each cycle during about 60 to about 80 percent of the duration of the cycle. It can be seen from the illustrated maximum curve B that the rest segment occurs from about 0.63 seconds to about 0.75 seconds. Accordingly, the rest segment R occurs from about 66 percent to about 79 percent of the total cycle duration in the maximum curve B. With respect to the minimum curve A, the rest segment R occurs from about 0.40 seconds to about 0.49 seconds. Accordingly, the rest segment R spans from about 63 percent to about 77 percent of the total cycle duration in the minimum curve.

A third segment, S3, follows the rest segment R and includes a major portion that is essentially a linear positive slope leading to a return to atmospheric pressure, the slope of S3 being more steep that the slope of S2.

It can also be seen from the graph that the time duration of each of the cycles varies with the amplitude of the vacuum. In other words, in a curve cycle where the amplitude of the vacuum is greater, the time duration of the entire cycle is correspondingly greater. In the illustrated cycle, the time duration of the cycle ranges from about 0.63 seconds to about 0.9 seconds (minimum to maximum curve).

Both the minimum and maximum curves A, B may be represented by the mathematical expression of Equation 1, which is a polynomial, by using the values given in Table 1 below:

Equation 1:

$$y(x)=V\left[\begin{array}{l}A_{10}(Tx)^{10}+A_9(Tx)^9+A_8(Tx)^8+A_7(Tx)^7+A_6(Tx)^6+\\A_5(Tx)^5+A_4(Tx)^4+A_3(Tx)^3+A_2(Tx)^2+A_1(Tx)+A_0\end{array}\right]$$

Table 1

	A_{10}	A_9	A_8	A_7	A_6
Maximum curve	0	0	-516560	1787300	-2473330
Minimum curve	0	0	-516560	1787300	-2473330
	A_5	A_4	A_3	A_2	A_1
Maximum curve	1752850	-680860	147200	-17360	370
Minimum curve	1752850	-680860	147200	-17360	370
	A_0	T	V		
Maximum curve	0	0.98	1.25		
Minimum curve	0	1.5	0.15		

where $y(x)$ is the vacuum in mmHg, $A(n)$ are coefficients of the polynomial, T is a duration constant, and V is an amplitude constant. Equation 1 is only one of many mathematical expressions that could be used to describe the curve shown in FIG. 25. The present invention should be understood to contemplate any equation or function that yields or approximates the vacuum envelope shown.

In a preferred embodiment, each cycle may be spaced by a rest period at or near atmospheric pressure. The time of each rest period may be from about 0.1 to about 2.0 seconds. More preferably, the rest period is about 0.25 seconds. Including the rest period, the entire cycle sequence may be performed from about 50-75 times or cycles per minute (CPM).

A preferred vacuum cycle for stimulating the milk ejection reflex by generating a rapid cyclical pressure change with a breastpump is shown in the graph of FIG. 26. The graph includes two separate curves, but with the same envelope or overall pattern. A first curve C, which ranges in pressure from 0 mmHg (atmospheric) to about –45 mmHg (vacuum), the minimum curve C, represents the

lower limit of the range of the vacuum cycle (lower amount of peak vacuum). A second curve D, which ranges in pressure from 0 mmHg to about –225 mmHg, the maximum curve D, represents the high limit of the range of the vacuum cycle (highest amount of peak vacuum). The minimum and maximum curves C, D differ in amplitude and share an envelope.

Both the minimum and maximum curves shown in FIG. 26 may be represented by the mathematical expression of Equation 1, a polynomial, by using the values given in Table 2 below:

Table 2

	A_{10}	A_9	A_8	A_7	A_6
Maximum curve	0	0	15000000	-34920000	32800000
Minimum curve	0	0	15000000	-34920000	32800000
	A_5	A_4	A_3	A_2	A_1
Maximum curve	-16040000	4340000	-616300	37000	-1000
Minimum curve	-16040000	4340000	-616300	37000	-1000
	A_0	T	V		
Maximum curve	8	0.95	1.3		
Minimum curve	8	1	0.25		

It can also be seen from the graph of FIG. 26 that the time duration of each of the minimum and maximum cycles C, D does not vary with the amplitude of the vacuum. In other words, in a curve cycle where the peak amplitude of the vacuum is greater, the time duration of the entire cycle is the same as that of curve having a lesser peak amplitude. In the illustrated cycle, the time duration of the cycle remains at 0.5 seconds whether at the minimum or maximum range of vacuum operation. In one preferred embodiment, no rest period is provided between cycles. Accordingly, the frequency of operation of the breastpump remains at about 120 CPM, since there is no pause between cycles in the preferred embodiment. In another embodiment, a rest period of 0.0 to 0.5 seconds is provided between vacuum cycles.

The mathematical expressions of the cycles of the present invention are provided herein as a presently preferred embodiment. Those skilled in the art will recognize that variations from the presently preferred embodiment and the resulting changes in curve envelopes, which provide the milk ejection and milk expression benefits disclosed herein are considered to fall within the scope of the present

invention. The specific minimum and maximum operating parameters are meant to be expressions of the best mode of practice, and should not be taken as limiting, except as otherwise stated herein.

Thus, while the invention has been described herein with relation to certain embodiments and applications, those with skill in this art will recognize changes, modifications, alterations and the like which still come within the spirit of the inventive concept, and such are intended to be included within the scope of the invention as expressed in the following claims.

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WHAT IS CLAIMED IS:

1. A method for operating a breastpump comprising:

generating a pressure change cycle according to a mathematical expression:

$$y(x) = V\left[\begin{array}{l} A_{10}(Tx)^{10} + A_9(Tx)^9 + A_8(Tx)^8 + A_7(Tx)^7 + A_6(Tx)^6 + \\ A_5(Tx)^5 + A_4(Tx)^4 + A_3(Tx)^3 + A_2(Tx)^2 + A_1(Tx) + A_0 \end{array}\right];$$

using the values in the following table:

	A_{10}	A_9	A_8	A_7	A_6
Maximum curve	0	0	-516560	1787300	-2473330
Minimum curve	0	0	-516560	1787300	-2473330
	A_5	A_4	A_3	A_2	A_1
Maximum curve	1752850	-680860	147200	-17360	370
Minimum curve	1752850	-680860	147200	-17360	370
	A_0				
Maximum curve	0				
Minimum curve	0				

wherein *T ranges* from about 0.98 to about 1.5 and *V* ranges from about 1.25 to about 0.15, *x* is time in seconds and *y(x)* is vacuum in mmHg, and repeating the pressure change cycle after a pause.

2. The method of Claim 1 wherein the pressure during the pause returns to atmospheric pressure.

3. The method of Claim 2 wherein the pause is from about 0.2 to about 2 seconds in duration.

4. The method of Claim 2 wherein the pause is about 0.25 seconds in duration.

5. A method for operating a breastpump to stimulate a milk ejection reflex comprising:

generating a pressure change cycle according to a mathematical expression:

$$y(x) = V\left[\begin{array}{l} A_{10}(Tx)^{10} + A_9(Tx)^9 + A_8(Tx)^8 + A_7(Tx)^7 + A_6(Tx)^6 + \\ A_5(Tx)^5 + A_4(Tx)^4 + A_3(Tx)^3 + A_2(Tx)^2 + A_1(Tx) + A_0 \end{array}\right];$$

using values as follows:

	A_{10}	A_9	A_8	A_7	A_6
Maximum curve	0	0	15000000	-34920000	32800000
Minimum curve	0	0	15000000	-34920000	32800000
	A_5	A_4	A_3	A_2	A_1
Maximum curve	-16040000	4340000	-616300	37000	-1000
Minimum curve	-16040000	4340000	-616300	37000	-1000
	A_0				
Maximum curve	8				
Minimum curve	8				

wherein T ranges from about 0.95 to about 1.0 and V ranges from about 1.3 to about 0.25, x is time in seconds and $y(x)$ is vacuum in mmHg,

Repeating the pressure change cycle after a pause, and

eliciting a milk ejection reflex.

6. The method of Claim 5 wherein the pressure during the pause returns to atmospheric pressure.

7. The method of Claim 6 wherein the pause is from 0.0 to about 0.5 seconds in duration..