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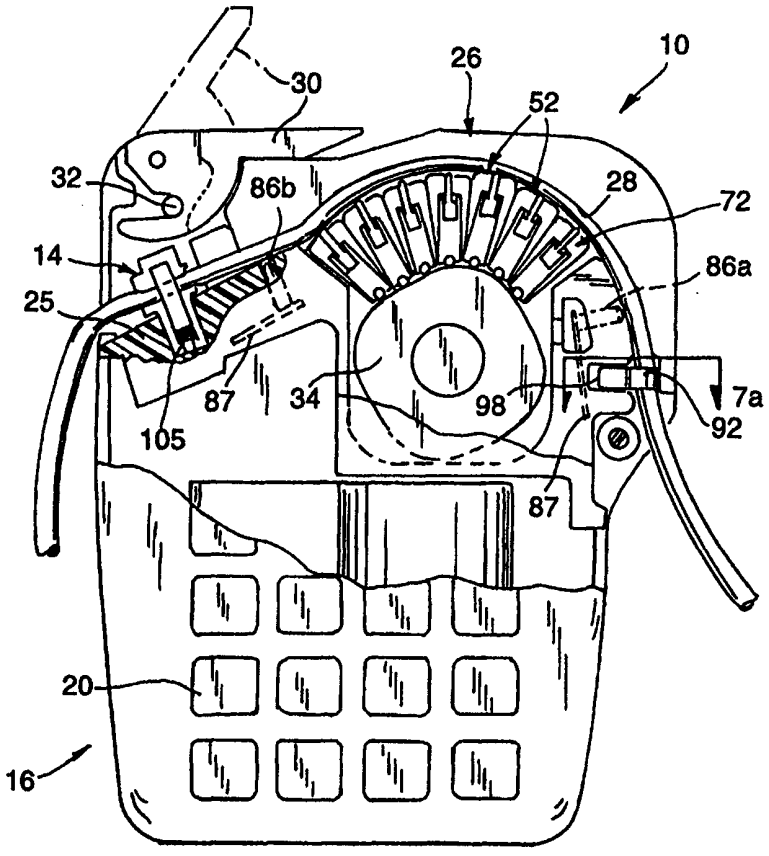
(57) Abstract

A curvilinear peristaltic pump (10) includes a rotatable cam (34) coupled to a drive unit (36) in a housing (16) having a platen member (26). Activation of the drive unit (36) rotates the cam (34) in a first direction and the deactivation of the drive unit (36) maintains the cam in a set position. The cam (34) moves a plurality of pump fingers (52) radially outwardly toward and radially inwardly away from the platen member (26). The pump (10) is used in conjunction with a disposable tubing assembly (12) which is provided with a shut-off valve (14) to selectively obstruct the flow of liquid through the tubing assembly (12).



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CURVILINEAR PERISTALTIC PUMP

Field of the Invention

The present invention relates generally to medical infusion pumps, and more particularly to a curvilinear peristaltic pump having a plurality of cam driven pumping fingers which sequentially engage a segment of resilient tubing to facilitate the flow of a liquid therethrough.

Background of the Invention

There is currently known in the prior art various types of peristaltic pumps which are typically used in medical applications for facilitating the metered intravenous infusion of a medicament into a patient. In addition to being used for infusion applications, prior art peristaltic pumps are also used for withdrawing fluids such as in a wound drainage system. These prior art pumps operate in a positive manner and are capable of generating substantial outlet pressures. The peristaltic pumps known in the prior art generally fall within one of two categories, i.e., linear peristaltic pumps and rotary peristaltic pumps. Conventional linear and rotary peristaltic pumps each typically have a section of resilient tubing positioned between a wall and a set of rollers or reciprocating pushers that progressively compress sections of the tubing to facilitate the pumping of a liquid therethrough.

More particularly, typical linear peristaltic pumps include those described in U.S. Patent Nos. 2,877,714 (Sorg, et al.), 4,671,792 (Borsannyi), 4,893,991 (Heminway, et al.), and 4,728,265 (Canon). While generally effective, these prior art linear peristaltic pumps are large, complex and cumbersome, requiring a drive shaft parallel to a resilient tube and a plurality of cams along the drive shaft to move respective ones of a plurality of pushers toward and away from the tube.

Rotary peristaltic pumps known in the prior art generally disposed a resilient tube along a circular path, with a plurality of rollers mounted around the circumference of a circular rotor sequentially rolling along the tube to occlude the same and force liquid therethrough. Typical rotary peristaltic pumps include those described in U.S. Patent Nos. 4,886,431 (Soderquist, et al.) and 3,172,367 (Kling). Though also generally effective, these pumps often have relatively low efficiencies and impose high shear and tension stresses on the tube, thus causing internal tube wall erosion or spallation. As a result, the tube may eventually be permanently deformed so that it becomes flattened into a more oval shape and carries less liquid, i.e., provides a decreased level of fluid flow therethrough.

In addition to the above-described linear and rotary peristaltic pumps, there is also known in the prior art another type of peristaltic pump having a tube arranged along a circular path with a cam member within the circle sequentially moving a plurality of blunt pushers or fingers outwardly to sequentially compress the tube from one end of the path to the other. These types of peristaltic pumps include those described in German Patent No. 2,152,352 (Gonner) and in Italian Patent No. 582,797 (Tubospir). Though these types of pumps tend to be less complex than linear peristaltic pumps, the pressure imposed by the blunt fingers typically reduces tube life, and sometimes causes internal tube wall erosion or spallation, thus resulting in particulate matter getting into the fluid stream. Additionally, tubes with different wall thicknesses cannot be accommodated by these particular prior art pumps. In this respect, with thinner than standard tubes, the fingers will not properly occlude the tube. Conversely, with thicker than standard tubes, the tube will close prematurely and be subject to excessive compression,

thereby requiring higher cam drive power and causing excessive wear on the cam and tube.

In recognition of the deficiencies associated with the prior art peristaltic pumps described above, Applicant developed the curvilinear peristaltic pump disclosed in U.S. Patent Nos. 5,575,631 (Jester) and 5,683,233 (Moubayed, et al) and PCT Application No. PCT/US97/03676 (Moubayed, et al.), the disclosures of which are incorporated herein by reference. This particular curvilinear peristaltic pump of the Applicant constituted an improvement over those known in the prior art by providing greater simplicity, small size, low drive power requirements and the ability to accommodate resilient tubes of varying wall thickness while reducing wear and internal erosion of the resilient tube. More particularly, this particular curvilinear peristaltic pump of the Applicant comprises a concave, curved platen for supporting a resilient tube, a multi-lobe cam rotatable about the center of the platen concavity, and a plurality of pump fingers which ride on the cam as cam followers and are guided to move in a radial direction toward and away from the platen. When the cam is rotated, the pump finger closest to the highest area (widest lobe) on the cam in the direction of rotation is moved outwardly in a radial direction to squeeze the tube against the platen. As the cam continues to rotate, the succeeding pump finger squeezes the tube as the preceding pump finger occludes the same, thus forcing the liquid in the tube to flow in the direction of cam rotation. As the cam rotation continues, the subsequent pump fingers sequentially squeeze the tube to push liquid and then occlude the tube, with the pump finger just behind the lobe moving away from the tube and allowing the same to expand and fill with the liquid.

Though this curvilinear peristaltic pump of the Applicant overcomes many of the deficiencies of the prior art peristaltic pumps, the design features of such pump

give rise to certain inefficiencies in its operation. In particular, the motor, pulley and drive belt used to rotate the cam create a susceptibility for slight amounts of forward rotation or reverse rotation (roll back) of the cam upon the deactivation of the motor. Such slight forward or reverse rotation of the cam results in the engagement of the pump fingers to the tube in a manner causing an undesirable positive flow or backflow of liquid therewithin subsequent to the deactivation of the motor. As such, in this curvilinear peristaltic pump of the Applicant, power must be continuously supplied to the motor for purposes of preventing any unwanted rotation of the cam. As will be recognized, the need to constantly maintain power to the motor substantially increases its power consumption (e.g., reduces the life of any batteries used to supply power to the motor).

In addition to the foregoing, in Applicant's existing curvilinear peristaltic pump, a "pump cycle" occurs when the first through the last pump fingers along the tube move toward and away from the platen. During each "pump cycle", the engagement of the pump fingers against the tube in the above-described manner forces liquid therethrough. However, due to the configuration of the cam and the inability of the drive unit to selectively adjust the rotational speed thereof, there is a "dead pump phase" between the pump cycles in Applicant's existing curvilinear peristaltic pump wherein liquid is not being forced through the tube. As will be recognized, it is significantly more desirable if the liquid were to flow through the tube at a more uniform, steady rate. The operational efficiency of Applicant's existing curvilinear peristaltic pump would also be increased if it were to include structures which stabilize the length of the tube in the pump chamber and prevent a backflow of liquid within the tube upon a discontinuation of positive liquid pressure therewithin. The present invention addresses and overcomes the

deficiencies of Applicant's existing curvilinear peristaltic pump, as well as the other peristaltic pumps currently known in the prior art.

Summary of the Invention

In accordance with the present invention, there is provided a curvilinear peristaltic pump for facilitating the pumping of a liquid through a length of resilient tubing. The pump comprises a housing including a pair of housing halves which are attached to each other. In addition to the housing, the pump comprises a platen member which is pivotally connected to the housing and movable between an operative position and a non-operative position relative thereto. The platen member defines an arcuate, generally concave inner surface, and includes an over-the-center latch mechanism for maintaining the same in its operative position relative to the housing.

The present pump further comprises a rotatable cam which is disposed within the housing and rotatable about the approximate center of the concavity of the inner surface of the platen member. The rotation of the cam is facilitated by a drive unit of the pump which is also disposed within the housing. The drive unit is mechanically coupled to the cam such that the activation of the drive unit results in the concurrent rotation of the cam in a first direction, and the deactivation of the drive unit maintains the cam in a set position. In the preferred embodiment, the drive unit comprises a cam shaft which extends from the cam and includes a worm gear attached thereto. In addition to the cam shaft and worm gear, the drive unit comprises an electric motor having a rotatable motor shaft extending therefrom which includes a worm mounted thereto. The worm is itself cooperatively engaged to the worm gear. Importantly, the engagement between the worm and the worm gear results in the rotation of the cam in the first direction upon the activation of the motor, with such engagement also

eliminating any rotation of the cam upon the deactivation of the motor. The electric motor of the drive unit is preferably powered by multiple batteries (e.g., C-cell batteries) which are stored within the housing.

The present pump further comprises a plurality of pump fingers which are movably attached to the housing and are arranged in side-by-side relation to each other so as to define a row. Each of the pump fingers has a first end which is cooperatively engaged to the cam and a second end which is disposed in spaced relation to the platen member. Attached to the housing is a pliable, transparent membrane of the pump which covers the second ends of the pump fingers and is used to prevent moisture from leaking into the interior of the housing. As such, the second ends of the pump fingers are covered by the membrane, and are disposed in substantially equidistantly spaced relation to the inner surface of the platen member when in its operative position. The membrane is exposed when the platen member is in its non-operative position. Each of the pump fingers preferably includes a plurality of roller members rotatably mounted within and protruding from the first end thereof, with the pump fingers being cooperatively engaged to the cam via the roller members.

In the present pump, the cam is configured to sequentially move the pump fingers radially outwardly toward and inwardly away from the inner surface of the platen member when rotated in the first direction by the drive unit. In this respect, a portion of the tubing may be extended between the inner surface of the platen member and the membrane (and hence the second ends of the pump fingers) such that the sequential movement of the pump fingers toward and away from the platen member results in liquid within the tubing being pumped in the first direction of rotation of the cam. As will be recognized, since the pumping of the liquid through the tubing is dependent upon the sequential engagement of the pump fingers thereagainst and the movement of the pump

fingers is dependent upon the rotation of the cam, the deactivation of the motor which eliminates any rotation of the cam due to the engagement between the worm and the worm gear assists in preventing any positive flow or backflow of liquid through the tubing.

In the present pump, the sequential movement of each of the pump fingers of the row toward and away from the platen member by the rotation of the cam defines a pump cycle. In the preferred embodiment, the cam is profiled or shaped so as to act against the first ends of the pump fingers in a manner causing the second ends thereof to engage the tubing such that the flow rate of liquid therethrough is substantially constant throughout each pump cycle. Such constant flow rate is achieved by forming the cam as a four lobe cam. In addition to the cam being shaped to provide a substantially constant flow rate throughout each pump cycle, the pump of the present invention is preferably provided with a motor speed control unit which is operable to selectively increase and decrease the rotational speed of the cam at prescribed intervals. More particularly, the motor speed control unit is operable to increase the rotational speed of the cam in the first direction between pump cycles for purposes of substantially eliminating the dead pumping phase which normally exists between pump cycles.

The motor speed control unit of the present pump is disposed within the housing and comprises an optical sensor which is electrically connected to the motor. The optical sensor is adapted to transmit a beam of light and sense any interruptions therein. In this respect, the optical sensor includes a light beam transmitter which is adapted to generate a beam of light, and a light beam receiver which is adapted to receive or sense the beam of light generated by the light beam transmitter. In addition to the optical sensor, the motor speed control unit comprises an encoder wheel which is attached to the cam shaft and rotatable thereby. The encoder wheel

includes a plurality of encoder arms extending radially therefrom and is oriented relative to the optical sensor such that the encoder arms intermittently interrupt the beam of light during the rotation of the encoder wheel by the cam shaft. Importantly, the number and size of the encoder arms is selected such that interruptions in the beam of light caused thereby correspond to pump cycles, with the optical sensor being operable to determine the beginning and end of each pump cycle and increase the power to the motor and hence the rotational speed of the cam between pump cycles. As will be recognized, the increased rotational speed of the cam between pump cycles substantially reduces the dead pump phase, thereby providing a more uniform rate of liquid flow through the tubing.

The present pump further comprises a plurality of pinch members which are movably attached to respective ones of the pump fingers and protrude from the second ends thereof. Each of the pinch members is biased radially outwardly toward the inner surface of the platen member and operable to substantially occlude the tubing when the pump finger to which it is attached is moved radially outwardly to a position closest to the inner surface of the platen member. To facilitate the attachment of a pinch member thereto, each of the pump fingers is provided with a transverse slot which is disposed within the second end thereof and transitions into a transverse cavity therewithin. Each of the pinch members preferably comprises a base portion which is disposed within the transverse cavity and a finger portion which extends from the base portion into the transverse slot. The finger portion defines a finger tip which protrudes from the second end of the pump finger. Extending between the base portion and the wall of the transverse cavity disposed furthest from the finger portion is a biasing spring of the pinch member. The present pump further comprises a pair of pressure sensor

members which are oriented within the housing adjacent respective ends of the row of pump fingers for engaging the tubing and generating electrical signals corresponding to the degree of compression or expansion thereof when acted upon by the pump fingers and pinch members.

The pump constructed in accordance with the present invention is preferably used in conjunction with a tubing assembly which is releasably attachable to the housing. The tubing assembly comprises a length of substantially straight, resilient tubing which is preferably fabricated from polyvinyl chloride (PVC). Attached to the tubing is a tubing locator pin and a shut-off valve which is operable to selectively obstruct the flow of liquid through the tubing in a direction opposite the first direction of rotation of the cam. The tubing locator pin and the shut-off valve are removably insertable into respective ones of a pair of recesses formed within the housing outwardly of each of the opposed ends of the row of pump fingers. Importantly, the tubing locator pin and the shut-off valve are attached to the tubing at locations whereat a portion of the tubing is extended over the second ends of the pump fingers when the tubing locator pin and the shut-off valve are removably inserted into their respective recesses within the housing. When the platen member is in its operative position, the tubing is extended between the second ends of the pump fingers and the platen member such that the sequential movement of the pump fingers toward and away from the platen member results in liquid within the tubing being pumped in the first direction of rotation of the cam.

In the present pump, the tubing locator pin and the shut-off valve of the tubing assembly are removably insertable into their respective recesses within the housing when the platen member is in its non-operative position. As indicated above, the portion of the tubing extended over the second ends of the pump fingers by the

insertion of the tubing locator pin and the shut-off valve into their respective recesses within the housing is captured between the second ends and the inner surface when the platen member is moved to its operative position.

In the preferred embodiment, the shut-off valve of the tubing assembly itself comprises a valve body having an opening therein for permitting the passage of the tubing therethrough. Movably attached to the valve body is a pinch arm which is engagable to the tubing passing through the opening. The pinch arm is movable between an open position whereat the tubing passing through the valve body is only partially collapsed thereby and not compressed by the pinch arm which allows for the flow of liquid through the tubing, and a closed position whereat the tubing passing through the valve body is completely collapsed by the pinch arm acting thereagainst which prevents the flow of liquid through the tubing. The shut-off valve further includes a biasing member which normally biases the pinch arm to the closed position, with the biasing member preferably comprising a spring which extends between the valve body and the pinch arm. The pinch arm of the shut-off valve itself includes a breakable detent tab formed thereon which maintains the pinch arm in its open position. The removal or breakage of the detent tab from the pinch arm results in the movement of the pinch arm to its closed position.

In the present pump, the platen member is sized and configured to move the pinch arm from its closed position to its open position when the platen member is moved to its operative position. Additionally, the platen member is pivotally connected to the housing at a location whereat the movement of the platen member from its non-operative position to its operative position results in the occlusion of the tubing by at least one of the pinch members prior to the movement of the pinch arm of the

shut-off valve from its closed position to its open position by the platen member.

In addition to the above-described pressure sensor members, the present pump is provided with a platen sensor which is disposed within the housing and operable to detect when the platen member is in the operative position. More particularly, the platen sensor comprises a Hall effect sensor which includes a magnet disposed within the over-the-center latch mechanism of the platen member. In addition to the magnet, the platen sensor includes a magnetic field detector which is disposed within the housing. The magnet and the magnetic field detector are oriented so as to be disposed directly adjacent each other when the platen member is in its operative position. The pump also includes a tubing sensor which is disposed within the housing and operable to detect when the tubing is extended over the membrane. More particularly, whereas the platen sensor is tripped by the movement of the platen member to its operative position, the tubing sensor is tripped by the insertion of the tubing locator pin into its corresponding recess within the housing. In the preferred embodiment, the platen sensor and the tubing sensor are electrically connected in series such that the drive unit may not be activated until the tubing is extended over the membrane and the platen member is in its operative position.

Advantageously, the tubing locator pin and shut-off valve of the tubing assembly may be added or attached to lengths of resilient tubing of differing diameters. Additionally, the use of off-the-shelf straight line, continuous PVC tubing in the present tubing assembly as opposed to a segment of silicone tubing having segments of PVC tubing adhesively secured thereto as is required by many prior art peristaltic pumps substantially reduces the costs associated with the present tubing assembly, in addition to providing increased reliability due to the absence of any adhesive joints. In the tubing assembly,

the shut-off valve attached to the tubing is maintained in its open position during shipment so as not to cause any premature deformation in the tubing. When the present pump and accompanying tubing assembly are ready for use, the detent tab is broken away from the pinch arm of the shut-off valve, thus causing the same to assume its normally closed position upon the tubing.

Brief Description of the Drawings

These, as well as other features of the present invention, will become more apparent upon reference to the drawings wherein:

Figure 1 is a front, top perspective view of the peristaltic pump of the present invention;

Figure 2 is a rear, top perspective view of the peristaltic pump of the present invention;

Figure 3 is a rear, bottom perspective view of the peristaltic pump of the present invention;

Figure 4 is a perspective view of the worm gear drive unit of the present peristaltic pump;

Figure 5 is a perspective view of the motor speed control unit of the present peristaltic pump;

Figure 6 is a perspective view of the platen member of the present peristaltic pump, illustrating the manner it is engageable to the housing thereof;

Figure 7 is a partial cross-sectional view of the present peristaltic pump, illustrating the manner in which the tubing assembly thereof is operatively captured between the pump fingers and platen member of the pump;

Figure 7a is a partial cross-sectional view illustrating the manner in which the tubing sensor of the present peristaltic pump is tripped by the insertion of the tubing locator pin of the tubing assembly into the housing;

Figure 8 is a partial cross-sectional view of the pump fingers of the present peristaltic pump,

illustrating the manner in which the pinch members thereof engage the tubing of the tubing assembly;

Figure 8a is a perspective view of one of the pump fingers of the present peristaltic pump;

Figure 9 is a perspective view of the tubing assembly of the present peristaltic pump;

Figure 10 is a perspective view of the tubing locator pin of the tubing assembly shown in Figure 9;

Figure 11 is a perspective view of the shut-off valve of the tubing assembly taken along line 11-11 of Figure 9;

Figure 12 is an exploded view of the shut-off valve shown in Figure 11;

Figure 13 is a cross-sectional view of the shut-off valve as in its open position;

Figure 14 is a cross-sectional view of the shut-off valve as in its closed position;

Figure 15a is a graph illustrating a typical pump cycle of a prior art rotary peristaltic pump;

Figure 15b is a graph illustrating a typical pump cycle of a prior art linear peristaltic pump;

Figure 15c is graph illustrating a typical pump cycle of the peristaltic pump of the present invention;

Figure 16 is a schematic of the circuit used to facilitate the functional interface between the motor speed control unit of the present peristaltic pump and the drive unit thereof; and

Figure 17 is a flow chart illustrating the primary hardware and software interfaces of the present peristaltic pump.

Detailed Description of the Preferred Embodiment

Referring now to the drawings wherein the showings are for purposes of illustrating a preferred embodiment of the present invention only, and not for purposes of

limiting the same, Figures 1-3 perspectively illustrate the curvilinear peristaltic pump 10 constructed in accordance with the present invention. The present pump 10 is preferably used in conjunction with an administration set or tubing assembly 12 which is shown in Figure 9 and will be described in more detail below. The tubing assembly 12 itself is provided with a novel and unique flow stop member or shut-off valve 14 of the present invention which is shown in Figures 11-14 and will also be described in more detail below.

PERISTALTIC PUMP

The present pump 10 is adapted to facilitate the pumping of a liquid through the tubing assembly 12, and comprises a housing 16. The housing 16 includes a front housing half 18a and a back housing half 18b which are rigidly attached to each other through the use of fasteners such as screws, though alternative attachment methods may also be employed in relation thereto. As seen in Figure 1, the front housing half 18a is provided with a keypad 20 and a visual display 22, the use of which will be discussed in more detail below. The back housing half 18b is provided with a removable door 24 for accessing a battery storage compartment within the interior of the housing 16. The front and back housing halves 18a, 18b are preferably fabricated from a plastic material, though alternative lightweight materials may be used for the fabrication thereof. In addition to the front and back housing halves 18a, 18b, the housing 16 comprises a support member 25 which defines a channel having a generally U-shaped cross-sectional configuration. The support member 25 is attached to the front and back housing halves 18a, 18b such that the channel defined thereby extends longitudinally between the upper ends of the front and back housing halves 18a, 18b. Referring now to Figures 1-4 and 6, the pump 10 further comprises a platen member 26 which is pivotally

connected to the support member 25 of the housing 16 and moveable between an operative position (as shown in Figures 1-3, 7 and 8) and a non-operative position (as shown in Figure 6) relative thereto. The platen member 26 defines an arcuate, generally concave inner surface 28. When the platen member 26 is in its operative position, it resides within the channel defined by the support member 25, with the inner surface 28 being shielded thereby. As best seen in Figures 6 and 7, the platen member 26 is provided with an over-the-center latch mechanism 30 on the end thereof opposite that pivotally connected to the support member 25. The latch mechanism 30 is cooperatively engagable to a pair of latch pins 32 protruding from respective ones of opposed inner surfaces of the support member 25 into the channel defined therebetween. As will be recognized, the engagement of the latch mechanism 30 to the latch pins 32 maintains or locks the platen member 26 within its operative position.

As further seen in Figure 6, the pump 10 includes a platen sensor 120 which is operable to detect when the platen member 26 is in its operative position. In the preferred embodiment, the platen sensor 120 is a Hall effect sensor which comprises a magnet 122 disposed within the over-the-center latch mechanism 30 of the platen member 26. In addition to the magnet 122, the platen sensor 120 includes a magnetic field detector 124 which is disposed within the support member 25 in close proximity to one of the latch pins 32 protruding therefrom. The magnetic field detector 124 is oriented so as to be disposed directly adjacent the magnet 122 when the platen member 26 is moved to its operative position and the latch mechanism 30 engaged to the latch pins 32. The use of the platen sensor 120 will be discussed in more detail below.

Referring now to Figure 7, the pump 10 further comprises a rotatable cam 34 which is disposed within the

interior of the housing 16 and rotatably mounted to the support member 25. More particularly, the cam 34 is mounted to the support member 25 so as to be rotatable about an axis which extends through the approximate center of the concavity of the arcuate inner surface 28 of the platen member 26 when the platen member 26 is in its operative position.

Referring now to Figure 4, the rotation of the cam 34 is facilitated by a drive unit 36 of the pump 10 which is also disposed within the interior of the housing 16 and attached to the support member 25. The drive unit 36 is mechanically coupled to the cam 34 such that the activation of the drive unit 36 results in the concurrent rotation of the cam in a first direction (i.e., the counter-clockwise rotation of the cam 34 when observed from the perspective shown in Figure 7), and the deactivation of the drive unit 36 maintains the cam in a set position. In the preferred embodiment, the drive unit 36 comprises a cam shaft 38 which extends from the cam 34. Attached to the cam shaft 38 is a worm gear 40 of the drive unit 36. In addition to the cam shaft 38 and worm gear 40, the drive unit 36 comprises a variable speed electric motor 42 which is attached to the support member 25 via a motor mount 44. Extending from the electric motor 42 is a rotatable motor shaft 46 which includes a worm 48 mounted thereto. The distal end of the motor shaft 46 is rotatably mounted within a bearing disposed within an aperture 50 extending through a portion of the motor mount 44. The worm 48 is itself cooperatively engaged to the worm gear 40.

In the drive unit 36, the engagement between the worm 48 and the worm gear 40 results in the rotation of the cam 34 in the first direction upon the activation of the motor 42. Such engagement also eliminates any rotation of the cam 34 upon the deactivation of the motor 42, the significance of which will be discussed in more detail below. The motor 42 of the pump 10 is

electrically connected to and powered by a multiple batteries which are stored within the interior of the housing 16 and accessible via the access door 24 provided on the back housing half 18b.

Referring now to Figures 6-8 and 8a, the pump 10 of the present invention further comprises a plurality of pump fingers 52 which are movably attached to the support member 25 and are arranged in side-by-side relation to each other so as to define an arcuate row. Each of the pump fingers 52 has a first end 54 which is cooperatively engaged to the cam 34 and a second end 56 which is disposed in spaced relation to the platen member 26 when the same is in its operative position. The pump 10 also includes a pliable membrane 126 which is preferably fabricated from a transparent or translucent material and is attached to the support member 25 so as to cover the second ends 56 of the pump fingers 52. Importantly, the membrane 126 functions to prevent any moisture from leaking into the interior of the housing 16. As such, the second ends 56 of the pump fingers 52 are covered by the membrane 126, and are disposed in substantially equidistantly spaced relation to the arcuate inner surface 28 of the platen member 26 when in its operative position. The membrane 126 is exposed (as shown in Figure 6) when the platen member 26 is in its non-operative position. The membrane is preferably formed to have a thickness of about 0.007 inches. As best seen in Figures 7, 8 and 8a, each of the pump fingers 52 preferably includes a plurality of roller members 58 rotatably mounted within and protruding from the first end 54 thereof. The roller members 58 of each pump finger 52 are arranged in a row. The pump fingers 52 are cooperatively engaged to the cam 34 via the roller members 58. As will be recognized, since the roller members 58 freely roll on the camming surfaces of the cam 34, wear on such camming surfaces is substantially reduced.

Referring now to Figure 5, the present pump 10 further comprises a motor speed control unit 60 which is operable to selectively increase and decrease the rotational speed of the cam 34 at prescribed intervals for reasons which will be discussed in more detail below. The motor speed control unit 60 is disposed within the interior of the housing 16 and comprises an optical sensor 62 which is attached to the motor mount 44 and electrically connected to the motor 42. The optical sensor 62 is adapted to transmit a beam of light L and sense any interruptions therein. In this respect, the optical sensor 62 includes a light beam transmitter 64 which is adapted to generate the beam of light L, and a light beam receiver 66 which is adapted to receive or sense the beam of the light L generated by the light beam transmitter 64.

In addition to the optical sensor 62, the motor speed control unit 60 comprises a shutter or encoder wheel 68 which is attached to the cam shaft 38 and rotatable thereby. The optical sensor 62 and encoder wheel 68 collectively define an optical encoder. The encoder wheel 68 includes four (4) encoder arms 70 extending radially therefrom in equidistantly spaced intervals of approximately 90 degrees. Importantly, the encoder wheel 68 is oriented relative to the optical sensor 62 such that the encoder arms 70 will intermittently interrupt the beam of light L during the rotation of the encoder wheel 68 by the cam shaft 38. As will also be discussed in more detail below, the number and size of the encoder arms 70 is selected such that interruptions in the beam of light L caused thereby correspond to pump cycles of the pump 10, with the optical sensor 62 being operable to determine the beginning and end of each pump cycle and increase the power to the motor 42 and hence the rotational speed of the cam 34 between pump cycles.

Referring now to Figures 7 and 8, the pump 10 further comprises a plurality of pinch members 72 which are movably attached to respective ones of the pump fingers 52 and protrude from the second ends 56 thereof. To facilitate the attachment of a pinch member 72 thereto, each of the pump fingers 52 is provided with a transverse slot 74 which is disposed within the second end 56 thereof and transitions into a transverse cavity 76 therewithin. Each of the pinch members 72 preferably comprises a base portion 78 which is disposed within the transverse cavity 76 and a finger portion 80 which extends from the base portion 78 into the transverse slot 74. The finger portion 80 defines a finger tip 82 which protrudes from the second end 56 of a respective one of the pump fingers 52. Extending between the base portion 78 and the wall of the respective transverse cavity 76 disposed furthest from the finger portion 80 is a biasing spring 84 of the pinch member 72. The biasing springs 84 function to bias the pinch members 72 radially outwardly toward the inner surface 28 of the platen member 26 when the platen member 26 is in its operative position for reasons which will also be discussed in more detail below.

Referring now to Figure 7, the present pump 10 further comprises a pair of pressure sensor members 86a, 86b, portions of which protrude from the support member 25 adjacent respective ends of the row of pump fingers 52. Each of the pressure sensor members 86a, 86b includes a beam 87 having a strain gauge disposed thereon. The functionality of the pressure sensor members 86a, 86b will also be described in more detail below.

TUBING ASSEMBLY

Referring now to Figures 7-14, the pump 10 constructed in accordance with the present invention is preferably used in conjunction with the tubing assembly

12 which is releasably attachable to the support member 25 of the housing 16. The tubing assembly 12 comprises a length of substantially straight, resilient tubing 88 which is preferably fabricated from polyvinyl chloride (PVC). Attached to each of the opposed ends of the tubing 88 are respective ones of a pair of connectors 90, such as standard Luer connectors. Additionally, attached to the tubing 88 is a tubing locator pin 92 (shown in Figure 10) and the shut-off valve 14 (shown in Figures 11-14) which is operable to selectively obstruct the flow of liquid through the tubing. As seen in Figure 10, the tubing locator pin 92 includes a generally C-shaped attachment portion 94 which is adapted to receive and fictionally engage the tubing 88 in a manner maintaining the tubing locator pin 92 in a desired location thereupon. In addition to the attachment portion 94, the tubing locator pin 92 includes a mounting portion 96 which is receivable into a complementary recess 98 formed within the support member 25 adjacent the location whereat the platen member 26 is pivotally connected thereto.

Referring now to Figure 7a, the present pump 10 further comprises a tubing sensor 128 which is disposed within the recess 98 formed within the support member 25. As will be discussed in more detail below, the tubing sensor 128 is operable to detect when the tubing assembly 12 is properly engaged to the support member 25, and is tripped by the insertion of the tubing locator pin 92 into the recess 98.

Referring now to Figures 11-14, the shut-off valve 14 of the tubing assembly 12 comprises a valve body 100. The valve body 100 defines a first slot 102 extending longitudinally therethrough and a second slot 104 extending laterally therethrough in generally perpendicular or transverse relation to the first slot 102. As such, the first and second slots 102, 104 collectively form a generally T-shaped pattern within the

valve body 100. The lower portion of the valve body 100 is insertable into a complementary recess 105 formed within the support member 25 adjacent the end thereof opposite that including the recess 98 formed therein.

In addition to the valve body 100, the shut-off valve 14 comprises a pinch arm 106 which has a generally H-shaped configuration and includes an opposed pair of side bar portions 108 which are interconnected by a cross bar portion 110 integrally connected thereto and extending generally perpendicularly therebetween. Formed on and extending generally perpendicularly from one side of the cross bar portion 110 is a post portion 112 of the pinch arm 106 which has a generally cylindrical configuration. As seen in Figures 12-14, the post portion 112 is sized having a length such that the distal end thereof protrudes beyond the lower ends of the side bar portions 108. Disposed on the post portion 112 is a biasing spring 114 of the shut-off valve 14. As further seen in Figures 12-14, the surface of the cross bar portion 110 opposite that having the post portion 112 extending therefrom and portions of the inner surfaces of the side bar portions 108 collectively define an opening 116 of the pinch arm 106. Additionally, as seen in Figures 11-13, when the pinch arm 106 is initially formed, the same is provided with a breakable detent tab 118 which is integrally connected to the lower end of one of the side bar portions 108, and thus is disposed adjacent the post portion 112. The use of the detent tab 118 will be described in more detail below. Those of ordinary skill in the art will recognize that the valve body 100 of the shut-off valve 14, as well as the pinch arm 106 thereof, may be provided in shapes other than for those described above.

In the shut-off valve 14, the pinch arm 106, including the biasing spring 114 mounted to the post portion 112, is movably attached to the valve body 100 via the receipt of the pinch arm 106 into the first slot

102. When the pinch arm 106 is properly inserted into the first slot 102, the upper ends of the side bar portions 108 thereof protrude from the upper end of the first slot 102 as seen in Figures 13 and 14, with the distal end of the post portion 112 extending into a reduced width section of the first slot 102 defined at the bottom end thereof. Additionally, the opening 116 defined by the pinch arm 106 is oriented so as to be in substantial alignment with the second slot 104 of the valve body 100. When the pinch arm 106 is initially attached to the valve body 100, the detent tab 118 engages the bottom end of the valve body 100 in a manner which maintains the biasing spring 114 in a state of compression and prevents the pinch arm 106 from reaching its maximum limit of upward travel.

In the tubing assembly 12, the shut-off valve 14 is attached to the tubing 88 via the advancement of the tubing 88 through the second slot 104 and opening 116. As seen in Figure 13, the second slot 104 of the valve body 100 is sized relative to the tubing 88 such that the wall of the tubing 88 and hence the lumen defined thereby is partially collapsed by the valve body 100 when the tubing 88 is advanced through the second slot 104 and opening 116. As will be recognized, the compression of the tubing 88 by the valve body 100 facilitates the frictional retention of the shut-off valve 14 at a prescribed location upon the tubing 88.

In the tubing assembly 12, the shut-off valve 14, and in particular its pinch arm 106, is moveable between an open position (as shown in Figure 13) and a closed position (as shown in Figure 14). When the pinch arm 106 is in its open position, the wall of the tubing 88 passing through the shut-off valve 14 is only partially collapsed by the valve body 100 and not compressed by the pinch arm 106. As such, the wall of the tubing 88 continues to define an open lumen which allows for the flow of liquid through the tubing 88. Conversely, when

the pinch arm 106 is moved to its closed position, it acts against and applies compressive pressure to the wall of the tubing 88 in a manner completely collapsing the same and hence the lumen defined thereby. As will be recognized, the complete collapse of the tubing 88 facilitated by the movement of the pinch arm 106 to its closed position prevents the flow of liquid through the tubing 88. Since the tubing 88 is already partially collapsed by the passage thereof through the second slot 104, the total length of movement of the pinch arm 106 from its open position to its closed position whereat the tubing 88 is completely collapsed thereby is only about a few millimeters. The biasing spring 114 normally biases the pinch arm 106 to its closed position. The movement of the pinch arm 106 to its open position is accomplished by the application of pressure to the upper ends of the side bar portions 108 protruding from the upper end of the first slot 102 of the valve body 100 in an amount sufficient to overcome the biasing force exerted by the biasing spring 114 and move the pinch arm 106 toward the reduced width bottom end of the first slot 102.

In the tubing assembly 12, the shut-off valve 14 attached to the tubing 88 is preferably maintained in its open position during shipment so as not to cause any premature permanent deformation in the tubing 88. As indicated above, the engagement of the detent tab 118 against the valve body 100 maintains the pinch arm 106 in its open position in the manner shown in Figure 13. When the pump 10 and accompanying tubing assembly 12 are ready for use, the detent tab 118 is fractured or broken away from the remainder of the pinch arm 106 by twisting it approximately ninety degrees, thus causing the pinch arm 108 to immediately assume its normally closed position relative to the tubing 88 as shown in Figure 14.

As indicated above, the mounting portion 96 of the tubing locator pin 92 is removably insertable into the

recess 98 of the support member 25, with the lower portion of the valve body 100 of the shut-off valve 14 being removably insertable into the recess 105 of the support member 25. As seen in Figure 7, the recesses 98, 105 are formed within the support member 25 outwardly of each of the opposed ends of the row of pump fingers 52. As further seen in Figure 7, in the tubing assembly 12, the tubing locator pin 92 and the shut-off valve 14 are attached to the tubing 88 at locations whereat a portion of the tubing 88 is extended over the membrane 126, and hence the second ends 56 of the pump fingers 52 (including the finger tips 82 protruding therefrom), when the tubing locator pin 92 and shut-off valve 14 are removably inserted into their respective recesses 98, 105.

As will be recognized, the tubing locator pin 92 and the shut-off valve 14 of the tubing assembly 12 are removably insertable into their respective recesses 98, 105 when the platen member 26 is in its non-operative position. As will be discussed in more detail below, the portion of the tubing 88 of the tubing assembly 12 extended over the second ends 56 of the pump fingers 52 by the insertion of the tubing locator pin 92 and the shut-off valve 14 into their respective recesses 98, 105 is captured between the second ends 56 (including the fingertips 82 of the pinch members 72 protruding therefrom) and the inner surface 28 when the platen member 26 is moved to its operative position.

In the tubing assembly 12, the tubing locator pin 92 and shut-off valve 14 may be added or attached to lengths of resilient tubing of differing diameters. Additionally, the use of off-the-shelf straight line, continuous PVC tubing in the present tubing assembly 12 as opposed to a segment of silicone tubing having segments of PVC tubing mechanically secured thereto as is required by many prior art peristaltic pumps substantially reduces the costs associated with the

present tubing assembly 12, in addition to providing increased reliability thereto due to the absence of any mechanical joints therein.

PERISTALTIC PUMP USE AND OPERATION

Having thus described the structural attributes of the pump 10 and accompanying tubing assembly 12, the preferred manner of using the same will now be described with particular reference to Figures 6-8. In the following discussion, it will be recognized that when the tubing 88 is described as being extended over the second ends 56 of the pump fingers 52 (including the fingertips 82 of the pinch members 72 protruding therefrom), or between the second ends 56 and the inner surface 28 of the platen member 26, the tubing 88 is actually being extended over the membrane 126 or between the membrane 126 and the inner surface 28. Similarly, in any instance when the second ends 56 and/or fingertips 82 are described as acting against the tubing 88, the contact therebetween actually occurs via the membrane 126 which covers the second ends 56 and fingertips 82. However, those of ordinary skill in the art will recognize that the membrane 126 need not necessarily be included in the pump 10, and that the tubing 88 may be extended directly over the second ends 56 of the pump fingers 52 and fingertips 82 of the pinch members 72. The pump 10 is used by initially moving the platen member 26 to its non-operative position as shown in Figure 6. Thereafter, the tubing assembly 12 is releasably attached to the pump 12 via the insertion of the mounting portion 96 of the tubing locator pin 92 into the recess 98, and the insertion of the lower portion of the valve body 100 of the shut-off valve 14 into the recess 105. As previously explained, the shut-off valve 14 and tubing locator pin 92 are attached to the tubing 88 of the tubing assembly 12 at locations whereat the insertion thereof into respective ones of the recesses 98, 105 results in a

portion of the tubing 88 being extended over the second ends 56 of the pump fingers 52 (including the finger tips 82 of the pinch members 72 protruding therefrom). The insertion of the tubing locator pin 92 into the recess 98 also results in the tripping of the tubing sensor 128. Additionally, a segment of the tubing 88 extending between the pump fingers 52 and shut-off valve 14 rests upon one of the pressure sensor members 86, with a segment of the tubing 88 extending between the pump fingers 52 and the tubing locator pin 92 resting upon the other pressure sensor member 86. As also previously indicated, when the tubing assembly 12 is initially attached to the pump 10, the shut-off valve 14 thereof resides in its normal closed position, with the pinch arm 106 thereof being engaged to and completely collapsing the tubing 88.

Subsequent to the attachment of the tubing assembly 12 to the pump 10 in the above-described manner, the platen member 26 is moved from its non-operative position to its operative position as shown in Figure 7. As indicated above, the movement of the platen member 26 to its operative position and engagement of the latch mechanism 30 thereof to the latch pins 32 results in the tripping of the platen sensor 120. When moved to its operative position, the inner surface 28 of the platen member 26 applies a slight amount of compressive pressure to that portion of the tubing 88 extending between the shut-off valve 14 and tubing locator pin 92. As such, the portion of the tubing 88 which is extended over the row of pump fingers 52 is slightly compressed between the inner surface 28 of the platen member 26 and second ends 56 of the pump fingers 52, including the finger tips 82 of the pinch member 72 protruding therefrom. As a result, the pump fingers 52, and more particularly the roller members 58 disposed within the second ends 56 thereof, are biased against the cam 34. Importantly, the platen member 26 is sized and configured to move the

pinch arm 106 of the shut-off valve 14 from its normal closed position to its open position when the platen member 26 is moved to its operative position. In this respect, a portion of the platen member 26 acts against and applies pressure to the upper ends of the side bar portions 108 of the pinch arm 106, thus facilitating the compression of the biasing spring 114 and resultant movement of the pinch arm 106 to its open position. Additionally, the platen member 26 is pivotally connected to the support member 25 at a location whereat the movement of the platen member 26 from its non-operative position to its operative position results in the occlusion of the tubing 88 by at least one of the pinch members 72, and more particularly the finger tip 82 thereof, prior to the movement of the pinch arm 106 of the shut-off valve 14 from its closed position to its open position by the engagement of the platen member 26 thereagainst. As such, irrespective of whether the platen member 26 is in its operative or non-operative position, the tubing 88 is always occluded by either the shut-off valve 14 or one of the pinch members 72, thus effectively preventing any backflow of liquid therethrough.

Subsequent to the movement of the platen member 26 to its operative position, the pump 10 may be activated to facilitate the pumping of liquid through the tubing assembly 12 thereby. The ability to activate the pump 10 occurs as a result of both the tubing sensor 128 and platen sensor 120 being tripped by the interface of the tubing assembly 12 to the support member 25 and the closure of the platen member 26 (i.e., the movement of the platen member 26 to its operative position). As indicated above, since the platen and tubing sensors 120, 128 are electrically connected to each other in series, both must be tripped in order for the pump 10, and in particular the drive unit 36 thereof, to be activated.

In the pump 10, the cam 34 is configured to sequentially move the pump fingers 52 radially outwardly toward and inwardly away from the inner surface 28 of the platen member 26 when rotated in the first direction by the drive unit 36. In this respect, as the cam 34 rotates and acts against the roller members 58 within the first ends 54, the pump fingers 52 are sequentially extended and retracted in a wave-like fashion as observed from the perspective shown in Figure 7, thus forcing liquid in the tubing 88 in the direction of rotation of the cam 34 (i.e., in a direction away from the end of the platen member 26 pivotally connected to the support member 25). As each successive pump finger 52 is fully radially extended outwardly and pressed against the tubing 88, the immediately preceding pump finger 52 begins to be withdrawn radially inwardly away from the tubing 88. When each pump finger 52 is moved to its position closest to the inner surface 28 of the platen member 26, the finger tip 82 of the pinch member 72 protruding from the second end 56 occludes the tubing 88. Thus, as indicated above, the rotation of the cam 34 forces liquid through the tubing 88 in the direction of cam rotation, with the occlusion of the tubing 88 which occurs as a result of the sequential action of the outwardly biased pinch members 72 thereagainst preventing any backflow of liquid within the tubing 88 when the platen member 26 is in its operative position, even upon the deactivation of the motor 42. As will be recognized, since the pumping of the liquid through the tubing 88 is dependent upon the sequential engagement of the second ends 56 of the pump fingers 52 thereagainst and the movement of the pump fingers 52 is dependent upon the rotation of the cam 34, the deactivation of the electric motor 42 which eliminates any rotation of the cam 34 due to the engagement between the worm 48 and the worm gear 40 assists in preventing any positive flow or backflow of liquid through the tubing 88.

In the pump 10, the sequential movement of the first through the last pump fingers 52 of the row toward and away from the platen member 26 by the rotation of the cam 34 defines a "pump cycle". During each "pump cycle", the engagement of the second ends 56 of the pump fingers 52 and pinch members 72 against the tubing 88 in the above-described manner forces liquid therethrough. As seen in Figure 15a, in prior art rotary peristaltic pumps, the pump cycles are generated in a generally sinusoidal fashion, with each of the pump cycles being separated by a "dead pump phase" wherein no liquid is being forced through the tube of the pump. Additionally, during the pump cycle itself, the flow rate of liquid through the tube of the prior art rotary peristaltic pump is not constant, but rather undergoing almost continuous changes in velocity. As seen in Figure 15b, in prior art linear peristaltic pumps, though a more constant rate of flow is achieved during each pump cycle, such pump cycles are separated by lengthy dead pump phases in which no liquid is being pumped through the tube of the prior art pump. As indicated above, it is significantly more desirable in a peristaltic pump for liquid to flow through the tube at a more uniform, steady rate with minimal changes in velocity or interruptions as are attributable to dead pump phases.

Referring now to Figure 15c, in the pump 10, the cam 34 is profiled or shaped so as to act against the roller members 58 protruding from the first ends 54 of the pump fingers 52 in a manner causing the second ends 56 and pinch members 72 to engage the tubing 88 such that the flow rate of liquid therethrough is substantially constant throughout each pump cycle. Such constant flow rate is achieved by forming the cam 34 as a four lobe cam. In addition to the cam 34 being shaped to provide a substantially constant flow rate throughout each pump cycle, the motor speed control unit 60 of the pump 10 is operable to increase the rotational speed of the cam 34

in the first direction between pump cycles for purposes of substantially eliminating the dead pumping phase which normally exists between pump cycles. In this respect, the number and size of the encoder arms 70 of the encoder wheel 68 is selected such that interruptions in the beam of light L caused thereby correspond to the pump cycles, with the optical sensor 62 being operable to determine the beginning and end of each pump cycle and increase the power to the motor 42 and hence the rotational speed of the cam 34 between pump cycles which substantially reduces the dead pump phase. Typically, an additional four (4) volts of power is supplied to the motor 42 to achieve the desired level of increased rotational speed of the cam 34. The reduction in such dead pump phases, coupled with the more uniform flow rate occurring during each pump cycle as achieved by the profiling or shaping of the cam 34, provides a substantially uniform or constant rate of liquid flow through the tubing 88 of the tubing assembly 12 during the operation of the pump 10.

Referring now to Figure 16, there is depicted an electrical schematic of the control circuit which functions as a closed loop feedback system and is used to facilitate the operational interface between the motor speed control unit 60 and drive unit 36 of the present pump 10. A full schematic of the control circuit is included in the present specification and illustrated below. As explained above, there is a dead zone portion of the pump cycle of the pump 10 where no pumping action occurs. Though this dead zone does not cause problems for higher infusion rates, it is highly undesirable in lower infusion rates. Accordingly, a speedup cycle has been implemented in the pump 10 to make its pump flow rate much more uniform by speeding up the pump rate during the dead zone portion of the pump cycle so that fluid flow is nearly constant, even at low flow rates.

In the pump 10, the speedup cycle is carefully tailored to minimize the acceleration command applied to

the motor drive circuitry of the electric motor 42 in order to reduce the power spike caused by a sudden increase in the speed of the electric motor 42. In this respect, a simple low pass filter would not be adequate due to the large speed change rate involved in the pump 10. Since for a simple RC time constant the initial speed change is greatest, with the rate asymptotically approaching final value, a linear ramped response is required to facilitate a constant acceleration of the electric motor 42 and reduce motor current power spikes. More particularly, a speed-up signal is required which starts from an initial commanded rate, ramps up to a speed-up rate, and then returns to a programmed rate.

To mechanize the speedup cycle in the pump 10, the optical sensor 62 of the motor speed control unit 60 is used to generate a signal when speedup is required. In the circuit schematically shown in Figure 16, the motor speedup signal generated by the optical sensor 62 is recovered and amplified to digital logic levels. The circuit also includes a gated temperature compensated current source and an integrated circuit which is a 4 to 1 analog multiplexer. The circuit generates a pulse width modulated (PWM) signal which enters the control input to the switch. During the "1" input, the switch is at ground. When the input is at "0", the switch is at a precision +2.5 volts. As such, the switch inverts the PWM signal and level converts it to a precision voltage for the proper input command to the driver of the electric motor 42. The input or motor speed command goes through a resistor and a capacitor, and is converted to a drive command. The same PWM signal is also sent through a resistor and a capacitor to recover the input command level to interact with the gated current generator. The circuit also includes a unity gain buffer amplifier to provide drive requirements for the switch. The speedup signal is at a much lower frequency than the

10 kHz PWM signal, and passes on to the electric motor 42 through a resistor when gated on.

During the operation of the pump 10, the pressure sensor members 86a and 86b generate electrical signals corresponding to the degree of expansion or compression, respectively, of the tubing 88 when acted upon by the pump fingers 52 and pinch members 72, thus providing warning of any over expansion and/or compression thereof. As indicated above, when the motor 42 is deactivated and the platen member 26 moved to its non-operative position, the shut-off valve 14 returns to its normal closed position and prevents any backflow of liquid through the tubing 88 in a direction opposite the first direction of rotation of the cam 34.

CONTROL SEQUENCE

Referring now to Figure 17, the pump 10 of the present invention is provided with an internal monitor and control unit 130 which monitors, controls and coordinates the various operations thereof. The monitor and control unit 130 implements software of a specific design and architecture which imparts to the pump 10 various functional attributes not found in prior art peristaltic pumps.

As seen in Figure 17, the monitor and control unit 130 is in electrical communication with a number of components of the pump 10, including the previously described key pad 20 which has an 19 key configuration. Included in the key pad 20 is an on/off key and a remote bolus button for the input of status and data to the software of the pump 10. Also in electrical communication with the monitor and control unit 130 is a beeper 132 of the pump 10 which is disposed within the interior of the housing 16. The beeper 132 contains two buzzers which operate at a single, fixed frequency. One of the buzzers, which is designated as the normal operation buzzer, is pulsed at varying widths, pulse

rates and total number of pulses, as a function of the event to be signaled thereby. The second buzzer, which is designated as the auxiliary buzzer, operates from a watch dog time out. The second buzzer can be tested once and then reset via a clear auxiliary beeper input event.

Also in electrical communication with the monitor and control unit 130 is a system clock 134 and the previously described display 22. The system clock 134 is a processor timer interrupt which is set at approximately 53.3 milliseconds. The display 22 preferably consists of a 100 x 32 dot graphical LCD display and three individual LED's which are located on the key pad 20. The LCD display is used to provide data information to the user, with the LED's being used to provide status information to the user. In addition to the above-described components, various pump sensors are in electrical communication with the monitor and control unit 130, including the above-described pressure sensor members 86, platen sensor 120, and tubing sensor 128. In addition to these particular sensors, the pump 10 may also be provided with air in-line sensors at the beginning and end of that portion of the tubing 88 extending over the membrane 126, and peristaltic cam drive sensors which monitor the revolution or rotation of the cam 34. The electric motor 42 of the drive unit 36 is also in electrical communication with the monitor and control unit 130, as is a power supply 136 of the pump 10. As previously explained, the electric motor 42 facilitates the rotation of the cam 34, and hence drives the pump 10. As also previously explained, the power supply 136 may comprise one or more batteries which are stored within the interior of the housing 16, such as a 3- volt battery or a lithium battery. Alternatively, the power supply 136 may comprise a 3-volt external power source which is electrically connected to the housing 16 and placed into electrical communication with the necessary components of the pump 10.

In addition to the foregoing, also in electrical communication with the monitor and control unit 130 is a system memory 138, a real time clock 140, a watch dog 142, and a serial communications port 144. The real time clock 140 provides a reference for the date and time of day, with this information being read therefrom on demand. The real time clock 140 may be reset to a pre-programmed value. The serial communications port 144 is preferably an asynchronous serial port, 9600 bps full duplex, with no RTS or CTS, RXD and TXD only. The watch dog 142 is an independent, re-triggered one shot which is attached to a mirocontroller NMI input and a motor inhibit control input of the pump 10. The watch dog 142 must be "petted" at least once per 1.6 seconds, and also provides a test capability which can be activated to cause the watch dog 142 to time out but not reset the microcontroller of the pump 10 one time after the power-up thereof.

The monitor and control unit 130 of the pump 10 controls the infusion process and monitors the process to prevent over infusion. The monitor and control unit 130 also provides for the user selection and programming of five different therapies, including:

1. Continuous infusion - designed to allow a constant programmed rate of infusion;

2. PCA or Patient Controlled Analgesia - designed for therapies that require a continuous rate of infusion, patient controlled demand boluses, or both;

3. TPN with Automatic Ramping - designed to allow a level rate of infusion of parenteral nutritional products with the option of tapering at the beginning, end or both of the infusion, and having an early ramp-down feature;

4. Intermittent Delivery - designed to deliver programmed intervals and rates of specified amounts of infusates and to optionally deliver small amounts of the

infusion between doses to keep the patient's access site patent; and

5. Variable Program - designed to allow varying amounts, rates and times of delivery of infusions up to twenty four (24) specified programs.

As such, the pump 10 can be used for intravenous, intra-arterial, epidural, subcutaneous, or enteral therapies. The pump 10 can also be used to deliver medications from a medication reservoir, from IV bags, or from syringes.

Upon the start-up of the pump 10, a "validate pump process" implemented by the software initiates the operation of the monitor and control unit 130, and more particularly the software thereof. The validate pump process performs a number of functions, including a "boot" which is entered from power-up reset and initializes the monitor and control unit 130 and the input/outputs thereof to the proper configuration. The boot performs a test on the boot code and start-up code of the software to verify their validity, and also is able to accept a special command to download code to a flash ROM. The boot also verifies that a valid program is downloaded into the flash ROM before operation of the pump 10 is permitted to proceed. The boot will also first verify via a CRC algorithm that the boot code is good.

In addition to the boot, the validate pump process performs a "start-up" which verifies that the pump 10, including both its hardware and software, is functioning properly by performing the required start tests on the monitor and control unit 130, system memory 138, pump monitor sensors 86, 120, 124, drive unit 36, and all aspects of the hardware of the pump 10. If these tests pass, control will transfer to a "program select" function of the validate pump process, otherwise it will transfer to a malfunction phase.

The program select function of the validate pump process provides a means to the user for selecting normal pump operation (transfer to programming), or allowing the user to perform special set-up functions. Access to such special set-up functions requires a special access code by the user, with such set-up transferring directly to the normal operation of the pump 10. These special set-up functions include printing the history files and other pertinent data of a patient. A further function of the validate pump process is "factory calibration" which provides for the calibration of the pump 10. These functions are also accessed only by a special access code, and are manually commanded.

The software of the monitor and control unit 130 also implements a "create therapy process" which accepts inputs from the user for programming up to five (5) different infusion therapies. Such programming includes the selection of the therapy to be programmed, the programming of the pump 10 and therapy options, and the programming of the prescription for the infusion. A therapy may be programmed as a new therapy, a repeat of an existing therapy, changes in an existing therapy, or continue with a therapy in process which was previously interrupted. After a therapy has been validated by requiring the user to select each prescription parameter with the push of the yes key of the key pad 20, execution will transfer to a notification menu to allow the start of the infusion.

The pump 10 of the present invention includes numerous other operational attributes which are implemented by various aspects of its hardware and software. A comprehensive treatment of this functionality and the hardware and software which implements the same is set forth below in the present specification.

Additional modifications and improvements of the present invention may also be apparent to those of

ordinary skill in the art. Thus, the particular combination of parts described and illustrated herein is intended to represent only one embodiment of the present invention, and is not intended to serve as limitations of alternative devices within the spirit and scope of the invention.

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Ambulatory Pump Users Manual

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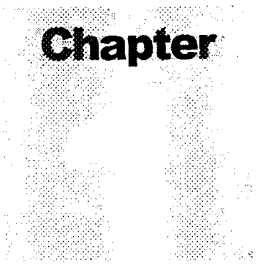
CHAPTER 1

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF FIGURES



Introduction

The **Curlin** *Ambulatory Infusion Pump has been designed with the user in mind and has the latest in friendly, simple to learn technology to allow fast and easy access to the features of this pump. With a little introduction and training, an operator will quickly be able to program and use this pump to deliver the therapies prescribed.*

Let's begin by introducing the pump itself. The Curlin pump is a clever, easy to use infusion device designed to meet the needs of the hospital or homecare patient. It operates accurately in any position and its small, compact and lightweight design allows mobility for ambulatory patients.

It can be carried in any of the three convenient carryall soft-packs, pole mounted, placed into the locked "safety shell" or set on a suitable surface for use.

Delivery Modes

The pump features five therapy delivery modes:

1. **Continuous Infusion** - designed to allow a constant programmed rate of infusion

2. **PCA or Patient Controlled Analgesia** -designed for therapies that require a continuous rate of infusion, patient controlled demand boluses or both.

3. **TPN with Automatic Ramping** -designed to allow a level rate of infusion of parenteral nutritional products with the option of tapering at the beginning, end or both of the infusion. This mode also has an early ramp-down feature.

4. **Intermittent Delivery** -designed to deliver programmed intervals and rates of specified amounts of infusates and to optionally deliver small amounts of the infusion between doses to keep the patient's access site patent.

5. **Variable Program** -designed to allow varying amounts, rates and times of delivery of infusions up to 24 specified programs.

Indications for Use

The **Curlin** pump can be used for intravenous, intra-arterial, epidural, subcutaneous, or enteral therapies. It can be used to deliver medications from the Curlin medication reservoir, from IV bags, or from syringes. A physician or a certified, licensed, healthcare practitioner must oversee any therapy. All patients and caregivers using the **Curlin** pump need to be instructed in its use by a qualified clinician and demonstrate an adequate level of proficiency in the use of the pump.

Special Features of the Curlin Pump

- Small, accurate, ambulatory volumetric infusion pump which provides reliable and safe delivery of infusion therapies.
- Inexpensive, safe and easy to load disposable Curlin administration sets featuring a unique, spring activated self-clamping "Flow-Stop"™ device which automatically clamps the tubing when the door of the pump is opened and prevents inadvertent over infusion.
- Quiet pump operation even when delivering high volumes.
- User-friendly, easy to teach programming which shortens staff inservice time and patient teaching time.
- "Helpful" Help Screens
- Four tamper-resistant lock levels assist in maintaining patient compliance and safety.
- Patient and therapy specific programming features via the Curlin Set-Up and Options Menus.
- Infuses in three units of delivery, milliliters (ml), milligrams (mg), and micrograms (μg)
- Retained programmed infusion settings are stored until cleared by the clinician, thus, eliminating the need to reprogram before each use.
- Two independent key press actions are required before the pump can be turned off, minimizing the accidental interruption of a therapy in progress.
- Powered by two readily available "C-Cell" batteries providing extended operating times.
- Attractive yet robust design is impact resistant and water-resistant.
- Audio alarms can be adjusted from high, medium or low to meet specific needs but cannot be totally disabled.
- Three sizes of convenient carry packs to assist the ambulatory patient in maintaining independence.

- Retained memory features allow the pump to easily resume a therapy from exactly where it left off when it is interrupted prior to completion.
- Small, compact, lockable safety shell with syringe adapter provides additional security when needed and is designed to be free standing, pole mounted or placed in the convenient soft carry case.
- Backlit illumination for display screen.
- Pump will not permit entering any programming value, which is outside of its predetermined range, or any computation that would take any parameter outside of its range.

IMPORTANT INFORMATION

The indicator shown at left appears throughout this manual to emphasize important information to note in the operation of the **Curlin** Pump. **Please read these sections carefully.**

Warnings, Dangers, Notices

IMPORTANT INFORMATION

- Note: Failure to properly comply with pump instructions could result in patient injury or death.
- U.S.A. federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.
- Do not use any pump or administration set which appears to be damaged or tampered with or if there is any indication of improper function.
- The Curlin pump is not intended for the administration of blood or cellular blood products.
- A possible explosion hazard may exist if the pump is used in the presence of flammable anesthetics or explosive gasses.
- This pump is fluid resistant and can withstand fluid spillage. It is not, however, designed for total submersion as moisture buildup within the case could cause damage to the operating components. Do not use the pump in the shower, sauna, steam bath, or position the pump where it could accidentally be dropped into a container of fluid (i.e., tub or toilet).

- Do not try to insert foreign objects into any of the pump connectors as this may damage the pump.

- When using the battery eliminator, the plug should only be connected into a grounded AC outlet.

- Use only non-rigid, non-vented fluid containers unless an air vent adapter is in place and the container is suspended from an IV pole.

- Use only Curlin administration sets in your Curlin pump. Do not unduly stretch the tubing of the administration set or leave the tubing in the pump for more than 24 hours when the pump is not running.

- Dispose of all used administration sets in accordance with all applicable regulatory and institutional requirements

- Do not use this pump with a pressure cuff applied to the medication reservoir bag or unduly squeeze or compress the bag during a running infusion.

- Remove all air from the administration set prior to connecting it to a patient's access site. Use Curlin administration sets with appropriate air-in-line filters any time the air-in-line sensitivity is disabled. The user should be taught to check all sites for proper aseptic connections and to check the administration sets for air leaks prior to and during the infusion. To minimize the formation of air bubbles or "out-gassing", all medications should be administered at the proper temperatures and removed from refrigerators as specified by the health care provider or pharmaceutical manufacturer.

- Do NOT prime the set while it is connected to a patient. Doing so could result in overdosing the patient and could cause injury or death.

- If any signs or symptoms of infiltration or inflammation are noted at the infusion site, stop the infusion and report it to the appropriate healthcare provider.

- Any warnings, precautions, or contraindications in the drug manufacturers labeling limit administration of any drug by this pump and via the Curlin administration sets.

- All drugs selected for Epidural Administration must be administered in accordance with the indications included in the manufacturers package insert accompanying the drug. **WARNING:** Delayed respiratory depression has been reported following continuous epidural administration of preservative-free morphine sulfate.

Pump Illustrations and Features

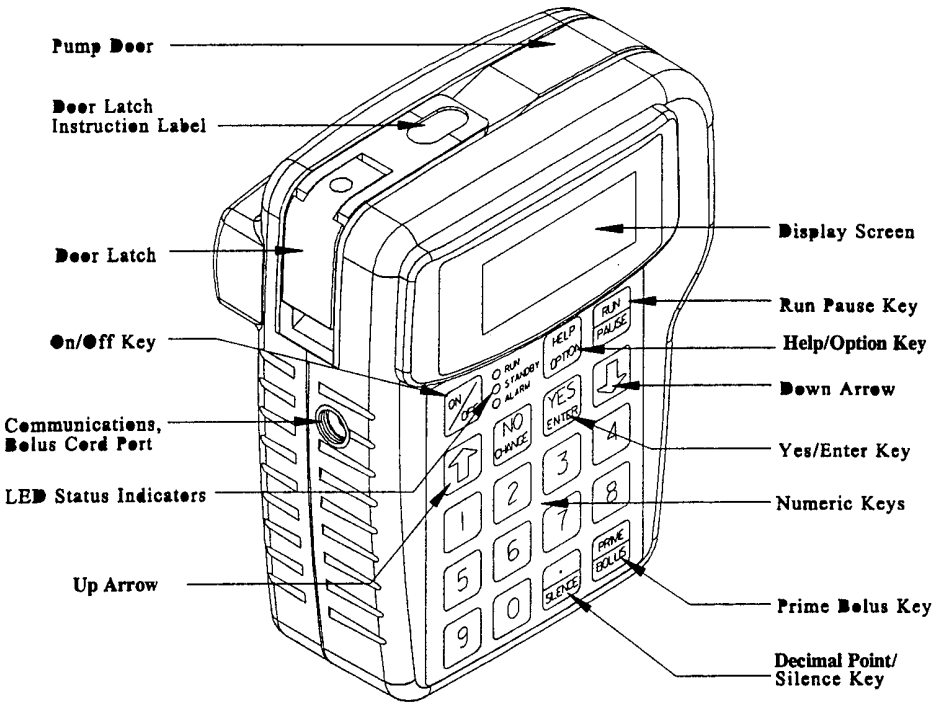


Figure 1.1 Curlin Pump - Front, Top Left View

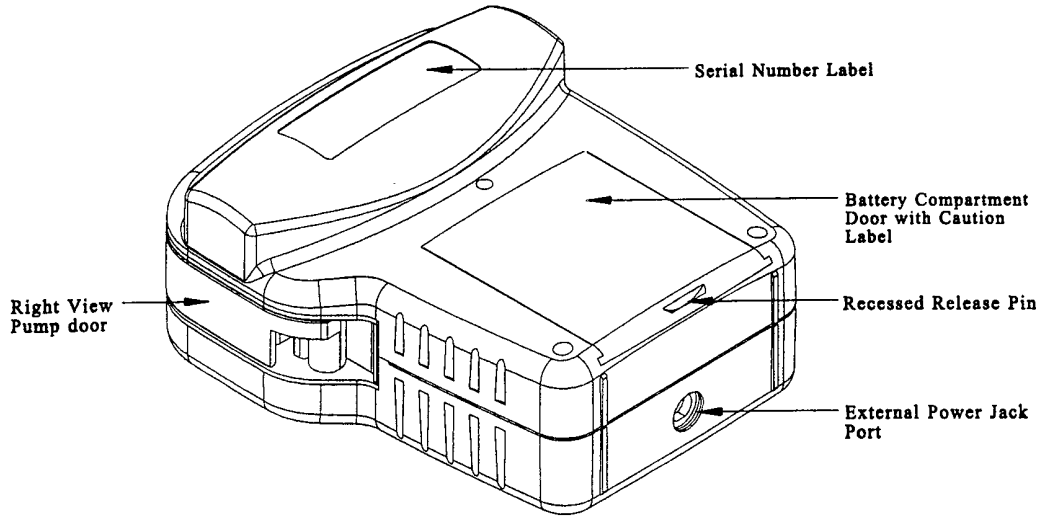
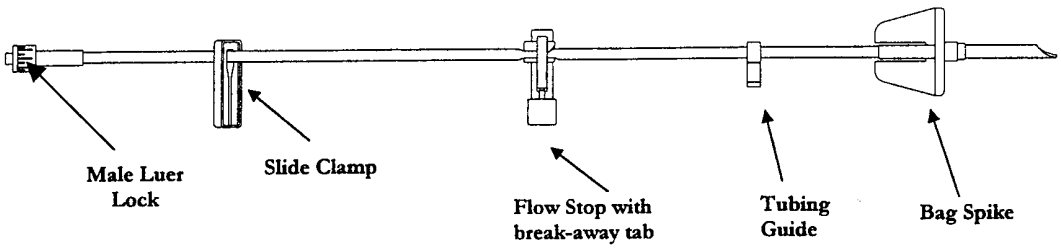


Figure 1.2 Curlin Pump - Back, Bottom, Right View

Disposable Administration Set Illustrations and Features

These samples are NOT drawn to scale



NOTE: An important feature of the Curlin Administration sets is the unique design of the "Flow Stop". When the set is new, the "Flow Stop" has a breakaway tab that keeps the "Flow Stop" open and allows the tubing to be gravity primed. When ready to load the administration set into the pump, remove this tab and the tubing will be clamped by the "Flow Stop". The **Curlin** "Flow Stop" prevents inadvertent over infusing of medication to the patient whenever the door of the pump is opened because it automatically reacts to clamp the tubing. The "Flow Stop" can, however, be opened after the tab is broken away by intentionally squeezing down on the moveable spring action section of the "Flow Stop". See figure 1.5 for an illustration of how to intentionally open the "Flow Stop".

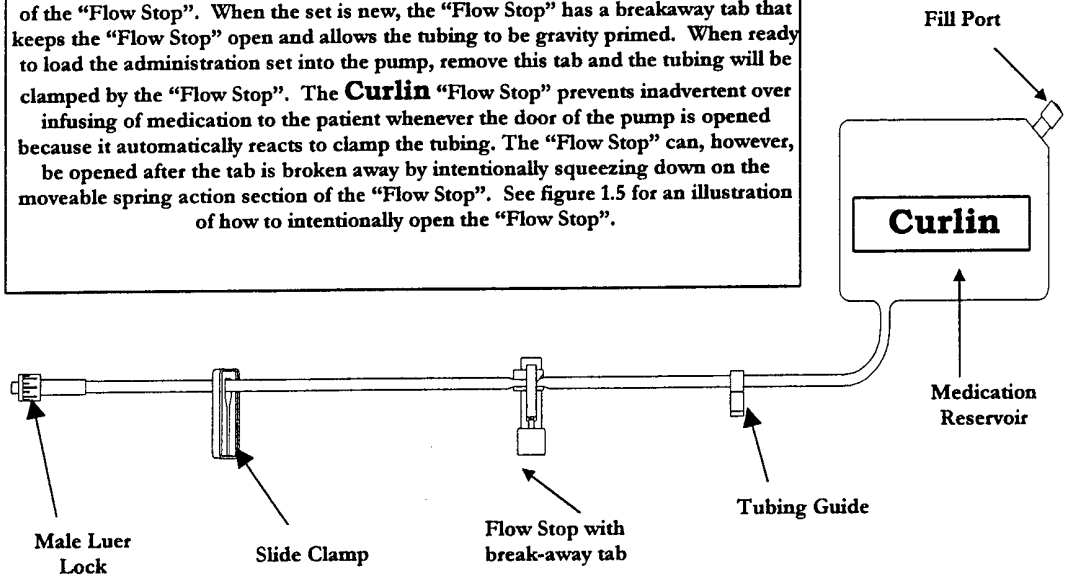
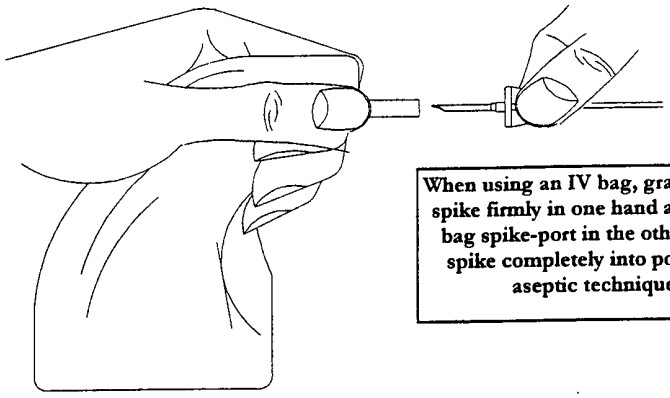
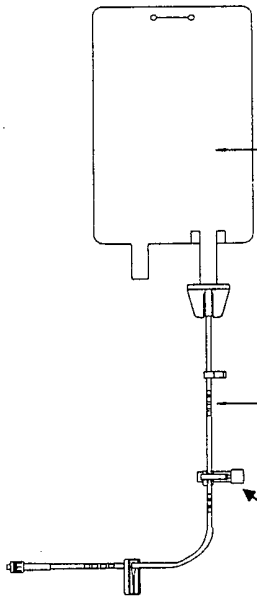


Figure 1.3 Samples of Curlin Administration Sets

Preparing Medication for Infusion



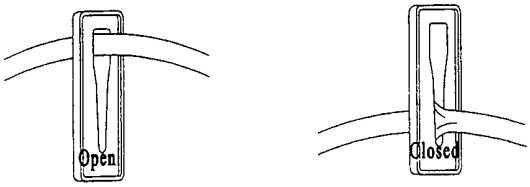
When using an IV bag, grasp the bag spike firmly in one hand and the IV bag spike-port in the other, insert spike completely into port using aseptic technique.



Holding bag with fill ports down, allows fluid to fill tubing and displace the air in the line. Be sure all air has been removed from the IV bag as well.

Air in the line moves down through the tubing as the fluid fills

Notice the breakaway tab on the "Flow Stop" is still in place, leaving the "Flow-Guard" open and allowing fluid to move through the tubing. If the tab has been removed, the set can be gravity primed by intentionally squeezing the flow-guard and thus releasing the clamping action. (See Figures 1.5 & 1.6)



In these illustrations the slide clamps are shown in their open and closed states.

Figure 1.4 Spiking the fluid container, gravity priming the set and using the slide clamp to close the tubing

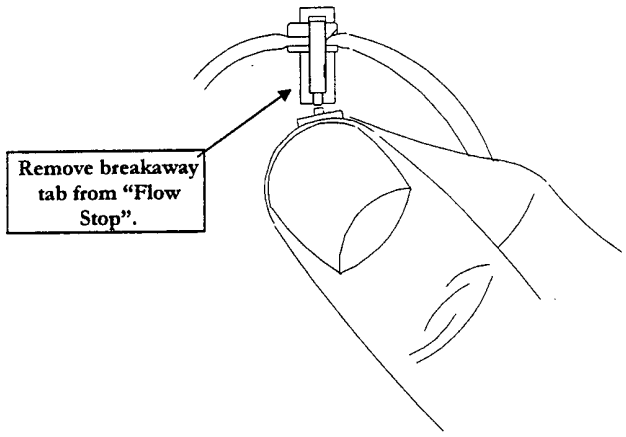


Figure 1.5 Curlin **Administration set "Flow Stop" with breakaway tab**

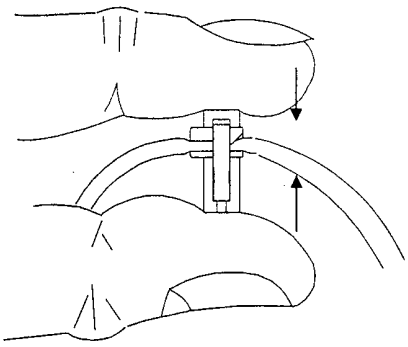
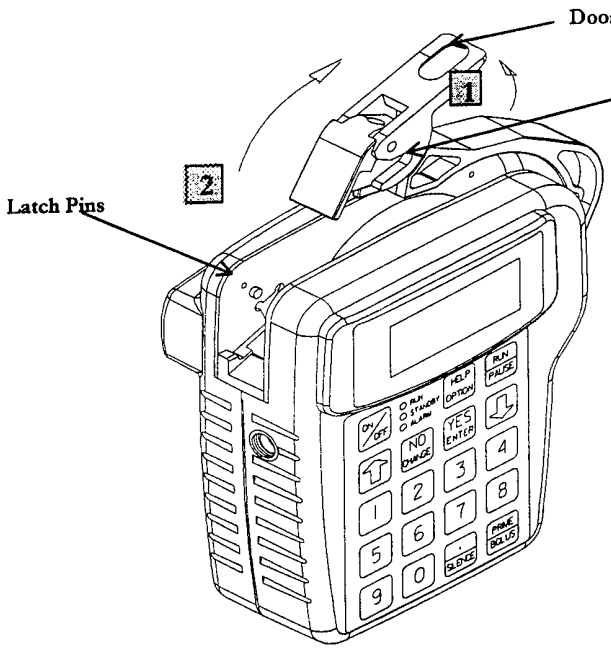


Figure 1.6 Intentionally opening the "Flow Stop"

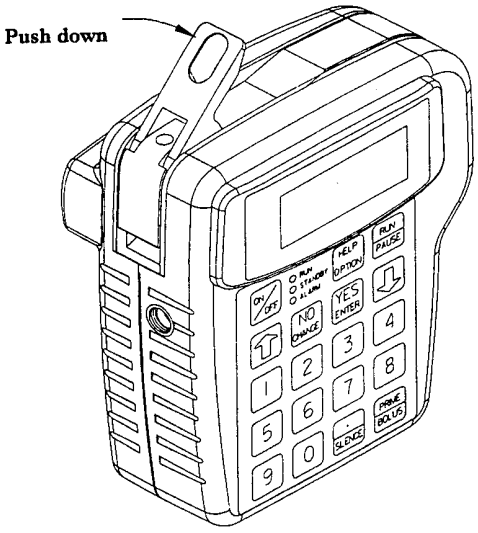
Opening and Closing the Pump Door

The pump door, located on the top of the Curlin pump, has a sturdy "over center" latching mechanism, which assists, in securely closing the door. Review the following figures and illustrations:



To open the pump door:
1. Pull the door latch up, releasing the latch hooks from the latch pins.
2. Grasp the door latch and pull upwards and to the right to open the entire door mechanism. Full range access is now available for installing the **Curlin** Administration set (see figures 1.9 and 1.10)

Figure 1.7 Opening the pump door



To close the pump door properly, move the entire door assembly to the left and downward until it is in its' closed position. Then push the door latch down until it locks. The "over-center" latching mechanism assures that the door closes easily and securely.

Figure 1.8 Closing the Pump door

Proper Installation of the Curlin Administration Set into the Pump

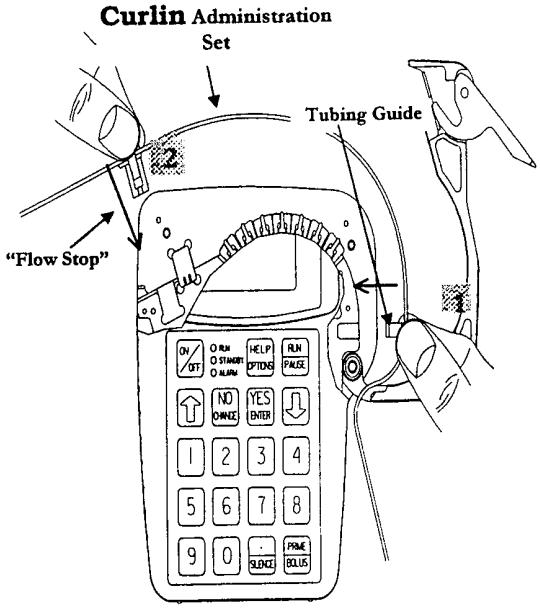


Figure 1.9 shows the Curlin pump with a cut-away of the display screen allowing you to visualize the receptacles for the small "tubing guide" on the right side of the pump and the larger "Flow Stop" on the left side of the pump. The arrows indicate the proper placement direction to fit these locators into their receptacles. Also, note that the "breakaway" tab has been removed from the "Flow Stop" allowing the administration set to be placed into the pump, correctly.

Figure 1.9 Proper installation of the Curlin administration set into the pump.

Choosing and installing the Curlin Administration Set

A number of distinctively designed ***Curlin*** administration sets are available to deliver each prescription accurately. (See ***Curlin*** product catalog). Each set is designed to meet the requirements of specific therapies, so if a basic bag spike set or a set with a medication reservoir is needed, with or without air eliminating filters, etc. there are several configurations from which to choose. Follow the healthcare provider's protocols for preparing the medication and the administration set prior to loading the set into the pump, remembering the following basic rules:

1. Examine the packaging and the administration set prior to use to assure the package integrity. Do not use the set if the package integrity is breached, as sterility cannot be guaranteed.

2. Gravity prime the administration set prior to removing the break-away tab on the "Flow Stop" or, if the tab has already been removed, squeeze the Flow Stop to reopen its clamping mechanism (see Figure 1.6) and remove all air from the medication container and the administration set.

3. Close the slide clamp on the administration set before the door of the pump is opened. This step along with the automatic clamping properties of the ***Curlin*** Administration sets "Flow Stop™" prevents inadvertent over infusion.

4. Use an administration set with an air-eliminating filter whenever the air-in-line detector is disabled or set to the "off" setting.

5. Follow institutional protocols or Intravenous Nursing Standards of Practice Guidelines in frequency of changing the administration sets. INS states, "change IV sets every 48 hours, (total parenteral nutrition, "TPN", administration sets shall be changed every 24 hours), or immediately upon suspected contamination or when the integrity of the product has been compromised" (Journal of Intravenous Nursing, Vol. 21, 1998)

6. Use aseptic technique and universal precautions as directed by your health care provider or institution.

7. Only use **Curlin** Administration sets with the **Curlin** pump.

8. Dispose of administration sets in accordance with agency or institutional guidelines.

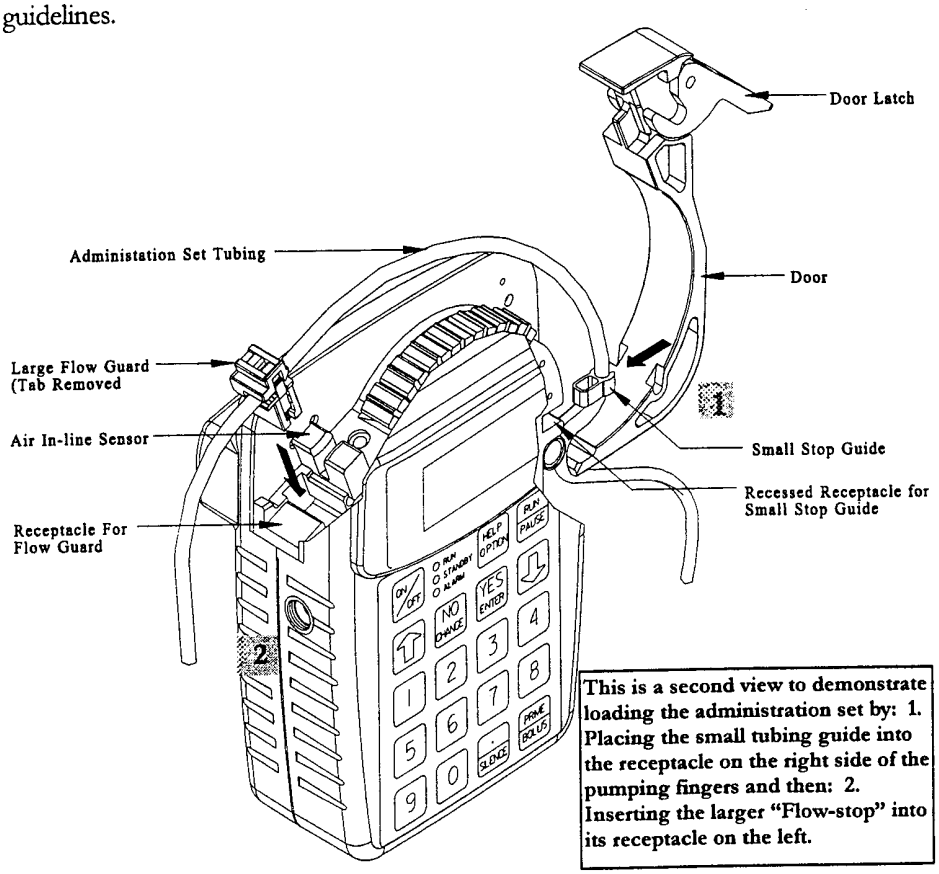


Figure 1.10 Top cut-away view of the Curlin pump with administration set placement

Installing the Batteries & Using External Power

The Curlin pump can be powered solely with the use of two "C-Cell" Batteries installed into the pump as shown in figure 1.11. A second alternative for power is the portable, rechargeable Battery Pack, shown in figure 1.12. The third alternative for power is to use the Battery Eliminator shown in figure 1.13 to plug the pump into an approved, grounded, 3-prong electrical wall outlet.

The battery compartment door is located on the back of the Curlin pump. To open the door, depress the recessed release pin (it may be helpful to use a small coin for this purpose), slide the battery door down, remove the old batteries and replace them with two (2) new "C-Cell" Alkaline batteries. Install them with the positive poles at the top as shown in figure 1.11. Always replace both batteries. Notice that the Battery Compartment Door does not slide completely off the compartment. This design is helpful in not loosing the door as well as facilitating easy closure of the compartment. Slide battery compartment door back to closed position until the recessed pin locks in place.

PLEASE NOTE:
Dispose of batteries in an environmentally safe manner. Do not incinerate them.

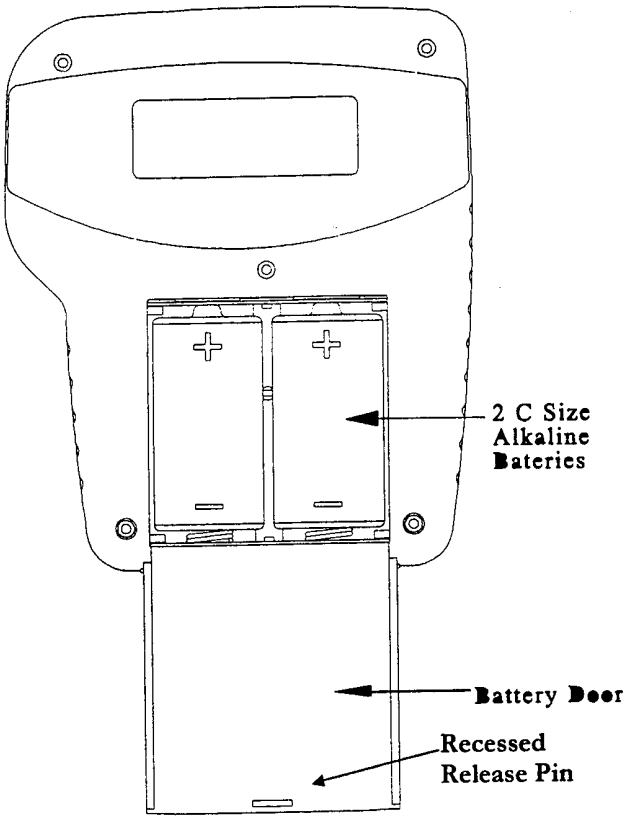


Figure 1.11 Installing Batteries into the Curlin Pump

IMPORTANT INFORMATION

Even if an external source is powering the pump, it is important to always install the two "C" Cell batteries. In the event of a power failure, the batteries will be a back up power source and the pump will continue to operate without interrupting the therapy in progress.

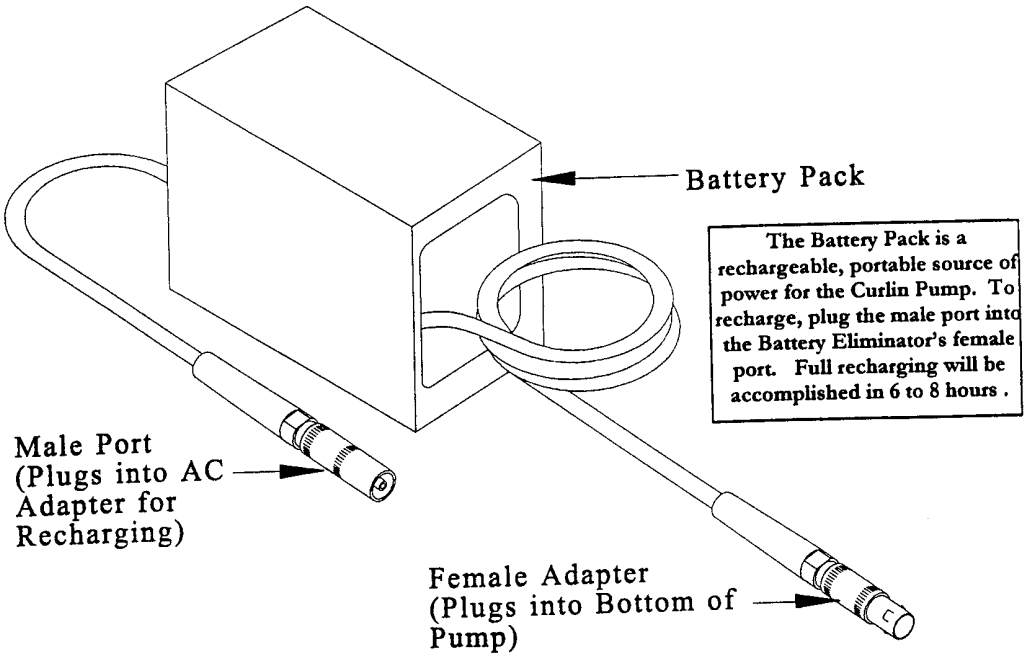


Figure 1.12 Battery Pack

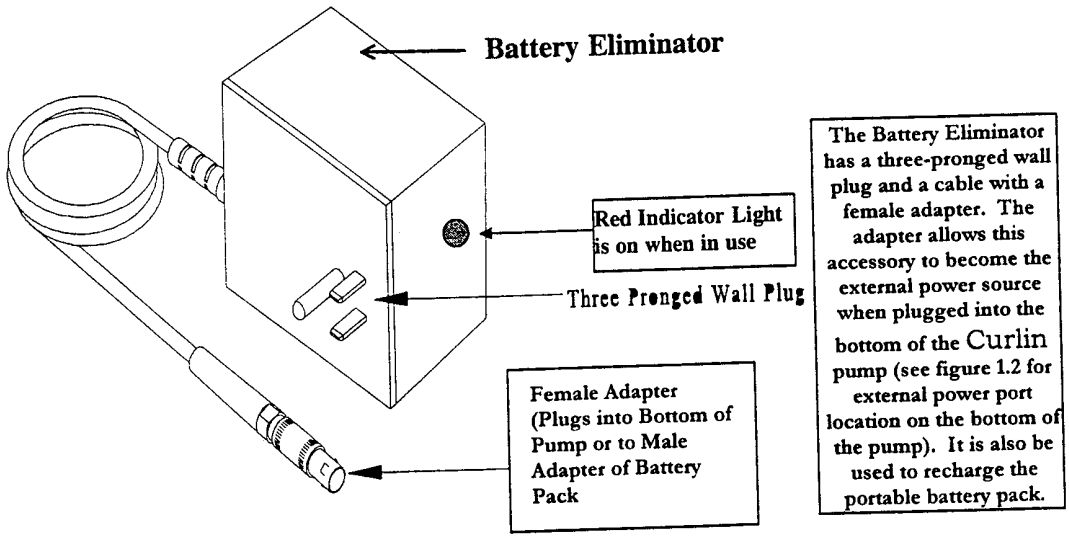
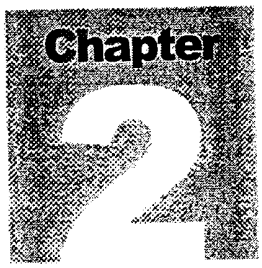


Figure 1.13 Battery Eliminator



Learning Pump Features

Learning to operate the Curlin *pump requires a few basic points of understanding which remain constant for every programming stage. It may be helpful to read through these steps first and then go back and use them to operate the* Curlin *pump.*

First, examine the key pad and the functions of the individual keys. Knowing how the keys, especially the dual function keys, work will allow the user to give commands to the pump.

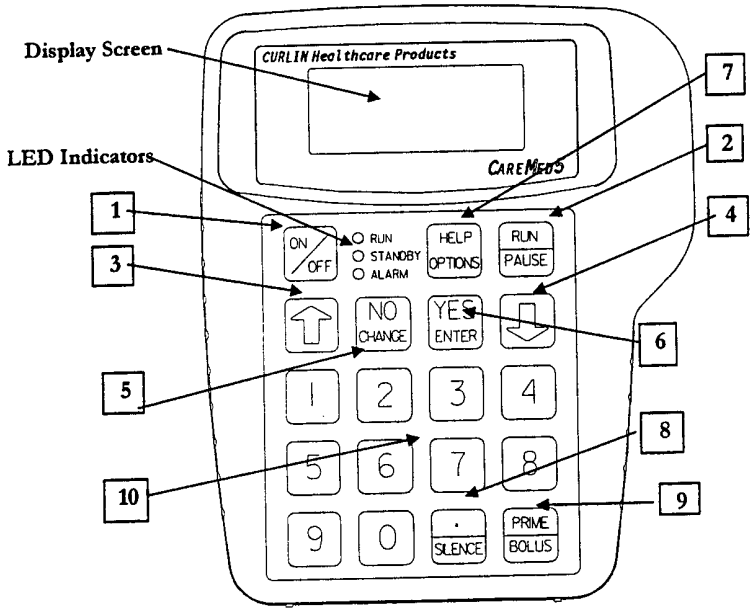


Figure 2.1 Key Pad

Keypad Function

1. **ON/OFF** Used to turn the pump on and off. The pump, in its running state, however, will not turn off until the "pause" key is used to stop the infusion first and then the "off" key can be pressed to turn the pump off. This feature prevents the interruption of an infusion with a single *accidental* press of the "off" key.

2. **RUN/PAUSE** Used to start or pause the motor of the pump which, in turn, starts or pauses fluid delivery. When the pump is running, pressing this key will pause the pump. When the pump is paused, pressing this key sequence, will start the pump.

3. ⇑ **Up arrow** Used to move the highlight bar or field cursor *up* on the screen.

4. ⇓ **Down arrow** Used to move the highlight bar or field cursor *down* on the screen.

5. **NO/CHANGE** Used to respond "no" to data or questions presented or to indicate "change" data displayed. Also, used to exit "HELP".

6. **YES/ENTER** Used to respond "YES" to data or questions presented or to "accept" data when prompted to press "enter" key.

7. **HELP/OPTIONS** Used to request help screen when pump is paused or to go to the options screen when the pump is running. Whenever the options screen is displayed, help is available with this key. When in a help screen, use the arrow keys to scroll through the help message and press "NO/CHANGE" key to exit.

8. **./SILENCE** Used as a decimal point when programming numeric data. Used also to temporarily silence the alarm (for one-minute intervals).

9. **PRIME/BOLUS** Used to prime fluid through tubing to clear it of air or to administer a patient demand bolus dose of medication in PCA therapy.

10. **0 - 9** Numeric keys - Used for data entry.

LED Indicators

This "three-light" feature gives the user feed back on the current status of the pump.

1. **O - Green** indicates RUNNING status of the pump and blinks when a therapy is in progress.

2. **O - Yellow** indicates STANDBY or ALERT status of the pump and blinks while pump is paused or whenever an alert status exists.

3. **O - Red** indicates a STOPPED or ALARM status of the pump and blinks whenever an alarm status exists.

Audio Indicator

An audible alarm is used to alert the user to a status of the pump, which requires user action or notification. The rate and number of beeps and volume further specify status. Three different volume levels, high, medium and low can be programmed for the audio feature; however, it cannot be totally disabled. The audio "beep" can be silenced for one minute intervals by pressing the "SILENCE" key except during a "malfunction" state, at which time the alarm continues and the user is instructed to turn the pump off. Chapter 9 lists the alerts, alarms and malfunctions and their associated audio cues.

Display Screen

The display screen provides a maximum of four lines of text, or fields, at any one time for feed back regarding the pump status, data entry and notifies user with prompts or messages when necessary. The screen has back lighting which remains lit all the time whenever the pump has AC power (plugged into an electrical outlet). If the pump is powered by battery or battery pack, the light remains on during any key press sequences. When no keys are pressed for two minutes, the light goes off to conserve battery power. Backlighting is resumed with any key press.

In most displays a "Therapy Identifier" Bar appears at the far left of the screen indicating which therapy is running or which programming screen is being considered. This Identifier also has another function and that is to alert the user when more text exists either above the top line or below the bottom line on the display screen. The Identifier bar will have an arrow configuration either pointing up or down or both whenever there is more text or it will appear as a squared off block if no further text exists.

The screen also has a cursor or highlight bar to tell the user which field is being considered. Use the up and down arrow keys to move the cursor. When the pump is running, a specially designed "running screen" appears to provide information regarding the status of that particular infusion. In the following chapters, each display screen will be explained.

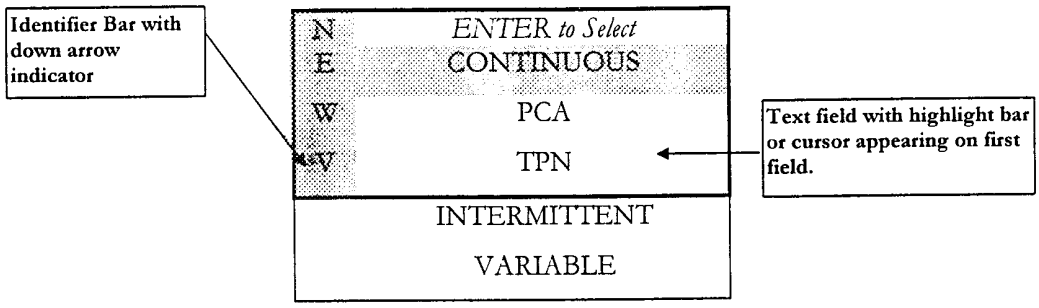


Figure 2.2 Sample of display screen

Chapter

Basics of Programming

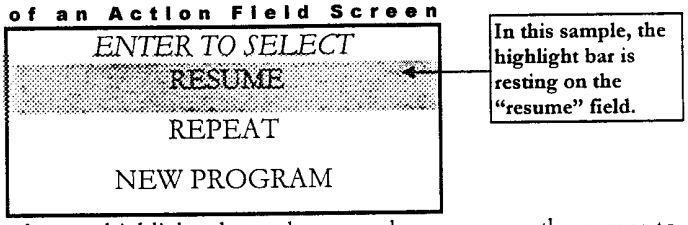
Programming the Curlin pump allows the operator to customize this device to meet the specific infusion needs of each individual patient.

Programming the Curlin pump requires initial orientation and training, but has been designed to be user friendly and self prompting. There are several different types of fields that appear on the display.

When the user is required to interact with the pump, a highlight bar or cursor will be present on the screen.

1. An action field allows the user to select a pump action from the menu.

Sample of an Action Field Screen



To select a field other than the one highlighted, use the arrow keys to move the cursor to the desired field. When the cursor is highlighting the correct field and the user presses the "YES/ENTER" key, the pump accepts the selection and executes that action. In the sample above, the pump would proceed to resume the therapy.

2. A Selection List Field allows the user to select from a predetermined list of values:

Sample of a Selection List Field

Label	Selection	next selection	Next selection
UNITS:	mg/hr	mg/hr	µg/hr

The above sample allows the operator to select which unit to use in programming, e.g. Units: ml/hr, mg/hr or μg/hr. Only one selection is displayed at a time and the cursor blinks indicating more choices are available. The selection displayed on the screen changes each time the user presses the "NO" key. Pressing the "YES" key accepts the selection and moves the cursor to the next field.

3. Data entry fields are used to specify parameters.

Sample of a Data Entry Screen

C	BAG Vol:	1000	Ml
O	Vol TBI:	300	Ml
N	RATE:	100	ml/hr
	TIME:	3:00	HH:MM

In the above sample, the cursor rests on a field requiring the user to enter numeric data for specific prescription information, i.e., a volume in the IV bag. The operator enters the correct information with the numeric keys and decimal point key. When the display shows the correct data and the user presses the "YES/ENTER" key, the pump accepts the selection and moves the cursor down to the next field.

4. Run Fields display information to the operator about the progress of the specific infusion whenever the pump is running:

Sample of a Run Screen

C	RATE:	100	ml/hr
O	[IIIIIIIIIIIIII	IIIIIIIIIIIII	.....]
N	Vol INF:	300	Ml
	REMAIN:	3:00	HH:MM

Displayed on the screen is the Mode Identifier, rate of pumping, a graphical image indicating the progress of the infusion, the amount already infused, and the time remaining for the infusion. No action is required on a run screen therefore no highlight bar appears.

5. User Notification Screens are messages displayed to the user for information.

Sample of User Notification Screen

PRESS
RUN TO START
NO TO CHANGE
OPTIONS OR **PRIME**

For all events such as Alarms, Alerts, Malfunctions, etc. notification screens will be displayed. The audio alarm will sound and the LEDs will also blink when a notification screen is displayed. Words representing keys are displayed in reverse video (shown here as bold text). The action requested by a notification screen is to either press a specified key or to resolve an alert or alarm.

Prompts are included on the screens that require the user to perform certain functions and when the pump is paused a help screen is available to display further directions. To access help, press the "HELP" key. Use the arrow keys to scroll through the help message and the "NO" key to exit help.

Starting the Pump

Start the pump by pushing the "ON" key. The following screen will display:

Welcome Screen

Welcome to BDC
30 Sep 98 24:00
Self Test.....

The above "Welcome" screen gives the date, time and a message that tells the user the pump is performing a self-diagnostic test. If the self-test fails, a new screen will appear stating "Malfunction, Turn Pump Off". (Note: there is no highlight bar because the user does not interact with this screen...the display automatically moves to the next screen.)

IMPORTANT INFORMATION

If, at any time, there is indication of pump damage, malfunction, or messages requiring the pump to be turned off, call the healthcare provider as directed and report the condition to the clinician. **Do not use the pump under these circumstances without consulting your healthcare provider.**

When the Curlin pump has successfully passed its self-test, a brief message of "System OK appears and the display moves to the next screen:

Power Status Screen

POWER SOURCE
BATTERY
low [||||||.....] high

This screen displays the active power source of the pump, whether batteries or external power. If the active source is the batteries, a graph will indicate how much charge remains in the batteries. This graph is only an *approximate estimation* of the charge left and is not intended to give a specific representation of battery life. The display will again automatically move to the next screen.

Preventive Maintenance Screen

Routine Preventive Maintenance Due 30 Sep 99

The above temporary screen will appear following the Welcome Screen ***only*** when the Maintenance Due date has arrived and until it has been reset during the actual maintenance performance.

Select Program or Setup Screen

ENTER to Select PROGRAM SETUP

This screen is the first requiring the user to act. It gives two selections from which to choose, "PROGRAM" or "SETUP". Using the up or down arrows, move the cursor to the desired field and then press the ENTER key.

"Program" allows the user to enter data required for the pump to deliver a prescribed therapy.

"Setup" requires a clinician access code (see access code information in Chapter 13) to be entered and allows the pump to be programmed by the clinician to perform a number of special functions.

Access Code

Clinician Access Code Screen

Enter Access Code CODE: **** (Invalid Code) EXIT? YES

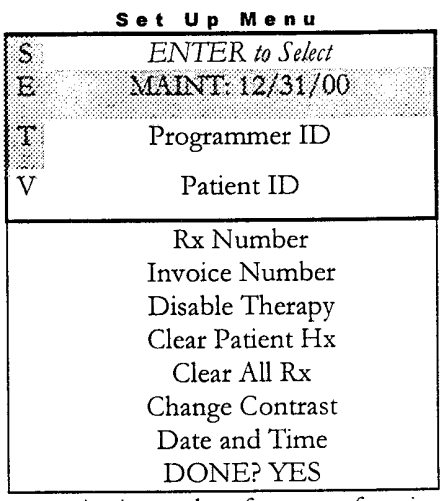
The clinician enters the four-digit access code and, if the code is valid, the display will automatically move to the requested screen or field. If an invalid code is accidentally entered, a message will display "Invalid Code" and the clinician can reenter the correct code.

IMPORTANT INFORMATION

If an access code screen displays and the access code is not known, use the down arrow to move the cursor to the "EXIT?" field. Press the "YES" key at this field to return to the previous screen and chose another selection. Also, remember, that the "HELP" key is available to give the user additional instruction any time the pump is in a paused state.

Look first at the *setup* menu and it's special customization features and then move on to the program menu:

Set Up



The setup menu lists special customization and performance functions of the pump:

(Note the Screen Identifier Bar at the left of the display has a down arrow at the bottom of the bar configuration indicating that there is more text to follow.)

IMPORTANT INFORMATION

The user may skip any of these functions by using the down arrow to move the cursor to the desired selection. When all SETUP functions are completed, move the cursor to the last field, "DONE? YES" and press the YES" key to exit this menu.

1. PREVENTIVE MAINTENANCE DATE: The first line highlighted relays the date the pump is to receive its annual routine preventive maintenance (PM) check. The clinician programming the pump for a patient should note the maintenance date. Once this date arrives, a "Routine Preventive Maintenance Due Date" message will briefly appear after the welcome screen. If the Maintenance Due date will occur during the time the patient is on service, the clinician may wish to select another Curlin pump for this patient. This will

avoid any undue concern on the patient's part at the notice of "maintenance due" and eliminate the need to recall a pump in service for maintenance.

2. PROGRAMMER ID: This optional feature gives the programmer an opportunity to use the numeric keypad to enter his or her assigned ID number (up to 10 digits). If this option is not to be used, it can be left at the default setting of "0" and skipped using the down arrow to scroll to the next field. Use of programmer ID information is held in the pump history. When the ID number is satisfactorily entered press the "YES" key to accept and move the cursor to the next field.

3. PATIENT ID: This optional feature is used to enter a patient ID number (up to 10 digits). When the ID number has been entered satisfactorily, press the "YES" key. The cursor records this ID number into the history log and moves the cursor to the next field. This field can also be left at a default setting of "0" and skipped entirely.

4. Rx NUMBER: This field is optional (defaults to "0") or is used to enter the prescription number. The Rx information may prove helpful in tracking a pump with its proper prescription order. Again, the numeric keypad is used to enter the correct Rx number (no letter characters can be entered, only numbers) When the number is correct, press the "YES" key to record the number and move to the next field.

5. INVOICE NUMBER: This optional field can be left at a default of "0" or will record the correct invoice number and may be helpful in the healthcare providers billing and tracking of this pump. Enter the selected invoice number (up to 10 digits) and when correct, press the "YES" key to move on to the next field.

6. DISABLE THERAPY: This field is used to customize the Curlin pump to the specific therapy ordered for the patient. When this function is selected by pressing the "YES" key, a menu appears listing all five of the possible therapies. The user can choose to ***disable*** from one to four of the therapies listed. Once a therapy is disabled, no further prompts will appear in programming for that therapy. This feature is very helpful when teaching a patient because it eliminates having to teach about unnecessary steps and also avoids having the patient accidentally enter a non-prescribed therapy setting. To ***disable*** a therapy, move the cursor to each therapy not being used and press the "YES" key. At least one therapy must remain enabled prior to exiting this screen.

Clearing Pump Settings

7. CLEAR PATIENT HISTORY: This feature can be used when a patient goes off service and the pump is returned to the healthcare provider. By selecting this feature, the user clears all specific patient settings, enables all therapies again, and resets the pump to its default settings. When this field is selected, an alert screen will appear, prior to clearing, asking the user if the history should be printed before clearing. This alert feature prevents an accidental clearing of history.

8. CLEAR ALL RX: This feature allows the user to clear all prescription data for a therapy setting, but still retain all patient history information and continue recording in the history file. Again, move the cursor to this field and press the "YES" key.

9. CHANGE CONTRAST: The contrast on the display screen can be adjusted up or down by using the arrows to adjust the brightness of the screen. When it is satisfactorily adjusted, the user presses the "YES" key and the cursor moves to the next field.

Changing Date and Time

10. CHANGE DATE AND TIME: When this field is selected the following screen will appear:

Change Date and Time Screen

M	AM/PM:	AM		AM	PM	24hr
O	TIME:	12:44	HH:MM	time is entered according to AM/PM selection		
D	DATE:	12/31/99	m/d/y			
E	ACCEPT?	YES/NO				

This screen is used to set the system Real Time Clock in the pump and will change the date and time displayed on the Welcome screen.

a) The user has the option of selecting AM, PM, or 24hr Military Time. Press the "NO" key until the correct selection appears on the field and then press the "YES" key to choose the selection and move the cursor to the next field.

b) The second field allows the user to use the numeric keys to set the actual time and AM, PM, or 24 hr if previously selected will remain displayed on field one. When the time is complete, press "YES" to accept the data and move to the Date Field.

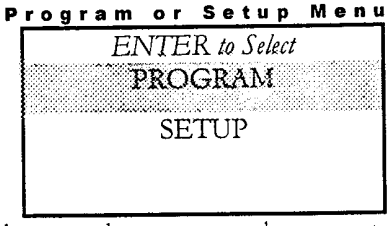
c) Using the numeric keys, enter the correct MM/DD/YY, using two digits for each, i.e. if the month is January, enter 01, if it is a single digit date, use the number preceded by a 0 and then enter the two digit year code, 99, 00, 01, etc. When the date is correct, press the "YES" key.

d) A final prompt will be given to "ACCEPT? YES". If any data needs to be corrected, use the arrow keys to locate the correct field, press NO to change the data there, enter the correct data, and then press "YES" again to confirm it is correct. Move the cursor back to the "ACCEPT? YES" field and press "YES". This action enters the time and date data and moves to the next field in the SETUP Menu.

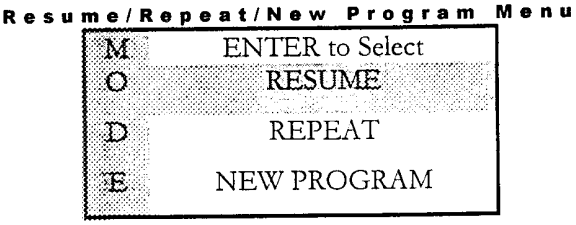
e) NOTE: If therapy is in progress, the date, time, clearing functions and disable therapy functions will not be accessible until the therapy is complete.

11. When setup is complete, move the cursor to the DONE? Field and press the "YES" to return to the Program or Set-Up Menu Screen.

Program



To select "PROGRAM", use the arrow keys to move the cursor to the "PROGRAM" field and press the "YES" key. The next screen will be displayed to begin programming the pump.

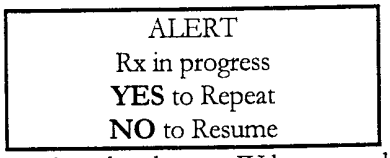


This screen gives the user three options:

1. RESUME-If a therapy is interrupted and the pump is turned off or paused prior to completion of the infusion, the user may select "RESUME" by moving the cursor to this field and pressing the "YES" key. This action will take the user to a notification screen where a prompt will be given to run the pump. At this time, the user can continue to infuse the prescription from the point where it was interrupted. (NOTE: Patients should be taught proper time frames for leaving their IV bags or medication reservoirs "hanging" during an interrupted state and, if indicated, to change to a new bag according to the healthcare providers policies and drug manufacturers instructions.)

2. REPEAT-If a therapy is complete and the user wishes to repeat the same prescription over again, this field is selected by moving the cursor to the "REPEAT" field and pressing the "YES" key. This action will take the user to a screen displaying the last programmed values of that therapy. (see Prescription Screen) The user can confirm or change the parameters of the infusion, hang a new bag of fluid, and repeat the therapy. (Some lock levels prevent any changes to the parameters at this level)

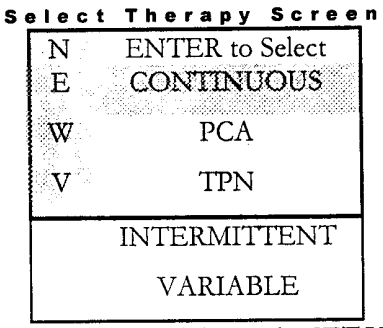
If a therapy is still in progress and the REPEAT function is selected, the following screen will display:



If the current infusion is to be discontinued and a new IV bag started, press "YES" to repeat. If the current infusion is to continue, press "NO" and the therapy will resume.

3. NEW PROGRAM-If the cursor is moved to this field and the "YES" key is pressed, the pump will move to the next programming screen:

Selecting a Therapy



This screen will display any therapy not disabled during the SET UP menu. Move the cursor to the appropriate therapy and select it by pressing the ENTER key. If only one therapy is enabled, this screen will *not* display and the pump will automatically move to the first screen for specific therapy programming.

Each therapy will now be considered separately in this manual and will have its own chapter heading.

Chapter

Continuous Therapy

Continuous Therapy is designed to allow a constant programmed rate of infusion.

To begin programming a Continuous Therapy consideration is given to specific patient customization features in the following "pre-infusion options" menu screen:

Pre-Infusion Options

Continuous Pre-Infusion Options Screen

	NEW	*PROGRAM*			
C O N V	LOCK:	**OFF**	1	2	3
	UNITS:	**ml**	mg	µg	
	CONCEN:	**---**	or numeric value for concentration (/ml)		
	UP Occlu:	**ON**	OFF		
	DN Occlu:	**LOW**	HIGH		
	AIL SENS:	**0.1 ml**	0.5 ml	OFF	
	AUDIO:	**HIGH**	LOW	MEDIUM	
	KVO Rate:	0.1 to 10 ml/hr			
	DELAY:	**OFF**	ON		
	Titrate Rx:	**OFF**	ON		
	DONE?	YES			

These menu items allow customizing the pump to meet each patient's specific needs and are selected prior to entering the prescription data. The pump's default settings are displayed in **bold**. Each field is individually explained on following pages: (Note: some of the lines are abbreviated to fit on the display screen; the full descriptions appear below)

1. LOCK: when the lock is set to "OFF" the clinician has access to all pump functions. After the pump is completely programmed, change the lock to meet the security needs of the patient. There are four choices in this field: OFF, 1, 2, or 3. Each level higher becomes more restrictive in the options available (see each lock level option screen in the following sections and the lock level table at the end of chapter 13). If the desired lock does not appear on the display screen, press the "NO/CHANGE" key until the correct level appears. Then, use the "YES/ENTER" key to accept the new lock selection. Once the pump has been set into a locked condition, any subsequent request to change the lock will require a clinician access code. (see Chapter 13 for access code information)

2. UNITS: allows the user to select from units of ml, mg, or μg depending on how the patient's prescription is written. The pump will allow a volume range of 0.1 to 400 **ml**/hr, therefore, if mg or μg are selected, the concentration requested in the next field will determine the upper and lower programming limits for mg and μg. Use the "NO/Change" key until the desired "units" appears on the display and then press the "YES/Enter" key to accept and move to the next field.

3. CONCEN: (Concentration)-this field is active whenever mg or μg are selected in the "units" field and requires data entry of the concentration of mg or μg per ml. When the correct data is entered using the numeric keys, press "YES" to accept and move the cursor to the next field. If ml is chosen in the "units" field, this line will not display.

4. UP Occlu: (Up Occlusion)-allows the user to select "on" or "off" for the pump to detect an occlusion between the medication bag and the pump. **Note:** If this field is set to "off" and an "up" occlusion (anything obstructing the flow of fluid from the container to the pump) does occur, *no alarm will sound.* It is recommended, therefore, that this setting be left in its default state of "ON". To do this, press "YES" to accept the "on" setting and move to the next field.

5. DN Occlu: (Down Occlusion)-allows the pump to sense an occlusion pressure in the line between the pump and the patients access site, e.g., a kink in the tubing between the pump and the patient, a blockage in the access site, a clamp left on the distal tubing. There are two options for this field: the "Low" setting (default setting) triggers the alarm when it detects in-line pressures at 8 psi (pounds per square inch), the "High" setting alarms when it detects in-line pressures at 18 psi. Press "NO" to change the selection and when the correct pressure setting appears, press the "YES" key to select and move the cursor to the next field.

6. AIL SENS: (Air In Line Sensitivity)-allows the user to select the amount of air the pump will detect in the administration set before it goes into an alarm state. The choices are 0.1 ml (the default setting), 0.5 ml and OFF. Use the "NO" key to change the options until the desired setting appears on the display and then press "YES" to select and move the cursor to the next line. (NOTE: When the "OFF" setting has been selected, any contiguous 2 ml bolus of air will still be detected and the pump will go into an alarm state and stop infusing until the situation is remedied.)

IMPORTANT INFORMATION **Whenever the AIL Sensitivity is set to OFF, use a Curlin administration set which has an air eliminating filter in line.**

Also, whenever the AIL Sensitivity is set to "OFF" and the "RUN" key is pressed, an alert message will appear on the screen (see below). This message alerts the user to the Air In Line Sensitivity being set to "OFF". The alert will require the user to answer yes or no to whether the administration set being used has an air-eliminating filter in line. This information is recorded into the pump's history log.

AIL Sensitivity Off-Alert Screen

AIL Sens OFF
Using In Line
Air Filter?
YES/NO

7. AUDIO: (Audio Volume)-allows the user to adjust the audio volume of the pump's alarm. There are three choices, High (default), Medium and Low. Use the "NO" key until the desired setting appears on the display and then press "YES" to select and move the cursor to the next field.

8. KVO Rate: (Keep Vein Open Rate)-used in between doses or at the end of a therapy when it is necessary to infuse very small amounts to maintain a patent access site. The field requires data entry using the numeric keys to set the rate at which fluid will be delivered in a "Keep Open" state. The pump defaults to a rate of 0.1ml/hour, can be set up to 10 ml/hour but cannot be set at a rate to exceed the therapy operating rate. When the desired KVO rate has been entered, press the "YES" key to accept and move the cursor to the next field.

9. DELAY Start: This field allows the infusion is to start at a later specified time. If the infusion is NOT to be delayed, select "Off", press "YES" to enter and the cursor will move to the next field. If the infusion **IS** to be delayed until a later time, select "ON", press "YES" to accept and the following screen will appear:

Continuous Delay Start Setting

C	DELAY START	
O	TIME: HH:MM	
N	AM	PM
V	DATE: MM/DD/YY	
	ACCEPT? YES/NO	

The time format (12 hr AM/PM or 24 hr Military) selected in the Setup Menu will apply in this table and if Military was selected the AM/PM field will not appear. If the entire delay start screen is to be aborted, press the "NO" key. When the start time and date are entered using the numeric keys and the data is accepted by pressing the "YES" key, the pump's clock will be set to start the infusion at the desired time and the display will return to the next field in the pre-infusion options menu. (**Note:** If the pump is not connected to the patient's access site at this time, the patient or caregiver should be taught proper techniques to access the infusion site prior to the scheduled start time.)

10. Titrate RX: (Titrate Prescription) Allows the clinician to program titration limits into the prescription settings of the pump. If there is no titration prescription, select "OFF", press "YES" to accept and the cursor will move to the next field. If a titration prescription has been written, select "ON", press the "YES" key to accept and the following screen will appear to program the titration parameters:

Continuous Titration Limit Screen

	TITRATE	*LIMITS*		
C				
O	MaxRATE:	1 to 400	ml/hr	res: 0.1 (<100) else 1. ml/hr, mg/hr or mcg/hr units
N	MaxTBI:	1 to 9999	ml	ml, mg, ug
V	TitrAMT	0 o 400	ml per	res: 0.1 (<100) else 1.0 ml/hr, mg/hr or mcg/hr units
	TitrCYCL:	0 to 999	hh:mm	
	ACCEPT?	YES		

a) MaxRATE: (maximum rate) limits. Use the numeric keys to enter the upper limits of the infusion rate. When the correct maximum titration rate has been entered, press "YES" and the cursor will move to the next field

b) MaxTBI: (Maximum Amount To Be Infused). Use the numeric keys to enter this amount and when correct, press the "YES" key to move on to the next field.

c) TitrAMT: (Titratation Amount) Some prescriptions include incremental level limitations. (e.g.: "Do not raise the rate more than 100 ml in 2 hours") If the prescription has these components, use the TitrAMT field and the TitrCYCL field to enter those limits. (Example: Enter the incremental titration amount level of 100 ml) using the numeric keys and press "YES" to move to the next field.

d) In the TitrCYCL: (Titration Cycle) field, enter the incremental time limit. (Example: Enter 02:00 hours.) If there is no incremental level component to the prescription, leave these fields, (TitrAMT and TitrCYCL), set at 0 and use the down arrow to move to the final field.

e) ACCEPT?: If there are any changes to be made, use the up or down arrows to move to that field, use the numeric keys to enter the corrected data and press "YES" to accept the new values. Move the cursor back to the ACCEPT? field and enter "YES". The Titration Limits are now entered and the display returns to the Pre-Infusion Options Screen. If the entire Titration Limit Screen is to be aborted, press "NO" to return to the pre-infusion options screen.

11. DONE?" If there are any changes to be made, use the up or down arrow keys to locate the field to be changed, use the numeric keys to enter the corrected information and press "YES" to accept the new data. If all the fields are acceptable, move the cursor to the "DONE?" field and press the "YES" key to move on to the next screen.

At the following screen the patient's prescription information is entered to complete the programming of the pump for a Continuous Therapy:

Continuous Program Menu

C	BAG Vol:	1 to 9999	ml	ml, mg, ug
O	Amt TBI:	1 to 9999	ml	
N	RATE:	.1 to 400	ml/hr	res: 0.1 (<100) else 1. ml/hr, mg/hr or mcg/hr units
V	TIME:	0 to 999:59	HH:MM	
	DONE?	YES		

1. Note that the Screen Identifier at the left side of the display, gives the abbreviation "CON" for Continuous Therapy and has a down arrow configuration which indicates that there are more than four (4) fields of text or lines of information to be considered.

2. BAG Vol: (IV Bag Volume) Using the numeric keys, enter the amount of fluid that the IV Bag, Medication Reservoir, or Syringe contains. NOTE: The volume used for priming via the pump or when a KVO rate is programmed is deducted from the Bag Volume. This will reduce the Bag Volume number. Bag Volume must be equal to or greater than the Amount To Be Infused; therefore, the Bag Volume entered now should be higher than the Amount To Be Infused. When the correct amount has been entered, press the "YES" key to accept this field and move on to the next.

3. Amt TBI: (Amount To Be Infused) Use the numeric keys to enter the actual amount of infusion to be delivered to the patient excluding any KVO amounts. the "Units" selected in the pre-infusion options menu will automatically appear in this field whether ml, mg or μg. when the amount is correctly entered, use the "YES" key to accept this field and to move to the next. (If Amt TBI entered is greater than Bag Volume, the pump will beep once to remind the user to recheck and change the number before the "YES" key will accept the value and move to the next field.

4. RATE: The Curlin pump can deliver from 0.1ml to 400 ml per hour. Use the numeric keys to enter the prescribed rate. When this field is correct, use the "YES" key to accept the rate and move to the next field.

5. TIME: displays the time required to complete the infusion. When the pump is given the Amount To Be Infused and the RATE at which to infuse, it will automatically calculate the Time and display it here. If the time is not acceptable, press the "NO" key to edit this field and enter the new TIME with the numeric keys. (Remember, by changing the time of the infusion, a new RATE will be calculated and will have to be accepted before exiting this menu. The amount to be infused will remain constant.) When the TIME field is satisfactory, press the "YES" key and move to the final field.

6. DONE?: If there are any changes to be made, use the up or down arrow keys to locate the field to be changed, use the numeric keys to enter the corrected information and press "YES" to accept the new data. If all the fields are acceptable, move the cursor to the "DONE?" field and press the "YES" key to move on to the next screen.

IMPORTANT INFORMATION

Before the infusion is started, it is important to consider a few remaining issues, such as checking the administration set to be sure it was primed or purged of all air. If it was not, the operator can use the pump's prime function to do so now. The pump may also need to be put into a higher security lock for patient safety by going to the Options Menu and changing the Lock. The following screen offers the user four choices:

Run Confirmation Screen

PRESS
RUN TO START
NO TO CHANGE
OPTIONS OR **PRIME**

Note that the user does not need to answer yes or no questions or enter data with the numeric keys as previously requested. This screen requires only that the user press the corresponding key on the keypad to begin the requested function. The following section explains each selection beginning with Prime:

Prime

The IV bag and administration set should be inspected and be free of all air and air bubbles prior to connecting it to the patient's access site. This function may have been done by gravity when the administration set was first connected to the bag (see Chapter 1, "Preparing Medication for Infusion"). However, if it was not done then or if there are any remaining air bubbles to be removed, the pump's "PRIME" function will assist in this process. To prime the set using the pump, follow these directions:

1. Press the "PRIME" key.
2. The following screen appears:

Prime Direction Screen

Disconnect Patient Release Clamps
HOLD **PRIME** key
YES to EXIT

IMPORTANT INFORMATION

3. Disconnect the administration set from the patient's access site using aseptic protocols. **NOTE: Priming with the set connected to the patient could result in overdose and may cause injury or even death to the patient.**
4. Release any clamps on the administration set.
5. Press and hold the "PRIME" key. Fluid will quickly be delivered through the administration set as long as the PRIME key is pressed or until 6 ml is pumped. The pump will then beep once and require repressing and holding the "PRIME" key again until 6 more milliliters is delivered. Continue this process until all air has been purged from the administration set. While the "PRIME" key is depressed the following screen appears:

PRIMING Release PRIME key to Stop Prime Amt: ml

6. When priming is complete release the "PRIME" key. The following screen will display:

PRESS
PRIME to Cont.
YES to Exit
Prime Amt: ml

7. To continue priming, push the PRIME key again. If Priming is complete, press "YES" to exit and return to the screen displayed when Prime was selected. The total amount of solution used in priming displays on the bottom field.

8. **NOTE:** The amount of fluid used in the priming process will be deducted from the Bag Volume Total, but will NOT be counted in the amount infused, because this amount is not to be delivered to the patient. The bag volume must still be equal to or greater than the Amount TBI in order to proceed with the infusion.

Options

At the beginning of Chapter 4, the "Pre-Infusion Options" were explained. Once the pump is programmed for a Continuous therapy, some of these same options are available if it becomes necessary to adjust the pump settings after an infusion has started. These "Running Options" (available while the pump is in a paused state or a running state) are accessible by pressing the "OPTIONS" key, are controlled by security lock levels, and will require a clinician access code to be entered if any lock level has been set. For information on changing security codes, see Chapter 13.

The following screens demonstrate the Continuous Therapy "Options" available under each security level. Once in a screen, use the up and down arrows to move the highlight bar to the desired option. Any new settings become effective when the "Options" screen is exited.

Continuous Run Options-LockOff

C O N V	*OPTIONS*	Lock 0	1	2	3
	LOCK:	OFF			
	Titrate	OFF	"ON" if enabled on pre-infusion options	Allow user to enter titration mode	
	UP Occlu:	ON	OFF		
	DN Occlu:	LOW	HIGH		
	AIL SENS:	0.1 ml	0.5 ml	OFF	
	KVO Rate:	0.1 – 10 ml/hr	Res 0.1 ml/hr		
	AUDIO:	HIGH	LOW	MEDIUM	
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

1. LOCK: This feature allows the clinician, when the lock set to "OFF", to have access to all pump settings. When the pump is completely programmed change the lock level to meet the security needs of the patient. There are four choices in this field: OFF, 1, 2, or 3. Each level higher becomes more restrictive in the options available to the patient or caregiver (see each lock option screen in following sections). If the desired lock does not appear on the display, press the "NO/CHANGE" key until the correct lock does appear, then press "YES/ENTER" to accept and move the cursor to the next field.

2. Titrate: If this feature was ***not*** selected in the Pre-infusion Options menu, the word "OFF" will appear. Move the cursor to the next field. If a Titrate prescription was programmed "ON" will appear and if the therapy is to be titrated now, press the "YES" key to go to the continuous titration menu:

Continuous Titration Menu

		TITRATE		
C				
O	Amt TBI:	1 to 9999	ml	ml, mg, ug Defaults to current Amt TBI
N	RATE:	.1 to 400	ml/hr	res: 0.1 (<100) else 1. ml/hr, mg/hr or mcg/hr units Defaults to current Rate
V	Time:		HH:MM	
	ACCEPT?	YES/NO		

This screen allows the user to change the rate and the amount to be infused within the pre-defined prescription limits. These pre-defined limits are displayed for reference when the "HELP" key is pressed at following fields:

a) Amt TBI: (Amount To Be Infused) Enter this amount with the numeric keys and when correct, press the "YES" key. NOTE: Amt TBI cannot exceed remaining Bag Volume and new value cannot be less than the amount already infused. If this field is changed, the "TIME" remaining displayed on the running screen will be recalculated.

b) Rate: Using the numeric keys, enter the new desired rate. When the new rate has been entered, press the "YES" key to move to the next field.

c) Time: The time remaining will be recalculated and entered here. Press "YES" to accept.

d) ACCEPT? YES/NO: Use the up/down arrows to move to any field and change the data entered at this time. To abort this screen entirely, press "NO" at this prompt and the display will return to the options menu. If the parameters are correct, press the "YES" key and the new rate will automatically be accepted. The display returns to the Options menu when this screen is exited.

e) New values will be in effect when the Options Menu is exited.

3. UP Occlu: (Up Occlusion)-this field allows the user to select "on" or "off" for the alarm detecting an occlusion between the medication bag and the pump, e.g. a kink in the tubing or a closed clamp. If this setting is turned off and an "up" occlusion does occur, no alarm will sound. It is recommended, therefore, that this setting be left in its default state of "ON". To do this, press "YES" to accept the "on" setting and move to the next field.

4. DN Occlu: (Down Occlusion)-this feature allows the pump to sense an occlusion pressure in the line between the pump and the patients access site, e.g., a kink in the tubing between the pump and the patient, a blockage in the access site, a clamp left on the distal tubing. There are two options for this field: the "Low" setting (default setting) triggers the alarm when it detects in-line pressures at 8 psi (pounds per square inch), the "High" setting alarms when it detects in-line pressures at 18 psi. Press "NO/Change" to change the selection and when the correct pressure setting appears, press the "YES" key to select and move the cursor to the next field.

5. AIL SENS: (Air In Line Sensitivity)-this feature allows the user to select the amount of air the pump will detect in the administration set tubing before it goes into an alarm state. The choices are 0.1 ml (the default setting), 0.5 ml and OFF. Use the "NO" key to change the options until the desired setting appears on the display and then press "YES" to select and move the cursor to the next line. NOTE: When the "OFF" setting has been selected any contiguous 2 ml bolus of air will still be detected and the pump will then go into an alarm state.

IMPORTANT INFORMATION **Whenever the AIL Sensitivity is set to OFF, chose a Curlin administration set with an air eliminating filter.**

Also, whenever the AIL Sensitivity is set to "OFF" and the "RUN" key is pressed, an alert message will appear on the screen (see below). This message alerts the user to the Air-In-Line Sensitivity being set to "OFF". The alert will require the user to answer yes or no to whether the administration set being used has an air eliminating filter in line and the above information is recorded in the pump's history log.

AIL Sensitivity Off-Alert Screen

AIL Sens OFF
Using In Line
Air Filter?
YES/NO

6. KVO Rate: (Keep Vein Open Rate)-this field requires data entry using the numeric keys to set the rate at which fluid will be delivered in a "Keep Open" state. The pump defaults to a rate of 0.1ml/hour, can be set up to 10 ml/hour but cannot be set at a rate to exceed the therapy operating rate.

7. AUDIO: (Audio Volume)- this feature allows the user to adjust the audio volume of the pump's alarm. There are three choices, High (default), Medium and Low. Use the "NO" key until the desired setting appears on the display and then press "YES" to select and move the cursor to the next field.

8. Power CK?: (Power Check) -This feature allows the user to recheck the battery charge. It will display the active power source of the pump, whether batteries or external power. If the active source is the batteries, a graph will indicate approximately how much charge remains in the batteries. To access this information, press "YES" and the Power Source Screen will display for 5 seconds and return to the Options Menu.

9. ACCEPT?: If the changes made in the Options Menu are acceptable, press the "YES" key. If the changes are not acceptable, use arrow keys to cursor up to any field for corrections, or abort all changes made in this menu by pressing the "NO" key, and return to the previous screen.

The following screens show the OPTIONS Menus for each lock level in Continuous Therapy:

Continuous Running Options-Lock 1

CONV	*OPTIONS*	*Lock 1*			
	LOCK:	1	2	3	OFF
	Titrate:	OFF	ON if enabled on pre-infusion options	Allow user to enter titration mode	
	AUDIO:	HIGH	LOW	MED	
	KVO Rate:	0.1 - 10 ml/hr	res 0.1 ml/hr		
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

Continuous Running Options-Lock 2

CONV	*OPTIONS*	*Lock 2*			
	LOCK:	2	3	OFF	1
	AUDIO:	HIGH	LOW	MED	
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

Continuous Running Options-Lock 3

CONV	*OPTIONS*	*Lock 3*			
	LOCK:	3	OFF	1	2
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

There are two remaining selections to consider from the "Run Confirmation Screen", **NO** to Change, and **RUN** to Start:

NO/CHANGE - If there are any changes to the programming screen, press the "NO/CHANGE" key and the programming screen will reappear to allow the operator to make changes.

Starting the Infusion

RUN - When all parameters are correct and the pump has been primed properly and connected to the patient's access site, press "RUN" to start the therapy. The pump will begin infusing and the following screen displays the status of the therapy:

Continuous Run Screen

C	RATE:	400	ml/hr
O	[||||||||||||||||	.....]
N	Vol INF:	25.4	ml
	REMAIN:	0 to 999HH	HH:MM

This screen displays as long as the infusion is running. Notice the information on each field:

1. The rate of the infusion in whichever units/hour has been selected.
2. A graphic bar representing the percentage of the completed infusion.
3. The volume infused and if mg or μg are the selected units, this field will toggle to display dose infused as well.
4. The remaining time to the completion of the infusion.
5. In addition to the display screen giving information regarding the status of the infusion, the green LED light blinks whenever the pump is infusing.

Interrupting an Infusion

The infusion can be paused at any time by pressing the "PAUSE" key and the following screen displays:

PAUSE MENU SCREEN

C	ENTER to Select
O	RESUME
N	REPEAT
	NEW PROGRAM

The screen offers the user three options:

1. RESUME: To resume the therapy in progress from where it left off, press the "YES" key at this field and the pump will return to the Run Screen and resume infusing the therapy.

2. REPEAT: To repeat the present therapy and add another IV container (bag, reservoir or syringe) with the same prescription as the previous container, press the "YES" key at this field. This action will take the user to a screen displaying the last programmed values of the therapy.

3. NEW PROGRAM: To program an entirely new prescription or different therapy, press the "YES" key at this field and the display will return to the "Select Therapy Screen". (the ability to change these parameters may be controlled by the lock level)

When the infusion is complete, the following screen will display:

Continuous Infusion Complete, KVO Screen

C O N	Infusion	Complete	
	.....		
	Vol INF:	0 to 9999	ml
	KVO Rate:	0.1 to 10	ml/hr

This screen displays:

1. "Infusion Complete" and the field blinks.

2. A graphic representation indicating the KVO rate in progress (smaller "dot" configuration)

3. Vol INF (Volume infused) If units are mg or μg, this field will also toggle to give the total dose infused.

4. KVO Rate: The preset KVO rate displays.

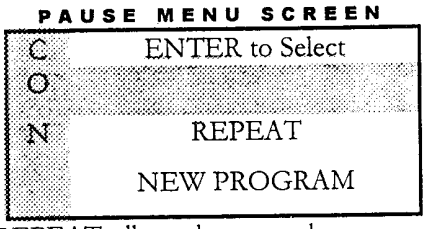
5. Infusion Complete is considered an alarm status and the audio alarm will beep once every 10 seconds to alert the user to this condition.

6. Additionally, the red LED will blink along with the green LED (green to indicate that the pump is infusing and red to indicate that the infusion complete alarm exists).

Stopping the Infusion

To halt the infusion, press the "PAUSE" key and then choose to:

1. Stop the pump if the total therapy is complete, by pressing the "OFF" key.
2. Or, select one of the options from the "Pause" screen:



a) REPEAT: allows the user to hang a new IV bag and repeat the entire therapy as previously programmed.

b) NEW PROGRAM: allows the user to select an entirely new program at this time.

c) (Note: The therapy has completed, therefore, RESUME is not an option at this time and is not displayed)

PCA Therapy

PCA or Patient Controlled Analgesia is designed for therapies requiring a continuous rate of infusion, patient controlled demand boluses or both. This Therapy is well suited for those patients requiring pain management with the use of analgesics.

To begin programming a PCA Therapy, consideration is given to specific patient customization features in the following "pre-infusion options" menu screen:

PCA Pre-Infusion Options Menu

	NEW	*PROGRAM*			
P C A V	LOCK:	**0**	1	2	3
	UNITS:	**ml**	mg	µg	
	CONCEN:	---	or numeric value for concentration (/ml)	field will not appear if units is ml	
	ADMIN Rt:	**IV**	SQ	EPI	
	UP Occul:	**ON**	OFF		
	DN Occul:	**LOW**	HIGH		
	AIL SENS:	**0.1 ml**	0.5 ml	OFF	
	AUDIO:	**HIGH**	LOW	MEDIUM	
	Load Dose:	**OFF**	ON		
	Titrate Rx:	**OFF**	ON		
	DONE?	YES			

These menu items customize the pump to meet each patient's specific needs and are selected prior to entering the prescription data. The pump's default settings are listed in **bold**. Each field is individually explained on the following pages: (Note: some of the lines are abbreviated to fit on the display screen; the full descriptions appear below)

1. LOCK: When the lock is set to "OFF" the clinician has access to all pump functions. After the pump is completely programmed, change the lock to meet the security needs of the patient. There are four choices in this field: OFF, 1, 2, or 3. Each level higher becomes more restrictive in the options available (see each lock level option screen in the following sections and the lock level table at the end of chapter 13). If the desired lock does not appear on the display screen, press the "NO/CHANGE" key until the correct level appears. Then, use the "YES/ENTER" key to accept the new lock selection. Once the pump has been set into a locked condition, any subsequent request to change the lock will require a clinician access code. (see Chapter 13 for access code information)

2. UNITS: allows the user to select from units of ml, mg, or μg depending on how the patient's prescription is written. The pump will allow a volume range of 0.1 to 400 **ml**/hr, therefore, if mg or μg are selected, the concentration requested in the next field will determine the upper and lower programming limits for mg and μg. Use the "NO/Change" key until the desired "units" appears on the display and then press the "YES/Enter" key to accept and move to the next field.

3. CONCEN: (Concentration)-this field is active whenever mg or μg are selected in the "units" field and requires data entry of the concentration of mg or μg per ml. When the correct data is entered using the numeric keys, press "YES" to accept and move the cursor to the next field. If ml is chosen in the "units" field, this line will not display

4. ADMIN Rt: (Administration Route)- allows the user to select from three routes of administration, the default setting of IV (intravenous) , SQ (subcutaneous) and EPI (epidural). Each of the routes has defined PCA settings as illustrated in the following table:

Administration Routes

Administration Route	Occlusion Setting (psi)	Maximum Basal Rate (ml/hr)	Fixed Bolus Rate (ml/hr)	Maximum Bolus Dose (ml)	Maximum Load Dose (ml)
Intravenous	8 or 18	50	125	50	50
Subcutaneous	8 or 18	5	90	5	5
Epidural	8 or 18	25	90	25	25

Figure 5.1 PCA Administration Route Default Settings

5. UP Occlu: (Up Occlusion)-allows the user to select "on" or "off" for the pump to detect an occlusion between the medication bag and the pump. **Note:** If this field is set to "off" and an "up" occlusion (anything obstructing the flow of fluid from the container to the pump) does occur, *no alarm will sound.* It is recommended, therefore, that this setting be left in its default state of "ON". To do this, press "YES" to accept the "on" setting and move to the next field.

6. DN Occlu: (Down Occlusion)-allows the pump to sense an occlusion pressure in the line between the pump and the patients access site, e.g., a kink in the tubing between the pump and the patient, a blockage in the access site, a clamp left on the distal tubing. There are two options for this field: the "Low" setting (default setting) triggers the alarm when it detects in-line pressures at 8 psi (pounds per square inch), the "High" setting alarms when it detects in-line pressures at 18 psi. Press "NO" to change the selection and when the correct pressure setting appears, press the "YES" key to select and move the cursor to the next field.

7. AIL SENS: (Air In Line Sensitivity)-allows the user to select the amount of air the pump will detect in the administration set before it goes into an alarm state. The choices are 0.1 ml (the default setting), 0.5 ml and OFF. Use the "NO" key to change the options until the desired setting appears on the display and then press "YES" to select and move the cursor to the next line. (NOTE: When the "OFF" setting has been selected, any contiguous 2 ml bolus of air will still be detected and the pump will go into an alarm state and stop infusing until the situation is remedied.)

IMPORTANT INFORMATION **Whenever the AIL Sensitivity is set to OFF, use a Curlin administration set which has an air eliminating filter in line.**

Also, whenever the AIL Sensitivity is set to "OFF" and the "RUN" key is pressed, an alert message will appear on the screen (see below). This message alerts the user to the Air In Line Sensitivity being set to "OFF". The alert will require the user to answer yes or no to whether the administration set being used has an air-eliminating filter. This information is recorded into the pump's history log.

AIL Sensitivity Off-Alert Screen

AIL Sens OFF
Using In Line
Air Filter?
YES/NO

8. AUDIO: (Audio Volume)-allows the user to adjust the audio volume of the pump's alarm. There are three choices, High (default), Medium and Low. Use the "NO" key until the desired setting appears on the display and then press "YES" to select and move the cursor to the next field.

9. Load Dose: (Loading Dose) - allows the clinician to program in a pre-infusion loading dose if it is prescribed. If a loading dose is not ordered, select "OFF" and no further screens will appear. If it is ordered, select "ON", press the "YES" key to accept and the following programming screen will display:

PCA Loading Dose Screen

P	Load Dose:	1 to 50	ml
C	RATE:	.1 to 125	ml/hr
A	TIME:	0 to 999:59	HH:MM
	ACCEPT?	YES/NO	

a) Load Dose: enter the prescribed loading dose. Note: the "units" will correspond to those previously programmed. Use the numeric keys to enter this dose and when correct, press "YES" to accept and move to the next field.

b) Rate: Enter the prescribed rate and when correct, press "YES" to accept and move to the next field.

c) Time: The pump will calculate the time based on the two previously entered fields. If the time displayed is correct, accept it by pressing the "YES" key and move onto the final data field. If any field needs to be changed, use the up arrows to move the cursor to that field, re-enter the correct data, and then press the "YES" key to accept again.

d) Accept?: If all parameters are now correctly entered, press the "YES" key. If this screen is to be totally aborted, press the "NO" key and the display will return to the original display and abort the loading dose screen.

e) The loading dose will be delivered just prior to the PCA infusion. The amount infused in the loading dose is included in the "amount infused", is logged into the history file and the bolus lockout time is set from the end of the loading dose. Because the loading dose is only used on initial start up of an infusion, it will not be re-prompted on repeat infusions, when new IV bags are added.

10. Titrate Rx: (Titrate Prescription) Allows the clinician to program titration limits into the prescription settings of the pump. If there is no titration prescription, select "OFF", press "YES" to accept and the cursor will move to the next field. If a titration prescription has been written, select "ON", press the "YES" key to accept and the following screen will appear to program the titration parameters:

PCA Titrate Limits Screen

P	*TITRATE*	*LIMITS*	
C	MaxRATE:	.1 to 50	ml/hr
A	TitrAMT:	.1 to 50	ml/
V	TitrCYCL:		HH:MM
	Bolus Dose:	1 to 50	ml
	Bolus Intrval:	1 to 60	MIN
	# Bolus/hr:	1 to 10	
	ACCEPT?	YES/NO	

a) MaxRATE: (maximum rate) limits. Use the numeric keys to enter the upper limits of the infusion rate. When the correct maximum titration rate is entered, press "YES" and the cursor will move to the next field.

b) TitrAMT: (Titration Amount) Some prescriptions include incremental level limitations. (e.g.: Do not raise the rate more than 1 ml in 12 hours) If the prescription has these components, use the TitrAMT field and the TitrCYCL field to enter those limits. (Example: Enter the incremental titration amount level of 1 ml) using the numeric keys and press "YES" to move to the next field.

c) TitrCYCL: (Titration Cycle) Enter the incremental time limit. (Example: Enter 12:00 hours.) If there is no incremental level component to the prescription, leave these fields, (TitrAMT and TitrCYCL) set at 0 and use the down arrow to move to the next field.

d) Bolus: The next three fields are used to program the Bolus Dose limits, the Bolus Interval limits, and the number of Bolus per hour. For each field use the numeric keys to enter the correct data and press "YES" to accept each entry and move on to the next.

e) ACCEPT?: If there are any changes to be made, use the up or down arrows to move to that field, use the numeric keys to enter the corrected data and press "YES" to accept the new values. Move the cursor back to the ACCEPT? field and enter "YES". The Titration Limits are now entered and the display returns to the Pre-Infusion Options Screen. If the entire Titration Limit Screen is to be aborted, press "NO" to return to the pre-infusion options screen.

11. DONE?: If any fields are not satisfactory, use the arrow keys to locate the field to be changed, enter the changes, press the "YES" key to accept the new values and then go back to the "DONE?" field. When all fields are satisfied with correct settings, press the "YES" key to exit this screen and move on to the PCA Programming Menu.

At the following screen, the patient's prescription information is entered to complete the programming of the pump for a PCA Therapy. The clinician has the option to set a basal rate of infusion, patient activated bolus dosing, or both on this screen.

Remember, there may be additional limits to rates and doses based on limits for the route of administration selected. (See Figure 5.1)

PCA Program Menu

P	BAG Vol:	1 to 9999	ml
C	Basal Rate:	.1 to 50	ml/hr
A	Bolus Dose:	.1 to 50	ml
V	Bolus Intrval:	1 to 60	MIN
	# Bolus/hr:	1 to 10	
	DONE?	YES	

1. Note that the screen Identifier gives the abbreviation "PCA" for Patient Controlled Analgesic Therapy and has a down arrow configuration which indicates that there are more than 4 fields of text or information to be considered.

2. BAG Vol: (IV Bag Volume) Using the numeric keys, enter the amount of fluid that the IV Bag, Medication Reservoir, or Syringe contains. NOTE: The volume used for priming via the pump is deducted from the Bag Volume. This will reduce the Bag Volume number. Bag Volume must be equal to or greater than the Amount To Be Infused; therefore, the Bag Volume entered now should be higher than the Amount To Be Infused. When the correct amount has been entered, press the "YES" key to accept this field and move on to the next.

3. Basal RATE: The Curlin pump in PCA Therapy will deliver from 0.1ml to 50 ml per hour, or the highest limit allowed for the administration route selected (see Figure 5.1)). Use the numeric keys to enter the prescribed rate (the "units" chosen in the pre-infusion menu will appear here). NOTE: If the rate of mg or μg falls out of the range of the pump (0.1 to 400 **ml**/hr) a beep will sound to alert the user and this field will not be accepted with the "YES" key until the rate is adjusted to fall within pump range. When rate is correct, use the "YES" key to accept and move to the next field.

4. Bolus Dose: Use the numeric keys to enter the prescribed bolus dose and when correct, press the "YES" key to accept and move on to the next field.

5. Bolus Intrval: (Bolus Interval). This field allows the clinician to enter the minimum amount of time prescribed between patient activated bolus dosing. Enter the time using the numeric keys and when correct, press the "YES" key to accept and move the cursor to the next field.

6. Bolus/hr: Using the numeric keys, enter the number (1 to 10) of boluses allowed per hour and when correct, press the "YES" key to accept and move to the last field.

IMPORTANT INFORMATION

7. DONE?: If the programming is not done, use the up or down arrow keys to locate the field to be changed, use the numeric keys to enter the corrected information and press "YES" to accept the new data. If all the fields are acceptable, at the "DONE?" prompt press the "YES" key to move on to the next screen.

Before the infusion is started, it is important to consider a few remaining issues, such as checking the administration set to be sure it was primed or purged of all air. If it was not, the operator can use the pump's prime function to do so now. The pump may also need to be put into a higher security lock for patient safety by going to the Options Menu and changing the lock setting. The following screen offers the user four choices:

Run Confirmation Screen

PRESS
RUN TO START
NO TO CHANGE
OPTIONS OR **PRIME**

Note that the operator does not need to answer yes or no questions or enter data with the numeric keys as previously requested. This screen requires only that the user press the corresponding key on the keypad to begin the requested function. The following section explains each selection beginning with Prime:

Prime

The IV bag and administration set should be inspected and be free of all air and air bubbles prior to connecting it to the patient's access site. This function may have been done by gravity when the administration set was first connected to the bag (see Chapter 1, "Preparing Medication for Infusion"). However, if it was not done then or if there are any remaining air bubbles to be removed, the pump's "PRIME" function will assist in this process. To prime the set using the pump, follow these directions:

1. Press the "PRIME" key.

2. The following screen appears:

Prime Direction Screen

Disconnect Patient Release Clamps
HOLD **PRIME** key
YES to EXIT

IMPORTANT INFORMATION

3. Disconnect the administration set from the patient's access site using aseptic protocols. **NOTE: Priming with the set connected to the patient could result in overdose and may cause injury or even death to the patient.**

4. Release any clamps on the administration set.

5. Press and hold the "PRIME" key. Fluid will quickly be delivered through the administration set as long as the PRIME key is pressed or until 6 ml is pumped. The pump will then beep once and require repressing and holding the "PRIME" key again until 6 more milliliters is delivered. Continue this process until all air has been purged from the administration set. While the "PRIME" key is depressed the following screen appears:

PRIMING
Release **PRIME**
Key to Stop
Prime Amt: ml

6. When PRIME is complete release the "PRIME" key. The following screen will display:

PRESS
PRIME to Continue
Yes to Exit
Prime Amt: ml

7. To continue priming, push the PRIME key again. If Priming is complete, press "YES" to exit and return to the screen displayed when Prime was selected. The total amount of solution used to prime displays on the bottom field.

8. **NOTE:** The amount of fluid used in the priming process will be deducted from the Bag Volume total, but will NOT be counted in the amount infused, because this amount is not to be delivered to the patient. The bag volume must still be greater than the Amount TBI when prime is complete.

Options

At the beginning of Chapter 5 the PCA "Pre-Infusion Options" were explained. Once the pump is programmed for "PCA" therapy, some of these same options are available if it becomes necessary to adjust the pump settings after an infusion has started. These "Running Options" (available while the pump is in a paused state or running state) are controlled by security lock levels and will require a clinician access code to be entered if a Lock has been set. For information on changing security codes, see Chapter 13.

The following screens demonstrate the PCA "Options" available under each security level. Once in a screen, use the up and down arrows to move the highlight bar to the desired option. Any new settings become effective when the "Options" screen is exited.

PCA Running Options-Lock Off

P C A V	*OPTION*	*MENU*	1	2	3
	LOCK:	OFF			
	Titrate:	OFF	ON	Allows user to enter titration mode	
	Clin Dose?:	YES	Allows user to enter clinician dose mode		
	UP Occlu:	ON	OFF		
	DN Occlu:	LOW	HIGH		
	AIL SENS:	0.1 ml	0.5 ml	OFF	
	AUDIO:	HIGH	LOW	MEDIUM	
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

1. LOCK: When the lock is set to "OFF" the clinician has access to all pump functions. After the pump is completely programmed, change the lock to meet the security needs of the patient. There are four choices in this field: OFF, 1, 2, or 3. Each level higher becomes more restrictive in the options available (see each lock level option screen in the following sections and the lock level table at the end of chapter 13). If the desired lock does not appear on the display screen, press the "NO/CHANGE" key until the correct level appears. Then, use the "YES/ENTER" key to accept the new lock selection. Once the pump has been set into a locked condition, any subsequent request to change the lock will require a clinician access code. (see Chapter 13 for access code information)

2. Titrate: If this feature was *not* selected in the Pre-infusion menu, the word "OFF" will appear. Move the cursor to the next field. If a Titrate prescription was programmed, "ON" will appear and if the therapy is to be titrated now, press the "YES" key to go to the PCA titration menu:

PCA Titrate Screen

		TITRATE	
P C A V	Basal Rate:	.1 to 50	ml/hr
	Bolus Dose:	1 to 50	ml
	Bolus Intrval:	1 to 60	MIN
	# Bolus/hr:	1 to 10	
	ACCEPT?	YES/NO	

This screen allows the user to change the basal rate and the bolus parameters within the pre-defined prescription limits. NOTE: Those limits are available for review by pressing the "HELP" key when the cursor is on any of the titration screen fields.

a) Basal Rate: Use the numeric keys to enter the new desired rate. When the correct rate has been entered, press the "YES" key to accept the rate and move to the next field.

b) Bolus Dose: Use the numeric keys to enter the new bolus dose and when correct, press "YES" to accept and move to the next field.

c) Bolus Interval: Use the numeric keys to enter the new bolus time interval and when correct, press "YES" to accept and move to next field.

d) #Bolus/hr: Use the numeric keys to enter the new number of boluses per hour, and when correct, press "YES" to move to the final step in the titration menu.

e) ACCEPT? YES/NO: Use the arrow keys to move to any field and change the data entered. To abort this screen entirely, press "NO" at this prompt and the display will return to the options menu. If the parameters entered are correct, press the "YES" key and the new rate will be accepted. The display returns to the Options menu when this screen is exited.

f) New values will be in effect when the Options menu is exited.

3. Clin Dose?: (Clinician Dose) allows an additional prescribed dose to be administered by a clinician at any time. Note: This field only appears if the Lock is set to "OFF". Cursor past this field if no Clinician Dose is needed. Press the "YES" key to select this field and to display the following screen:

PCA Set Clinician Dose screen

P	Clin Dose:	1 to 50	ml	ml, mg, ug
C	RATE:	.1 to 125	ml/hr	Desired Rate limited by bolus rate Admin Rt. ml/hr, mg/hr or mcg/hr units.
A	TIME:	0 to 999:59	HH:MM	
	ACCEPT?	YES/NO		

a) Clin Dose: (Clinician Dose) Use the numeric keys to enter the prescribed dose. When correct, press the "YES" key to accept and move to the next field.

b) RATE: Use the numeric keys to enter the rate (rate will be limited to maximum allowed for selected Administration Route), when correct, press the "YES" key to accept and move the cursor to the next field.

c) TIME: calculated by the pump using data from the two previous fields. If the user wants to change the calculated time using the numeric keys to do so, the "rate" will be changed. When the "YES" key is pressed, the cursor will move up to the new rate which will blink to let the operator know that this new rate must be verified by pressing the "YES" key again.

d) ACCEPT?YES: If the Clinician Dosing is to be aborted entirely, press "NO", the screen will abort, and return to the Options Menu. If the clinician dose is correct, press "YES" at the accept field. The clinician dose data will be saved into the program and the cursor will return to the Options Menu. To start the delivery of the Clinician Dose, move the cursor to the last field on the *Options Menu*, (Accept?), press the "YES" key to accept and exit the Options Menu Screen. If the pump was in a paused state when the OPTIONS key was pressed, it will return to the original screen displaying at that time. From that point the user is prompted to the "RUN" key to begin the Clinician Dosing. If the pump was running at the time "Options" was selected, the clinician dosing will begin as soon as the "Options" Menu is accepted. When clinician dose starts, the following screen displays:

Clinician Dose Run Screen

P	*CLINICIAN*	*DOSE*	
C	[||||||||||||||||	.....	.....]
A	Amt INF:	25.4	Ml
	REMAIN:	0 to 72	HH:MM

When the clinician dose is complete, the pump will beep twice, return to the previous running rate and resume the PCA therapy. The lock out time for bolus dosing will restart at the end of the clinician dose to prevent a bolus from being delivered too quickly after a clinician dose.

4. UP Occlu: (Up Occlusion)-this field allows the user to select "on" or "off" for the alarm detecting an occlusion between the medication bag and the pump, e.g., a kink in the tubing, a closed clamp. If this setting is turned off and an "up" occlusion does occur, no alarm will sound. It is recommended, therefore, that this setting be left in its default state of "ON". To do this, press "YES" to accept the "on" setting and move to the next field.

5. DN Occlu: (Down Occlusion)-this feature allows the pump to sense an occlusion pressure in the line between the pump and the patients access site, e.g., a kink in the tubing between the pump and the patient, a blockage in the access site, a clamp left on the distal tubing. There are two options for this field: the "Low" setting (default setting) triggers the alarm when it detects in-line pressures at 8 psi (pounds per square inch), the "High" setting alarms when it detects in-line pressures at 18 psi. Press "NO" to change the selection and when the correct pressure setting appears, press the "YES" key to accept and move the cursor to the next field.

6. AIL SENS: (Air In Line Sensitivity)-this feature allows the user to set the amount of air the pump will detect in the tubing before it goes into an alarm state. The choices are 0.1 ml (the default setting), 0.5 ml and OFF. Use the NO" key to change the options until the desired setting appears on the display and then press "YES" to select and move the cursor to the next line. NOTE: When the "OFF" setting has been selected, any contiguous 2 ml bolus of air will still be detected and the pump will go into an alarm state.

IMPORTANT INFORMATION **Whenever the AIL Sensitivity has been set to OFF, a Curlin administration set containing an air eliminating filter should be in use.**

Also, when the "OFF" setting has been selected, an alert message will appear at the press of the "RUN" key alerting the user to the Air In Line Sensitivity being set to "OFF". The alert message (seen below) will require the user to answer yes or no to whether the administration set has an air eliminating filter in line.

AIL Sensitivity Off-Alert Screen

AIL Sens OFF
Using In Line
Air Filter?
YES/NO

7. AUDIO: (Audio Volume) This feature allows the user to adjust the audio volume of the pump's alarm setting. There are three choices, High (default), Medium and Low. Use the "NO" key until the desired setting appears on the display and then press "YES" to select and move the cursor to the next field.

8. Power CK?: (Power Check) -This feature allows the user to recheck the battery charge. It will display the active power source of the pump, whether batteries or external power. If the active source is the batteries, a graph will indicate approximately how much charge remains in the batteries. To access this information, press "YES" and the Power Source Screen will display for 5 seconds and return to the Options Menu.

9. ACCEPT?: If the changes made in the Options Menu are acceptable, press the "YES" key. If the changes are not acceptable, the user can cursor up to any field for corrections, or abort all changes made in this menu by pressing the "NO" key, and return to the previous screen.

The following screens show the OPTIONS Menus for each lock level in the PCA Therapy:

PCA Running Options-Lock 1

	OPTION	*MENU*			
PCA V	LOCK:	1	2	3	OFF
	Titrate:	OFF	ON	Allows user to enter titration mode	
	AUDIO:	HIGH	LOW	MEDIUM	
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

PCA Running Options-Lock 2

	OPTION	*MENU*			
PCA V	LOCK:	2	3	OFF	1
	AUDIO:	HIGH	LOW	MEDIUM	
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

PCA Running Options-Lock 3

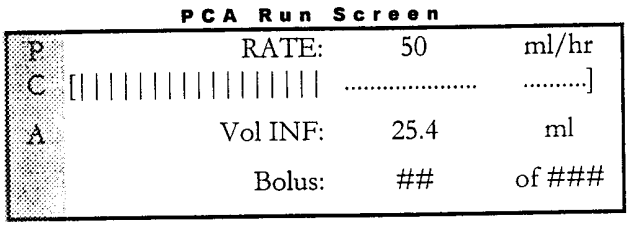
	OPTION	*MENU*			
PCA V	LOCK:	3	OFF	1	2
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

There are two remaining selections to consider from the "Run Confirmation Screen", **NO** to Change, and **RUN** to Start:

NO/CHANGE - If there are any changes to be made to the programming screen, press the "NO/CHANGE" key and the programming screen will reappear to allow the operator to make changes.

Starting the Infusion

RUN - When all parameters are correct, the pump has been primed properly and connected to the patient's access site press "RUN" to start the therapy. The pump will begin infusing and the following screen will appear to give data on the status of the therapy:

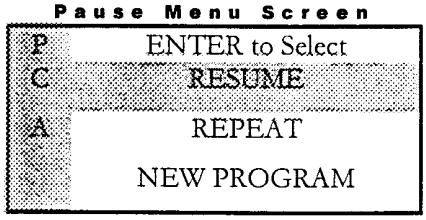


This screen will continue to display as long as the infusion is running. Notice the information on each field:

1. The first field displays the rate of the infusion.
2. The second field is a graphic bar representing the percentage of the completed infusion.
3. The third field displays volume infused and if mg, or μg are the selected units, will also toggle to display dose infused.
4. The fourth line displays number of bolus delivered per number of boluses tried per bag volume. If a bolus is being delivered, the word Bolus will flash. When the bolus is done, both numbers in Bolus (## of ##) will change, indicating that another bolus had been delivered. If the patient attempts a bolus prior to the amount of time set between boluses, only the second number will increase, giving the clinician information on the number of boluses delivered of the actual number attempted.
5. In addition to the display screen accumulating information regarding the status of the infusion, the green LED light blinks whenever the pump is infusing.

Interrupting an Infusion

The infusion can be paused at any time by pressing the "PAUSE" key and the following screen displays:



The screen offers the user three options:

1. RESUME: To resume the therapy in progress from where it left off, press the "YES" key at this field, the pump will return to the Run Screen and resume infusing the therapy.

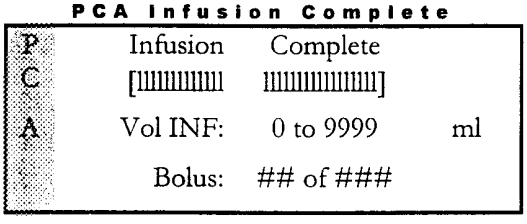
2. REPEAT: To repeat the present therapy and add another IV container (bag, reservoir or syringe) with the same prescription as the previous container, press the "YES" key at this field. This action will take the user to a screen displaying the last programmed values of the therapy.

3. NEW PROGRAM: To program an entirely new prescription or different therapy, press the "YES" key at this field and the display will return to the "Select Therapy Screen". (the ability to change these parameters may be controlled by the lock level)

Infusion Complete

A message will display "Low Volume" and a single audio alert will sound 30 minutes prior to the completion of the infusion. Additionally, at 10 minutes prior to the end of the infusion the message and single beep will occur at one minute intervals until the Bag Volume is depleted and then the following screen will display:

(NOTE: To temporarily silence the alarm press the "Silence" key.)



This screen displays the total volume infused (toggling with the total dose infused if "units" is set to mg or μg) The graphic representation indicates all volume is infused. In PCA delivery mode, there is no KVO rate at the end of an infusion, therefore, the pump stops infusing and is in an urgent alarm state, with "Infusion Complete" blinking, the red LED display blinking and the urgent alarm sounding. The user should at this time pause the pump, add a new IV bag or medication reservoir and administration set and repeat the therapy or chose to stop the therapy. Once the pump is paused, pressing the "OFF/ON" key will turn the pump off.

CHAPTER

TPN Therapy with Automatic Ramping

This therapy is designed to allow a level rate of infusion of parenteral nutritional products with the option of tapering at the beginning, end or both of the infusion. It also has an early ramp-down feature.

To begin programming the TPN Therapy, consideration is given to specific patient customization features in the following "pre-infusion options" menu screen:

Pre-Infusion Options

TPN Pre-Infusion Options Screen

T	*NEW*	*PROGRAM*		
P	LOCK:	**OFF**	1	2
N	UP Occlu:	**ON**	OFF	
V	DN Occlu:	**LOW**	HIGH	
	AIL SENS:	**0.1 ml**	0.5 ml	OFF
	AUDIO:	**HIGH**	LOW	MEDIUM
	KVO Rate:	0.1 to 10 ml/hr		
	DELAY:	**OFF**	ON	
	DONE?	YES		

These menu items allow customizing the pump to meet each patient's specific needs and are selected prior to entering the prescription data. The pump's default settings are displayed in **bold**. Each field is individually explained on the following pages: (Note: some of the lines are abbreviated to fit on the display screen; the full description appears below)

1. LOCK: when the lock is set to "OFF" the clinician has access to all pump functions. After the pump is completely programmed, change the lock to meet the security needs of the patient. There are four choices in this field: OFF, 1, 2, or 3. Each level higher becomes more restrictive in the options available (see each lock level option screen in the following sections and the lock level table at the end of chapter 13). If the desired lock does not appear on the display screen, press the "NO/CHANGE" key until the correct level appears. Then, use the "YES/ENTER" key to accept the new lock selection. Once the pump has been set into a locked condition and this menu is exited, any subsequent request to change the lock will require a clinician access code. (see Chapter 13 for access code information)

2. UP Occlu: (Up Occlusion)-allows the user to select "on" or "off" for the pump to detect an occlusion between the medication bag and the pump. **Note:** If this field is set to "off" and an "up" occlusion (anything obstructing the flow of fluid from the container to the pump) does occur, *no alarm will sound.* It is recommended, therefore, that this setting be left in its default state of "ON". To do this, press "YES" to accept the "on" setting and move to the next field.

3. DN Occlu: (Down Occlusion)-allows the pump to sense an occlusion pressure in the line between the pump and the patients access site, e.g., a kink in the tubing between the pump and the patient, a blockage in the access site, a clamp left on the distal tubing. There are two options for this field: the "Low" setting (default setting) triggers the alarm when it detects in-line pressures at 8 psi (pounds per square inch), the "High" setting alarms when it detects in-line pressures at 18 psi. Press "NO" to change the selection and when the correct pressure setting appears, press the "YES" key to select and move the cursor to the next field.

4. AIL SENS: (Air In Line Sensitivity)-allows the user to select the amount of air the pump will detect in the administration set before it goes into an alarm state. The choices are 0.1 ml (the default setting), 0.5 ml and OFF. Use the "NO" key to change the options until the desired setting appears on the display and then press "YES" to select and move the cursor to the next line. (NOTE: When the "OFF" setting has been selected, any contiguous 2 ml bolus of air will still be detected and the pump will go into an alarm state and stop infusing until the situation is remedied.)

IMPORTANT INFORMATION

Whenever the AIL Sensitivity is set to OFF, use a Curlin administration set which has an air eliminating filter in line.

Also, whenever the AIL Sensitivity is set to "OFF" and the "RUN" key is pressed, an alert message will appear on the screen (see below). This message alerts the user to the Air In Line Sensitivity being set to "OFF". The alert will require the user to answer yes or no to whether the administration set being used has an air-eliminating filter. This information is recorded into the pump's history log.

AIL Sensitivity Off-Alert Screen

AIL Sens OFF
Using In Line
Air Filter?
YES/NO

5. AUDIO: (Audio Volume)-allows the user to adjust the volume of the pump's alarm. There are three choices, High (default), Medium and Low. Use the "NO" key until the desired setting appears on the display and then press "YES" to select and move the cursor to the next field.

6. KVO Rate: (Keep Vein Open Rate)-this field requires data entry using the numeric keys to set the rate at which fluid will be delivered in a "Keep Open" state. The pump defaults to a rate of 0.1ml/hour, can be set up to 10 ml/hour but cannot be set at a rate to exceed the therapy operating rate.

7. DELAY: (Delay Start)-this field allows the infusion is to start at a later specified time. If the infusion is NOT to be delayed, select "Off", press "YES" to enter and the cursor will move to the next field. If the infusion **IS** to be delayed until a later time, select "ON", press "YES" to accept and the following screen will appear:

TPN Delay Start Setting

T	DELAY START	
P	TIME: HH:MM	
N	AM	PM
Y	DATE: MM/DD/YY	
	ACCEPT? YES/NO	

The time format (12 hr AM/PM or 24 hr Military) selected in the Setup Menu will apply in this table and if Military was selected the AM/PM field will not appear. If the entire delay start screen is to be aborted, press the "NO" key. When the start time and date are entered using the numeric keys and the data is accepted by pressing the "YES" key, the pump's clock will be set to start the infusion at the desired time and the display will return to the next field in the pre-infusion options menu. (**Note:** If the pump is not connected to the patient's access site at this time, the patient or caregiver should be taught proper techniques to access the infusion site prior to the scheduled start time.)

7. DONE?" If there are any changes to be made, use the up or down arrow keys to locate the field to be changed, use the numeric keys to enter the corrected information and press "YES" to accept the new data. If all the fields are acceptable, move the cursor to the "DONE?" field and press the "YES" key to move on to the next screen.

At the following screen, the patient's prescription information is be entered to complete the programming of the pump:

TPN Programming Screen

T	BAG Vol:	1 to 9999	ml
P	Amt TBI:	1 to 9999	ml
N	Max Rate:	.1 to 400	ml/hr
V	UP Ramp:	0 to 999 HH	HH:MM
	DN Ramp:	0 to 999 HH	HH:MM
	Total Time:	0 to 999 HH	HH:MM
	DONE?	YES	

1. Note the screen Identifier gives the abbreviation "TPN" for Total Parenteral Nutrition and has a down arrow configuration which indicates that there are more than 4 fields of text or information to be considered.

2. BAG Vol: (IV Bag Volume) Using the numeric keys, enter the amount of fluid that the IV Bag contains. NOTE: The volume used for priming via the pump or when a KVO rate is programmed is deducted from the Bag Volume. This will reduce the Bag Volume number. Bag Volume must be equal to or greater than the Amount To Be Infused; therefore, the Bag Volume entered now should be higher than the Amount To Be Infused. When the correct amount has been entered, press the "YES" key to accept this field and move on to the next.

3. Amt TBI: (Amount To Be Infused) Use the numeric keys to enter the actual amount of infusion to be delivered to the patient excluding any KVO amounts. When the amount is correctly entered, use the "YES" key to accept this field and to move to the next. (If Amt TBI entered is greater than Bag Volume, the pump will beep once to remind the user to recheck and change the number before the "YES" key will accept the value and move to the next field.

4. Max RATE: (Maximum Rate) or rate of the level infusion. The Curlin pump can deliver from 0.1ml to 400 ml per hour. Use the numeric keys to enter the prescribed rate. When this field is correct, use the "YES" key to accept the rate and move to the next field. The operator may choose to let the pump calculate the rate by skipping this field and entering Total Time.

5. UP Ramp: This optional feature allows the beginning of the infusion to gradually be tapered up to the level infusion rate over a specified period of time. Enter the up ramp time period using the numeric keys and when correct, press the "YES" key to accept this field and move to the next. Since this field is optional, "0" may be entered and accepted.

6. DN Ramp: (Down Ramp) is an optional feature allowing the infusion to gradually be tapered down over a specified period of time at the end of the level infusion. Enter the down ramp time period using the numeric keys and when correct, press the "YES" key to accept and move the cursor to the next field. Since this field is optional, "0" may be entered and accepted.

7. Total Time: This field displays the entire time period over which the infusion will be delivered. When the pump is given the Volume To Be Infused, the RATE at which to infuse, and the up and down ramp times, it will automatically calculate the Total Time and display it here. Or the operator may have chosen to program the total time and let the pump calculate the level rate of infusion. If so, the cursor will go back to the " MAX Rate" field, display the rate and require the operator to accept it by pressing the "YES" key. If the time is not acceptable, enter the new TIME with the numeric keys. When the TIME field is satisfactory, press the "YES" key and move to the final field.

8. DONE?: If there are any changes to be made, use the up or down arrow keys to locate the field to be changed, use the numeric keys to enter the corrected information and press "YES" to accept the new data. If all the fields are acceptable, at the "DONE?" prompt press "YES" to move to the next screen.

IMPORTANT INFORMATION

Before the infusion is started, it is important to consider a few remaining issues, such as checking the administration set to be sure it was primed or purged of all air, or perhaps the pump may need to be put into a security lock level for patient safety. The following screen will offer the user four choices:

Run Confirmation Screen

PRESS
RUN TO START
NO TO CHANGE
OPTIONS OR **PRIME**

Note that the user does not need to answer "YES" or no questions or enter data with the numeric keys as previously requested. This screen requires that the user press the corresponding key on the keypad to begin the requested function. The following section explains each selection beginning with Prime:

Prime

The IV bag and administration set should be inspected and be free of all air and air bubbles prior to connecting it to the patient's access site. This function may have been done by gravity when the administration set was first connected to the bag (see Chapter 1, "Preparing Medication for Infusion"). However, if it was not done then or if there are any remaining air bubbles to be removed, the pump's "PRIME" function will assist in this process. To prime the set using the pump, follow these directions:

1. Press the "PRIME" key.
2. The following screen appears:

Prime Direction Screen

Disconnect Patient Release Clamps HOLD **PRIME** key **YES** to EXIT

IMPORTANT INFORMATION

3. Disconnect the administration set from the patient's access site using aseptic protocols. **NOTE: Priming with the set connected to the patient could result in overdose and may cause injury or even death to the patient.**
4. Release any clamps on the administration set.
5. Press and hold the "PRIME" key. Fluid will quickly be delivered through the administration set as long as the PRIME key is pressed or until 6 ml is pumped. The pump will then beep once and require repressing and holding the "PRIME" key again until 6 more milliliters is delivered. Continue this process until all air has been purged from the administration set. While the "PRIME" key is depressed the following screen appears:

PRIMING Release PRIME key to Stop Prime Amt: ml

6. When priming is complete release the "PRIME" key. The following screen will display:

PRESS
PRIME to Cont.
YES to Exit
Prime Amt: ml

7. To continue priming, push the PRIME key again. If Priming is complete, press "YES" to exit and return to the screen displayed when Prime was selected. The total amount of solution used in priming displays on the bottom field.

8. **NOTE:** The amount of fluid used in the priming process will be deducted from the Bag Volume Total, but will NOT be counted in the amount infused, because this amount is not to be delivered to the patient. The bag volume must still be equal to or greater than the Amount TBI in order to proceed with the infusion.

Options

At the beginning of Chapter 6 the TPN "Pre-Infusion Options" were explained. Once the pump is programmed for TPN therapy, some of these same options will be available if it becomes necessary to further adjust the pump settings after an infusion has started. These "Running Options" (available while the pump is in a paused state or a running state) are accessible by pressing the "OPTIONS" key, are controlled by security lock levels, and will require a clinician access code to be entered if any lock level has been set. For information on changing security codes, see Chapter 13.

The following screens demonstrate the TPN "Options" available under each security level. Once in a screen, use the up and down arrows to move the highlight bar to the desired option. Any new settings become effective when the "Options" screen is exited.

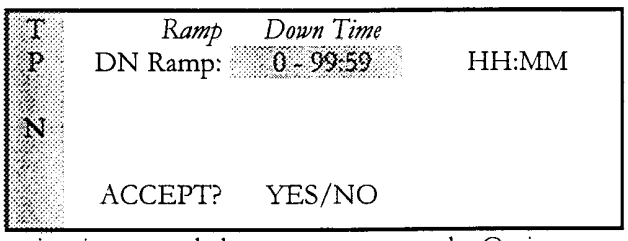
TPN Running Options-Lock OFF

	OPTION	*MENU*			
T P	LOCK:	OFF	1	2	3
N	DN Ramp:	NO	YES		
V	UP Occlu:	ON	OFF		
	DN Occlu:	LOW	HIGH		
	AIL SENS:	0.1 ml	0.5 ml	OFF	
	AUDIO:	HIGH	LOW	MEDIUM	
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

1. Lock: When set to "OFF" this feature allows the clinician to have access to all pump settings. When the pump is completely programmed change the lock level to meet the security needs of the patient. There are four choices in this field: OFF, 1, 2, or 3. Each level higher becomes more restrictive in the options available to the patient or caregiver (see each lock option screen in following sections). If the desired lock does not appear on the display, press the "NO/CHANGE" key until the correct lock does appear then press "YES/ENTER" to accept and move the cursor to the next field.

Early Down Ramp

2. DN Ramp: (Early Down Ramp) During a TPN infusion it may be necessary or desirable to stop the level rate of infusion and begin an early down ramp process. Selecting Early Ramp Down by pressing the "YES/ENTER" key when the highlight bar is on this field brings a second screen as seen below. If the lock level allows, the operator may adjust the preprogrammed ramp-down time period prior to starting the ramp down.



When the new time is accepted, the screen returns to the Options menu. The Early Down Ramp phase begins when the Options menu is exited.

3. UP Occlu: (Up Occlusion)-this field allows the user to select "on" or "off" for the alarm detecting an occlusion between the medication bag and the pump, e.g. a kink in the tubing or a closed clamp. If this setting is turned off and an "up" occlusion does occur, no alarm will sound. It is recommended, therefore, that this setting be left in its default state of "ON". To do this, press "YES" to accept the "on" setting and move to the next field.

4. DN Occlu: (Down Occlusion)-this feature allows the pump to sense an occlusion pressure in the line between the pump and the patients access site, e.g., a kink in the tubing between the pump and the patient, a blockage in the access site, a clamp left on the distal tubing. There are two options for this field: the "Low" setting (default setting) triggers the alarm when it detects in-line pressures at 8 psi (pounds per square inch), the "High" setting alarms when it detects in-line pressures at 18 psi. Press "NO/Change" to change the selection and when the correct pressure setting appears, press the "YES" key to select and move the cursor to the next field.

5. AIL SENS- (Air In Line Sensitivity)-this feature allows the user to select the amount of air the pump will detect in the administration set tubing before it goes into an alarm state. The choices are 0.1 ml (the default setting), 0.5 ml and OFF. Use the "NO" key to change the options until the desired setting appears on the display and then press "YES" to select and move the cursor to the next line. NOTE: When the "OFF" setting has been selected any contiguous 2 ml bolus of air will still be detected and the pump will then go into an alarm state.

IMPORTANT INFORMATION

Whenever the AIL Sensitivity is set to OFF, chose a Curlin administration set with an air eliminating filter.

Also, whenever the AIL Sensitivity is set to "OFF" and the "RUN" key is pressed, an alert message will appear on the screen (see below). This message alerts the user to the Air-In-Line Sensitivity being set to "OFF". The alert will require the user to answer yes or no to whether the administration set being used has an air eliminating filter in line and the above information is recorded in the pump's history log.

AIL Sensitivity Off-Alert Screen

AIL Sens OFF
Using In Line
Air Filter?
YES/NO

6. AUDIO: (Audio Volume)- this feature allows the user to adjust the audio volume of the pump's alarm. There are three choices, High (default), Medium and Low. Use the "NO" key until the desired setting appears on the display and then press "YES" to select and move the cursor to the next field.

7. Power CK?: (Power Check) -This feature allows the user to recheck the battery charge. It will display the active power source of the pump, whether batteries or external power. If the active source is the batteries, a graph will indicate approximately how much charge remains in the batteries. To access this information, press "YES" and the Power Source Screen will display for 5 seconds and return to the Options Menu.

8. ACCEPT?: If the changes made in the Options Menu are acceptable, press the "YES" key. If the changes are not acceptable, use arrow keys to cursor up to any field for corrections, or abort all changes made in this menu by pressing the "NO" key, and return to the previous screen.

The following screens show the OPTIONS menus for each of the lock levels in TPN Therapy:

TPN Running Options-Lock 1

	OPTION	MENU			
T P N	LOCK:	1	2	3	Off
	DN Ramp:	NO	YES		
V	AIL Sens:	0.1 ml	0.5 ml	OFF	
	AUDIO:	High	Med	Lo	
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

TPN Running Options-Lock 2

	OPTION	MENU			
T P	LOCK:	2	3	OFF	1
N	DN Ramp:	NO	YES		
V	AUDIO:	High	Med	Lo	
	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

TPN Running Options-Lock 3

	OPTION	MENU			
T P	LOCK:	3	OFF	1	2
N	Power CK?	YES	Always enabled	Allow user to enter Power Check	
	ACCEPT?	YES/NO			

There are two remaining selections to consider from the "Run Confirmation Screen", **NO** to Change, and **RUN** to Start:

NO/CHANGE - If there are any changes to the programming screen, press the "NO/CHANGE" key and the programming screen will reappear to allow the operator to make changes.

Starting the Infusion

RUN - When all parameters are correct and the pump has been primed properly and connected to the patient's access site, press "RUN" to start the therapy. The pump will begin infusing and the following screen displays the status of the therapy:

TPN Run Screen

T	RATE:	400	ml/hr
P	[|||||||||||	.....	.....]
N	Vol INF:	25.4	ml
	REMAIN:	0 to 999HH	HH:MM

This screen will continue to display as long as the infusion is running. Notice the information on each field:

1. The first field displays the rate of the infusion. If the therapy is in a ramp up or down phase, the rate will change accordingly to reflect the gradual increase or decrease in rate.
2. The second field is a graphic bar representing the percentage of the completed infusion. It also depicts the up or down ramping phase with gradually taller or shorter lines on the bar graph.
3. The third field displays volume infused.
4. The fourth field displays the remaining time to the completion of the infusion.
5. In addition to the display screen accumulating information regarding the status of the infusion, the green LED light blinks whenever the pump is infusing.

Interrupting an Infusion

The infusion can be paused at any time by pressing the "PAUSE" key and the following screen displays:

PAUSE MENU SCREEN

T	ENTER to Select
P	RESUME
N	REPEAT
	NEW PROGRAM

The screen offers the user three options: **(consider adding the 4th: "Early Ramp Down Now?"

1. RESUME: To resume the therapy in progress from where it left off, press the "YES" key at this field and the pump will return to the Run Screen and resume infusing the therapy.

2. REPEAT: To repeat the present therapy and add another IV bag with the same prescription as the previous bag, press the "YES" key at this field. This action will take the user to a screen displaying the last programmed values of the therapy.

3. NEW PROGRAM: To program an entirely new prescription or different therapy, press the "YES" key at this field and the display will return to the "Select Therapy Screen". (the ability to change these parameters may be controlled by the lock level)

When the infusion is complete, the following screen will display:

TPN Infusion Complete, KVO

T	Infusion	Complete	
P	.....		
N	Vol INF:	0 to 9999	ml
	KVO Rate:	0.1 to 10	ml/hr

This screen displays:

1. "Infusion Complete" and the field blinks.

2. A graphic representation indicating the KVO rate in progress (smaller "dot" configuration)

3. Vol INF (Volume infused) Displays the total volume infused.

4. KVO Rate: The preset KVO rate displays.

5. Infusion Complete is considered an alarm status and the audio alarm will beep once every 10 seconds to alert the user to this condition.

6. Additionally, the red LED will blink along with the green LED (green to indicate that the pump is infusing at a KVO rate and red to indicate that the infusion complete alarm exists).

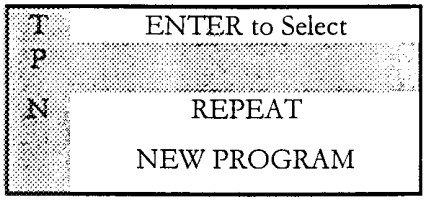
Stopping the Infusion

To halt the infusion, press the "PAUSE" key and then choose to:

1. Stop the pump if the total therapy is complete, by pressing the "OFF" key.

2. Or, select one of the options from the "Pause" screen:

PAUSE MENU SCREEN



1. REPEAT: To repeat the present therapy and add another IV bag with the same prescription press the "YES" key at this field. This action will take the user to a screen displaying the last programmed values of the therapy.

2. NEW PROGRAM: To program an entirely new prescription or different therapy, press the "YES" key at this field and the display will return to the "Select Therapy Screen". (the ability to change these parameters may be controlled by the lock level)

3. Note: The therapy has completed, therefore, RESUME is not an option at this time and is not displayed.

Chapter

Intermittent Therapy

Intermittent Therapy is designed to deliver programmed intervals and rates of specified amounts of infusates and to optionally deliver small amounts of the infusion between doses to keep the patient's access site patent.

To begin programming an Intermittent therapy consideration is given to specific patient customization features in the following "pre-infusion options" menu screen:

Pre-Infusion Options

Intermittent Pre-Infusion Options Screen

	NEW	*PROGRAM*			
	LOCK:	**OFF**	1	2	3
	UNITS:	**ml**	mg	µg	
	CONCEN:	---	or numeric value for concentration (/ml)	NA if units is ml	
	UP Occlu:	**ON**	OFF		
	DN Occlu:	**LOW**	HIGH		
	AIL SENS:	**0.1 ml**	0.5 ml	OFF	
	AUDIO :	**HIGH**	LOW	MEDIUM	
	KVO Rate:	0 to 10 ml/hr			
	DELAY:	**OFF**	ON		
	DONE?	YES			

These menu items were designed to meet each patient's specific needs and are selected prior to entering the prescription data. The pump's default settings are displayed in **bold**. (Note: some of the lines are abbreviated to fit on the display screen; the full description appears below)

1. LOCK: when the lock is set to "OFF" the clinician has access to all pump functions. After the pump is completely programmed, change the lock to meet the security needs of the patient. There are four choices in this field: OFF, 1, 2, or 3. Each level higher becomes more restrictive in the options available (see each lock level option screen in the following sections and the lock level table at the end of chapter 13). If the desired lock does not appear on the display screen, press the "NO/CHANGE" key until the correct level appears. Then, use the "YES/ENTER" key to accept the new lock selection. Once the pump has been set into a locked condition, any subsequent request to change the lock will require a clinician access code. (see Chapter 13 for access code information)

2. UNITS: allows the user to select from units of ml, mg, or μg depending on how the patient's prescription is written. The pump will allow a volume range of 0.1 to 400 **ml/**hr, therefore, if mg or μg are selected, the concentration requested in the next field will determine the upper and lower programming limits for mg and μg. Use the "NO/Change" key until the desired "units" appears on the display and then press the "YES/Enter" key to accept and move to the next field.

3. CONCEN: (Concentration)-this field is active whenever mg or μg are selected in the "units" field and requires data entry of the concentration of mg or μg per ml. When the correct data is entered using the numeric keys, press "YES" to accept and move the cursor to the next field. If ml is chosen in the "units" field, this line will not display.

4. UP Occlu: (Up Occlusion)-allows the user to select "on" or "off" for the pump to detect an occlusion between the medication bag and the pump. **Note:** If this field is set to "off" and an "up" occlusion (anything obstructing the flow of fluid from the container to the pump) does occur, *no alarm will sound.* It is recommended, therefore, that this setting be left in its default state of "ON". To do this, press "YES" to accept the "on" setting and move to the next field.

5. DN Occlu: (Down Occlusion)-allows the pump to sense an occlusion pressure in the line between the pump and the patients access site, e.g., a kink in the tubing between the pump and the patient, a blockage in the access site, a clamp left on the distal tubing. There are two options for this field: the "Low" setting (default setting) triggers the alarm when it detects in-line pressures at 8 psi (pounds per square inch), the "High" setting alarms when it detects in-line pressures at 18 psi. Press "NO" to change the selection and when the correct pressure setting appears, press the "YES" key to select and move the cursor to the next field.

6. AIL SENS: (Air In Line Sensitivity)-allows the user to select the amount of air the pump will detect in the administration set before it goes into an alarm state. The choices are 0.1 ml (the default setting), 0.5 ml and OFF. Use the "NO" key to change the options until the desired setting appears on the display and then press "YES" to select and move the cursor to the next line. (NOTE: When the "OFF" setting has been selected, any contiguous 2 ml bolus of air will still be detected and the pump will go into an alarm state and stop infusing until the situation is remedied.)

IMPORTANT INFORMATION

Whenever the AIL Sensitivity is set to OFF, use a Curlin administration set which has an air eliminating filter in line.

Also, whenever the AIL Sensitivity is set to "OFF" and the "RUN" key is pressed, an alert message will appear on the screen (see below). This message alerts the user to the Air In Line Sensitivity being set to "OFF". The alert will require the user to answer yes or no to whether the administration set being used has an air-eliminating filter in line. This information is recorded into the pump's history log.

AIL Sensitivity Off-Alert Screen

AIL Sens OFF
Using In Line
Air Filter?
YES/NO

7. AUDIO: (Audio Volume)-allows the user to adjust the audio volume of the pump's alarm. There are three choices, High (default), Medium and Low. Use the "NO" key until the desired setting appears on the display and then press "YES" to select and move the cursor to the next field.

8. KVO Rate: (Keep Vein Open Rate)-used in between doses or at the end of a therapy when it is necessary to infuse very small amounts to maintain a patent access site. The field requires data entry using the numeric keys to set the rate at which fluid will be delivered in a "Keep Open" state. The range for KVO rate in Intermittent therapies is 0 to 10 ml/hour but cannot be set at a rate to exceed the therapy operating rate. Setting the KVO rate at "0" is allowed for those patients who disconnect from the pump between intermittent dosing. When the desired KVO rate has been entered, press the "YES" key to accept and move the cursor to the next field.

9. DELAY: This field allows the infusion is to start at a later specified time. If the infusion is NOT to be delayed, select "Off", press "YES" to enter and the cursor will move to the next field. If the infusion **IS** to be delayed until a later time, select "ON", press "YES" to accept and the following screen will appear:

Intermittent Delay Start Setting

I	DELAY START	
N	TIME: HH:MM	
T	AM	PM
V	DATE: MM/DD/YY	
	ACCEPT? YES/NO	

The time format (12 hr AM/PM or 24 hr Military) selected in the Setup Menu will apply in this table and if Military was selected the AM/PM field will not appear. If the entire delay start screen is to be aborted, press the "NO" key. When the start time and date are entered using the numeric keys and the data is accepted by pressing the "YES" key, the pump's clock will be set to start the infusion at the desired time and the display will return to the next field in the pre-infusion options menu. (**Note:** If the pump is not connected to the patient's access site at this time, the patient or caregiver should be taught proper techniques to access the infusion site prior to the scheduled start time.)

10. Done?: If there are any changes to be made, use the up or down arrow keys to locate the field to be changed, use the numeric keys to enter the corrected information and press "YES" to accept the new data. if all the fields are acceptable, move the cursor to the "DONE?" field and press the "YES" key to move on to the next screen.

At the following screen, the patient's prescription information is entered to complete the programming of the pump:

Intermittent Program Menu

I	BAG Vol:	1 to 9999	ml	
N	Amt/Dose:	.1 to 999	ml	res: 0.1 (<100) else 1. ml, mg or mcg units
T	Dose Time:	0 to 999 HH	HH:MM	max 72:99 HH:MM
V	Dose Rate:	.1 to 400	ml/hr	res: 0.1 (<100) else 1. ml/hr, mg/hr or mcg/hr units
	Dose Freq:	0 to 999 HH	HH:MM	time from start of one dose to another
	#Doses/BAG:			Calculated but user can override
	REQ Vol:	1 to 9999	ml	Calculated, not programmed
	Total Time:	0 to 999 HH	HH:MM	Calculated, not programmed
	DONE?	YES		

1. Note that the screen Identifier gives you the abbreviation "INT" for Intermittent Therapy and has a down arrow configuration which indicates that there are more than 4 fields of text or information to be considered.

2. BAG Vol: (IV Bag Volume) Using the numeric keys, enter the amount of fluid that the IV Bag contains. NOTE: The volume used for priming via the pump or when a KVO rate is programmed is deducted from the Bag Volume.

3. Amt/Dose: (Amount per Dose) Using the numeric keys, enter the actual amount per dose to be delivered to the patient. The "Units" selected in the pre-infusion options menu will automatically appear in this field whether ml, mg or μg. When the amount is correctly entered, use the "YES" key to accept this field and to move to the next.

4. Dose Time: Using the numeric keys, enter the amount of time over which each dose is to be infused. When correctly entered, use the "YES" key to accept this field and to move on to the next.

5. Dose Rate: Rate at which each dose is to be delivered. The Curlin pump can deliver from 0.1ml to 400 ml per hour. Use the numeric keys to enter the prescribed rate (again the units chosen in the pre-infusion menu will appear here), when it is correct, use the "YES" key to accept the rate and move to the next field.

6. Dose Freq: (Dose Frequency) represents the time from the start of one dose to the start of the next. (e.g., every six hours) Use the numeric keys to enter the dose frequency and when correct, press the "YES" key to accept the cycle time and to move on to the next field.

NOTE: The next three fields are automatically calculated for the operator based on the information already programmed and are helpful in giving the user additional information for managing an intermittent therapy. At each of these fields, the user presses the "YES" key to accept and move to the next field.

7. #Dose/BAG: displays the number of doses that can be delivered from the BAG Volume given. The user can change this number to a lower number of doses per bag, but cannot change to a greater number.

8. REQ Vol: (Required Volume) needed for the programmed number of doses including the amount needed for KVO rates (if a KVO rate is programmed. The pump calculates this volume for the user based on previously programmed information and the user cannot change the data in this field. Use the down arrow or the "YES" key to move to the next field.

9. Total Time: displays the total time required to deliver the number of doses in this bag volume. The pump calculates this time based on previously programmed information and the user cannot change data in this field. Use the down arrow or the "YES" key to move to the next field.

10. DONE?: If there are any changes to be made, use the up or down arrow keys to locate the field to be changed, use the numeric keys to enter the corrected information and press "YES" to accept the new data. If all the fields are acceptable, move the cursor to the "DONE?" field and press the "YES" key to move on to the next screen.

IMPORTANT INFORMATION

Before the infusion is started, it is important to consider a few remaining issues, such as checking the administration set to be sure it was primed or purged of all air, or perhaps the pump may need to be put into a security lock level for patient safety. The following screen offers four choices:

Run Confirmation Screen

PRESS
RUN TO START
NO TO CHANGE
OPTIONS OR **PRIME**

Note that the user does not need to answer "YES" or no questions or enter data with the numeric keys as previously requested. This screen requires that the user press the corresponding key on the keypad to begin the requested function. The following section explains each selection beginning with Prime:

Prime

The IV bag and administration set should be inspected and be free of all air and air bubbles prior to connecting it to the patient's access site. This function may have been done by gravity when the administration set was first connected to the bag (see Chapter 1, "Preparing Medication for Infusion"). However, if it was not done then or if there are any remaining air bubbles to be removed, the pump's "PRIME" function will assist in this process. To prime the set using the pump, follow these directions:

1. Press the "PRIME" key.
2. The following screen appears:

Prime Direction Screen

Disconnect Patient Release Clamps
HOLD **PRIME** key
YES to EXIT

IMPORTANT INFORMATION

3. Disconnect the administration set from the patient's access site using aseptic protocols. **NOTE: Priming with the set connected to the patient could result in overdose and may cause injury or even death to the patient.**

4. Release any clamps on the administration set.

5. Press and hold the "PRIME" key. Fluid will quickly be delivered through the administration set as long as the PRIME key is pressed or until 6 ml is pumped. The pump will then beep once and require repressing and holding the "PRIME" key again until 6 more milliliters is delivered. Continue this process until all air has been purged from the administration set. While the "PRIME" key is depressed the following screen appears:

PRIMING
Release PRIME
key to Stop
Prime Amt: ml

6. When priming is complete release the "PRIME" key. The following screen will display:

PRESS
PRIME to Cont.
YES to Exit
Prime Amt: ml

7. To continue priming, push the PRIME key again. If Priming is complete, press "YES" to exit and return to the screen displayed when Prime was selected. The total amount of solution used in priming displays on the bottom field.

8. **NOTE:** The amount of fluid used in the priming process will be deducted from the Bag Volume.

Options

At the beginning of Chapter 7, the Intermittent "Pre-Infusion Options" were explained. Once the pump is programmed for a "Intermittent" therapy, some of these same options will be available if it becomes necessary to further adjust the pump settings after an infusion has started. These "Running Options" (available while the pump is in a paused state or running state) are accessible by pressing the "OPTIONS" key, are controlled by security lock levels and will require a clinician access code to be entered if any lock level has been set. For information on changing security codes, see Chapter 13.

The following screens demonstrate the Intermittent "Options" available under each security level. Once in a screen, use the up and down arrows to move the highlight bar to the desired option. Any new settings become effective when the "Options" screen is exited.

Intermittent Running Options-Lock OFF

	OPTION	*MENU*		
I N T V	LOCK:	OFF	1	2
	UP Occlu:	ON	OFF	
	DN Occlu:	LOW	HIGH	
	AIL SENS:	0.1 ml	0.5 ml	OFF
	KVO Rate:	0 - 10 ml/hr	res 0.1 ml/hr	
	NEXT Dose:	0 to 999	HH:MM	
	AUDIO:	HIGH	LOW	MED
	Power CK?	YES		
	ACCEPT?	YES/NO		

1. LOCK: This feature allows the clinician, when the lock set to "OFF", to have access to all pump settings. When the pump is completely programmed change the lock level to meet the security needs of the patient. There are four choices in this field: OFF, 1, 2, or 3. Each level higher becomes more restrictive in the options available to the patient or caregiver (see each lock option screen in following sections). If the desired lock does not appear on the display, press the "NO/CHANGE" key until the correct lock does appear, then press "YES/ENTER" to accept and move the cursor to the next field.

2. UP Occlu: (Up Occlusion)-this field allows the user to select "on" or "off" for the alarm detecting an occlusion between the medication bag and the pump, e.g. a kink in the tubing or a closed clamp. If this setting is turned off and an "up" occlusion does occur, no alarm will sound. It is recommended, therefore, that this setting be left in its default state of "ON". To do this, press "YES" to accept the "on" setting and move to the next field.

3. DN Occlu: (Down Occlusion)-this feature allows the pump to sense an occlusion pressure in the line between the pump and the patients access site, e.g., a kink in the tubing between the pump and the patient, a blockage in the access site, a clamp left on the distal tubing. There are two options for this field: the "Low" setting (default setting) triggers the alarm when it detects in-line pressures at 8 psi (pounds per square inch), the "High" setting alarms when it detects in-line pressures at 18 psi. Press "NO/Change" to change the selection and when the correct pressure setting appears, press the "YES" key to select and move the cursor to the next field.

4. AIL SENS: (Air In Line Sensitivity)-this feature allows the user to select the amount of air the pump will detect in the administration set tubing before it goes into an alarm state. The choices are 0.1 ml (the default setting), 0.5 ml and OFF. Use the "NO" key to change the options until the desired setting appears on the display and then press "YES" to select and move the cursor to the next line. NOTE: When the "OFF" setting has been selected any contiguous 2 ml bolus of air will still be detected and the pump will then go into an alarm state.

IMPORTANT INFORMATION **Whenever the AIL Sensitivity is set to OFF, chose a Curlin administration set with an air eliminating filter.**

Also, whenever the AIL Sensitivity is set to "OFF" and the "RUN" key is pressed, an alert message will appear on the screen (see below). This message alerts the user to the Air-In-Line Sensitivity being set to "OFF". The alert will require the user to answer yes or no to whether the administration set being used has an air eliminating filter in line and the above information is recorded in the pump's history log.

AIL Sensitivity Off-Alert Screen

AIL Sens OFF
Using In Line
Air Filter?
YES/NO

5. KVO Rate: (Keep Vein Open Rate)-this field requires data entry using the numeric keys to set the rate at which fluid will be delivered in a "Keep Open" state. The pump defaults to a rate of 0.1ml/hour, can be set up to 10 ml/hour but cannot be set at a rate to exceed the therapy operating rate.

6. NEXT Dose: Allows the time of the next dose to be changed. Use the numeric keys to enter the desired time for the start of the next dose. When correct, press the "YES" key to accept and move to the next field.

7. AUDIO: (Audio Volume)- this feature allows the user to adjust the audio volume of the pump's alarm. There are three choices, High (default), Medium and Low. Use the "NO" key until the desired setting appears on the display and then press "YES" to select and move the cursor to the next field.

8. Power CK?: (Power Check) -This feature allows the user to recheck the battery charge. It will display the active power source of the pump, whether batteries or external power. If the active source is the batteries, a graph will indicate approximately how much charge remains in the batteries. To access this information, press "YES" and the Power Source Screen will display for 5 seconds and return to the Options Menu.

9. ACCEPT?: If the changes made in the Options Menu are acceptable, press the "YES" key. If the changes are not acceptable, use arrow keys to cursor up to any field for corrections, or abort all changes made in this menu by pressing the "NO" key, and return to the previous screen.

IMPORTANT INFORMATION

If a KVO rate is programmed for the Intermittent Therapy, the patient does not disconnect in between dosing and the pump automatically cycles through dosing and KVO without audio alerts sounding.

If the KVO rate is set at "0" and the patient has been instructed in the proper techniques of connecting and disconnecting the pump between dosing, the pump can be off between those doses. The internal time clock of the pump continues to monitor the dosing cycle.

1. When the pump is turned back on within 30 min prior to or 30 min past the next dose schedule, no changes will be made in the original scheduling except to lengthen or shorten the "KVO" time between dosing to comply with next dose time.

2. When the pump is turned back on 31or more minutes past the Next Dose Time, the dose will be ready for delivery when pump is turned on. All subsequent dosing will be shifted to keep the dosing cycle consistent unless the "NEXT Dose" Option is used to change the dose time.

3. If a dose in progress is interrupted for less than 30 minutes and the pump is turned back on, the dose in progress will resume and the only adjustment will be to shorten the KVO time between dosing.If a dose in progress is interrupted for 31 or more minutes and the pump is turned back on, the dose will be skipped unless the "NEXT Dose" Option is used to change the dose time.

4. If the KVO cycle is interrupted, no changes occur in dosing time cycles.

The following screens show the OPTIONS Menus for each lock level in the Intermittent Therapy:

Intermittent Running Options-Lock 1

	OPTION	*MENU*			
I N T V	LOCK:	1	2	3	OFF
	Next Dose:	0 to 999	HH:MM		
	AUDIO:	HIGH	LOW	MED	
	KVO Rate:	0 - 10 ml/hr	res 0.1 ml/hr		
	Power CK?	YES			
	ACCEPT?	YES/NO			

Intermittent Running Options-Lock 2

I	*OPTION*	*MENU*			
N	LOCK:	2	3	OFF	1
T	Next Dose:	0 to 999	HH:MM		
V	AUDIO:	HIGH	LOW	MED	
	Power CK?	YES			
	ACCEPT?	YES/NO			

Intermittent Running Options-Lock 3

I	*OPTION*	*MENU*			
N	LOCK:	3	OFF	1	2
T	Power CK?	YES			
	ACCEPT?	YES/NO			

There are two remaining selections to consider from the "Run Confirmation Screen", **NO** to Change, and **RUN** to Start:

NO/CHANGE - If there are any changes to the programming screen, press the "NO/CHANGE" key and the programming screen will reappear to allow the operator to make changes.

Starting the Infusion

RUN - When all parameters are correct and the pump has been primed properly and connected to the patient's access site, press "RUN" to start the therapy. The pump will begin infusing and the following screen displays the status of the therapy:

Intermittent Run Screen

I			
	RATE:	400	ml/hr
N	[||||||||||||	.....	.....]
T	Vol INF:		ml
	Amt INF: Dose		mg, μg
	# of ##:		
	REMAIN:	0 to 999	HH:MM

This screen continues to display as long as the infusion is in progress. Notice the information on each field.

1. The first field displays the rate of the infusion in whichever units/hour has been selected. KVO rates (when running) are displayed here as well.

2. The second field is a graphic representation of the amount of the dose in progress or the KVO cycle remaining.

3. The third field toggles to give Volume Infused, and, if units are mg or μg, the Amount Infused, as well as the Dose Number of the Total Doses in progress.

4. The fourth field gives the time remaining time for the entire number of doses in the Bag Volume programmed.

Interrupting an Infusion

The infusion can be paused at any time by pressing the "PAUSE" key and the following screen displays:

PAUSE MENU SCREEN

I	ENTER to Select
N	RESUME
T	REPEAT
	NEW PROGRAM

The screen offers the user three options:

1. RESUME: To resume the therapy in progress from where it left off, press the "YES" key at this field and the pump will return to the Run Screen and resume infusing the therapy.

2. REPEAT: To repeat the present therapy and add another IV bag with the same prescription as the previous bag, press the "YES" key at this field. This action will take the user to a screen displaying the last programmed values of the therapy.

3. NEW PROGRAM: To program an entirely new prescription or different therapy, press the "YES" key at this field and the display will return to the "Select Therapy Screen". (the ability to change these parameters may be controlled by the lock level)

IMPORTANT INFORMATION

Remember, this therapy is time dependent and the following rules apply for interruptions in therapy:

If a KVO rate is programmed for the Intermittent Therapy, the patient does not disconnect in between dosing and the pump automatically cycles through dosing and KVO without audio alerts sounding.

If the KVO rate is set at "0" and the patient has been instructed in the proper techniques of connecting and disconnecting the pump between dosing, the pump can be off between those doses. The internal time clock of the pump continues to monitor the dosing cycle.

1. When the pump is turned back on within 30 min prior to or 30 min past the next dose schedule, no changes will be made in the original scheduling except to lengthen or shorten the "KVO" time between dosing to comply with next dose time.

2. When the pump is turned back on 31or more minutes past the Next Dose Time, the dose will be ready for delivery when pump is turned on. All subsequent dosing will be shifted to keep the dosing cycle consistent unless the "NEXT Dose" Option is used to change the dose time.

3. If a dose in progress is interrupted for less than 30 minutes and the pump is turned back on, the dose in progress will resume and the only adjustment will be to shorten the KVO time between dosing.If a dose in progress is interrupted for 31 or more minutes and the pump is turned back on, the dose will be skipped unless the "NEXT Dose" Option is used to change the dose time.

4. If the KVO cycle is interrupted, no changes occur in dosing time cycles.

When the infusion is complete (all doses of this IV bag are administered), the following screen displays:

Intermittent Infusion Complete

I	Infusion	Complete	
N	.....		
T	Vol INF:	0 to 9999	ml
	KVO Rate:	0.1 to 10	ml/hr

This screen displays:

1. "Infusion Complete" and the field blinks.

2. A graphic representation indicating the KVO rate in progress (smaller "dot" configuration)

3. Vol INF (Volume infused) Displays the total volume infused.

4. KVO Rate: The preset KVO rate displays.

5. Infusion Complete is considered an alarm status and the audio alarm will beep once every 10 seconds to alert the user to this condition.

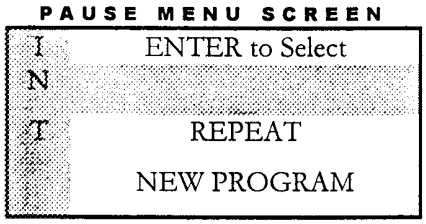
6. Additionally, the red LED will blink along with the green LED (green to indicate that the pump is infusing at a KVO rate and red to indicate that the infusion complete alarm exists).

Stopping the Infusion

To halt the infusion, press the "PAUSE" key and then choose to:

1. Stop the pump if the total therapy is complete, by pressing the "OFF" key.

2. Or, select one of the options from the "Pause" screen:



1. REPEAT: To repeat the present therapy and add another IV bag with the same prescription press the "YES" key at this field. This action will take the user to a screen displaying the last programmed values of the therapy.

2. NEW PROGRAM: To program an entirely new prescription or different therapy, press the "YES" key at this field and the display will return to the "Select Therapy Screen". (the ability to change these parameters may be controlled by the lock level)

3. Note: The therapy has completed, therefore, RESUME is not an option at this time and is not displayed.

Chapter

Variable Therapy

This therapy is designed to allow 24 specified programs of varying amounts, rates and times of delivery. It is especially helpful in the programming required for circadian therapies.

To begin programming a Variable Therapy consideration is given to specific patient customization features in the following "pre-infusion options" menu screen:

Pre-Infusion Options

Pre-Infusion Options Screen

V A R V	*NEW*	*PROGRAM*	1	2	3
	LOCK:	**OFF**			
	UNITS:	**ml**	mg	µg	
	CONCEN:	---	or numeric value for concentration (/ml)	NA if units is ml	
	UP Occlu:	**ON**	OFF		
	DN Occlu:	**LOW**	HIGH		
	AIL SENS:	**0.1 ml**	0.5 ml	OFF	
	AUDIO:	**HIGH**	LOW	MEDIUM	
	KVO Rate:	0 to 10 ml/hr			
	DELAY:	**OFF**	ON		
	DONE?	YES			

These menu items allow customizing the pump to meet each patient's specific needs and are selected prior to entering the prescription data. The pump's default settings are displayed in **bold**. Each field is individually explained on following pages: (Note: some of the lines are abbreviated to fit on the display screen; the full descriptions appear below)

1. LOCK: when the lock is set to "OFF" the clinician has access to all pump functions. After the pump is completely programmed, change the lock to meet the security needs of the patient. There are four choices in this field: OFF, 1, 2, or 3. Each level higher becomes more restrictive in the options available (see each lock level option screen in the following sections and the lock level table at the end of chapter 13). If the desired lock does not appear on the display screen, press the "NO/CHANGE" key until the correct level appears. Then, use the "YES/ENTER" key to accept the new lock selection. Once the pump has been set into a locked condition, any subsequent request to change the lock will require a clinician access code. (see Chapter 13 for access code information)

2. UNITS: allows the user to select from units of ml, mg, or μg depending on how the patient's prescription is written. The pump will allow a volume range of 0.1 to 400 **ml/**hr, therefore, if mg or μg are selected, the concentration requested in the next field will determine the upper and lower programming limits for mg and μg. Use the "NO/Change" key until the desired "units" appears on the display and then press the "YES/Enter" key to accept and move to the next field.

3. CONCEN: (Concentration)-this field is active whenever mg or μg are selected in the "units" field and requires data entry of the concentration of mg or μg per ml. When the correct data is entered using the numeric keys, press "YES" to accept and move the cursor to the next field. If ml is chosen in the "units" field, this line will not display.

4. UP Occlu: (Up Occlusion)-allows the user to select "on" or "off" for the pump to detect an occlusion between the medication bag and the pump. **Note:** If this field is set to "off" and an "up" occlusion (anything obstructing the flow of fluid from the container to the pump) does occur, *no alarm will sound.* It is recommended, therefore, that this setting be left in its default state of "ON". To do this, press "YES" to accept the "on" setting and move to the next field.

5. DN Occlu: (Down Occlusion)-allows the pump to sense an occlusion pressure in the line between the pump and the patients access site, e.g., a kink in the tubing between the pump and the patient, a blockage in the access site, a clamp left on the distal tubing. There are two options for this field: the "Low" setting (default setting) triggers the alarm when it detects in-line pressures at 8 psi (pounds per square inch), the "High" setting alarms when it detects in-line pressures at 18 psi. Press "NO" to change the selection and when the correct pressure setting appears, press the "YES" key to select and move the cursor to the next field.

6. AIL SENS: (Air In Line Sensitivity)-allows the user to select the amount of air the pump will detect in the administration set before it goes into an alarm state. The choices are 0.1 ml (the default setting), 0.5 ml and OFF. Use the "NO" key to change the options until the desired setting appears on the display and then press "YES" to select and move the cursor to the next line. (NOTE: When the "OFF" setting has been selected, any contiguous 2 ml bolus of air will still be detected and the pump will go into an alarm state and stop infusing until the situation is remedied.)

IMPORTANT INFORMATION **Whenever the AIL Sensitivity is set to OFF, use a Curlin administration set which has an air eliminating filter in line.**

Also, whenever the AIL Sensitivity is set to "OFF" and the "RUN" key is pressed, an alert message will appear on the screen (see below). This message alerts the user to the Air In Line Sensitivity being set to "OFF". The alert will require the user to answer yes or no to whether the administration set being used has an air-eliminating filter in line. This information is recorded into the pump's history log.

AIL Sensitivity Off-Alert Screen

AIL Sens OFF
Using In Line
Air Filter?
YES/NO

7. AUDIO: (Audio Volume)-allows the user to adjust the audio volume of the pump's alarm. There are three choices, High (default), Medium and Low. Use the "NO" key until the desired setting appears on the display and then press "YES" to select and move the cursor to the next field.

8. KVO Rate: (Keep Vein Open Rate)-used in between doses or at the end of a therapy when it is necessary to infuse very small amounts to maintain a patent access site. The field requires data entry using the numeric keys to set the rate at which fluid will be delivered in a "Keep Open" state. The pump defaults to a rate of 0.1ml/hour, can be set up to 10 ml/hour but cannot be set at a rate to exceed the therapy operating rate. When the desired KVO rate has been entered, press the "YES" key to accept and move the cursor to the next field.

9. DELAY Start: This field allows the infusion is to start at a later specified time. If the infusion is NOT to be delayed, select "Off", press "YES" to enter and the cursor will move to the next field. If the infusion **IS** to be delayed until a later time, select "ON", press "YES" to accept and the following screen will appear:

Variable Delay Start Setting

V	DELAY START	
A	TIME: HH:MM	
R	AM	PM
V	DATE: MM/DD/YY	
	ACCEPT? YES/NO	

The time format (12 hr AM/PM or 24 hr Military) selected in the Setup Menu will apply in this table and if Military was selected the AM/PM field will not appear. If the entire delay start screen is to be aborted, press the "NO" key. When the start time and date are entered using the numeric keys and the data is accepted by pressing the "YES" key, the pump's clock will be set to start the infusion at the desired time and the display will return to the next field in the pre-infusion options menu. (**Note:** If the pump is not connected to the patient's access site at this time, the patient or caregiver should be taught proper techniques to access the infusion site prior to the scheduled start time.)

10. DONE?" If there are any changes to be made, use the up or down arrow keys to locate the field to be changed, use the numeric keys to enter the corrected information and press "YES" to accept the new data. If all the fields are acceptable, move the cursor to the "DONE?" field and press the "YES" key to move on to the next screen.

At the following screens, the patient's prescription information is entered to complete the programming of the pump.

Variable Therapies are programmed in individual dose screens. Prior to entering information about each individual dose, the bag volume and number of total doses per bag is entered on the initial programming screen. Once the total number of doses is entered and accepted, the pump will subsequently display a screen for each dose to program in Amount, Rate and Time:

Variable Program Menu1

V	Bag Vol:	1 to 9999	ml
A	# Doses:	1 to 24	
R			
	DONE?	YES	

Variable Program Menu 2

V	Dose #:	1	of ##	## is total number of doses
A	Amt TBI:	1 to 1000	ml	ml, mg or mcg units
R	RATE:	.1 to 400	ml/hr	res: 0.1 (<100) else 1. ml/hr, mg/hr or mcg/hr units
V	TIME:	0 to 999 HH	HH:MM	max 72:99 HH:MM
	DONE?	YES		

One dose per screen is entered.

V	Dose #:	2	of ##	## is total number of doses
A	Amt TBI:	1 to 1000	ml	ml, mg or mcg units
R	RATE:	.1 to 400	ml/hr	res: 0.1 (<100) else 1. ml/hr, mg/hr or mcg/hr units
V	TIME:	0 to 999 HH	HH:MM	max 72:99 HH:MM
	DONE?	YES		

1. Dose #: The dose number on the first field changes to indicate which dose is currently being programmed. The total number of doses is also displayed and the pump will only prompt programming screens for the number of doses indicated. Use the down arrow key or the "YES" key to move to the next field.

2. Amt TBI: Use the numeric keys to enter the amount to be delivered in this dose. The "Units" selected in the pre-infusion options menu will automatically appear in this field whether ml, mg or μg. When the amount is correctly entered, press the "YES" key to accept and move to the next field.

3. RATE: The Curlin pump can deliver from 0.1 ml to 400 ml per hour. Use the numeric keys to enter the prescribed rate for this dose. When this field is correct, press the "YES" key to accept and move to the next field.

4. TIME: (calculated by pump) Displays the time required to complete this dose. If the time is not acceptable, press the "NO" key to edit this field and enter the new TIME. (Remember, by changing the time, a new RATE will be calculated and will have to be accepted before exiting this menu. When the time is correct, press "YES" to accept and move to the next field.

5. DONE?: If there are any changes to be made, use the arrow keys to locate the field to be changed, use the numeric keys to enter the corrected information and press "YES" to accept the new data. If all fields are acceptable, move the cursor to the "DONE?" field and press the "YES" key to accept and move on to the next dose programming screen. When the total number of doses are programmed the pump will display the Run Confirmation Screen.

After all of the intermittent doses are programmed, a summary screen is displayed indicating the total number of doses and the total time and volume required:

V	Total Doses:	1- 24
A	Total Time:	1 - 999HH:MM
R	VOL Req:	1 - 9999 ml
	DONE?:	YES

1. Total Doses: The field displays the total number of doses programmed.

2. Total Time: The pump calculates the total time required to deliver the total number of doses.

3. VOL Req: (Volume Required) The pump calculates the total volume required to deliver the doses.

4. DONE?: If any of the information is NOT acceptable, press the "NO" key and the display will return to the initial programming screen to allow changes to be made in bag volume and total number of doses.

Before the infusion is started, it is important to consider a few remaining issues, such as checking the administration set to be sure it was primed or purged of all air. If it was not, the operator can use the pump's prime function to do so now. The pump may also need to be put into a higher security lock for patient safety by going to the Options Menu and changing the Lock. The following screen offers the user four choices:

Run Confirmation Screen

PRESS
RUN TO START
NO TO CHANGE
OPTIONS OR **PRIME**

Note that the user does not need to answer yes or no questions or enter data with the numeric keys as previously requested. This screen requires only that the user press the corresponding key on the keypad to begin the requested function. The following section explains each selection beginning with Prime:

Prime

The IV bag and administration set should be inspected and be free of all air and air bubbles prior to connecting it to the patient's access site. This function may have been done by gravity when the administration set was first connected to the bag (see Chapter 1, "Preparing Medication for Infusion"). However, if it was not done then or if there are any remaining air bubbles to be removed, the pump's "PRIME" function will assist in this process. To prime the set using the pump, follow these directions:

1. Press the "PRIME" key.

2. The following screen appears:

Prime Direction Screen

Disconnect Patient Release Clamps HOLD **PRIME** key **YES** to EXIT

IMPORTANT INFORMATION

3. Disconnect the administration set from the patient's access site using aseptic protocols. **NOTE: Priming with the set connected to the patient could result in overdose and may cause injury or even death to the patient.**

4. Release any clamps on the administration set.

5. Press and hold the "PRIME" key. Fluid will quickly be delivered through the administration set as long as the PRIME key is pressed or until 6 ml is pumped. The pump will then beep once and require repressing and holding the "PRIME" key again until 6 more milliliters is delivered. Continue this process until all air has been purged from the administration set. While the "PRIME" key is depressed the following screen appears:

PRIMING Release PRIME key to Stop Prime Amt: ml

6. When priming is complete release the "PRIME" key. The following screen will display:

PRESS
PRIME to Cont.
YES to Exit
Prime Amt: ml

7. To continue priming, push the PRIME key again. If Priming is complete, press "YES" to exit and return to the screen displayed when Prime was selected. The total amount of solution used in priming displays on the bottom field.

8. **NOTE:** The amount of fluid used in the priming process will be deducted from the Bag Volume Total, but will NOT be counted in the amount infused, because this amount is not to be delivered to the patient. The bag volume must still be equal to or greater than the Amount TBI in order to proceed with the infusion.

Options

At the beginning of Chapter 8, the Variable "Pre-Infusion Options" were explained. Once the pump is programmed for a Variable therapy, some of these same options will be available if it becomes necessary to further adjust the pump settings after an infusion has started. These "Running Options" (available while the pump is in a paused state or running state) are accessible by pressing the "OPTIONS" key, are controlled by security lock levels and will require a clinician access code to be entered if any lock level has been set. For information on changing security codes, see Chapter 13 which may be removed from this manual for patient security.

The following screens demonstrate the Variable Therapy "Options" available under each security level. Once in an option screen, use the up and down arrows to move the highlight bar to the desired option. Any new settings become effective when the "Options" screen is exited.

Variable Running Options-Lock 0

V A R V	*OPTION*	*MENU*			
	LOCK:	OFF	1	2	3
	UP Occlu:	ON	OFF		
	DN Occlu:	LOW	HIGH		
	AIL SENS:	0.1 ml	0.5 ml	OFF	
	KVO Rate:	0 - 10 ml/hr	res 0.1 ml/hr		
	AUDIO:	HIGH	LOW	MEDIUM	
	Power CK?	YES			
	ACCEPT?	YES/NO			

Variable Running Options-Lock 1

V A R V	*OPTION*	*MENU*			
	LOCK:	1	2	3	OFF
	AUDIO:	HIGH	LOW	MEDIUM	
	KVO Rate:	0 - 10 ml/hr	res 0.1 ml/hr		
	Power CK?	YES			
	ACCEPT?	YES/NO			

Variable Running Options-Lock 2

	OPTION	MENU			
V					
A	LOCK:	2	3	OFF	1
R	AUDIO:	HIGH	LOW	MEDIUM	
V	Power CK?	YES			
	ACCEPT?	YES/NO			

Variable Running Options-Lock 3

	OPTION	MENU			
V					
A	LOCK:	3	OFF	1	2
R	Power CK?	YES			
	ACCEPT?	YES/NO			

There are two remaining selections to consider from the "Run Confirmation Screen", **NO** to Change, and **RUN** to Start:

NO/CHANGE - If there are any changes to the programming screen, press the "NO/CHANGE" key and the programming screen will reappear to allow the operator to make changes.

Starting the Infusion

RUN - When all parameters are correct and the pump has been primed properly and connected to the patient's access site, press "RUN" to start the therapy. The pump will begin infusing and the following screen displays the status of the therapy:

Variable Run Screen

V	RATE:	0 - 400	ml/hr
A	[||||||||||||	.....	.....]
R	Vol INF:		ml
	REMAIN:	0 to 999	HH:MM

This information toggles with the following:

Variable Run Screen

```
V   Dose #:    of ###
A  [|||||||||||||||.....................  ..........]
R   Dose Inf:    mg/µg
    REMAIN:    (volume)        ml
```

This screen displays as long as the infusion is running. Notice the information on each field:

1. The rate of the infusion in whichever units/hour has been selected, this field toggles to also display the Dose # of Total Doses.
2. A graphic bar representing the percentage of the completed dose.
3. Volume infused and if mg or µg are the selected units, this field will toggle to display dose infused as well.
6. The remaining time to the completion of the infusion, toggles with total remaining volume.
7. In addition to the display screen giving information regarding the status of the infusion, the green LED light blinks whenever the pump is infusing.

Interrupting an Infusion

The infusion can be paused at any time by pressing the "PAUSE" key and the following screen displays:

PAUSE MENU SCREEN

```
V      ENTER to Select
A          RESUME
R          REPEAT
        NEW PROGRAM
```

The screen offers the user three options:

1. RESUME: To resume the therapy in progress from where it left off, press the "YES" key at this field and the pump will return to the Run Screen and resume infusing the therapy.

2. REPEAT: To repeat the present therapy and add another IV container (bag, reservoir or syringe) with the same prescription as the previous container, press the "YES" key at this field. This action will take the user to a screen displaying the last programmed values of the therapy.

3. NEW PROGRAM: To program an entirely new prescription or different therapy, press the "YES" key at this field and the display will return to the "Select Therapy Screen". (the ability to change these parameters may be controlled by the lock level)

When the infusion is complete, the following screen will display:

Variable Infusion Complete, KVO Screen

V	Infusion	Complete	
A	.....		
R	Vol INF:	0 to 9999	ml
	KVO Rate:	0.1 to 10	ml/hr

This screen displays:

1. "Infusion Complete" and the field blinks.

2. A graphic representation indicating the KVO rate in progress (smaller "dot" configuration)

3. Vol INF (Volume infused) If units are mg or μg, this field will also toggle to give the total dose infused.

4. KVO Rate: The preset KVO rate displays.

5. Infusion Complete is considered an alarm status and the audio alarm will beep once every 10 seconds to alert the user to this condition.

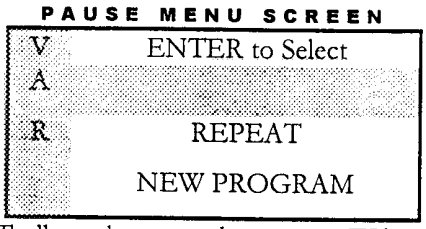
6. Additionally, the red LED will blink along with the green LED (green to indicate that the pump is infusing and red to indicate that the infusion complete alarm exists).

Stopping the Infusion

To halt the infusion, press the "PAUSE" key and then choose to:

1. Stop the pump if the total therapy is complete, by pressing the "OFF" key.

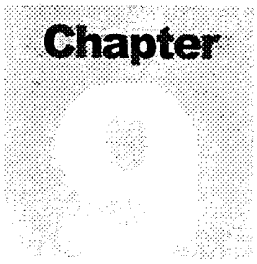
2. Or, select one of the options from the "Pause" screen:



a) REPEAT: allows the user to hang a new IV bag and repeat the entire therapy as previously programmed.

b) NEW PROGRAM: allows the user to select an entirely new program at this time.

c) (Note: The therapy has completed, therefore, RESUME is not an option at this time and is not displayed)



Troubleshooting

This section assists in interpreting visual and audible alert and alarm messages that may occur during the use of the ***Curlin*** *pump.*

IMPORTANT INFORMATION

Alerts, Alarms, and Malfunctions

Alerts, Alarms and Malfunctions are classes of events that are reported to the user and logged to the history file. They are reported using the LCD display, LEDs and Audio Alarms.

Alerts

Alerts report conditions that need correction by the user but are not safety issues. A message is displayed on the LCD (for 2 seconds), the Audio alarm is sounded, and the yellow Alarm LED is flashed. While the alert condition exist, the alert message, LED and beep will occur every minute (except Maintenance Date which occurs each time the pump is turned on). Note that Alerts can be silenced (audio only) by pressing the Silence key after the alert has been detected, however, the silenced condition will only remain for one minute, after which the beep will be re-enabled. The alarm volume is selected in the options menu. The beep is a single beep for a short duration

The following table lists the alert situations, explains the condition under which the alert will occur and gives the message displayed on the screen:

Alerts	# of Beeps/duration	Condition	LCD Displays
Low Battery	2 quick	Approximately 1 hour of battery power is left	ALERT LOW BATTERY
Low Bag Volume	(see Condition)	Calculated based on time remaining for infusion. At 30 min. remaining, a single beep will occur and message displays. At 10 min. remaining, one beep will sound every min. until Infusion Complete occurs and that message will then display.	ALERT LOW BAG VOL
Empty Bag	2 quick	Occurs when bag volume has infused.	ALERT EMPTY BAG
Release/Remove PCA Cord	2 quick	Not in PCA therapy and press of Remote Bolus occurs	ALERT NOT in PCA NO BOLUS ALLOWED
Air In Line Disabled	2 quick	When infusion is running and user has disabled AIL	ALERT AIR IN LINE DISABLED
Maintenance Date (Only displayed when pump is turned on)	2 quick	Current Date > Maintenance Date	ALERT PERFORM ROUTINE MAINTENANCE

Let's address the individual alert messages and address how to resolve them:

ALERT MESSAGE	RESOLUTION
1. Low Battery	Replace the batteries (see chapter 1 for instructions)
2. Low Bag Volume	Prepare to add another IV bag or to end the infusion
3. Release/Remove PCA Cord	Remove the remote bolus cord from the pump
4. Air In Line Disabled	Use administration set with an air eliminating filter and monitor tubing for presence of air bubbles
5. Maintenance Date	Send pump for routine maintenance

Alarms

IMPORTANT INFORMATION

Alarms are conditions that need correction by the user and may be a safety issue, but are not malfunctions of the pump. All alarm conditions stop the infusion, except the "Infusion Complete" Alarm which allows the KVO rate, when programmed, to continue infusing. When an alarm occurs, a message is displayed on the screen, the Audio alarm is sounded, and the Red Alarm LED is flashed. A specific number of beeps identify the type of alarm. The message stays on the screen until the user presses the "YES" key. The silence key can be pressed which disables the audio for one minute, after which the audio is re-enabled. The user must clear the cause of the alarm or it will reoccur when the infusion is restarted.

The following table lists the alarm situations, explains the condition under which the alarm will occur and gives the message displayed on the screen:

Alarms	Duration of Beep	Number of Beeps	LCD Display
Infusion Complete	Medium	3	(See Infusion Complete, KVO Screen.)
Air In Line	Medium	3	ALARM AIR IN LINE
Occlusion Down Stream	Medium	3	ALARM DOWN OCCLUSION
Occlusion Up Stream	Medium	3	ALARM UP OCCLUSION
Administration Set Not Installed	Medium	3	ALARM SET NOT INSTALLED
Empty Bag	Medium	3	ALARM EMPTY BAG
Unattended Pump	Medium	3	ALARM UNATTENDED
Door Open	Medium	3	ALARM DOOR OPEN
Empty Battery	Medium	3	ALARM EMPTY BATTERY

Let's address the individual alarm messages and how to resolve them:

ALARM MESSAGE	RESOLUTION
1. Infusion Complete	Turn pump off or add another IV bag, using the "Repeat" function and begin another infusion.
2. Air In Line	Remove air from administration set per protocol. (Disconnect from patient's access site prior to using prime function)
3. Occlusion Down Stream	Check administration set from pump to patient access site for potential causes of occlusion: if lower clamp is closed, open it, if tubing is kinked, straighten it, if filter may be blocked, replace administration set, or if patient access site may be obstructed, check it according to protocol
4. Occlusion Up Stream	Check administration set from IV bag to pump for potential causes of occlusion. If a clamp is in place, open it, if tubing is kinked, straighten it. Replace administration set if indicated.
5. Administration Set Not Installed	Install appropriate Curlin administration set for desired therapy. NOTE: Use *ONLY* Curlin administration sets.
6. Empty Bag	Turn pump off or add another IV bag.
7. Unattended Pump	When pump is placed in a paused state and left unattended, this alarm will sound; to resolve, either turn the pump off or continue with operating procedure.
8. Door Open	Close pump door properly.
9. Empty Battery	Replace both "C" Cell batteries.

Malfunctions

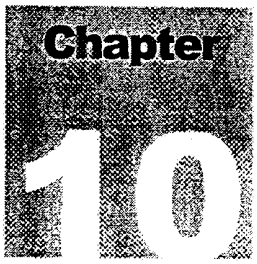
IMPORTANT INFORMATION

Malfunctions are serious failures in the pump and must immediately stop the infusion. A message is displayed on the LCD, the audio alarm is sounded at the highest volume and for a constant duration (no beeping). The Alarm and Standby LEDs are lit and stay on. **The only allowed action by the user is to turn the pump off.**

Malfunction notices are listed on the following table:

Malfunction	LCD Display
Over Infusion	MALFUNCTION OVER INFUSION
Motor Speed Too High	MALFUNCTION MOTOR SPEED TOO HIGH
Motor Speed Too Low	MALFUNCTION MOTOR SPEED TOO LOW
RTC/System Clock Failure	MALFUNCTION RTC/SYS CLK FAILURE
Stuck Key	MALFUNCTION STUCK KEY
Air In Line sensor Failure	MALFUNCTION AIR IN LINE FAILURE
Input Strain Beam Failure	MALFUNCTION INPUT STRAIN BEAM FAILURE
Output Strain Beam Failure	MALFUNCTION OUTPUT STRAIN BEAM FAILURE
Door Sensor Failure	MALFUNCTION DOOR SENSOR FAILURE
Auxiliary Battery Failure	MALFUNCTION AUX BATTERY FAILURE
Lithium Battery Failure	MALFUNCTION LITHIUM BATTERY FAILURE

Motor Voltage Failure	MALFUNCTION MOTOR VOLTAGE FAILURE
Vcc Failure	MALFUNCTION Vcc FAILURE
7.5 Volt Failure	MALFUNCTION 7.5 VOLT FAILURE
ROM CRC Failure	MALFUNCTION ROM CRC FAILURE
RAM CRC Failure	MALFUNCTION RAM CRC FAILURE
RAM Read/Write Failure	MALFUNCTION RAM READ/WRITE FAILURE
Audio Failure	MALFUNCTION AUDIO FAILURE
Self Test Failure	MALFUNCTION SELF TEST FAILURE
Watch Dog Time Out	MALFUNCTION WATCH DOG TIMEOUT



Accessories

There are a number of helpful accessories for use with the **Curlin** *pump and their descriptions and diagrams for use are included in this chapter.*

1. Battery Eliminator/Charger

This accessory can be used with the pump as the primary source of power or for charging the lead acid battery pack. The battery eliminator has a 3-prong plug to be plugged into a standard 3-prong, grounded wall receptacle and a 6-foot cable which plugs into the power outlet on the bottom of the pump. The red indicator light is "on" whenever the battery eliminator is connected to 120 V AC.

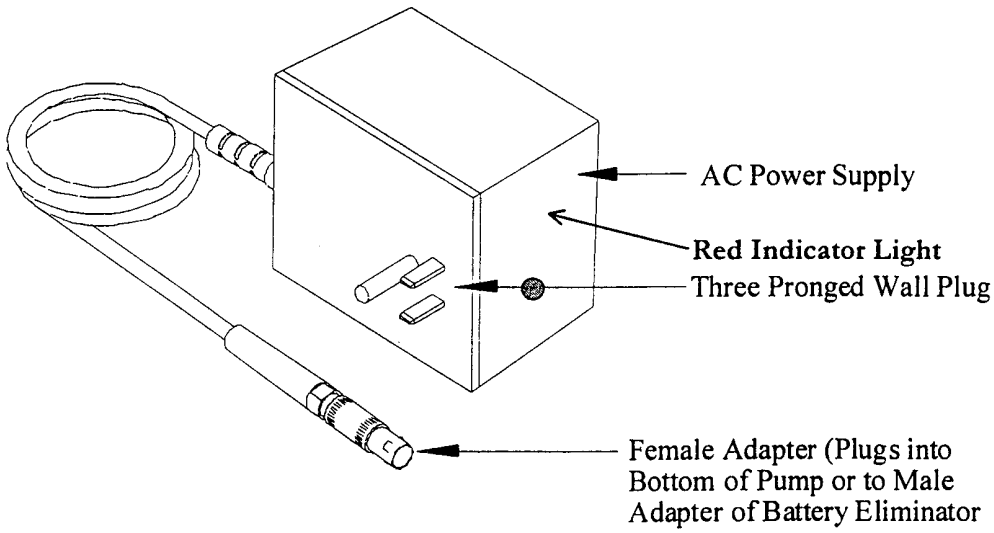


Figure 10.1 Battery Eliminator/charger

2. Battery Pack

This accessory is an external, rechargeable, lead acid battery pack that can be used as an additional, long-life, portable, external source of power. It can be recharged using the battery eliminator/charger.

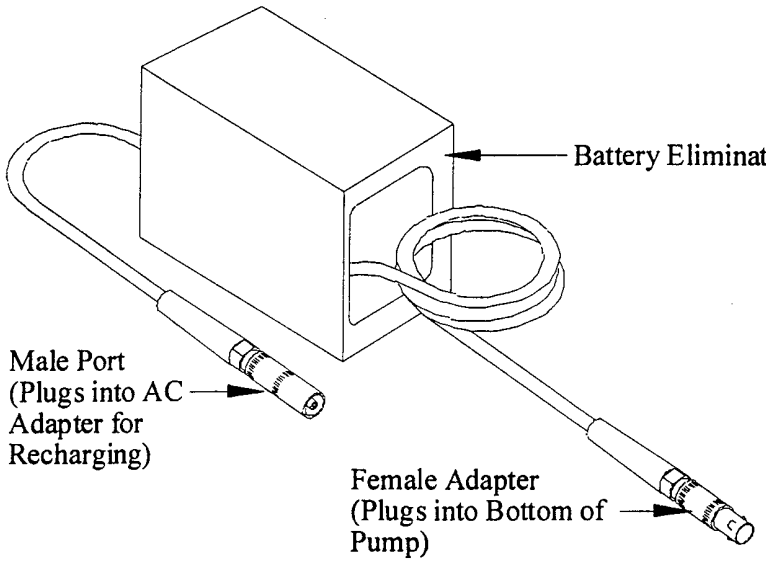


Figure 10.2 Battery Pack

3. Soft Carry Packs

These carry packs come in three sizes and are designed to provide user comfort and convenience. Each carry pack has diagrams printed inside to illustrate specific placement of the **Curlin** pump, IV bag, tubing, and battery pack. The fabric is durable, attractive, and easily cleaned using warm or cold water in the gentle washing machine cycle. They must be "drip" dried and NOT placed into a clothes dryer. They are intended for use as a single patient item.

- **Small Pack** - The small pack is designed to accommodate the Curlin pump and a collapsible solution container of up to 250 ml with an attached administration set. This pack is ideal for use as a "fanny pack", can be used with the shoulder strap, or can be worn using the belt loop.

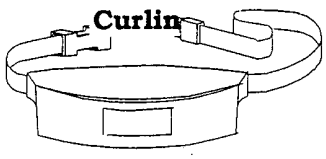


Figure 10.3 Small Carry Pack

- **Medium Carry Pack** - The Medium Carry Pack is designed to accommodate the Curlin pump, the external battery pack, and any collapsible solution container of up to 500 ml. It will also accommodate the lockable safety shell accessory. This bag can be carried over the shoulder or worn as a fanny pack.

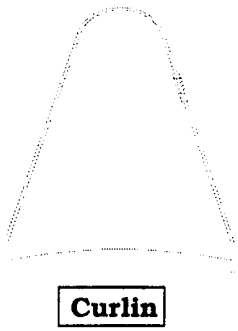
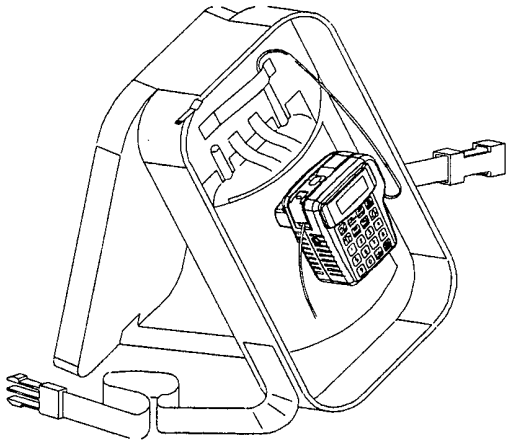


Figure 10.4 Medium Carry Pack

- **Back-Pack** - The Back-Pack is designed to accommodate the Curlin pump, the external battery pack, and any collapsible solution container of up to 4 liter size. It can be worn as a back-pack, carried by the handle at the top or with the shoulder strap. It is also designed to be free-standing in a upright configuration.



Notice the placement of the pump and solution container, using the handy Velcro straps to secure the IV bag, the tubing and the pump. The Back-Pack is shown in its upright, free standing configuration.

Figure 10.5 Back-Pack

4. Detachable Pole Clamp

The pole clamp will attach to the Lockable Safety Shell or the Pump Holster and can accommodate a pole of .75 to 1.25 inch diameter.

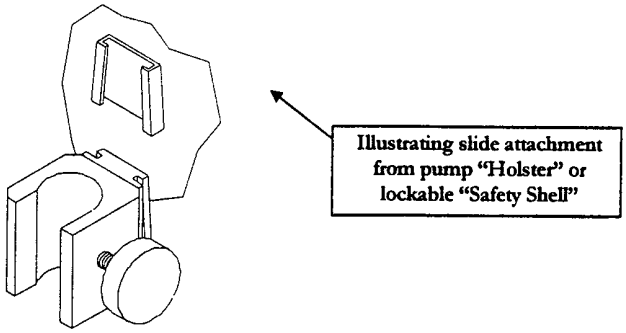


Figure 10.6 Detachable Pole Clamp

5. Remote Bolus Switch and Cable

This 5 foot flexible cable offers a remote push button switch for the patient's use in administering bolus dosing in the PCA therapy. This accessory cannot be used in any therapy except PCA and if it is left connected for any other therapy, an alert message will display on the pump screen instructing the operator to remove this cable.

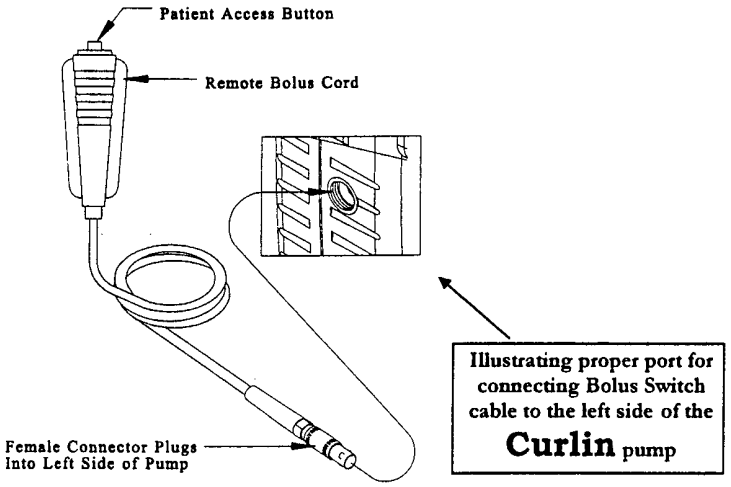


Figure 10.7 Remote Bolus Switch

6. Solid Safety Shell

This accessory is a hard plastic, durable, case that can contain the **Curlin** pump, a medication bag container with capacity of 110 ml or syringes of 10, 20 or 30cc volume, and the administration set. The case has an easy grip handle, **is lockable with a key**, and will secure the medication bag, the administration set and the pump and yet allow access to the pump's keypad, controls, communication connectors and battery door. The pump can be pole mounted using the detachable pole clamp, set on a stable flat surface or carried in the "Medium Pack" carry case. The Curlin administration set can be secured so that kinking of the tubing does not occur.

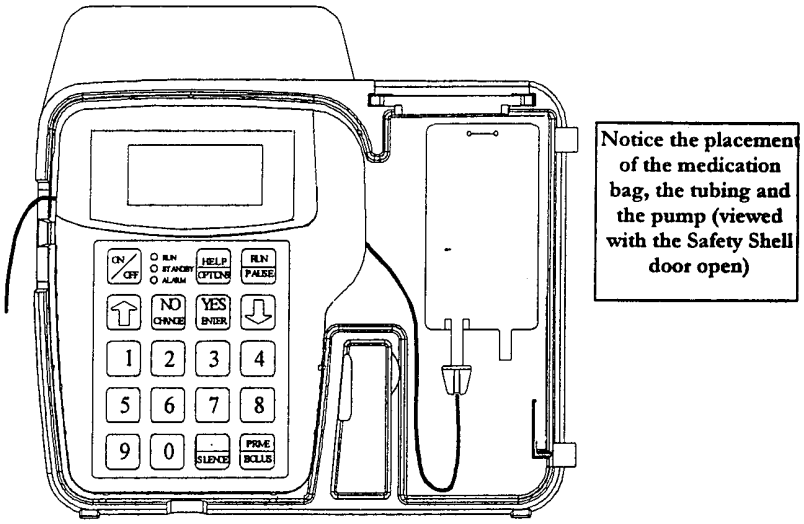


Figure 10.8 Lockable "Safety Shell"

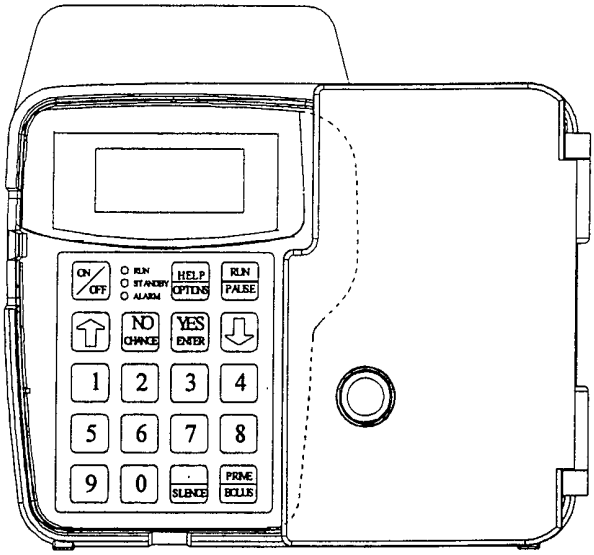


Figure 10.9 Lockable "Safety Shell" viewed with door closed

7. Safety Shell with Syringe Adapter

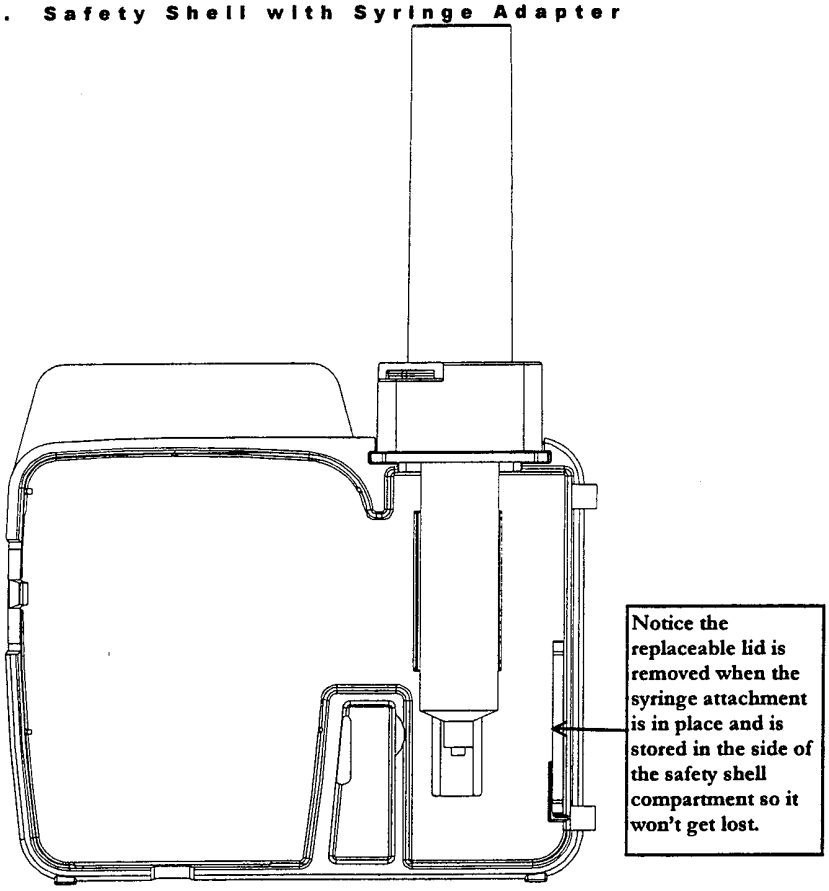


Figure 10.10 Safety Shell demonstrating placement of syringe

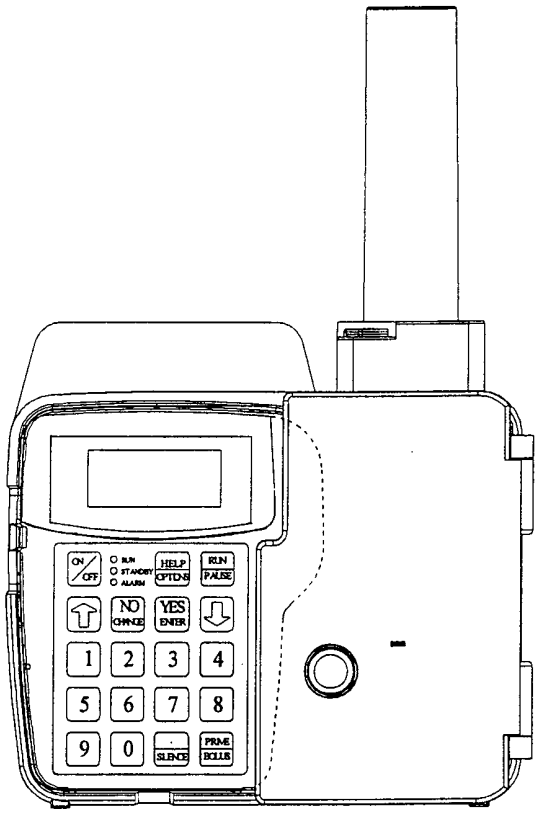
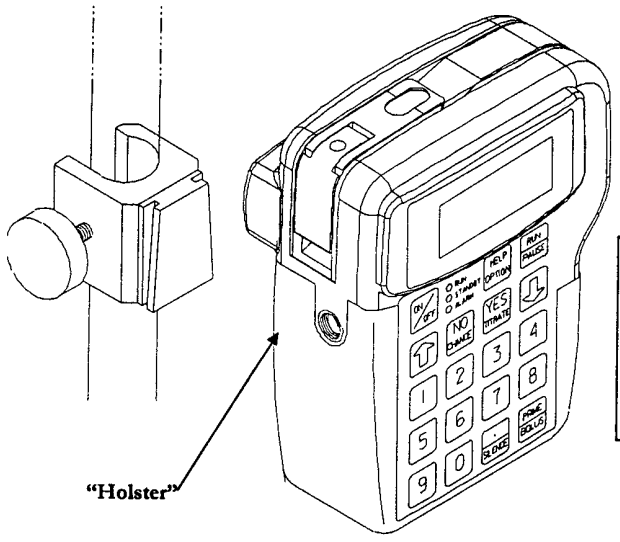


Figure 10.11 Safety Shell with Syringe Attachment (viewed with door locked)

8. Pump Holster

This accessory is a simple "slide pump in" case with a pole clamp mounting bracket on the back, allowing the pump to securely be mounted onto a pole and yet allow the user easy access to the display, keypad, controls, battery compartment and connectors for external power or communications.



Curlin pump sitting in the holster with pole mount attached to an IV pole. The back of the holster slides onto the pole mount.

Figure 10.12 Pump "Holster"

Chapter 7

Cleaning, Storage and Maintenance

The Curlin Ambulatory Infusion pump has been designed to provide a pleasing, clean, user-friendly appearance with robust features thereby insuring a reliable and easily maintained medical device. Following the guidelines for care listed below will assure the best appearance and longest life of this device.

Cleaning

1. The Curlin pump case is designed to be resistant to fluid spillage from any direction but is *not* to be immersed in any solutions. Keep the inside of the pumping section clean, dry and free of fluid spillage when installing a Curlin administration set. This area can be cleaned, rinsed and dried without harming the pump.

2. Clean the pump with any of the following:

- Warm soapy water (do not submerse)
- Isopropyl Alcohol
- Household bleach, diluted 9:1 with water
- Cidex commercial disinfectant

IMPORTANT INFORMATION

The following cleaning/disinfecting methods are specifically prohibited:

- Do not use full strength bleach
- Do not Autoclave or use steam sterilization
- Do not clean in a dishwasher
- Do not use Acetone, lacquer thinner or any other solvents or abrasive cleansers to clean the pump

With proper care, the pump will retain its attractive finish for many years of service.

Storage

Whenever the pump is not in use, it should ideally be stored in its hard shell packing case. It should be cleaned, repacked in this case and stored in an area where temperatures do not go below -20° F or above 140°F. All accessories should be stored in their original packing containers to insure longest service.

Maintenance

Yearly preventive maintenance checks are recommended and will be prompted in the "Set-Up" menu and on the display when the date occurs. This date accrues from the date of factory release and is reset when each annual maintenance check is completed.

Any time a malfunction message occurs, or any time a pump appears to be tampered with or shows any indication of not performing to standards, the pump should be returned to the Healthcare Provider dispensing the pump.

At no time should the hard case of the pump be opened by unauthorized personnel.

Warranty

Becton Dickinson Curlin, LLC warrants that reasonable care has been taken in manufacturing each **Curlin** ambulatory infusion pump. BDC further warrants that the pump will be free of defects in workmanship or materials for a period of one (1) year after the date of shipment when properly used, cared for and maintained.

If, during that one-year period, this product is found to be defective in workmanship or materials, the pump will be repaired or replaced. This action shall not extend the term of the warranty beyond the original term as set forth above. To obtain warranty service, call the BDC Maintenance number issued on your pump case (TBD) and request a Repair and Return Authorization Number. Reference the RRA number when returning the pump to BDC.

This warranty will not apply if any defective conditions or damage occurs in whole or in part by negligence, whether by dropping, misuse, abuse, improper installation, repair or alteration by anyone other than a duly authorized BDC technician. Chapter

Chapter

Technical Specifications

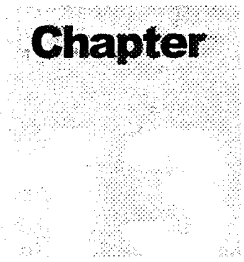
The following specifications apply to the Curlin Ambulatory Infusion Pump:

ITEM	SPECIFICATION
Pumping Mechanism:	Curvelinear peristaltic finger action
Size:	
Height:	< 5.10 inches
Width:	< 4.1 inches
Depth:	< 2.25 inches
Weight:	< 20 ounces without batteries
Case Material:	UL rated flame-retardant, non-toxic high strength plastic
Impact Resistance	Able to withstand a 3-foot drop to a wooden surface without damage.
Operating Environment	
Temperature:	40 to 105°F
Relative Humidity:	15 to 95%
Atmospheric:	525 to 795 mm HG
Storage Temperature Range:	-20° to 140°F

Power Requirements	
Battery, approximate operating time	45 hours at rate of 125 ml/hr
Internal memory battery	5 years
User Interface	
Displays	Graphic LCD, 4 text fields, 16 characters per field
Flow Rates	0.1 to 400 ml/hr
KVO Rates	0 to 10 ml/hr
Volume Accuracy	± 5% any rate and type of fluid for the following conditions: 1. 50° to 90° F. 2. -100 mmHg to 400 mmHG back pressure 3. Set usage to 72 hours continuous 4. Fluid container head height sensitivity of less than 1.5% per ft. for ± 2 ft ±10 % for any rate and type of fluid for the following conditions: 1. 40° to 104° F 2. -100 to 900 mmHg back-pressure 3. Set Usage to 96 hours continuous 4. Fluid container head height sensitivity of less than 1.5% per ft. for ±2 ft.
Administration Sets	Proprietary **Curlin** administration sets
Fill volume for administration sets	Non filtered microbore sets = 6 ml Non filtered macrobore sets = 12 ml

Down Occlusion Detection Time	For rates >10 ml/hr = <4 min. For rates 1 to <10 ml/hr =<20 min. For rates 0.5 to 1 ml/hr = <2 hr. For rates 0.1 to 0.5ml/hr = not specified
Up Occlusion Detection Time	For rates >10 ml/hr = <4 min. For rates 1 to <10 ml/hr =<20 min. For rates 0.1 to 1 ml/hr =<2 hr.

Any further performance or technical specification information may be obtained by calling BDC at (TBD phone number).



Clinician Access Code

This chapter can be removed prior to initial patient training and instruction on the Curlin pump so that the intended locked functions or secured functions of the pump cannot be accessed except by a trained clinician. Removal of this chapter will assist in patient safety.

Whenever it is necessary for the clinician to "unlock" a secured lock level in the options menu, the following screen will appear:

Clinician Access Code

Enter Access Code
CODE: ****

(Invalid Code)

EXIT? YES

The access code for the **Curlin** pump is given below:

Clinician Access Code

1234

(Actual code TBD)

Whenever the access code screen appears, use the numeric keys to enter the above code. The actual numbers will not appear on the screen but four asterisks will display. When the correct code is entered, the pump automatically moves on to the next screen. If an invalid access code is entered, the user has the option of re-entering the code or exiting the screen by pressing the "YES" key at the exit prompt.

The following table illustrates which features are controlled under which lock levels:

Lock Level Table

Menu Item	Item Range	Therapies Used In	Active Locks
Units	mg, µg, ml	all	0
Concentration	mg, µg	all	0
Admin Route	IV, SQ, Epi, Art	PCA	0
Up Pressure	on, off	all	0
Down Pressure	hi, lo	all	0
Dn Ramp Now	yes, no	TPN	0, 1, 2
Air In Line	off, 0.1 ml, 0.5 ml	all	0
Lock Level	0, 1, 2, 3	all	0
KVO Rate	0.0 to 10 ml/hr	Cont, TPN, Int, Var	0
Delay Start	on, off	Cont, TPN, Int, Var	0
Audio Volume	1 - 9	all	0, 1, 2
Power Check Display	on, off	all	0, 1, 2, 3
Load Dose	on, off	PCA	0
Prime Function		all	0, 1, 2
Repeat Function		all	0, 1, 2
Resume Function		all	0,. 1,. 2
Titration	on, off	Cont, PCA	0, 1
Clinician Dose	on, off	Cont, PCA	0

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

NOTICE

Product design and/or specifications may be changed without notice. The information contained in this specification is current as of date of issue.

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

TABLE OF CONTENTS

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

LIST OF FIGURES

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	**DATE:** 4/24/98	**REV** A

1. INTRODUCTION

1.1. SCOPE

This document describes the software design and architecture for the Curlin Healthcare Products ambulatory, multi-therapy, volumetric, infusion pump. This document contains the process flows, control flows and data definitions for the software. It is a "design to" document and is intended to provide the basis for the design of the software. This document will not be maintained. The design in this document will be transferred to the actual code.

1.2. APPLICABLE DOCUMENTS

- Ambulatory Multi-Therapy Volumetric Infusion Pump Software Requirements Specification, 340-9002.
- Ambulatory Multi-Therapy Volumetric Infusion Pump Hardware/Software Interface requirements, 340-9003.

2. DESIGN DEFINITION

This document is divided into three sections, software/hardware interface definition, process and control flow definitions, and data and event definitions.

The hardware/software interface requirements are also specified in a separate specification. The interface specification contains the context diagram for the software, a definition of the inputs and outputs to/from the software from/to the hardware, and a description of the hardware terminators for these inputs and outputs.

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

2.1. HARDWARE/SOFTWARE INTERFACE DEFINITION

The following context diagram shows the interface between the hardware and the software, followed by the definition of the hardware terminators.

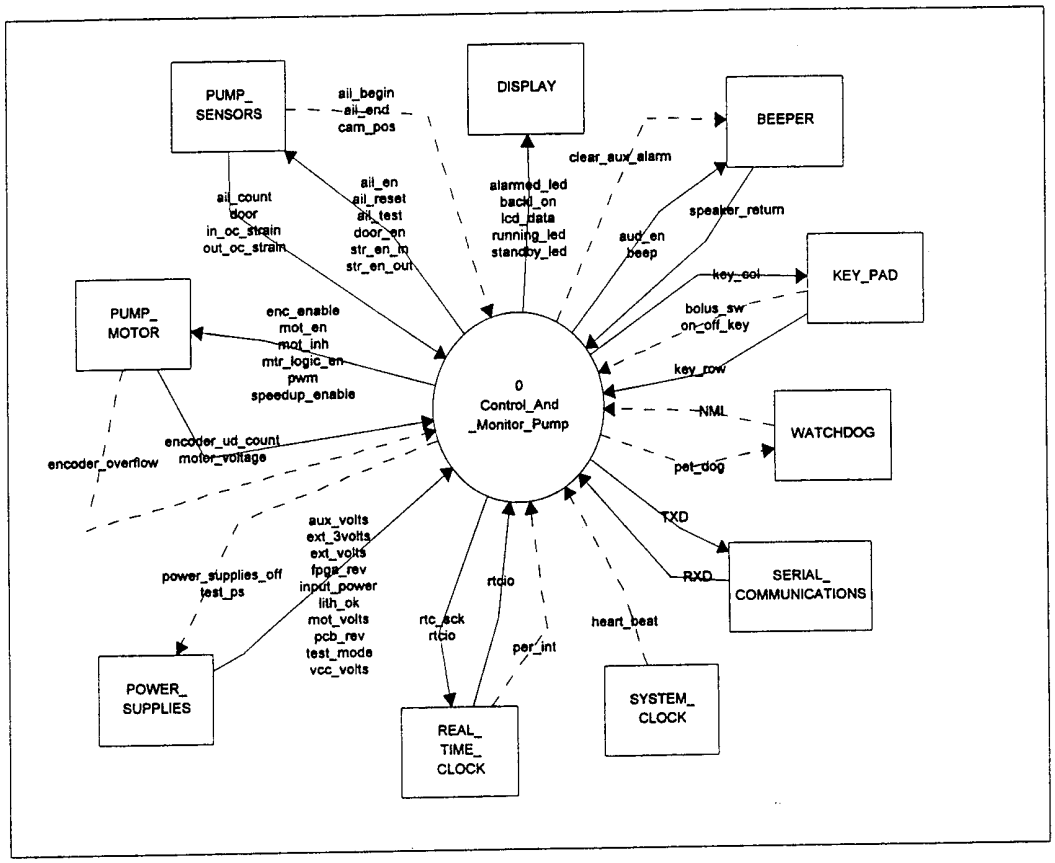


Figure 1 Context Diagram

2.1.1. KEY_PAD

The key configuration consists of an 18 key keypad, an ON/OFF key and a remote bolus button for the input of status and data to the software.

2.1.2. BEEPER

The beeper contains two buzzers which operates at a single, fixed frequency. One of the buzzers, which is designated as the normal operation beeper, is pulsed at varying widths, pulse rates and total number of pulses, as function of the event to be signaled by the buzzer. The second buzzer, which is designated

as the auxiliary buzzer, operates from the watch dog time out. It can be tested once and then reset via the clear_aux_beeper input event.

2.1.3. SYSTEM_CLOCK

This is the processor timer interrupt, which is set at 53.3 msec.

2.1.4. DISPLAY

The display consists of a 100X32 dot graphical LCD display and three individual LED's (which are located on the keypad). The LCD is used to provide data information to the user and the LED's are used to provide status information to the user.

2.1.5. PUMP_SENSORS

The pump consists of the peristaltic pumping mechanism and associated sensors, which include:
- air in line sensors, beginning and end,
- occlusion strain gages on the input and outlet of the tube in the pump,
- peristaltic cam drive sensor, four per motor revolution and
- pump door sensor.

2.1.6. PUMP_MOTOR

The motor which drives the peristaltic pumping mechanism. Attached to the motor is a magnetic encoder which has fourteen counts per motor revolution. A NN:1 gear connects the motor shaft to the pumping mechanism.

2.1.7. POWER_SUPPLIES

There are four power sources:
- 3 volt battery,
- external power source (3 volt),
- auxiliary battery and
- lithium battery.

There are two power supplies:
- the 7.5 volt motor drive supply and
- the 5.0 volt Vcc electronics supply.

2.1.8. REAL_TIME_CLOCK

The real time clock provides the reference for the date and time of day. The date and time is read from the RTC on demand. The RTC may be reset to a preprogrammed value.

2.1.9. SERIAL_COMMUNICATIONS

Asynchronous serial port, 9600 bps, full duplex, no RTS or CTS, RXD and TXD only.

2.1.10. WATCHDOG

The watchdog is an independent re-triggered one shot which is attached to the micro controller NMI input and motor inhibit control input. The watchdog must be petted at least once per 1.6 seconds. The watchdog also provides a test capability, which can be activated to cause the watchdog to time out but not reset the micro controller one time after power up.

2.2. PROCESS DEFINITION

This section describes the process flows and control flow for the ambulatory pump software. The process flow is described first, followed by the associated control flow. A description of the inputs and outputs for each process and flow is provided in the next section, data definition. All inputs required for the control flow diagram are transferred to the control flow via the associated process flow. The process diagram shows where control and data items are generated, and where the data items are used. The use of the control events are shown in the control flow diagrams. The control flow diagrams show the states and the control events which cause switching to the particular state.

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

2.2.1. Control_And_Monitor_Pump

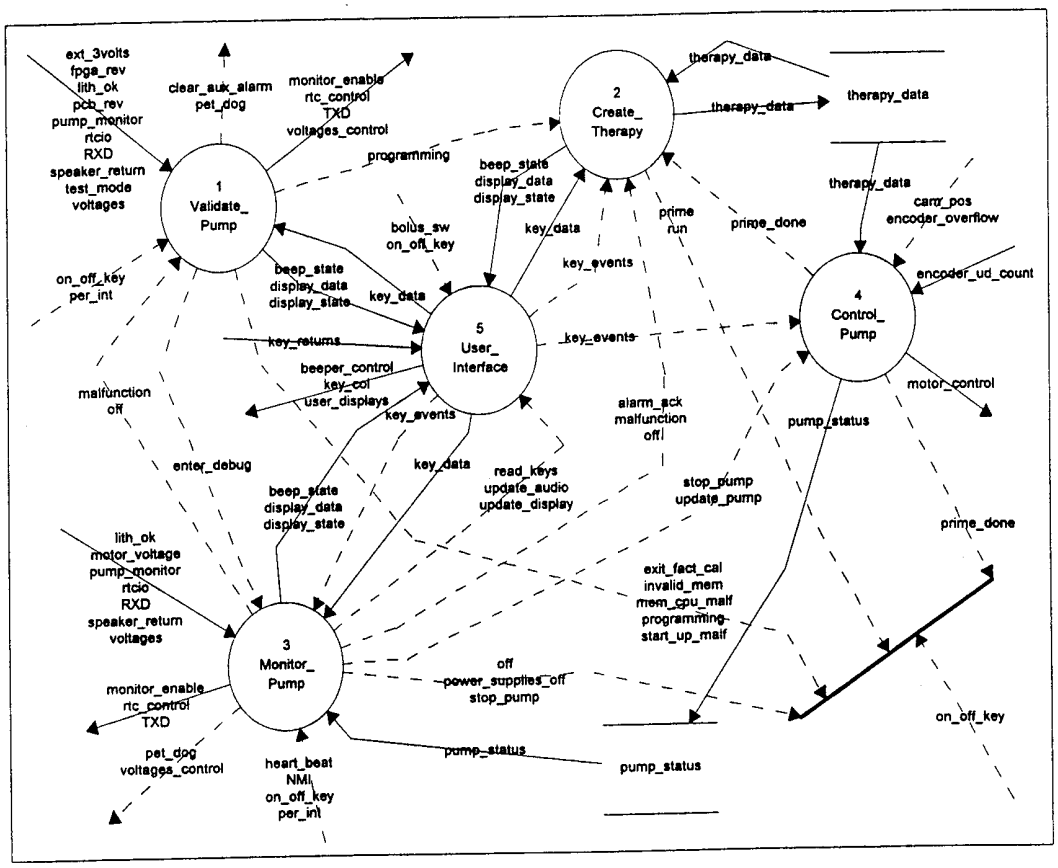


Figure 2 Flow Diagram Control_And_Monitor_Pump

The ambulatory infusion pump controls the infusion process and monitors the process to prevent over infusion. It provides for the user selection and programming of five different therapies:

Continuous,
TPN Automatic Ramping,
Intermittent Delivery,
Variable Program Delivery and
Patient Controlled Analgesia (PCA).

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	**DATE:** 4/24/98	**REV** A

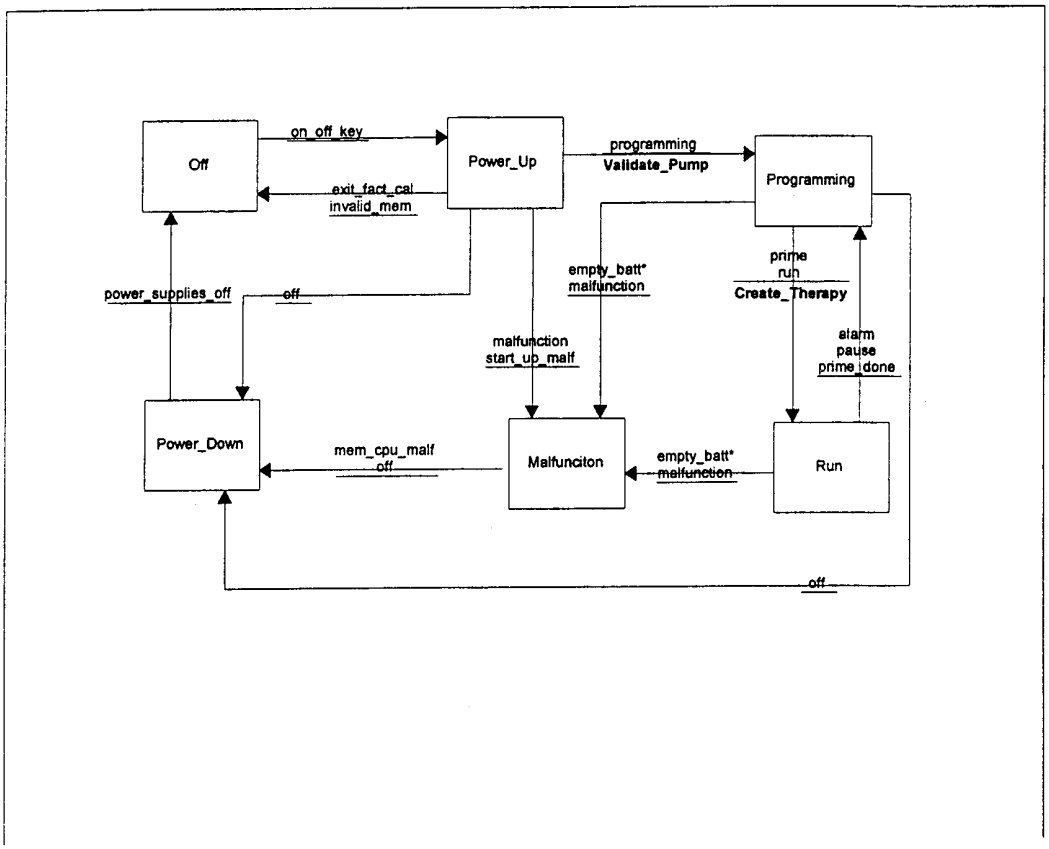


Figure 3 Control Specification Control_And_Monitor_Pump

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

2.2.1.1. Validate_Pump

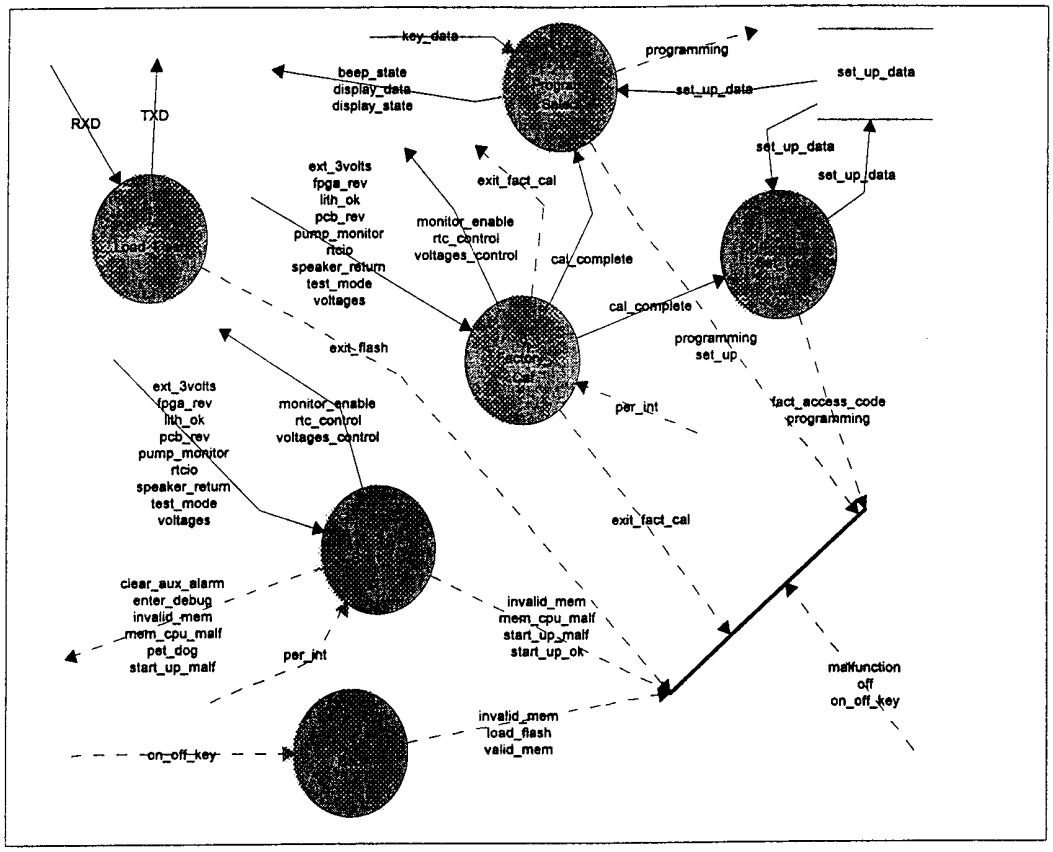


Figure 4 Flow Diagram Validate_Pump

The Validate_Pump process initiates the software operation. It performs the functions defined below.

- Boot will initialize the hardware and software, verify good boot code, download flash ROM code if commanded and verify good Start_Up code. Boot will transfer to Start_Up only if good boot and Start_Up code is verified.
- Start_Up will verify that the pump is functioning properly;
- Program_Select allows selection of performing special set up functions or transferring to normal pump operation.
- Set_Up will permit the user to perform certain utility functions and perform certain pumping settings, one of which is to select to perform factory calibration. Set_Up will transfer directly to normal pump operation, when complete.

- Factory_Cal allows automated testing of the pump at the factory level. Entry to factory cal will require a special access code. Factory cal will not transfer to normal pump operation, but rather will turn the pump off.

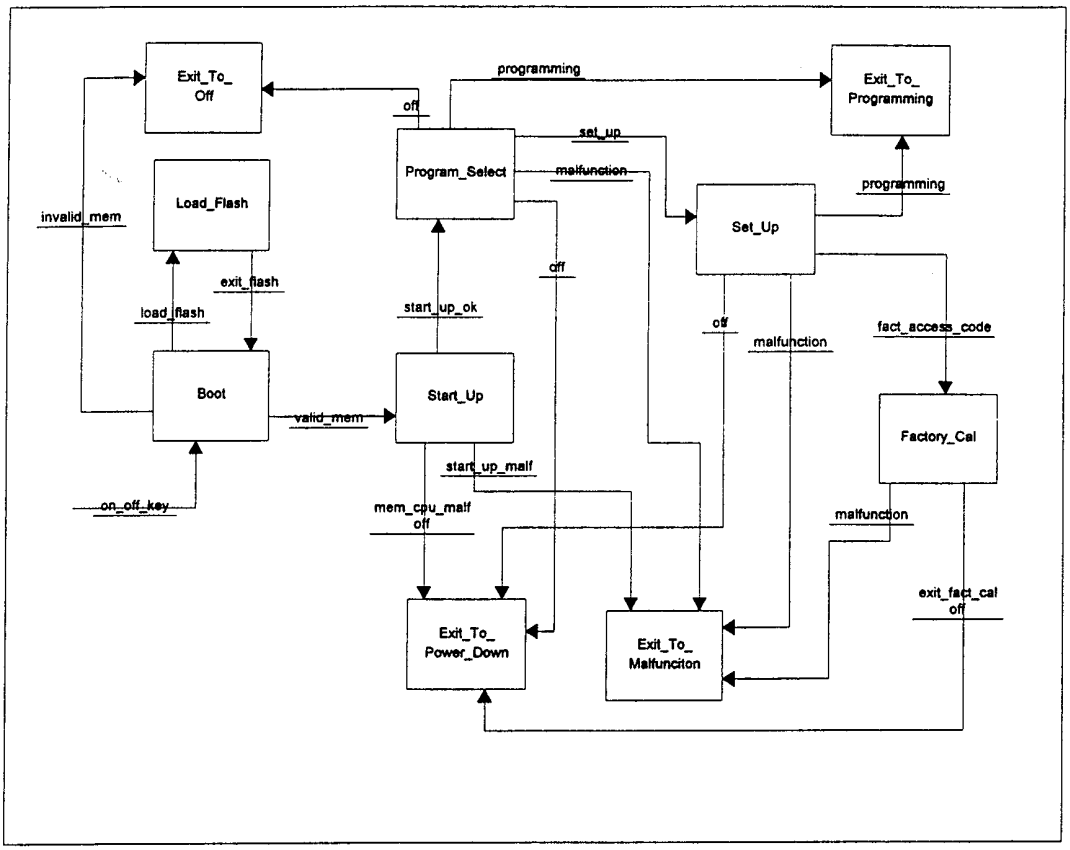


Figure 5 Control Specification Validate_Pump

2.2.1.1.1. Boot

Boot is entered from power up reset and initializes the cpu and I/O to the proper configuration. Boot will perform a test on the boot code and the start up code to verify that these sections are valid. It will also accept a special command to download code to the flash ROM. Boot will verify that a valid program is down loaded into the flash ROM before operation is permitted to proceed from boot. Boot will first verify via a CRC algorithm, that the boot code is good.

2.2.1.1.2. Load_Flash

Load_Flash allows code to be down loaded to the flash ROM. Load_Flash may only be entered from and exit to Boot. Load_Flash shall contain it's own serial interface code for downloading the flash ROM code. This code shall be always be pre-programmed into the flash ROM.

2.2.1.1.3. Start_Up

Start_Up will verify that the pump, both hardware and software, is functioning properly by performing the required start tests on the CPU, memory, pump monitor sensors, motor control, and all aspects of the pump hardware. If the tests pass, control will transfer to Program_Select, otherwise it will transfer to Malfunction.

2.2.1.1.4. Program_Select

Program_Select shall provide a means to the user for selecting normal pump operation (transfer to programming) or allow the user to perform special set up functions. Access to set up requires a special access code by the user. set up will transfer directly to normal pump operation.

2.2.1.1.5. Set_Up

Set_Up allows the user to perform special set up functions, including printing the history files and other pertinent data. Access to set up requires a special access code by the user. Set up will transfer directly to normal pump operation.

2.2.1.1.6. Factory_Cal

Factory_Cal provides for calibration of the pump. These functions are accessed only by a special access code and will be manually commanded. At a future time, this function will provide for remote operation of calibration as well as remote control of normal pump operation to enhance factory calibration and testing. A semaphore shall be set after a valid factory calibration has been performed. Pump operation shall be inhibited if this semaphore has not been set. Factory_Cal will exit to Set_Up.

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

2.2.1.2. Create_Therapy

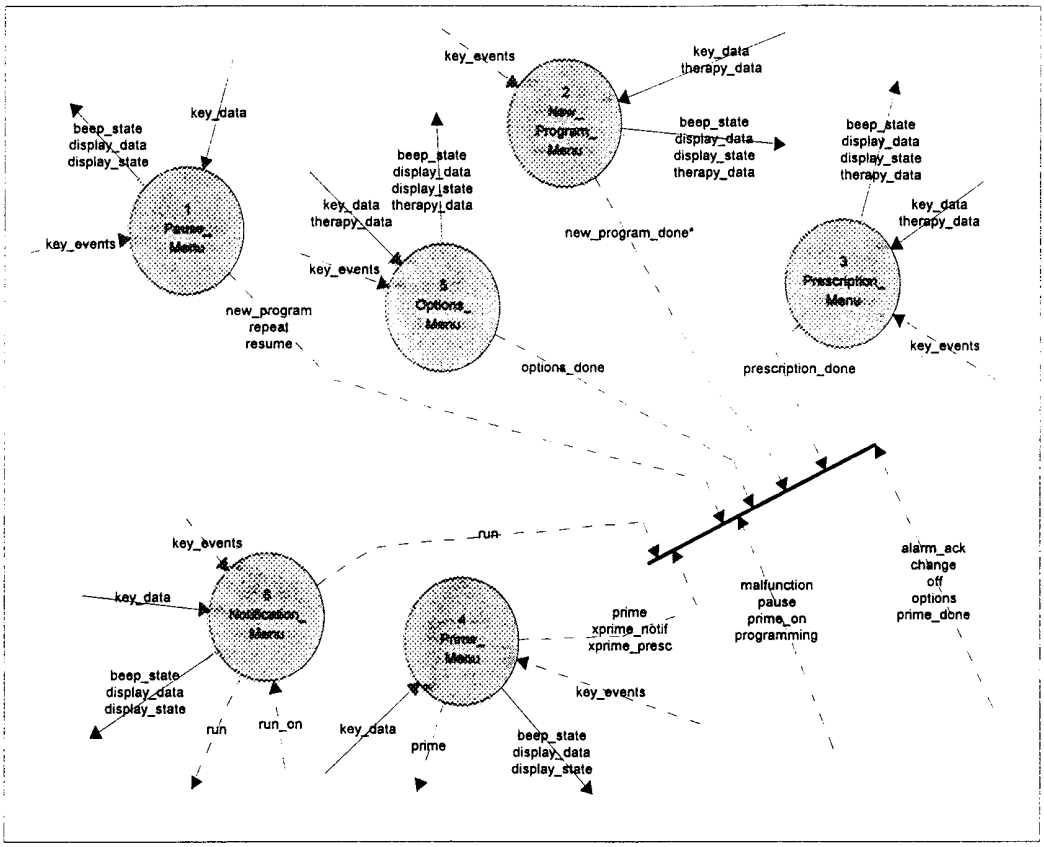


Figure 6 Flow Diagram Create_Therapy

The Create_Therapy process will accept inputs from the user for programming up to five different infusion therapies. Programming includes

- the selection of the therapy to be programmed,
- programming of the pump and therapy options and
- programming the prescription for the infusion.

A therapy may be programmed as

- a new therapy,
- a repeat of an existing therapy,
- changes in an existing therapy or
- continue with a therapy in process, which was interrupted.

After a therapy has been validated by requiring the user to select each prescription parameter with a yes key push, execution will transfer to the Notification_Menu, to allow starting the infusion.

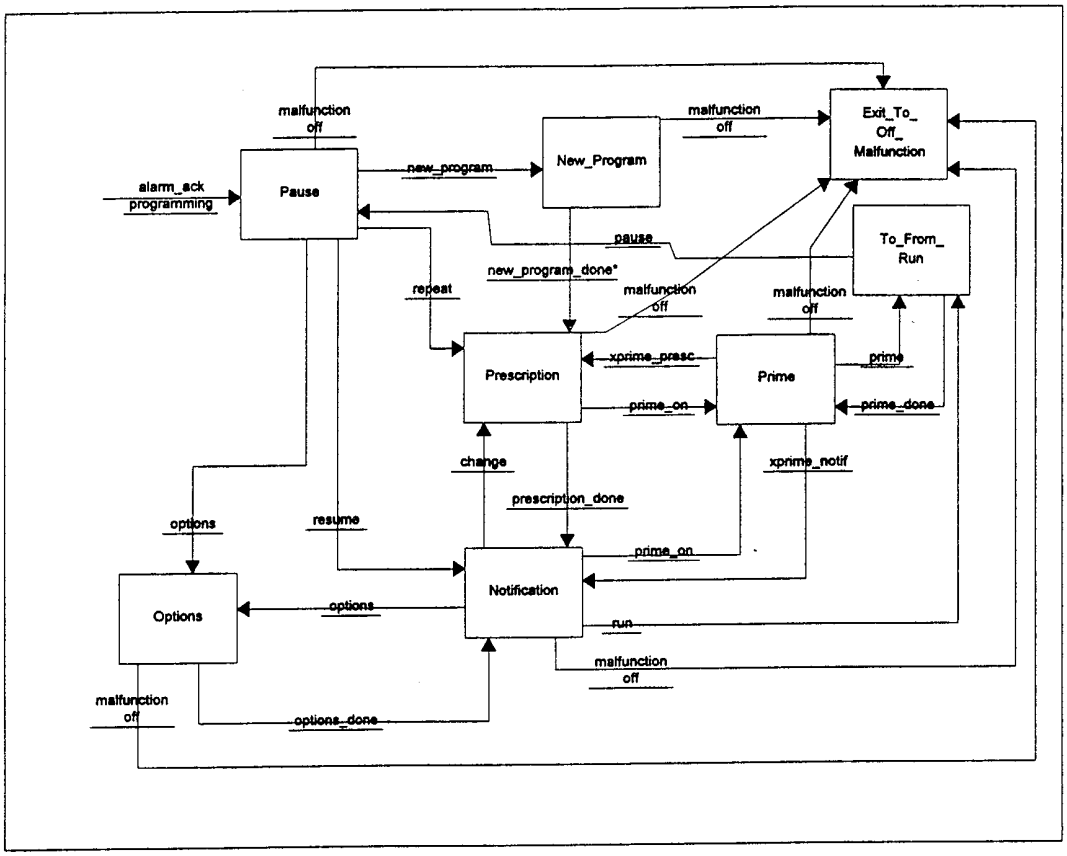


Figure 7 Control Specification Create_Therapy

2.2.1.2.1. Pause_Menu

The Pause_Menu is the entry state for the Create_Therapy state. From pause, the user may select to create a new therapy, repeat or modify an existing therapy or resume an existing therapy which was in progress.

2.2.1.2.2. New_Program_Menu

The New_Program_Menu provides all the interface to the user for programming the initial therapy options. When complete, control will be passed to the Prescription_Menu.

2.2.1.2.3. Prescription_Menu

The Prescription_Menu provides all the interface to the user for programming the therapy prescription. When complete, control will be passed to the Notification_Menu.

2.2.1.2.4. Prime_Menu

The Prime_Menu provides the user with the capability to prime the pump. Pressing the prime key in this mode will transfer control to the run state. Exit from the prime menu will be back to the state from which it came, Prescription_Menu or Notification_Menu.

2.2.1.2.5. Options_Menu

The Options_Menu provides the user with the capability to modify the therapy options.

2.2.1.2.6. Notification_Menu

The Notification_Menu is the gate keeper for the Run state, which satisfies the requirement that at least two key presses are required to start the pump. The Notification_Menu is always entered prior to activating the pump. From the Notification_Menu, the user can go back and change the prescription or the options or prime the pump, in addition to entering the Run state.

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

2.2.1.3. Monitor_Pump

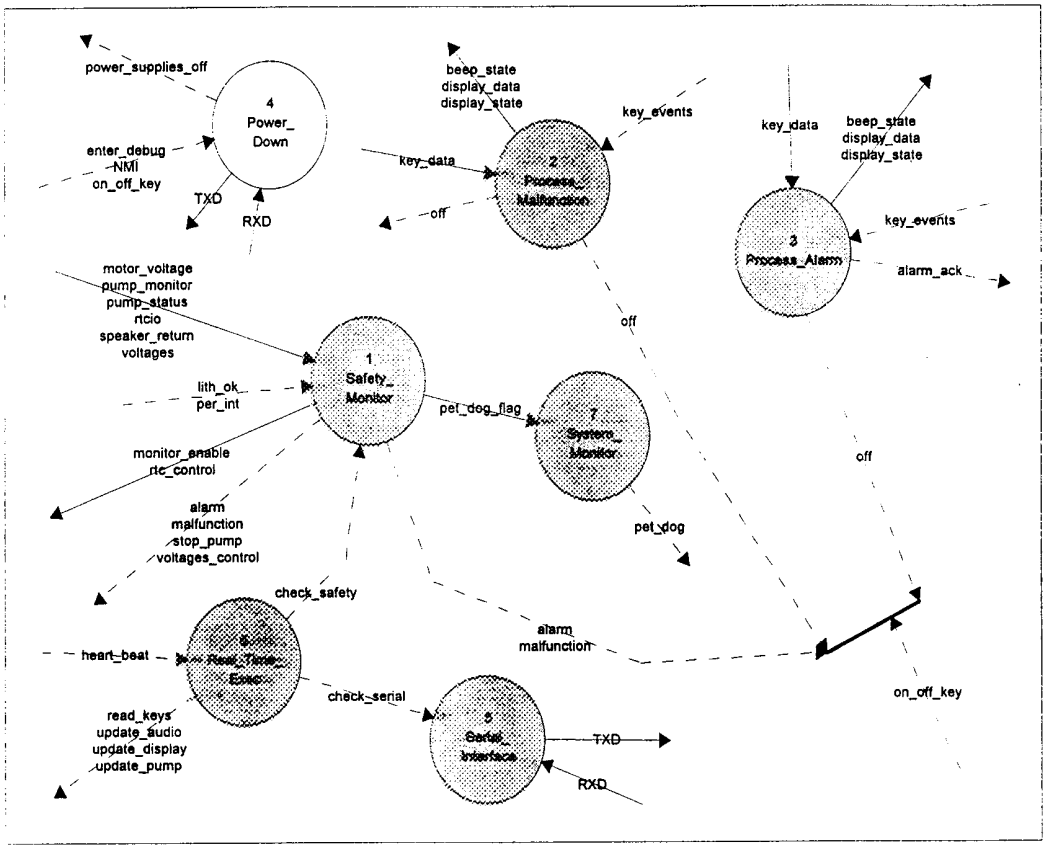


Figure 8 Flow Diagram Monitor_Pump

Monitor_Pump performs all activities of monitoring the status of the pump. This process includes the real time executive, safety monitor, arm processing, malfunction processing, system monitor and serial interface.

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

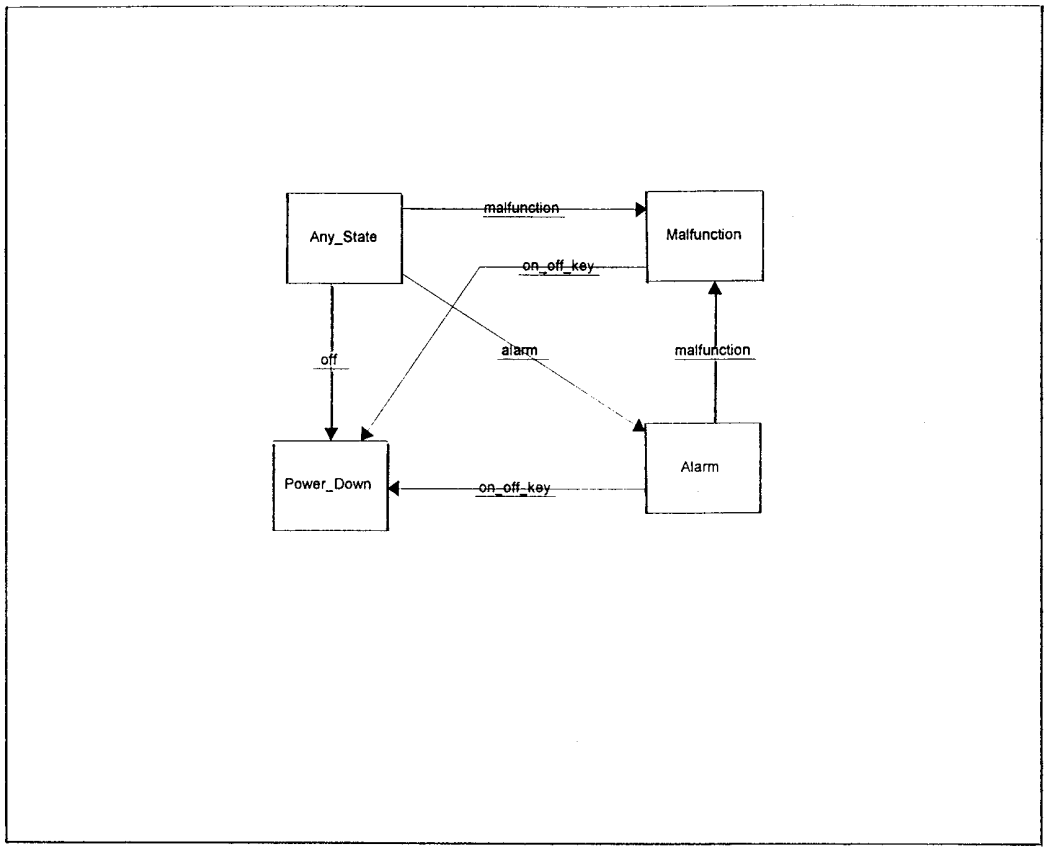


Figure 9 Control Specification Monitor_Pump

2.2.1.3.1. Safety_Monitor

The Independent Safety Monitor task will run once every one second under control of the real time executive. It will monitor all of the pump functions while the pump is running.

```
if(pump not running) return;

// check for air in line
enable the air in line sensors;
read the air in line sensors;
disable the air in line sensors;
if(air in line out of tolerance)
{
        set air in line alarm;
```



```
        exit to error display state;
    }

    // check for occlusion
    enable strain beams;
    read strain beams for occlusion;
    disable strain beams;
    if(occlusion)
    {
        set occlusion alarm;
        exit to error display state;
    }

    // check for door open
    enable door sensor;
    read door sensor;
    disable door sensor;
    if(door open)
    {
        set door open alarm;
        exit to error display state;
    }

    // check for over infusion
    if(motor_position > commanded_position)
    {
        set over infusion alarm;
        exit to error display state;
    }

    // check RAM read/write
    address RAM byte to test;
    copy byte to x reg;
    write 6 to byte;
    verify write;
    write A to bytes;
    verify byte;
    write x reg to memory;
    advance byte pointer;
    if(test fail)
    {
        set RAM alarm;
```



```
        exit to error display state;
}

// check RAM CRC
address RAM byte to test;
add byte to CRC;
advance pointer;
if(end of CRC)
{
        if(CRC failure)
        {
                set ROM CRC  alarm;
                exit to error display state;
        }
        CRC = 0;
        reset pointer;
}

// check ROM CRC
address ROM byte to test;
add byte to CRC;
advance pointer;
if(end of CRC)
{
        if(CRC failure)
        {
                set ROM CRC alarm;
                exit to error display state;
        }
        CRC = 0;
        reset pointer;
}

// check rtc and system clock against each other.
if(|current_time - previous_time| > MAX_TIME_VARIATION)
{
        if(checksum failure)
        {
                set clock alarm;
                exit to error display state;
        }
}
```

2.2.1.3.2. Process_Malfunction

Process_Malfunction displays a visual and audio message for the malfunction that has occurred and saves the malfunction reference to the history file. The first order of business is to make sure the pump has stopped. If not, the pump is turned off.

2.2.1.3.3. Process_Alarm

Process_Alarm displays a visual and audio message for the alarm that has occurred and saves the alarm reference to the history file. The first order of business is to make sure the pump has stopped. If not, the pump is turned off.

2.2.1.3.4. Power_Down

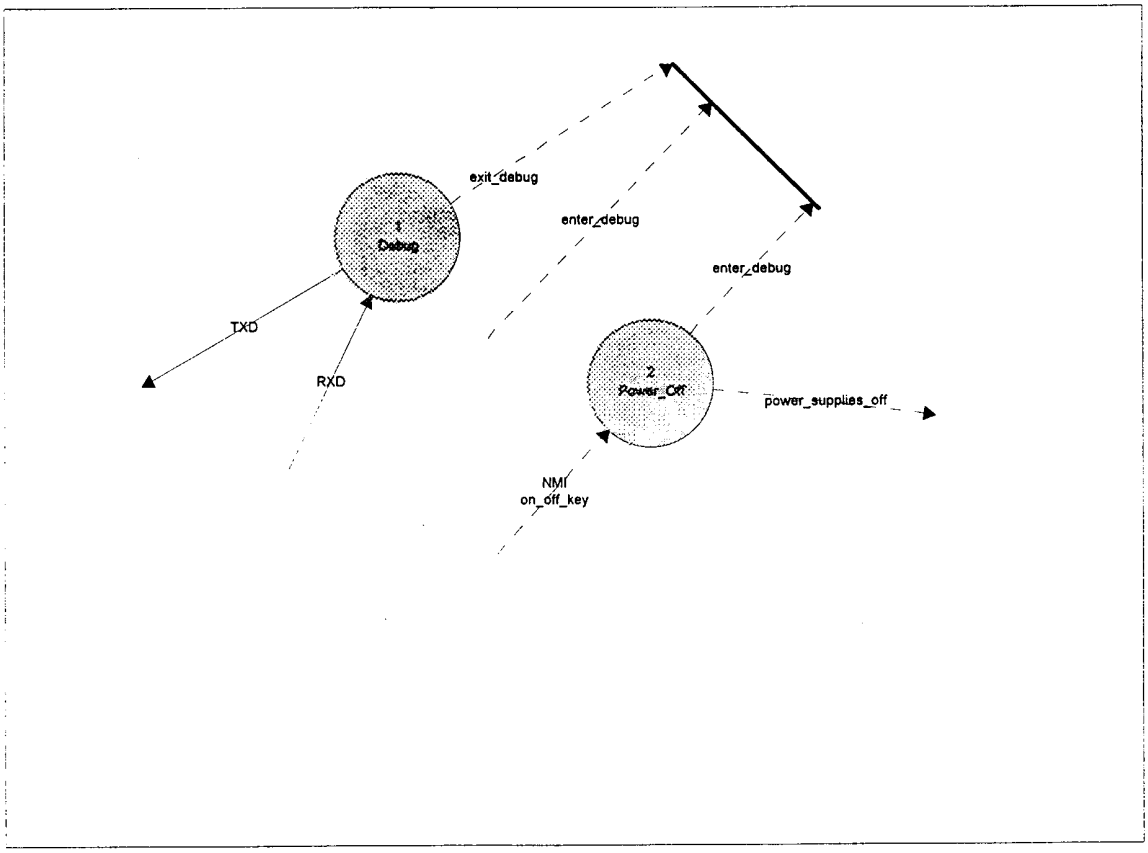


Figure 10 Flow Diagram Power_Down

Power_Down controls turning off the pump.

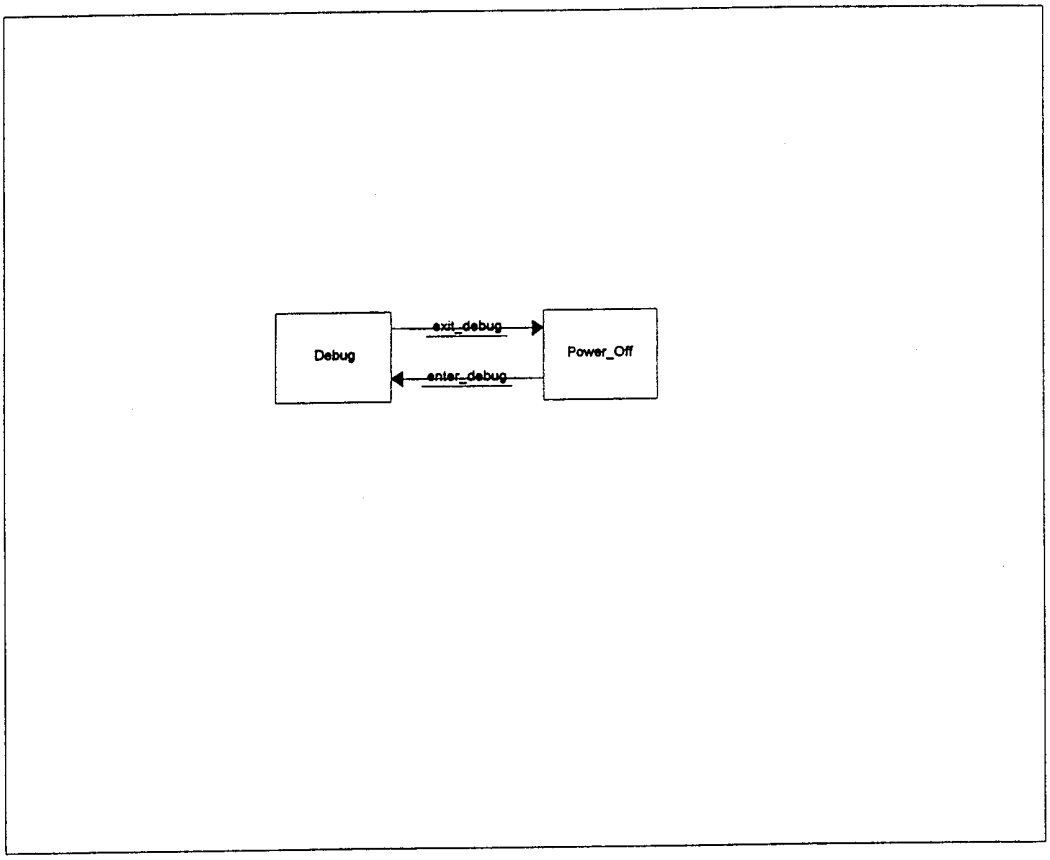


Figure 11 Control Specification Power_Down

2.2.1.3.4.1. Debug

Debug is the resident software monitor code that allows the developer or tester to view the contents of memory and the processor registers for diagnostic purposes. Debug is accessible via a special command from boot or from power down following a malfunction.

2.2.1.3.4.2. Power_Off

Power_Off decides if the pump should be turned off now or go to an endless loop and wait for the user to press the on_off_key.

2.2.1.3.5. Serial_Interface

This task will transmit data from the transmit buffer and receive data from the serial input line.

```
// tranmsmit byte from the transmit_buffer
if((xmt_out_ptr != xmt_in_ptr) && UART xmit buffer empty)
{
        UART xmit buffer = transmit_buffer(xmt_out_ptr);
        advance xmt_out_ptr;
}

// put received UART byte into the receive_buffer
if(UART recv buffer full flag)
{
        if(receive_buffer full)
        {
                load transmit buffer with receive_buffer full error code;
                set receive_buffer full error state;
        }
        receive_buffer(recv_in_ptr) = UART recv buffer;
        advance recv_in_ptr;
}
```

2.2.1.3.6. Real_Time_Exec

heart_beat
read_keys
update_audio
update_pump
count_time
check_safety
check_serial
update_display

The RTExec schedules each of the background tasks to run each time the heart_beat
occurs.

decrement the counter for each of the tasks;

for(all counters)

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

```
{
        if(counter == 0)
        {
                set task run flag;
                reload counter with schedule time interval;
        }
}
```

run each of the tasks that run each time the RTExec runs;

run the first task in priority that has it's task run flag set and reset the task run flag;

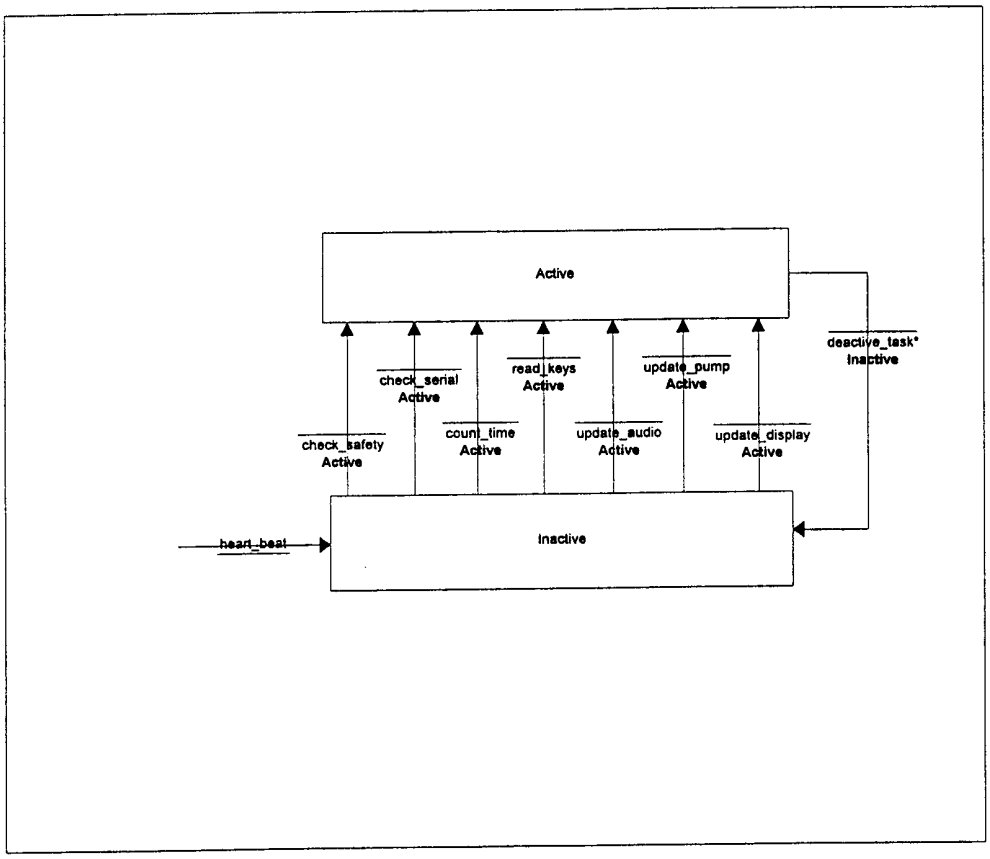


Figure 12 Control Specification Real_Time_Exec

2.2.1.3.7. System_Monitor

The System_Monitor monitors the pet_dog_flag and when set, will pet the watch dog and reset the flag.

2.2.1.4. Control_Pump

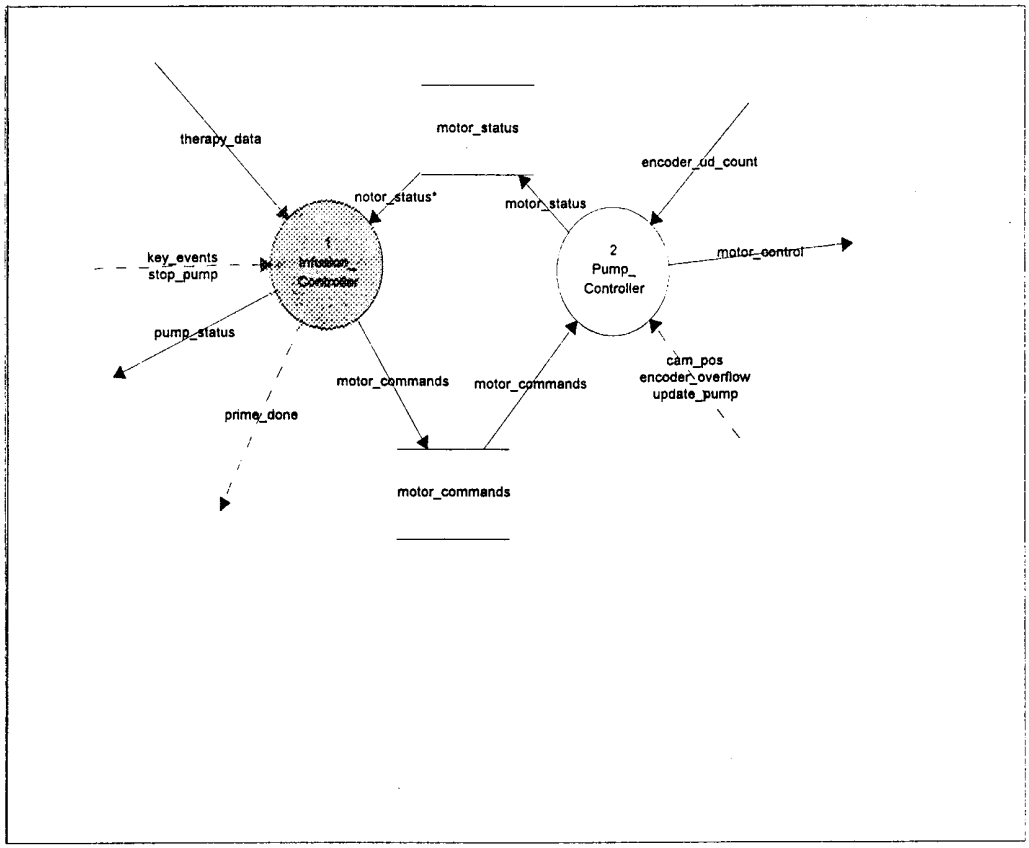


Figure 13 Flow Diagram Control_Pump

Control pump accepts a valid therapy from the therapy data source, and controls the speed and timing of the motor to deliver the prescribed infusion dose and rate. The entire control of the prescription is handled by control pump.

2.2.1.4.1. Infusion_Controller

The Infusion_Controller, when run is activated, will process the therapy data per the therapy commanded by the Create_Therapy state. The Infusion_Controller provide motor rate in counts per second and volume to be infused in total

encoder counts to the Pump_Controller, which controls the speed of the pump. The infusion controller will update these variables as the dose and rate change per the prescription. The status will be read from the pump controller and the run display will be updated at a one second rate with the accumulated parameters and any changes in commanded rate and VTBI. If a stop pump command is received, the pump will be turned off, including the motor voltage which will also be disabled.

2.2.1.4.2. Pump_Controller

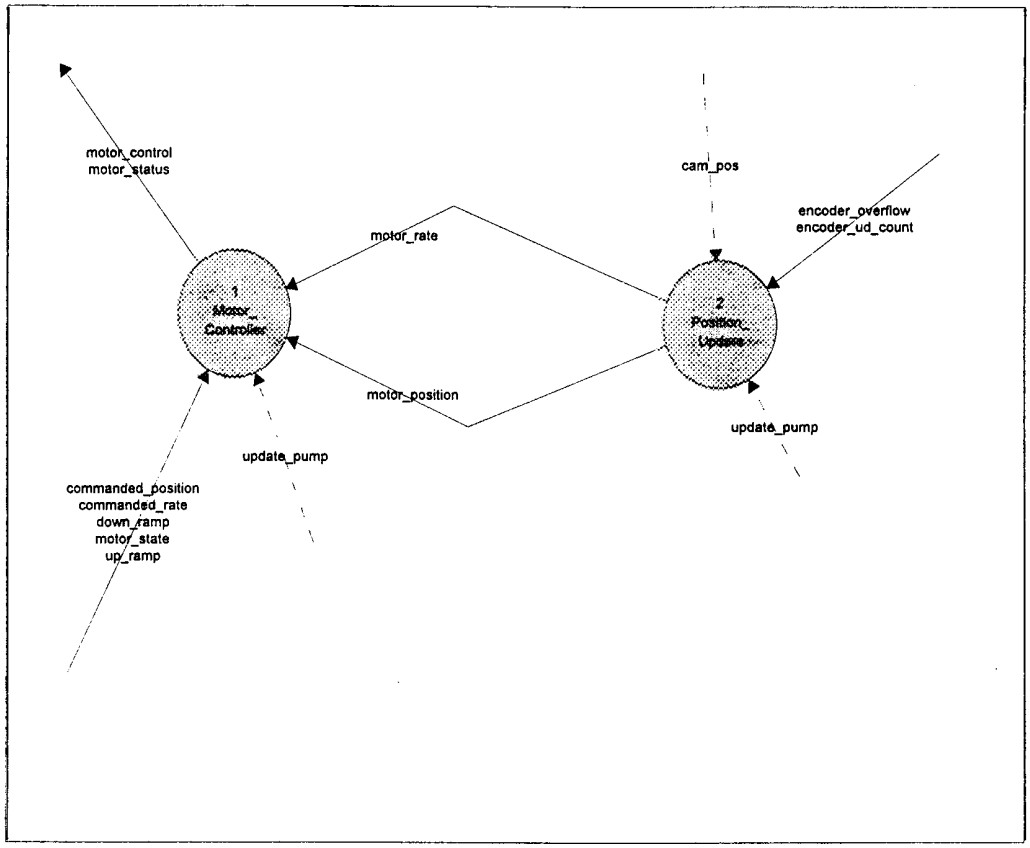


Figure 14 Flow Diagram Pump_Controller

2.2.1.4.2.1. Motor_Controller

```
void MotorController()
{
        DT = sample period;
```



```
        local static variable long   mrate; // current commanded motor rate
        local static variable long   theta; // current encoder up/down counter value
        local static variable long   thetap; // past encoder up/down counter value
        local static variable long   dtheta; // change in encoder up/down counter
        local static variable long   desired_position; // this must be initialized to
zero
        temp long                    error_position;
        temp long                    error_rate;

        theta = ReadEncoder(); // read encoder up/down counter
        dtheta = theta - thetap; // calculate change in position
        thetap = theta; // store past value of theta
        desired_position += DT*mrate; // calculate desired position
        error_position = desired_position - theta;
        error_rate = mrate - dtheta

        switch(motor_mode) // check mode
        {
        case(STOP) //stop the motor
                pwm = 0;
                disable_motor;
                break;

        case(LOW) //infusion at low rate, but not KVO
        case(HIGH) // infusion at high rate
                if(((motor_rate > MAX_LOW_RATE || motor_rate <
MIN_LOW_RATE)
                        && case == LOW) || ((motor_rate > MAX_HIGH_RATE ||
                        motor_rate < MIN_HIGH_RATE)  && case == HIGH))
                {
                        report motor_rate out of range; // commanded rate too high
or low
                        pwm = 0;
                        disable_motor;
                        ChangeState(DisplayError);
                }
                else
                {
                        if(motor_rate - mrate < min_delta_rate)
                        {
                                mrate -= DT*down_ramp; // DT = sample interval
                                pwm = convert mrate to pwm;
```



```
                    }
                    elseif(motor_rate - mrate > min_delta_rate)
                    {
                        mrate += DT*up_ramp;
                        pwm = convert mrate to pwm;
                    }
                    else
                    {
                        mrate = motor_rate;
                        rate_error = motor_rate - actual_rate;
                        pwm = RateCompensation(rate_error);
                    }
                }
                break;

        case(KVO) // KVO rate commanded
                if(motor_rate > MAX_KVO_RATE || motor_rate < MIN_KVO_RATE)
                {
                    report motor_rate out of range; // commanded rate too high
or low
                    pwm = 0;
                    disable_motor;
                    ChangeState(DisplayError);
                }
                else
                {
                    pwm = CalculateKVO(); // calculate the new KVO rate
                }
                break;
        }
}
```

2.2.1.4.2.2. Position_Update

motor_position is a long integer.

The lower integer, lower_motor_position, is a copy of the encoder_ud_count. The upper integer is incremented whenever the encoder_overflow occurs.

Every time the MotorControl task is called, the lower motor_position is updated with the encoder_ud_count, and if encoder_overflow has occurred, the upper_motor_position is incremented by 1.


```
if(encoder_overflow)
{
        reset encoder_overflow;
        upper_motor_position++;
        if(!upper_motor_position) notify error;
}
past_motor_position = lower_motor_position;
lower_motor_position = encoder_ud_count;
motor_rate = lower_motor_position - past_motor_position;
```

The interrupts will remain disabled during these readings, so that partial motor positions are not read by other tasks.

2.2.1.5. User_Interface

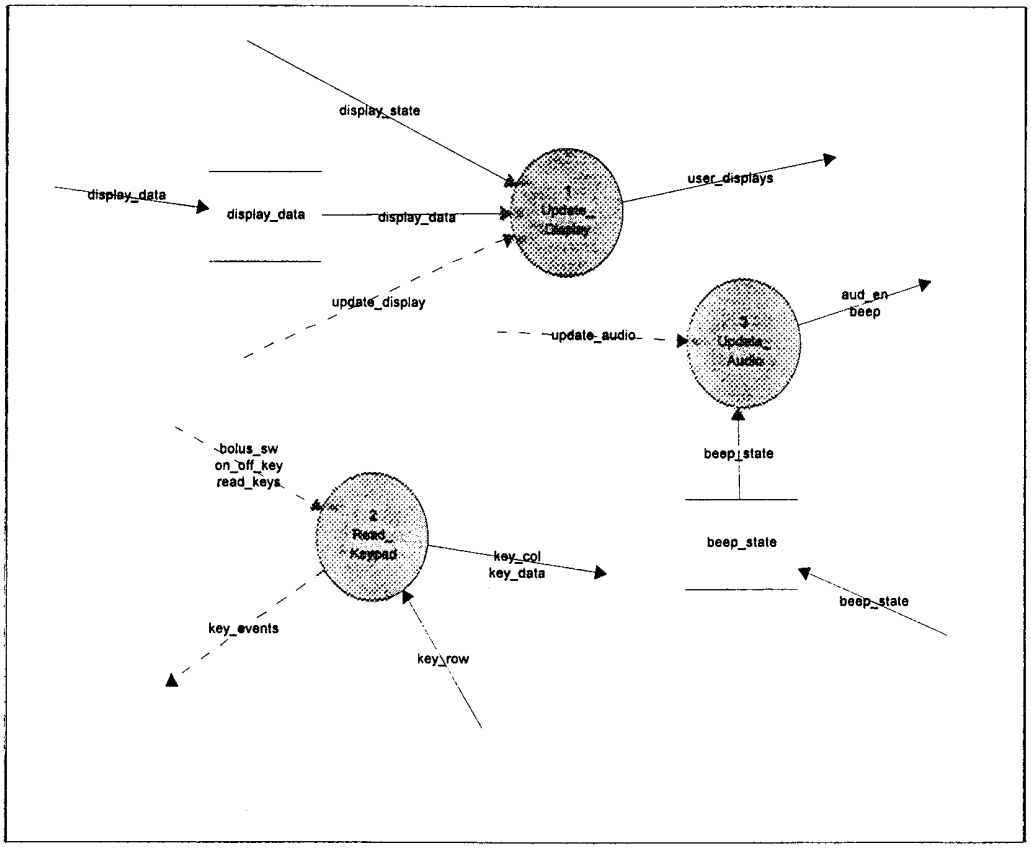


Figure 15 Flow Diagram User_Interface

The User_Interface provides information to the user via the display and receives information from the user via the keypad. This information exchange allows creating or changing therapy data files.

2.2.1.5.1. Update_Display

This task will update the LCD and LED's and flash the LCD and/or the LEDs.

The LCD is updated based on the following:

1) Valid keypad data entry for state.
2) State of the pump changes.
3) State of the pump is Run, requiring continuous update.
4) Alarm or Malfunction occurs.

Updates not associated with a key entry still use functions indicated in the ProcessKey (key) function below.

```
if (keypad entry)
        ProcessKey (key);

ProcessKey(int key)
{
        /*Keep pointer to the current mode data and screen info*/

        SCROLL_MENU *s = currentMenu;       /*current state menu*/
        FIELD *f  = &s ->field  [s->cur_pos];       /*current field from mode table
array*/

        /*Check for current machine state */

        if (state == Current machine state){

        /*Find the valid case for the key entry*/
        switch (key){

                case RUN_PAUSE:

                        if (at Notification Menu)
                                state = RUN; /*going to start pump*/

                                get run data(for therapy FIELD);
```



```
                    display and update data(for therapyRun
currentMenu);

                if (at Run screen)
                    state = PAUSED;    /*Halt the pump*/

                    get pause data (for paused FIELD);
                    display data (for paused currentMenu);

            case UP:

                if (at any non_running state){
                    check to see if at head of list (for currentMenu FIELD
list);
                    if (not at head of list){
                        check to see if at top line (for currentMenu);
                        if (at top line){
                            shift (currentMenu down);
                            move cursor to (currentMenu FIELD -1);
                        else
                            move cursor to (currentMenu FIELD -1);

                }

                if (at running state)
                    do nothing;

            case DN:
                if (at any non_running state){
                    check to see if at end of list (for currentMenu FIELD
list);
                    if (not at end of list)
                        check to see if at bottom line (for currentMenu);
                        if (at bottom line){
                            shift (currentMenu up);
                            move cursor to (currentMenu FIELD +1);
                        else
                            move cursor to (currentMenu FIELD +1);
                }

                if (at running state)
                    do nothing;
```



```
                case YES/ENTER:

                        if (at running state)
                                do nothing;
                        else{
                        highlight (currentMenu FIELD);
                        if (edit field){

                                check valid range (for FIELD);

                                if (valid and not an action screen){

                                        /*automatically calculate other dependent
    field(s)*/
                                        update (dependent FIELDs data);
                                        if not at end of list(for stateFIELD array){
                                                move cursor to (currentMenu FIELD +1);
                                                highlight (currentMenu FIELD);
                                        }
                                        else
                                                state=nextState;
                                else
                                        state=nextState;


                case NO/CHANGE:
                        if (at running state)
                                do nothing;

                        if (edit field){
                                flash (currentMenu FIELD);

                        if (end of list){
                                check to see if Selection type FIELD ();
                                        if (yes)
                                                move to and display next item
                                                        in list(current Menu FIELD);
                                                if (at last item in list)
                                                        go back to first item in list;

                                check to see if all FIELDs for currentMenu have
```



```
                                    been acknowledged if required ();
                                    if (not)
                                        goto FIELD and highlight ();
                                    if (yes)
                                        state = nextState;
                                check to see if NO means to revert back to previous
                                    values ();
                                    if (yes)
                                        current value = previous values;
                                        go to head of list and display
(currentMenu);
                    }

            /*for numeric and period entries see below*/
            case ZERO:
            case ONE:
            case TWO:
            case THREE:
            case FOUR:
            case FIVE:
            case SIX:
            case SEVEN:
            case EIGHT:
            case NINE:
            case PERIOD:
            /*----------------------------------------
                if (at running state)
                    do nothing;

                if (edit field){
                    handlenumerics (for FIELD);
                    display entry (currentMenu FIELD);


            case PRIME_BOLUS:

                if (state == PROGRAMMING || NOTIFICATION){
                    currentMenu=primeInstruction menu;
                    state = PrimeRun;
                }

                if (state == PrimeRun){
```



```
                        currentMenu = priming menu;
                        while (PRIME_BOLUS key)        /*key held */
                              flash marque text;
                    }

                    if (state == PCARun)
                        flash Bolus text until completion of bolus;


              case HELP/OPTIONS:

                    if (non_running state){
                        /*display menu to select help or options*/
                        currentMenu = help_option screen;

                    if (running state){
                        currentMenu = mode_options screen;


      case ON_OFF:

                    if (non_running state)
                        turn LCD backlight off;
                    else
                        do nothing;
      default:
        break;
```

/*----------*/

Each pump state and therapy has an associated FIELD array which allows parameters to be programmed and stored. Each field consists of the following struct:

```
/*Data Field Types*/

typedef struct
{
  char *str;                  /* Identifier string for this field */
  const char *graphic;          /* Graphic bit map for the field label */
  const char **list;           /* Choice list for each item */
  int     (*infptr)(void);     /* Function for entry to this field */
```



```
    int     (*outfptr)(void);     /* Function for exit from this field */
    const char *help;             /* pointer to help message */
    int     type;                 /* Data type (FLOAT, INT) */
    float   data;                 /* Data */
    float   min;                  /* Minimum Value   */
    float   max;                  /* Maximum Value   */
    const char *G_units;          /* Graphic for units */
    int     width;                /* Width parameter for printf() routine */
    int     precision;            /* Precision parameter for printf() routine */
    char    state;                /* Accepted or NOT Accepted */
}FIELD;
```

The following struct allows the manipulation the fields on the LCD as required in the above section:

```
typedef struct
{
  char    *name;                  /* Name for this menu */
  FIELD   *field;                 /* Field array pointer */
  char    *marque;                /* marquee for first line of display */
  int     num_fields;             /* number of fields in this menu */
  int     head;                   /* Display start point */
  int     cur_pos;                /* Cursor position */
} SCROLL_MENU;
```

Each state of the pump has an associated screen. The screen is bitmapped 100 columns x 32 rows. The following print to LCD functions will write to the LCD:

1) Graphic bitmap:

```
putGRFBLK (xpixel_loc, y_pixel_loc, video_presentation,
G_name);
```

2) bitmap font (6x8 multiple space location):

```
xyprintf(x_char_loc, y_char_loc, video_presentation, "name");
```

3) bitmap font (6x8 location based on pixels):

```
xygprintf (xpixel_loc, ypixel_loc, video_presentation, " name");
```



```
/*-------------------------------------------------------------------------------*/

if (!flash_display_timer)
{
        flash_display_timer = FLASH_TIME;
        if (flash_LCD)
        {
                if (flash_toggle)
                {
                        flash_toggle = 0;
                        turn LCD off;
                }
                else
                {
                        flash_toggle = 1;
                        turn LCD on;
                }
        }
        else LCD on;
        if (set_alarm)
                if (flash_alarm)
                {
                        if (flash_toggle) turn alarm_LED on;
                        {
                                flash_toggle = 0;
                                turn alarm LED off;
                        }
                        else
                        {
                                flash_toggle = 1;
                                alarm_LED = on;
                        }
                }
                else alarm_LED = on;
        }
        if (set_running)
        {
                if (flash_running)
                {
                        if (flash_toggle) running_LED on;
```



```
                    {
                        flash_toggle = 0;
                        running_LED = off;
                    }
                    else running_LED off;
                    {
                        flash_toggle = 1;
                        running_LED = on;
                    }
                }

        if (flash_standby)
            if (flash_toggle) standby_LED on;
            {
                flash_toggle = 0;
                LCD off;
            }
            else standby_LED off;
            {
                flash_toggle = 1;
                LCD on;
            }
        }
}
```

2.2.1.5.2. Read_Keypad

This task will read all keys and buttons and output an event in case there is a change in the key/button state.

```
for(key_col = 1; key_col < 4; key_col++)  // scan all of the keypad matrix
{
    row_value = ReadRows();  // read the 5 rows
    SetKeyActive(row_value);  // set the key flag for any key pressed
}
if(!bolus_sw) set bolus key flag;  // set the flags for the independent buttons
if(!on_off_sw) set on_off key flag;

if(key_flags)
{
    if(more than one key pressed)
    {
```



```
                issue multiple key press alarm;  // only one key may be pressed
        }
        else if(active_key_flags != key_flags)
        {
                issue key_event;  // tell the SystemMonitor what event to process
                start stuck_key_timer;
        }
        else
        {
                if(stuck_key_timer timed out) issue stuck key alarm;
        }
}
active_key_flags = key_flags;  // update active key flags to current key flags
```

2.2.1.5.3. Update_Audio

This task controls the beep sound.

```
if(beep_state == OFF) aud_en = 0;
else
{
        aud_en = 1;
        ProcessBeep(beep_state);
}
```

2.3. DATA DEFINITIONS

This section contains the description of all inputs and outputs to/from the software modules, both software and hardware, and data and events.

2.3.1. ail_begin

This data input provides air in line measurement from the beginning of the pump.

2.3.2. ail_count

The data input ail_count the accumulated air in line measurement since the last ail_reset.

2.3.3. ail_en

This data output enables the two occlusion strain gages.

2.3.4. ail_end

This data input provides air in line measurement from the end of the pump.

2.3.5. ail_reset

The ail_reset data input resets the ail_count to zero.

2.3.6. ail_test

This data output enables the test of the two strain gages.

2.3.7. alarm

The alarm event is generated by the independent safety monitor whenever an alarm condition is detected.

2.3.8. alarmed_led

This data output turns on the ALARM LED.

2.3.9. alarm_ack

The alarm_ack event is generated whenever the user acknowledges an alarm message.

2.3.10. aud_en

This data output enables the beeper.

2.3.11. aux_volts

The aux_volts is an analog input from the auxiliary battery that supplies voltage to the aux alarm.

2.3.12. backl_on

This data output turns on the backlight.

2.3.13. beep

This data output, when asserted, causes the beeper to sound, and when de-asserted, causes the beeper to be quite.

2.3.14. beeper_control

The beeper_control data input provides the interface to control of the beeper, which include the beep command and the beeper enable command.

2.3.15. beep_state

The beep_state data item describes the type of beep which is to be performed.

2.3.16. bolus_on

The bolus_on event indicates that the bolus key or the bolus switch has been pushed.

2.3.17. bolus_sw

This input event is from the remotely mounted Bolus switch. Normally open switch.

2.3.18. cal_complete

The cal_complete data output indicates, when asserted, that the pump has been calibrated and may perform infusion. If cal_complete has not been asserted, exit from the Validate_Pump state will be prohibited. A message shall be displayed to the user indicating that the pump needs calibration.

2.3.19. cam_pos

This event indicates that one of the four cam position sensors has passed. There are four per revolution of the motor. The line is high when the peristaltic position is for not pumping and low for pumping. An interrupt occurs on the low to high transition.

2.3.20. change

The change event is generated by the user selecting the no to change selection from the notification menu.

2.3.21. check_safety

The check_safety event is the scheduled time for the IndependentSafetyMonitor task to run, which is approximately 1 second or 19 heart beat intervals. This is controlled by the real time executive.

2.3.22. check_serial

The check_serial event is the scheduled time for the SerialInterface task to run, which is approximately 200 msec or 4 heart beat intervals. This is controlled by the real time executive.

2.3.23. clear_aux_alarm

The clear_aux_alarm event causes the auxiliary beeper to turn off during the watch dog test procedure during start up testing.

2.3.24. commanded_position

commanded_ position is an unsigned long integer and represents the total integration of the motor shaft during a single therapy. motor_position is zeroed at the beginning of a therapy.

max value is 2e32 or 4,294,967,296 or 226.7 liters
resolution is 5.2793e-5 ml/count

2.3.25. commanded_rate

commanded_rate is an unsigned integer and represents the speed to which the motor has been commanded to run. It has units of encoder counts per controller update period.

2.3.26. count_time

The count_time event is the scheduled time for the TimeCounters task to run This interval is 53.3 msec. This is controlled by the real time executive.

2.3.27. display_data

display_data is information to the user formatted for the LCD display.

2.3.28. display_flash

display_flash is a semaphore to indicate that certain portions of the LCD display are to turn on or off.

2.3.29. display_state

display_state defines the type of display updates which are to be performed, including none.

2.3.30. display_update

display_update is a semaphore that indicates that the LCD display is to be updated.

2.3.31. door

This data output indicates the status of the pump door. The door is open when this line is asserted.

2.3.32. door_en

The door_en data output enables the door sensor, so that the door sensor can be turned off when the pump is not running.

2.3.33. down_ramp

The down_ramp data item is the time before infusion complete to start ramping the infusion down to zero.

2.3.34. encoder_overflow

This event input from the encoder indicates that the encoder 16 bit up down counter has transitioned from FFFF to 0000.

2.3.35. encoder_ud_count

This data input is a 16 bit number which represents the contents of the encoder up down counter. The number is read by two single byte reads. The upper byte must be read first.

2.3.36. enc_enable

enc_enable enables the motor encoder. Disable removes the power to the encoder for power management.

2.3.37. enter

The enter event is generated whenever the enter key has been pressed.

2.3.38. enter_debug

The enter_debug event is asserted when the proper request for entering debug have been verified.

2.3.39. exit_debug

The exit_debug event is generated whenever the user terminates use of debug.

2.3.40. exit_fact_cal

The exit_fact_cal event is generated by the user to exit the Factory_Cal state.

2.3.41. exit_flash

The exit_flash event is set when the down load to flash ROM is completed.

2.3.42. ext_3volts

ext_3volts is a discrete input that indicates the source of the system power,
a high indicates external power and
a low indicates the local battery is being used.

2.3.43. ext_volts

The ext_volts is an analog input from the external power supply, either a battery eliminator or charger. A battery eliminator will be from 4.0 to 5.5 volts. The battery charger will be from 10.0 to 12.0 volts.

2.3.44. fact_access_code

The fact_access_code event occurs when a valid factory access code has been entered for performing factory calibration.

2.3.45. fpga_rev

The revision number of the FPGA. This revision number is read from the FPGA.

2.3.46. heart_beat

The heart beat event provides the execute command to the real time executive. The real time executive executes on each heart beat, which is beat is 53.3 msec.

2.3.47. input_power

This is the A/D analog input from the power source, either battery voltage or external power.

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	**DATE:** 4/24/98	**REV** A

2.3.48. invalid_mem

The invalid_mem event indicates that Boot has found an error in the memory validation process.

2.3.49. in_oc_strain

This is an analog A/D input from the strain gage on the input side of the tube. The purpose is to measure occlusion.

2.3.50. key_col

These 4 outputs are the column strobes for the 18 key keypad. Selects none or one of four. Only one shall be active at a time.

2.3.51. key_data

key_data contains the numeric (0-9), decimal point, up arrow, down arrow and enter key information from the key pad. The variables can be the ASCII representation of the key symbols. key_data could be a FIFO buffer with separate input and output pointers.

2.3.52. key_events

key_events is key occurrences converted to events for the user interface. Most keys produce more than one event, e.g. the run/pause key produces the run and the pause event. These can be combined into a single event during implementation, but for clarity in this document, they are separated into two events. Prime_on means pushing the prime/options key and prime off means releasing the prime/options key.

2.3.53. key_returns

These data inputs register the key presses of the user. There are five inputs from the five rows of an 18 key keypad. In addition there are two independent key/button inputs, ON/OFF key and a remote bolus button.

2.3.54. key_row

These are five data inputs from the 5 rows of the 18 key keypad. Read as each column strobe is turned on.

2.3.55. lcd_data

This data output is the data channel for the data stream to the LCD alpha numeric display.

2.3.56. lith_ok

lith_ok is a discrete input from a lithium battery that supplies power to the battery backed up RAM. The input going low indicates that the lithium battery has expired.

2.3.57. load_flash

The load_flash event is generated whenever the correct access has been asserted in boot.

2.3.58. malfunction

The malfunction event is generated whenever a malfunction is detected by the safety monitor.

2.3.59. mem_cpu_malf

The mem_cpu_malf event indicates that boot has found an error in the memory or the cpu operation.

2.3.60. monitor_enable

These outputs provide control and test enable to the pump.

2.3.61. motor_commands

The motor_commands provide control information to the MotorController from the InfusionController. These commands provide position, rate, ramp up and down and state information to the controller via the following set functions:
SetInfusionVolume(commanded_position),
SetPumpSpeed(commanded_rate),
SetRampUpRate(up_ramp),
SetRampDownRate(down_rate) and
SetPumpMode(motor_state).

2.3.62. motor_control

motor_control are the enable and motor voltage control signals to the motor drive circuit.

2.3.63. motor_control_data

motor_control_data consists of the information required to maintain the motor at a prescribed rate.

2.3.64. motor_position

motor_ position is an unsigned long integer and represents the total integration of the motor shaft during a single therapy. motor_position is zeroed at the beginning of a therapy.

max value is 2e32 or 4,294,967,296 or 226.7 liters
resolution is 5.2793e-5 ml/count

2.3.65. motor_rate

motor_rate is an unsigned integer and represents the actual speed at which the motor is running. It has units of encoder counts per controller update period.

2.3.66. motor_state

motor_state indicates the state of the motor control.

run,
stop or
KVO.

2.3.67. motor_status

The motor_status consists of two variables, motor_error and motor_parameters. These variables are accessed via the function

int ReadMotorStatus(long *motor_parameters).

The function returns an integer which is the value of motor_error and returns a reference to an array pointer of integers, motor_parameters[].

2.3.68. motor_voltage

This data input is via the microcontroller A/D input and is the voltage across the motor.

2.3.69. mot_en

This data output enables the motor. This must be asserted for the motor to run.

2.3.70. mot_inh

This data output inhibits the motor from running and must be de-asserted for the motor to run.

2.3.71. mot_volts

This is the A/D analog input from the 7.5 volt motor drive voltage.

2.3.72. mtr_logic_en

This data output enables the +5 volts to the motor logic.

2.3.73. new_program

The new_program event is generated whenever the user selects new program from the notification menu.

2.3.74. NMI

The NMI event is the non maskable interrupt which is activated by the watchdog time out. The function vectored to by this interrupt will process pump shut down.

2.3.75. off

The off event can be generated by any function to indicated that the existing state must be changed to the Power_Down state to turn off the pump.

2.3.76. on_off_key

This input vent is from the ON/OFF key on the keypad or remotely mounted ON/OFF, normally open switch.

2.3.77. options

The options event is generated whenever the user selects to modify the selected options for a therapy.

2.3.78. options_done

The options_done event is generated whenever the user completes programming the options for a therapy.

2.3.79. out_oc_strain

This is an analog A/D input from the strain gage on the output side of the tube. The purpose is to measure occlusion.

2.3.80. pause

The pause event is generated the run/pause key is pressed and the pump is running.

2.3.81. pcb_rev

The revision number of the printed circuit board. The revision number will occupy three input lines, thus the rev number can be from 0 to 7.

2.3.82. per_int

These input from the real time clock indicates that a set time has occurred and is tied to an interrupt.

2.3.83. pet_dog

This output is required to be asserted and de-asserted once every TBD second to keep the watch dog from timing out. The minimum time between assertion and de-assertion is TBD micro seconds.

2.3.84. pet_dog_flag

The pet_dog_flag is set by the lowest priority task of the real time executive. The system monitor, which is not under control of the real time executive will pet the watch dog whenever the flag is set and then reset the flag.

2.3.85. power_supplies_off

This output, when asserted, turns the power supplies off, and turns them on when de-asserted

SOFTWARE REQUIREMENTS SPECIFICATION	340-9005	
AMBULATORY MULTI-THERAPY VOLUMETRIC INFUSION PUMP	DATE: 4/24/98	REV A

2.3.86. prescription_done

The prescription_done event is generated whenever the user finishes programming a prescription.

2.3.87. prime

The prime event occurs when the proper prime requests have been answered and the pump is ready to perform the prime function. Prime will be performed as long as the prime key is held down or until 6 ml of infusion has been pumped.

2.3.88. prime_done

prime_done indicates that either the prime key has been released or the 6 ml limit on prime volume has been reached.

2.3.89. prime_on

The prime_on event is generated whenever the prime/bolus key is pressed and the pump is not running.

2.3.90. programming

The programming event indicates that the pump is ok and normal pump operation may begin. This event is generated by the Program_Select state or the SetUp state.

2.3.91. pump_monitor

These inputs from the pump provide status and safety information to the software.

2.3.92. pump_status

pump_status data will consist of the following:
- therapy type in progress,
- current infusion state (base or basal rate/ dosage/ KVO),
- actual infusion rate,
- current volume infused,
- infusion tine remaining,
- number of bolus/ clinical/ load doses given and
- number of bolus/ clinical/ load doses attempted.

2.3.93. pwm

This output is the pwm motor voltage to the motor from the processor. The pwm switches between 0 and 7.5 volts at a frequency of XX Hz.

2.3.94. read_keys

read_keys is the scheduled time for the MonitorKeys task to run, which is the heart beat interval. This is controlled by the real time executive.

2.3.95. read_rtc

read_rtc is the scheduled time for the Date_Time_Monitor task to run This interval is 1 second. This is controlled by the real time executive.

2.3.96. receive_buffer

The receive buffer contains data which has been received from serial communications hardware UART. The buffer contains enough room for two complete messages. The buffer will have a data in pointer and a data out pointer. Whenever the pointers are equal, the buffer is empty. A serial data received event will be set whenever new data is received by the buffer. The data in pointer points to the position in the buffer that the next byte received from the serial communications interrupt will be put. The data out pointer points to the next byte to be read from the receive buffer by the foreground state.

2.3.97. repeat

The repeat event is generated whenever the user selects repeat from the notification menu.

2.3.98. resume

The resume event is selected by the user from the notification menu.

2.3.99. rtcio

This is a bi-directional input/output line which contains the real time clock data into and out of the real time clock.

2.3.100. rtc_control

The outputs, rtc_control, provide data transfer control of the data to/from the real time clock.

2.3.101. rtc_sck

This output clocks out the data from the real time clock on each transition. Data is transferred on a ???? transition.

2.3.102. run

The run event is generated when the therapy has been verified and the run key has been pressed.

2.3.103. running_led

This output, when asserted, turns on the RUN LED.

2.3.104. run_on

The run_on event is generated whenever the run/pause key is pressed.

2.3.105. RXD

This input is the serial data input from the outside world.

2.3.106. set_up

The set_up event is generated whenever the user selects set up from the program select menu, which causes the Set_Up state to be activated.

2.3.107. set_up_data

set_up_data is as follows:
maintenance due date,
programmer ID,
patient ID,
prescription number,
invoice number,
disable therapy (on/off),
patient history,
pump history,
display contrast level,
current date and time,
language,
serial number,
calibrated volume,
calibrated out beam,

calibrated in beam,
calibrated air in line and
calibration complete semaphore.

2.3.108. speaker_return

speaker_return is an analog input for testing the beeper.

2.3.109. speedup_enable

speedup_enable enables the speed up circuit in the motor drive circuit for low speed operation. This output is disabled for normal/high speed operation.

2.3.110. standby_led

This output, when asserted, turns on the STANDBY LED.

2.3.111. start_up_malf

The start_up_malf event indicates that a failure has occurred during the start up diagnostics.

2.3.112. start_up_ok

This event indicates that start up has been successfully completed. It contains set_up_done and programming events.

2.3.113. stop_pump

The stop_pump events are those events which cause the pump to stop, from either normal or abnormal conditions.

2.3.114. str_en_in

This output enables the input strain gage.

2.3.115. str_en_out

This output enables the output strain gage.

2.3.116. test_mode

test_mode is a strapped input. A high indicates that the system is in the normal operating mode. A low indicates that the unit is in the special factory test mode.

2.3.117. test_ps

This output, when asserted, causes the power supply to perform a test of the 5.0 volt supply.

2.3.118. therapy

therapy is the data item that indicates the therapy type to be active.

2.3.119. therapy_data

The therapy_data data item consists of all the data required to provide the given therapy, which includes the selected therapy, prescription and options.

2.3.120. transmit_buffer

The transmit buffer contains data which is to be transmitted by the serial communications. The buffer contains enough room for two complete messages. The buffer will have a data in pointer and a data out pointer. Whenever the pointers are equal, the buffer is empty. The data in pointer points to the position in the buffer that the next byte to be transmitted will be put by the foreground state. The data out pointer points to the next byte to be transmitted by the serial communication .

2.3.121. TXD

This output is the serial transmit data from the processor.

2.3.122. update_audio

The update_audio event is the scheduled time for the AudioController task to run The interval is 250 msec. This is controlled by the real time executive.

2.3.123. update_display

The update_display event is the scheduled time for the DisplayController task to run The interval is 250 msec. This is controlled by the real time executive.

2.3.124. update_pump

This event is the scheduled interval between updating the pump controller. The period is one heart_bead period.

2.3.125. up_ramp

The up_ramp data item is the time to ramp up from zero to the specified infusion rate.

2.3.126. user_displays

These outputs are to the various display functions within the user interface.

2.3.127. valid_mem

The valid_mem event is asserted whenever the boot code successfully validates the boot code and validates the flash ROM code.

2.3.128. vcc_volts

This is the A/D analog input from the 5.0 volt electronics Vcc voltage.

2.3.129. voltages

These inputs are via the microcontroller A/D converter and are the actual voltages from the power supplies.

2.3.130. voltages_control

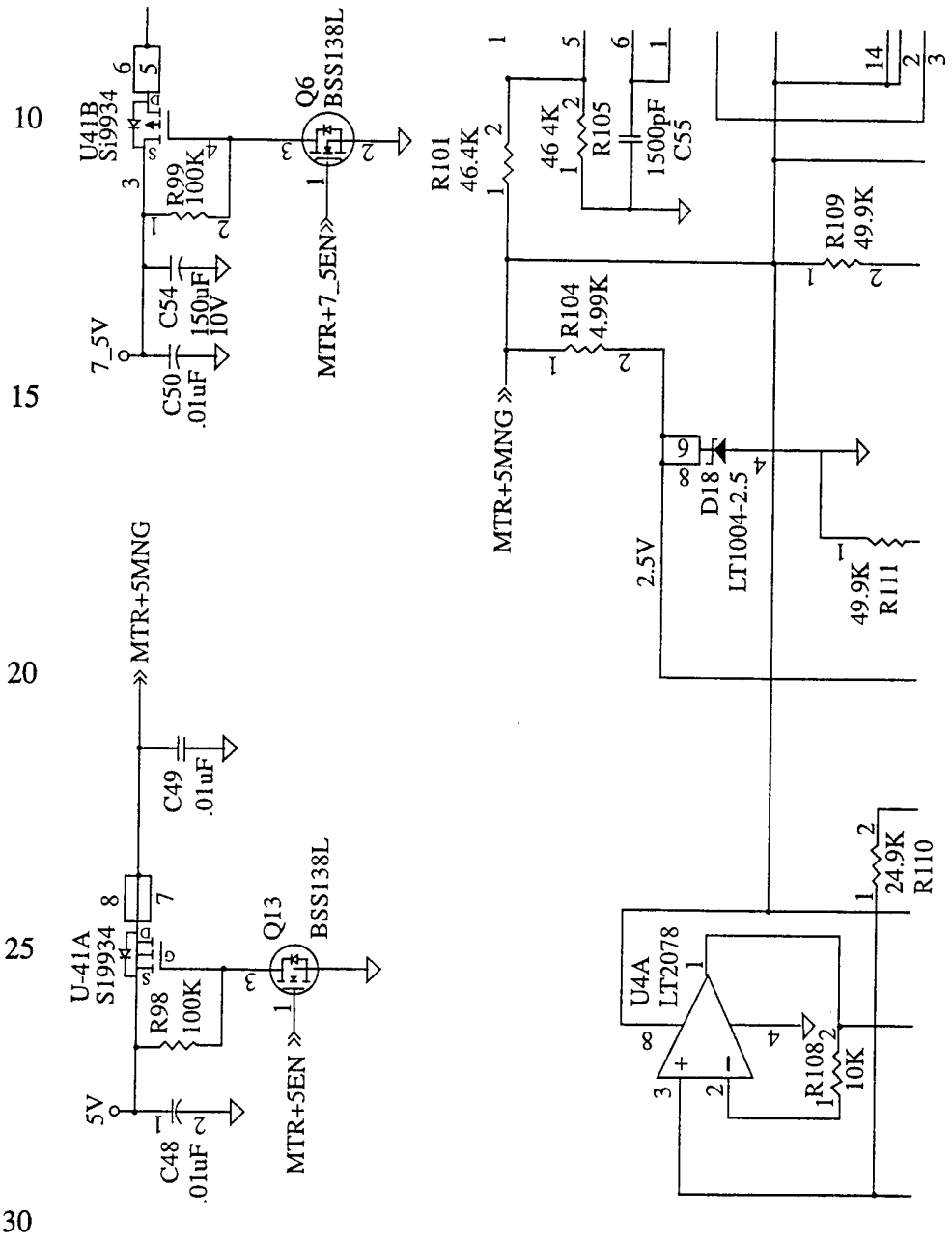
These outputs control the state of the power supplies and reference voltages.

2.3.131. xprime_notif

The xprime_notif event is generated whenever prime is complete and the entry to prime was from notification.

2.3.132. xprime_presc

The xprime_presc event is generated whenever prime is complete and the entry to prime was from prescription.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R99
100K
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10V
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R101
46.4K
46.4K
R105
1500pF
C55
R109
49.9K
R104
4.99K
MTR+5MNG »
D18
LT1004-2.5
2.5V
49.9K
R111
» MTR+5MNG
C49
.01uF
U-41A
S19934
Q13
BSS138L
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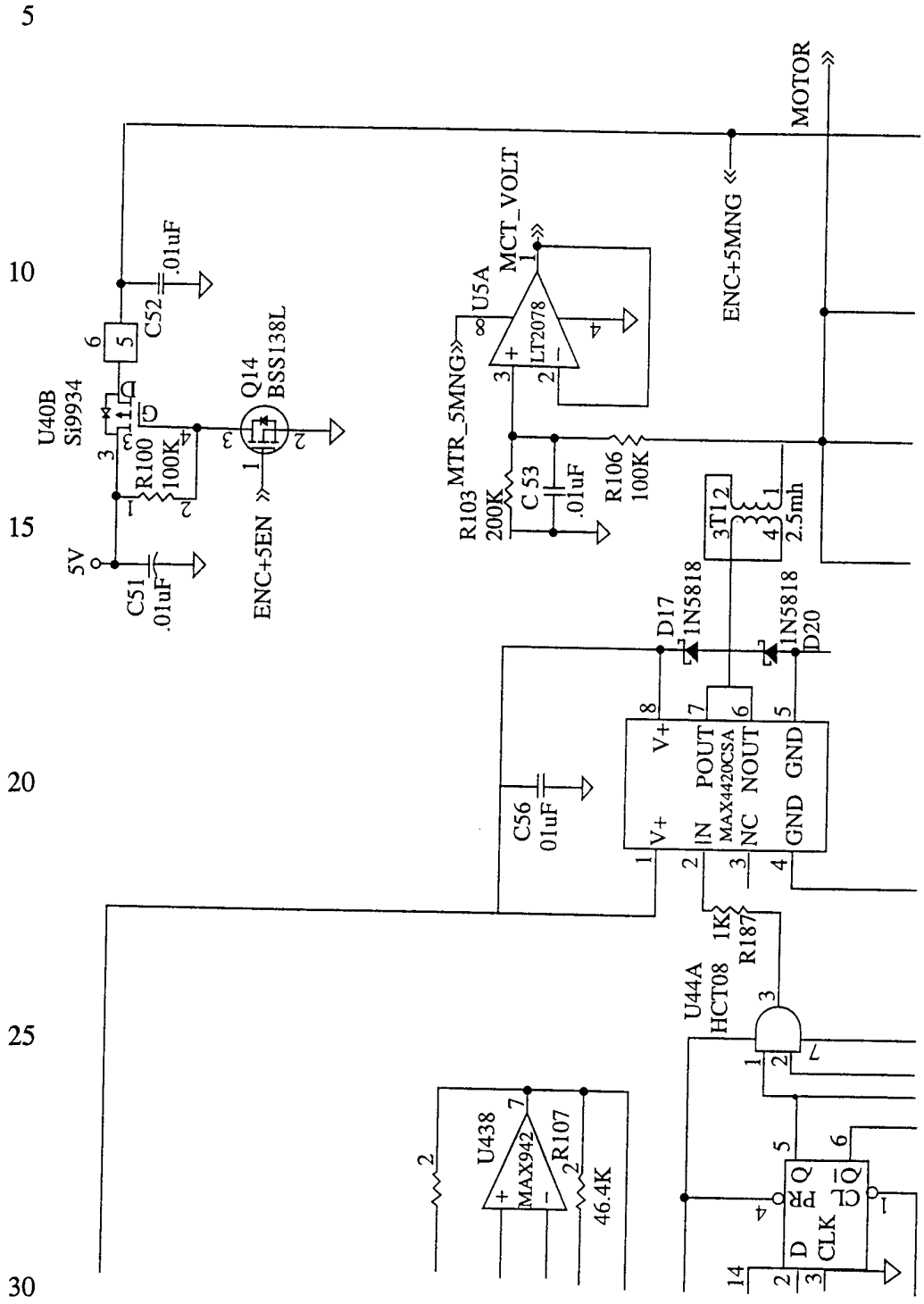
R110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C52
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U40B
Si9934
R100
100K
Q14
BSS138L
ENC+5EN
5V
C51
.01uF
C56
01uF
V+
IN
NC
GND
POUT
NOUT
GND
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PR
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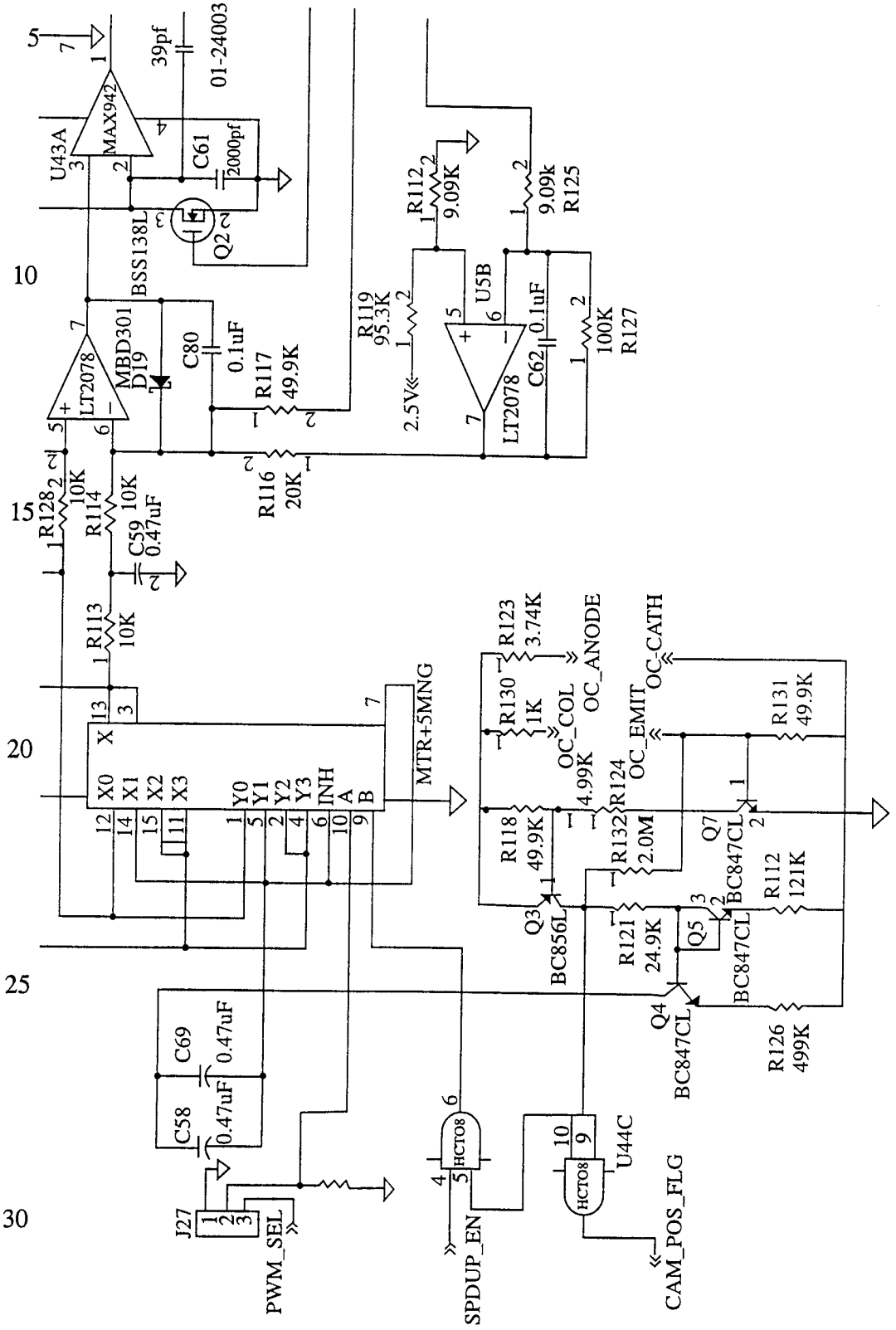
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01-24003
C61
200pf
Q2
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MBD301
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C80
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R117
49.9K
R116
20K
R119
95.3K
2.5V
U5B
LT2078
C62
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R112
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R130
1K
OC_COL
OC_ANODE
OC_EMIT
OC_CATH
R124
4.99K
R118
49.9K
R132
2.0M
R131
49.9K
Q7
BC847CL
R112
121K
Q3
BC856L
R121
24.9K
Q5
BC847CL
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BC847CL
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SPDUP_EN
HCT08
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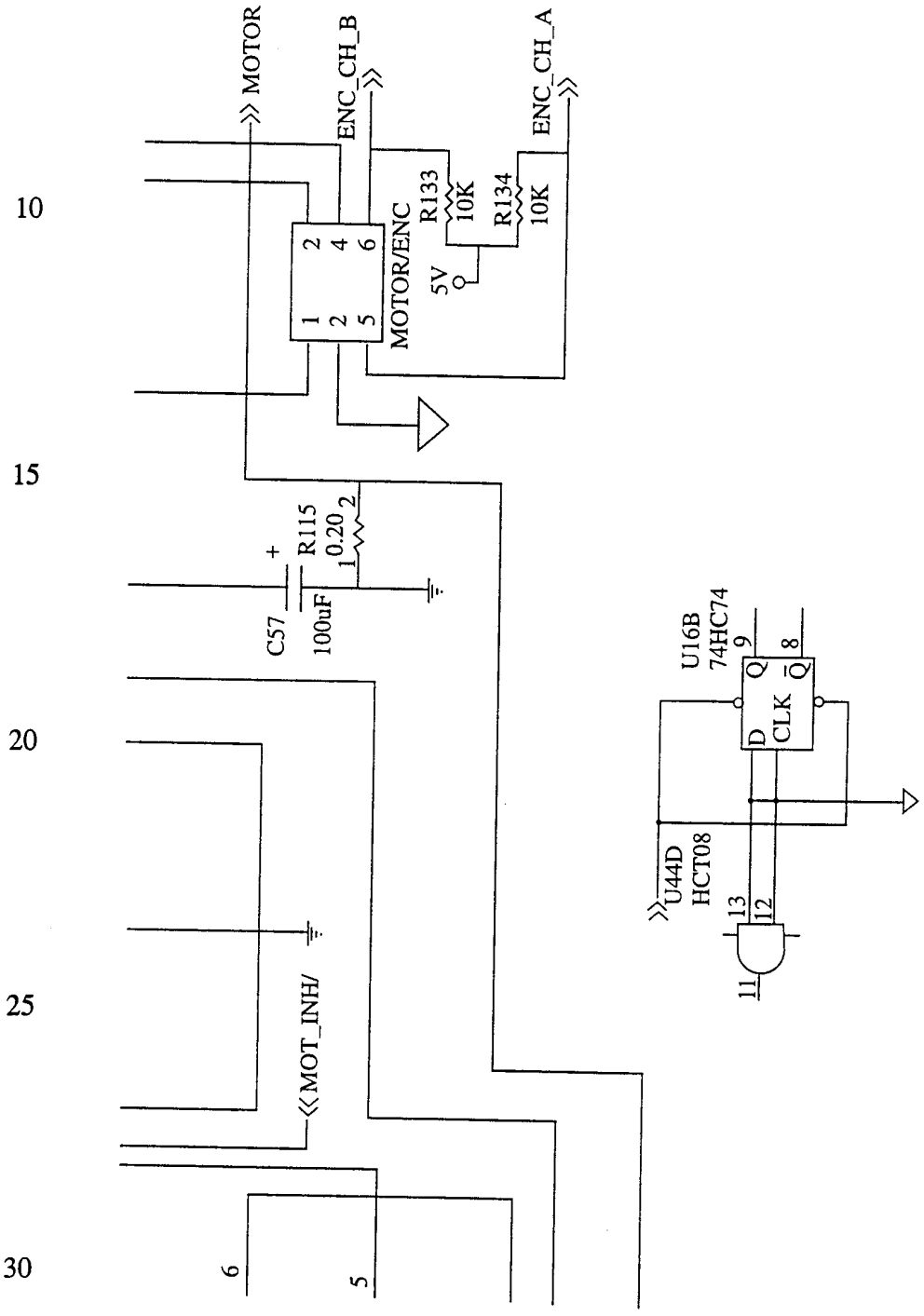
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ENC_CH_B
ENC_CH_A
MOTOR/ENC
R133
10K
R134
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R115
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100uF
U16B
74HC74
U44D
HCT08
MOT_INH/
6
5

WHAT IS CLAIMED IS:

1. A curvilinear peristaltic pump for facilitating the pumping of a liquid through a length of resilient tubing, the pump comprising:

a housing;

a platen member attached to the housing;

a rotatable cam disposed within the housing;

a drive unit disposed within the housing and mechanically coupled to the cam such that the activation of the drive unit results in the concurrent rotation of the cam in a first direction and the deactivation of the drive unit maintains the cam in a set position;

a plurality of pump fingers movably attached to the housing, each of the pump fingers having a first end which is cooperatively engaged to the cam and a second end which is disposed in spaced relation to the platen member, the cam being configured to sequentially move the pump fingers radially outwardly toward and inwardly away from the platen member when rotated in the first direction by the drive unit;

wherein a portion of the tubing may be extended between the platen member and the second ends of the pump fingers such that the sequential movement of the pump fingers toward and away from the platen member results in liquid within the tubing being pumped in the first direction of rotation of the cam.

2. The pump of Claim 1 wherein the drive unit comprises:

a cam shaft extending from the cam;

a worm gear attached to the cam shaft;

an electric motor having a rotatable motor shaft extending therefrom; and

a worm mounted to the motor shaft and cooperatively engaged to the worm gear;

wherein the engagement between the worm and the worm gear results in the rotation of the cam in the first direction upon the activation of the motor, with such engagement eliminating any rotation of the cam upon the deactivation of the motor.

3. The pump of Claim 2 wherein:

the sequential movement of each of the pump fingers toward and away from the platen member by the rotation of the cam defines a pump cycle; and

the pump further comprises a motor speed control unit which is electrically connected to the motor and operable to increase the rotational speed of the cam in the first direction between pump cycles.

4. The pump of Claim 3 wherein the motor speed control unit comprises:

an optical sensor electrically connected to the motor, the optical sensor being adapted to transmit a beam of light and sense any interruptions therein; and

an encoder wheel attached to the cam shaft and rotatable thereby, the encoder wheel including a plurality of encoder arms extending radially therefrom and being oriented relative to the optical sensor such that the encoder arms intermittently interrupt the beam of light during the rotation of the encoder wheel by the cam;

the number and size of the encoder arms being selected such that interruptions in the beam of light caused thereby correspond to pump cycles, with the optical sensor being operable to determine the beginning and end of each pump cycle and increase the power to the motor and thus the rotational speed of the cam between pump cycles.

5. The pump of Claim 1 wherein:

the sequential movement of each of the pump fingers toward and away from the platen member by the rotation of the cam defines a pump cycle; and

the cam is shaped so as to act against the first ends of the pump fingers in a manner causing the second ends thereof to engage the tubing such that the flow rate of liquid therethrough is substantially constant throughout each pump cycle.

6. The pump of Claim 5 wherein the cam comprises a four-lobe cam.

7. The pump of Claim 1 further comprising a pliable membrane which is attached to the housing and covers the second ends of the pump fingers.

8. The pump of Claim 7 wherein:

the platen member defines an arcuate, generally concave inner surface and is pivotally connected to the housing so as to be moveable between an operative position whereat the membrane is covered thereby and the second ends of the pump fingers are disposed in substantially equidistantly spaced relation to the inner surface, and a non-operative position whereat the membrane is exposed;

the tubing being extensible between the membrane and the inner surface of the platen member.

9. The pump of Claim 8 wherein the platen member includes an over-the-center latch mechanism for maintaining the platen member in its operative position relative to the housing.

10. The pump of Claim 8 further comprising:

a platen sensor disposed within the housing and operable to detect when the platen member is in the operative position; and

a tubing sensor disposed within the housing and operable to detect when the tubing is extended over the membrane.

11. The pump of Claim 10 wherein the platen sensor and the tubing sensor are electrically connected in

series such that the drive unit may not be activated until the tubing is extended over the membrane and the platen member is in the operative position.

12. The pump of Claim 10 wherein the platen sensor is a Hall effect sensor comprising:

a magnet which is disposed within the platen member; and

a magnetic field detector which is disposed within the housing;

the magnet and the magnetic field detector being oriented so as to be disposed directly adjacent each other when the platen member is in the operative position.

13. The pump of Claim 1 further comprising a plurality of pinch members movably attached to respective ones of the pump fingers and protruding from the second ends thereof, each of the pinch members being biased radially outwardly toward the platen member and operable to substantially occlude the tubing when the pump finger to which it is attached is moved radially outwardly to a position closest to the platen member.

14. The pump of Claim 13 wherein each of the pump fingers includes a transverse slot which is disposed within the second end thereof and transitions into a transverse cavity therewithin, and each of the pinch members comprises:

a base portion disposed within the transverse cavity;

a finger portion extending from the base portion into the transverse slot, the finger portion defining the a finger tip which protrudes from the second end of the pump finger; and

a biasing spring extending between the base portion and the pump finger.

15. The pump of Claim 1 wherein each of the pump fingers includes a plurality of roller members rotatably mounted within and protruding from the first end thereof,

the pump fingers being cooperatively engaged to the cam via the roller members.

16. The pump of Claim 1 wherein the pump fingers are arranged in a row and the pump further comprises a pair of pressure sensor members disposed within the housing adjacent respective ends of the row of pump fingers for engaging the tubing and generating electrical signals corresponding to the degree of compression thereof.

17. A curvilinear peristaltic pump, comprising:

a housing;

a platen member attached to the housing;

a rotatable cam disposed within the housing;

a drive unit disposed within the housing and mechanically coupled to the cam, the activation of the drive unit resulting in the concurrent rotation of the cam in a first direction;

a plurality of pump fingers movably attached to the housing, each of the pump fingers having a first end which is cooperatively engaged to the cam and a second end which is disposed in spaced relation to the platen member, the cam being configured to sequentially move the pump fingers radially outwardly toward and inwardly away from the platen member when rotated in the first direction by the drive unit; and

a tubing assembly releasably attachable to the housing and comprising:

a length of resilient tubing;

a tubing locator pin attached to the tubing; and

a shut-off valve attached to the tubing and operable to selectively obstruct the flow of liquid therethrough in a direction opposite the first direction;

wherein the tubing locator pin and the shut-off valve are removably insertable into

the housing and attached to the tubing at locations whereat a portion of the tubing is extended over the second ends of the pump fingers when the tubing locator pin and the shut-off valve are removably inserted into the housing, the tubing being extensible between the second ends and the platen member such that the sequential movement of the pump fingers toward and away from the platen member results in liquid within the tubing being pumped in the first direction of rotation of the cam.

18. The pump of Claim 17 wherein the tubing of the tubing assembly is fabricated from polyvinyl chloride.

19. The pump of Claim 17 further comprising a pliable membrane which is attached to the housing and covers the second ends of the pump fingers.

20. The pump of Claim 19 wherein:

the platen member defines an arcuate, generally concave inner surface and is pivotally connected to the housing so as to be movable between an operative position whereat the membrane is covered thereby and the second ends of the pump fingers are disposed in substantially equidistantly spaced relation to the inner surface, and a non-operative position whereat the membrane is exposed;

the tubing locator pin and the shut-off valve of the tubing assembly being removably insertable into the housing when the platen member is in the non-operative position, with the portion of the tubing extended over the membrane by the insertion of the tubing locator pin and the shut-off valve into the housing being captured between the membrane and the inner surface when the platen member is in the operative position.

21. The pump of Claim 20 wherein the shut-off valve comprises:

a valve body having an opening therein for permitting the passage of the tubing therethrough; and

a pinch arm movably attached to the valve body and engagable to the tubing passing through the opening;

the pinch arm being movable between an open position whereat the tubing passing through the valve body is not compressed by the pinch arm which allows the flow of liquid through the tubing, and a closed position whereat the tubing passing through the valve body is collapsed by the pinch arm which prevents the flow of liquid through the tubing.

22. The pump of Claim 21 wherein:

the shut-off valve further includes a biasing member for normally biasing the pinch arm to the closed position; and

the platen member is sized and configured to move the pinch arm from the closed position to the open position when the platen member is moved to the operative position.

23. The pump of Claim 22 wherein the biasing member comprises a spring which extends between the valve body and the pinch arm.

24. The pump of Claim 22 wherein the pinch arm includes a breakable detent tab formed thereon which maintains the pinch arm in the open position, the removal of the detent tab from the pinch arm resulting in the movement of the pinch arm to the closed position.

25. The pump of Claim 22 further comprising a plurality of pinch members movably attached to respective ones of the pump fingers and protruding from the second ends thereof, each of the pinch members being biased radially outwardly toward the inner surface of the platen member and operable to substantially occlude the tubing when the pump finger to which it is attached is moved

radially outwardly to a position closest to the inner surface.

26. The pump of Claim 25 wherein the platen member is pivotally connected to the housing at a location whereat the movement of the platen member from the non-operative position to the operative position results in the occlusion of the tubing by at least one of the pinch members prior to the movement of the pinch arm of the shut-off valve from the closed position to the open position by the platen member.

27. The pump of Claim 20 further comprising:

a platen sensor disposed within the housing and operable to detect when the platen member is in the operative position; and

a tubing sensor disposed within the housing and operable to detect when the tubing is extended over the membrane;

the tubing sensor being tripped by the insertion of the tubing locator pin into the housing, with the platen sensor being tripped by the movement of the platen member to the operative position.

28. The pump of Claim 27 wherein the platen sensor and the tubing sensor are electrically connected in series such that the drive unit may not be activated until the tubing locator pin is inserted into the housing and the platen member is in the operative position.

29. The pump of Claim 28 wherein the platen sensor is a Hall effect sensor comprising:

a magnet which is disposed within the platen member; and

magnetic field detector which is disposed within the housing;

the magnet and the magnetic field detector being oriented so as to be disposed directly adjacent each other when the platen member is in the operative position.

30. The pump of Claim 17 wherein the pump fingers are arranged in a row and the pump further comprises a pair of pressure sensor members disposed within the housing adjacent respective ends of the row of pumping fingers for engaging the tubing and generating electrical signals corresponding to the degree of compression thereof.

31. A tubing assembly for use in a peristaltic pump having a housing, a platen member attached to the housing, a rotatable cam disposed within the housing, and a plurality of pump fingers movably attached to the housing and cooperatively engaged to the cam such that the rotation of the cam sequentially moves the pump fingers outwardly toward and inwardly away from the platen member, the tubing assembly comprising:

a length of resilient tubing;

a tubing locator pin attached to the tubing; and

a shut-off valve attached to the tubing and operable to selectively obstruct the flow of liquid therethrough.

32. The tubing assembly of Claim 31 wherein the housing includes a pair of recesses disposed therein, and the tubing locator pin and the shut-off valve are attached to the tubing at locations whereat a portion of the tubing is extended over the pump fingers when the tubing locator pin and the shut-off valve are removably inserted into respective ones of the recesses.

33. The pump of Claim 31 wherein the tubing of the tubing assembly is fabricated from polyvinyl chloride.

34. The pump of Claim 31 wherein the shut-off valve comprises:

a valve body having an opening therein for permitting the passage of the tubing therethrough; and

a pinch arm movably attached to the valve body and engagable to the tubing passing through the opening;

the pinch arm being movable between an open position whereat the tubing passing through the valve body is not compressed by the pinch arm, and a closed position whereat the tubing passing through the valve body is collapsed by the pinch arm.

35. The pump of Claim 34 wherein the shut-off valve further includes a biasing member for normally biasing the pinch arm to the closed position.

36. The pump of Claim 35 wherein the biasing member comprises a spring which extends between the valve body and the pinch arm.

37. The pump of Claim 35 wherein the pinch arm includes a breakable detent tab formed thereon which maintains the pinch arm in the open position, the removal of the detent tab from the pinch arm resulting in the movement of the pinch arm to the closed position.

38. A shut-off valve for use in a tubing assembly comprising a length of resilient tubing, the shut-off valve comprising:

a valve body having an opening therein for permitting the passage of the tubing therethrough; and

a pinch arm movably attached to the valve body and engagable to the tubing passing through the opening;

the pinch arm being movable between an open position whereat the tubing passing through the valve body is not compressed by the pinch arm, and a closed position whereat the tubing passing through the valve body is collapsed by the pinch arm.

39. The pump of Claim 38 wherein the shut-off valve further includes a biasing member for normally biasing the pinch arm to the closed position.

40. The pump of Claim 39 wherein the biasing member comprises a spring which extends between the valve body and the pinch arm.

41. The pump of Claim 39 wherein the pinch arm includes a breakable detent tab formed thereon which maintains the pinch arm in an open position, the removal of the detent tab from the pinch arm resulting in the movement of the pinch arm to the closed position.

42. A curvilinear peristaltic pump for facilitating the pumping of a liquid through a length of resilient tubing, the pump comprising:

a housing;

a rotatable cam disposed within the housing;

a drive unit disposed within the housing and mechanically coupled to the cam such that the activation of the drive unit results in the concurrent rotation of the cam in a first direction;

a plurality of pump fingers movably attached to the housing and cooperatively engaged to the cam which is configured to sequentially move the pump fingers radially outwardly and inwardly when rotated in the first direction by the drive unit, with such sequential movement of each of the pump fingers facilitated by the rotation of the cam defining a pump cycle; and

a motor speed control unit which is electrically connected to the drive unit and operable to increase the rotational speed of the cam in the first direction between pump cycles.

43. A curvilinear peristaltic pump, comprising:

a housing;

a visual display disposed on the housing;

a drive unit disposed within the housing; and

a control unit disposed within the housing and in electrical communication with the visual display and the drive unit;

the control unit being operative to cause the pump to selectively implement any one of multiple therapy modalities and to generate a visual progress scale on the visual display corresponding to the particular therapy modality being implemented by the pump.

44. The pump of Claim 43 wherein:

the control unit is operative to implement therapy modalities selected from the group consisting of:

continuous therapy;
PCA therapy;
TPN therapy;
intermittent therapy; and
variable therapy; and

the visual progress scale generated on the visual display by the control unit during the implementation of the TPN therapy depicts up and down ramping phases thereof.

45. The pump of Claim 43 wherein:

a battery is disposed within the housing for supplying power to the control unit; and

the control unit is further operative to selectively generate a battery scale on the visual display corresponding to an available charge of the battery upon the activation of the pump.

46. The pump of Claim 43 wherein the control unit is further operative to generate an identifier bar on the visual display having an arrow configuration which points in at least one direction corresponding to additional text which is presentable on the visual display.

47. The pump of Claim 46 wherein:

the visual display of the pump defines left and right sides; and

the control unit is operative to generate the arrow configuration of the identifier bar at the left side of the visual display.

48. In a curvilinear peristaltic pump having a housing, a visual display disposed on the housing, a drive unit disposed within the housing, and a control unit which is disposed within the housing in electrical communication with the visual display and the drive unit and operative to cause the pump to selectively implement any one of multiple therapy modalities, the improvement comprising:

a visual progress scale which is generated on the visual display by the control unit and corresponds to the particular therapy modality being implemented by the pump.

49. An administration set for use with a curvilinear peristaltic pump having a housing, a plurality of pump fingers movably attached to the housing, a drive unit disposed within the housing for sequentially moving the pump fingers, and a sensor disposed within the housing for detecting the presence of the administration set, the administration set comprising:

a length of straight line, resilient tubing; and

at least one locating member positionable upon the tubing at a location whereat the locating member is operative to trip the sensor when a portion of the tubing is extended over the pump fingers;

the tripping of the sensor being required to facilitate the activation of the drive unit.

50. The administration set of Claim 49 wherein the locating member comprises a tubing locator pin attached to the tubing.

51. The administration set of Claim 50 further comprising a flow stop member attached to the tubing and operative to selectively obstruct the flow of liquid therethrough.

52. The administration set of Claim 49 wherein the tubing is fabricated from polyvinyl chloride compound.

53. An administration set for use with a curvilinear peristaltic pump having a sensor for detecting the presence of the administration set, the administration set comprising:

a length of straight line, resilient tubing; and

at least one locating member positionable upon the tubing at a location whereat the locating member is operative to trip the sensor when a portion of the tubing is cooperatively engaged to the pump;

the tripping of the sensor being required to facilitate the operation of the pump.

54. The administration set of Claim 53 wherein the locating member comprises a tubing locator pin attached to the tubing.

55. The administration set of Claim 54 further comprising a flow stop member attached to the tubing and operative to selectively obstruct the flow of liquid therethrough.

56. The administration set of Claim 53 wherein the tubing is fabricated from polyvinyl chloride compound.

57. An administration set for use with a curvilinear peristaltic pump having a housing which includes a plurality of pump fingers movably attached thereto, the administration set comprising:

a length of straight line, resilient tubing; and

at least one locating member removably insertable into the housing and positionable upon the tubing at a location whereat the insertion of the locating member into the housing ensures that a portion of the tubing is in contact with the pump fingers.

58. The administration set of Claim 57 comprising a pair of locating members removably insertable into the housing and positionable upon the tubing at locations whereat the insertion of the locating members into the

housing ensures that a portion of the tubing is in contact with the pump fingers.

59. The administration set of Claim 58 wherein the locating members comprise:

a tubing locator pin attached to the tubing; and

a flow stop member attached to the tubing and operative to selectively obstruct the flow of liquid therethrough.

60. The administration set of Claim 57 wherein the tubing is fabricated from polyvinyl chloride compound.

61. An administration set for use with a curvilinear peristaltic pump, the administration set comprising:

a length of straight line, resilient tubing; and

at least one locating member removably insertable into the pump and positionable upon the tubing at a location whereat the insertion of the locating member into the pump ensures that a portion of the tubing is in contact with the pump.

62. The administration set of Claim 61 comprising a pair of locating members removably insertable into the housing and positionable upon the tubing at locations whereat the insertion of the members into the pump ensures that a portion of the tubing is in contact with the pump.

63. The administration set of Claim 62 wherein the locating members comprise:

a tubing locator pin attached to the tubing; and

a flow stop member attached to the tubing and operative to selectively obstruct the flow of liquid therethrough

64. The administration set of Claim 61 wherein the tubing is fabricated from polyvinyl chloride compound.

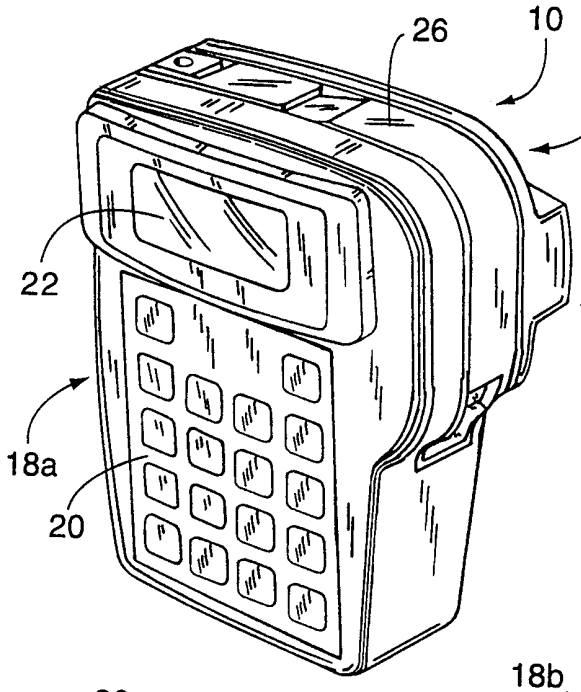


Fig. 1

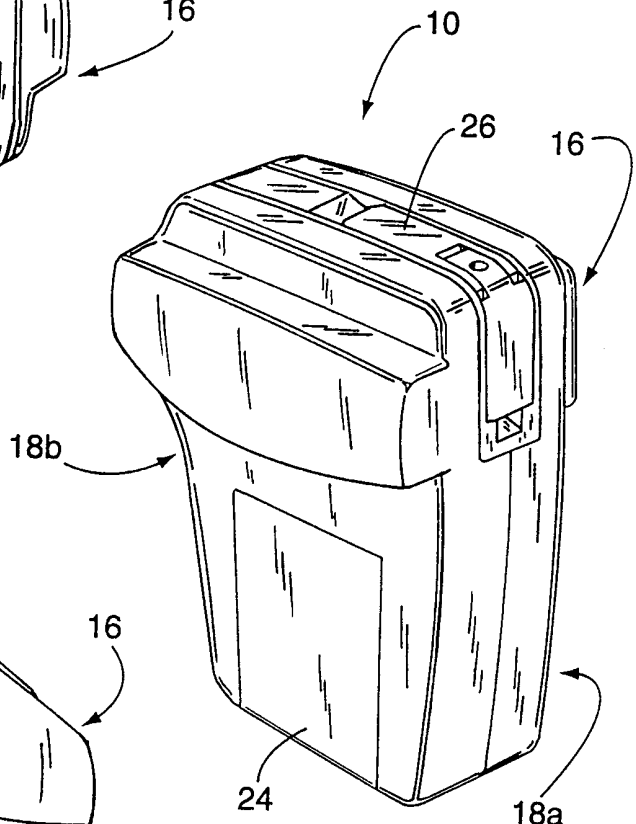


Fig. 2

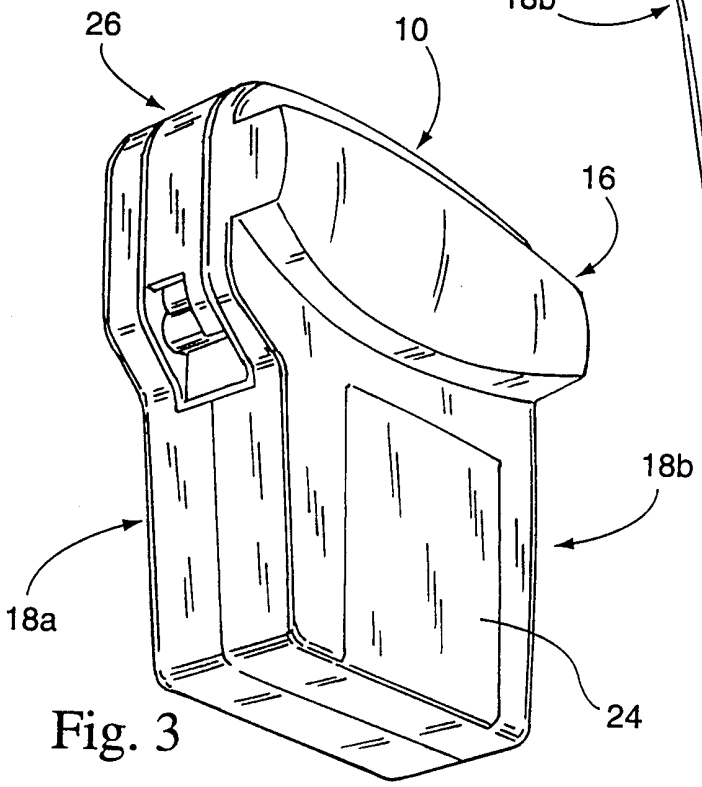
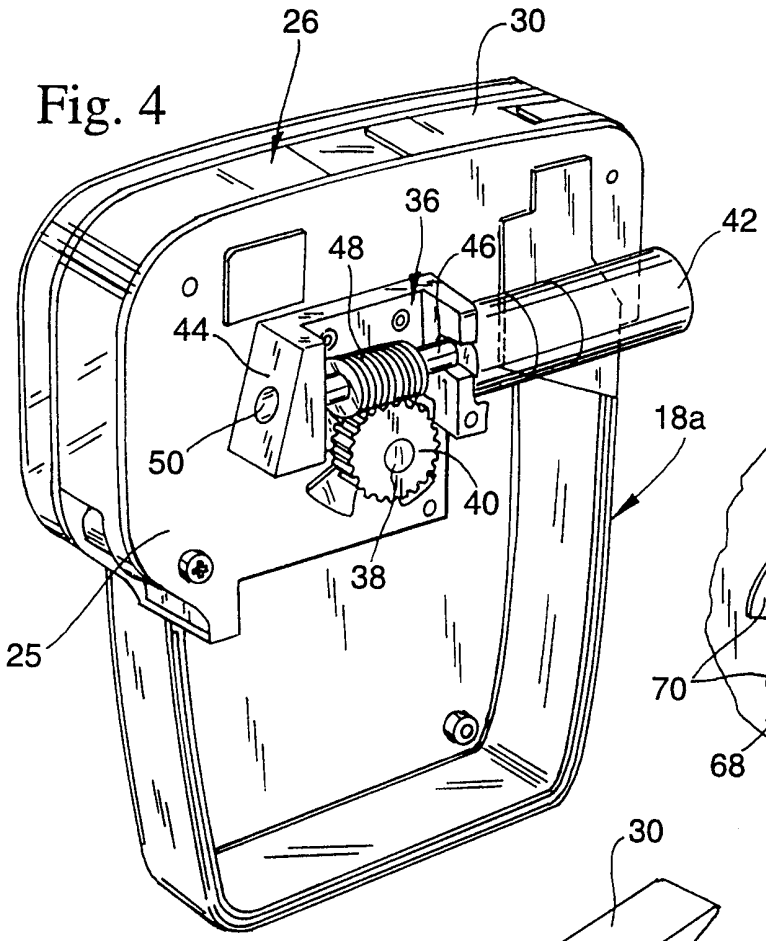


Fig. 3

Fig. 4



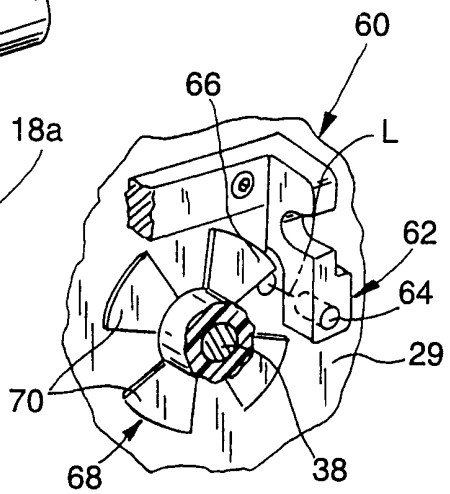


Fig. 5

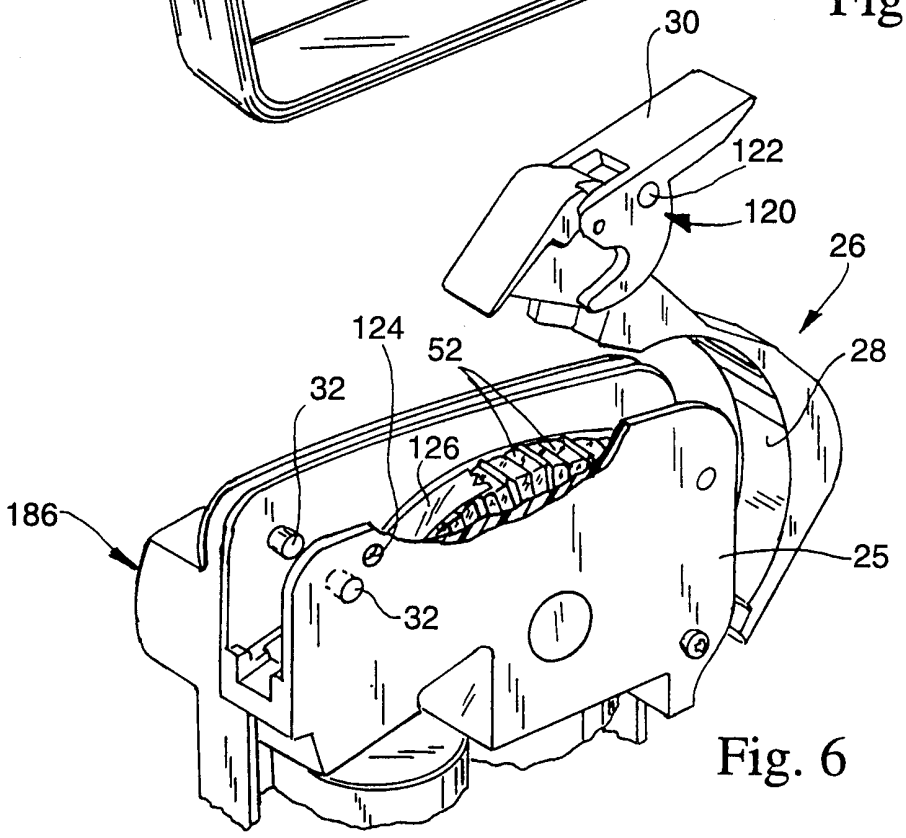


Fig. 6

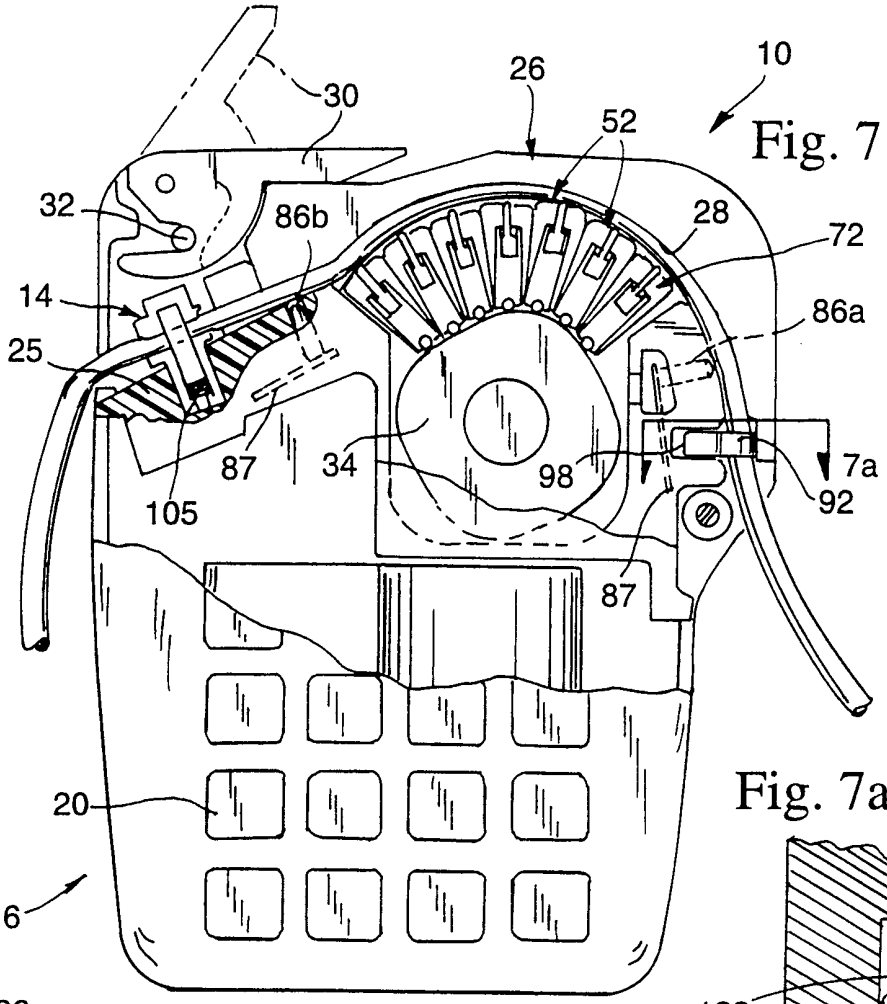


Fig. 7

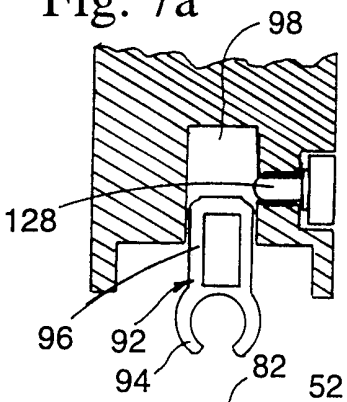


Fig. 7a

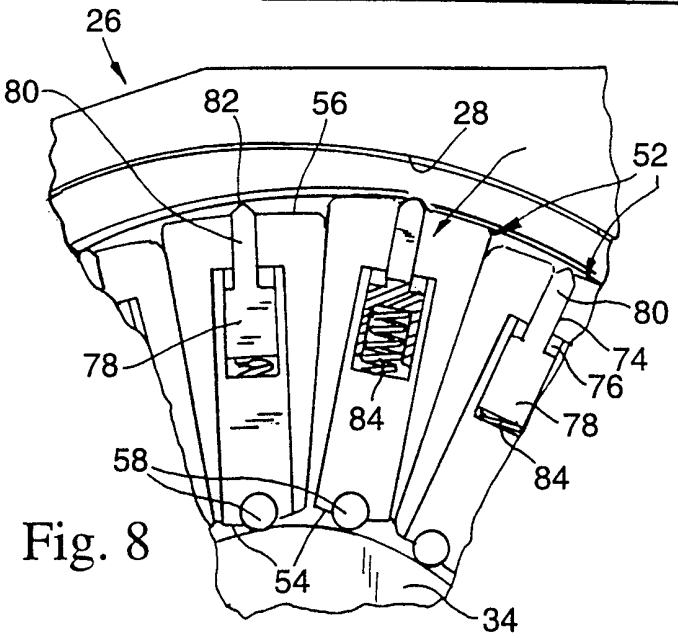


Fig. 8

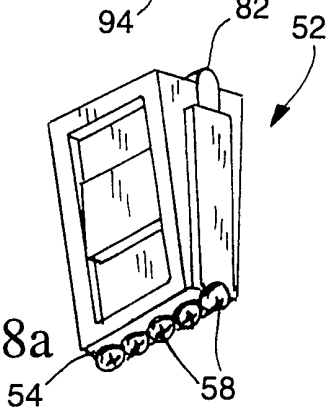


Fig. 8a

Fig. 9

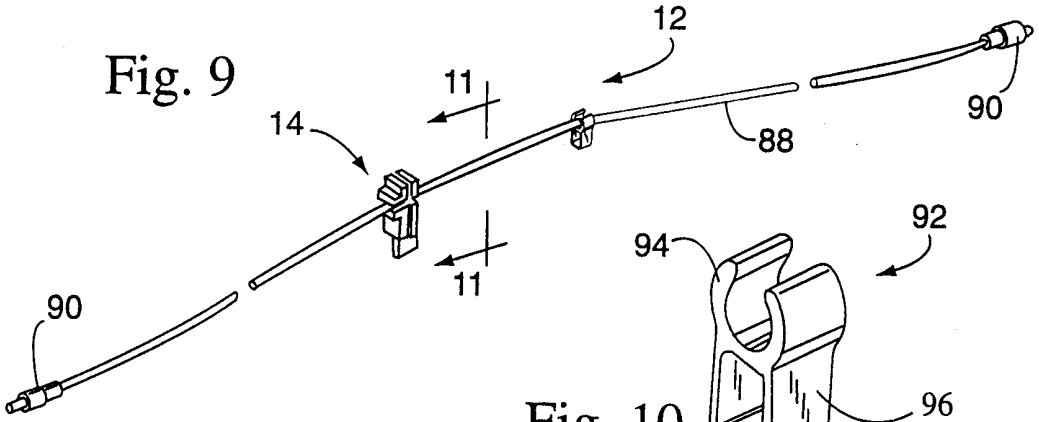


Fig. 10

Fig. 11

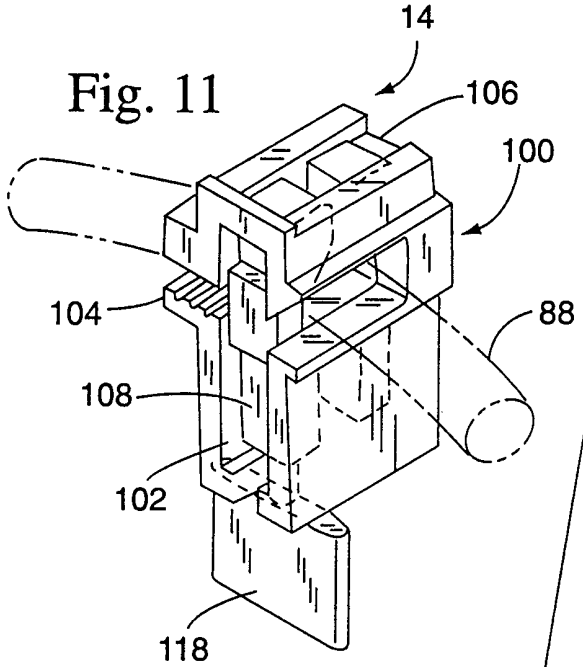


Fig. 12

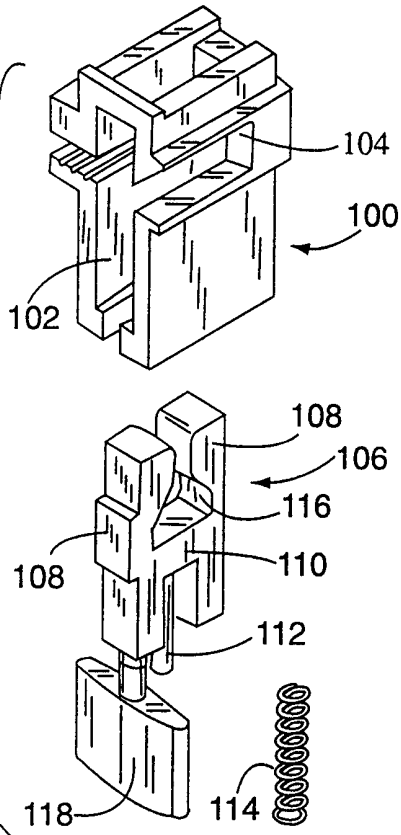
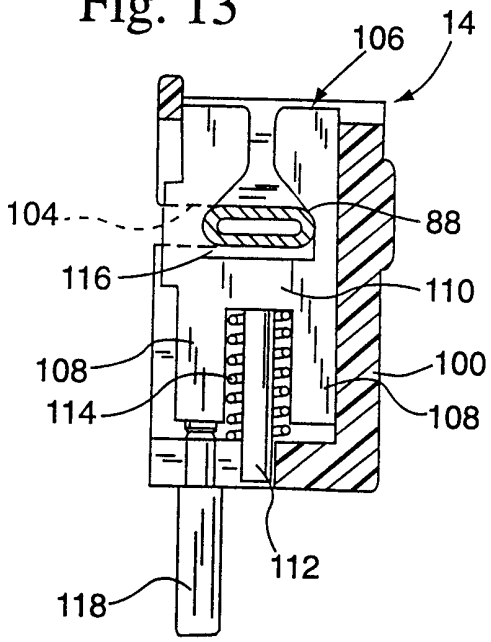


Fig. 13



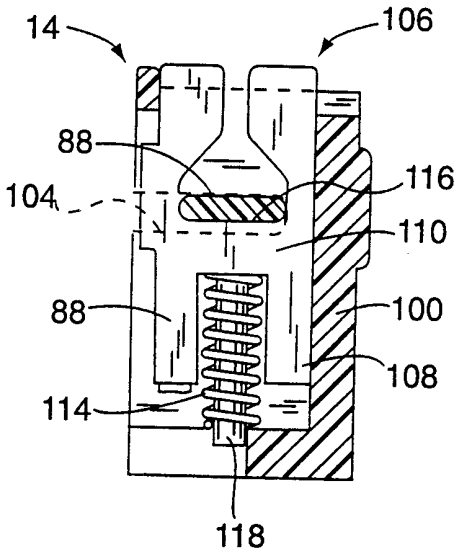


Fig. 14

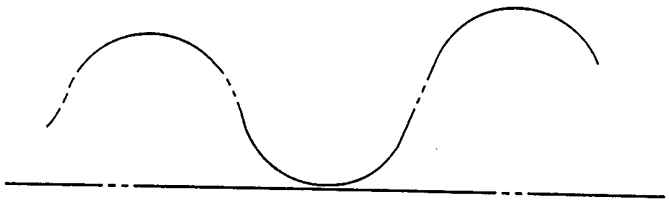


Fig. 15
(PRIOR ART)

Fig. 15b
(PRIOR ART)

Fig. 15c

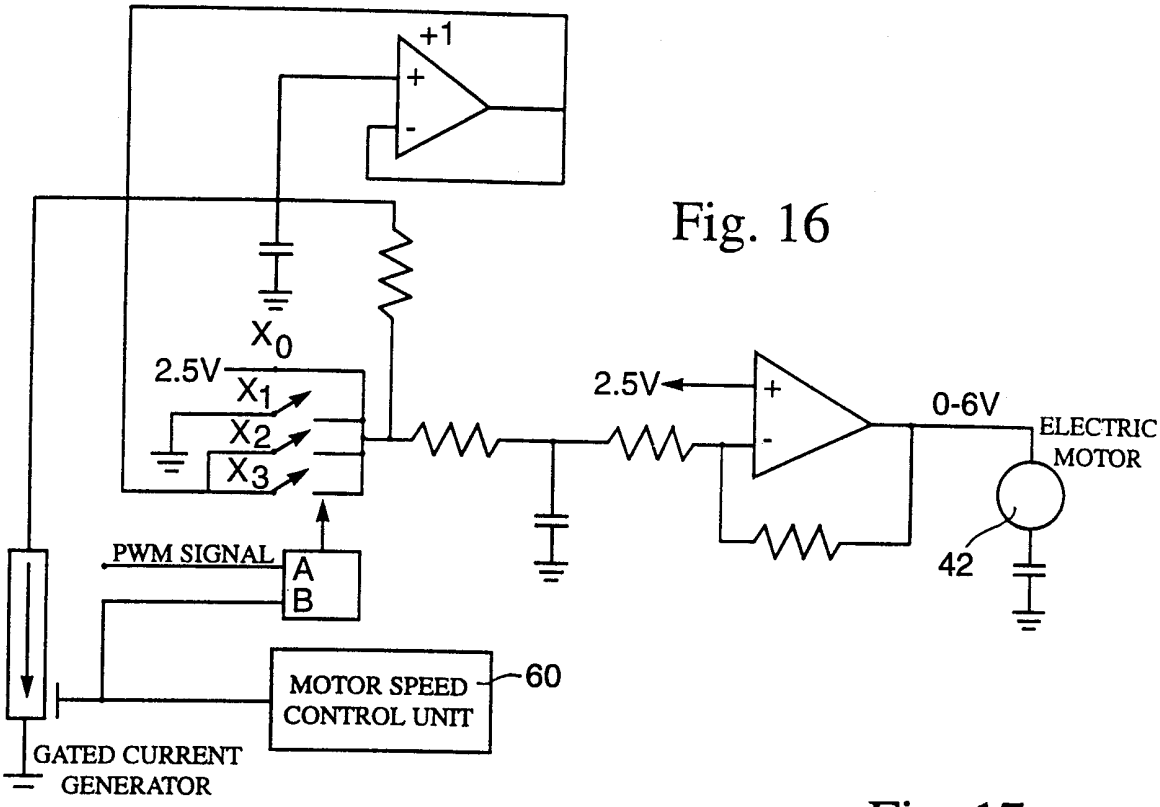

+1
+
-
X_0
2.5V
X_1
X_2
X_3
2.5V
+
-
0-6V
ELECTRIC MOTOR
42
PWM SIGNAL
A
B
MOTOR SPEED CONTROL UNIT
60
GATED CURRENT GENERATOR

Fig. 16

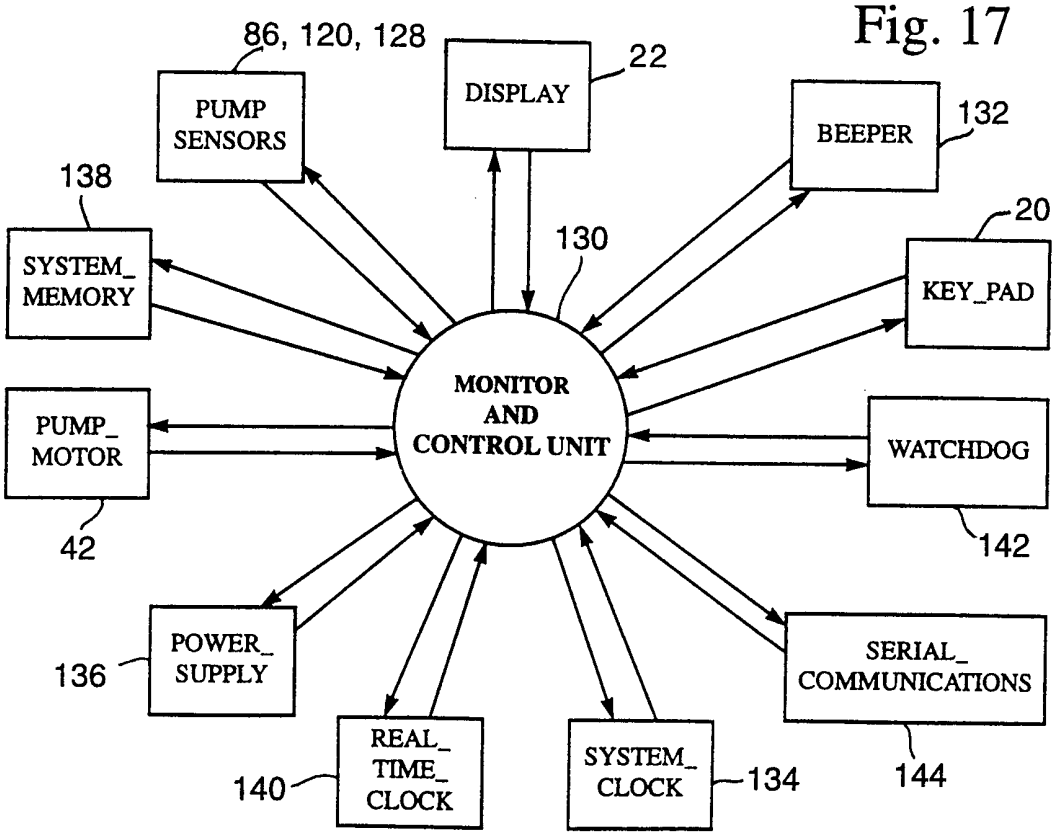

86, 120, 128
PUMP SENSORS
DISPLAY
22
BEEPER
132
138
SYSTEM_ MEMORY
130
20
KEY_PAD
MONITOR AND CONTROL UNIT
PUMP_ MOTOR
42
WATCHDOG
142
POWER_ SUPPLY
136
SERIAL_ COMMUNICATIONS
144
REAL_ TIME_ CLOCK
140
SYSTEM_ CLOCK
134

Fig. 17

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/26336

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :F04B 49/06,43/08; A61M 1/00, 31/00
US CL :417/44.1, 474, 477.3; 604/67, 153

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)

U.S. : 417/44.1, 474, 477.3; 604/67, 153

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)

APS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 5,575,631 A (JESTER) 19 November 1996 (19-11-96), see entire document, in particular Figures 1-4.	1, 5-6, 13-15 -------- 2-4, 7-12, 16-37, 42, 48-56
X -- Y	US 5,078,683 A (SANCOFF et al.) 07 January 1992 (07-01-92), Figure 1and column 6, lines 31-37.	31 ----- 64
X ----- Y	FR 1,529,535 A (GUYOT) 21 June 1968 (21-06-68), Figures 1-3.	38-40 ------- 16-37, 41

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

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 12 JANUARY 2000	Date of mailing of the international search report 17 MAR 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL K. GRAY Diane Smith for Telephone No. (703) 308-6196

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/26336

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,322,422 A (NATWICK et al.) 21 June 1994 (21-06-94), entire document, in particular Figure 3, column 9.	57-63
X	US 5,630,710 A (TUNE et al.) 20 May 1997 (20-05-97), entire document, in particular Figures 2, 32-34, 35A.	43-47