MEDFUSION MODEL 2001/2010

MEDFUSION SYRINGE INFUSION PUMP

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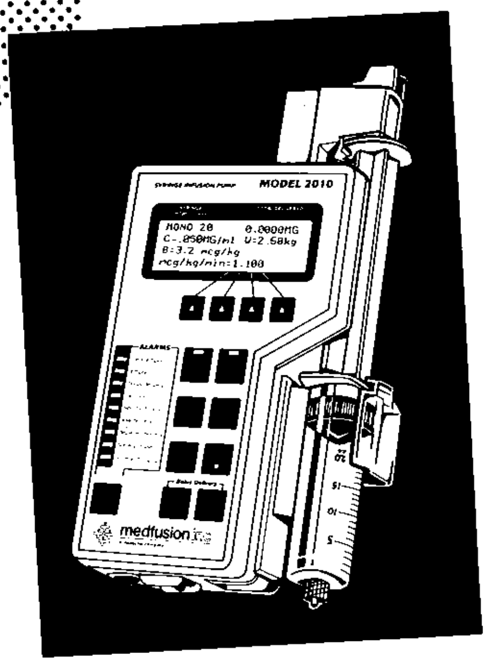

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SERVICE MANUAL

medfusion inc
A medex inc company

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S/N 8858

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SECTION 1. INTRODUCTION

The purpose of this service manual is to provide information for qualified biomedical personnel to service the MEDFUSION syringe infusion pump Model 2001/2010. The information presented in this manual has been verified. However, Medfusion assumes no responsibility for inaccuracies. Furthermore, MEDFUSION INC. reserves the right to make changes to improve reliability, safety, function , or design. Check the date on this manual. If it is over two years, call Medfusion to determine if any changes have been made. Please refer to the current Operation Manual for detailed operating instructions.

Medfusion strongly suggests that you do not attempt to repair or disassemble your 2001/2010 syringe pump until you have received service training from Medfusion.

SECTION 2. SPECIFICATIONS (2001)

Overall Size	4.5" wide X 3.0" high X 7.5" long
Weight	2.5 Pounds
Accuracy	+/- 3%, excluding syringe variations
Infusion Modes	Continuous, Volume Over Time, Intermittent Auto, Intermittent Manual
Flow Rate	00.01 to 99.99 ml/hour in increments of 0.01, or 0.1 to 356.0 ml/hour in increments of 0.1
Syringe Selection	Three Manufacturers: Becton-Dickinson (B-D); Monoject (Mono); Terumo (Terumo) Syringe Sizes: B-D 1, 3, 5, 10, 20, 30, 60 ml Mono 1, 3, 6, 12, 20, 35, 60 ml Teru 1, 3, 5, 10, 20, 30, 60 ml (Fill Volume: 1,3,6,12,25,35,60) Special request available for other syringe manufacturers
Syringe Fill Volume	All syringe sizes will fill to maximum stated volumes
Power	AC 95-135V, 60Hz; International voltages available DC internal rechargeable batteries
Syringe Programming	The pump automatically senses the syringe size when loaded properly
Recharge Time	With Pump ON: 16 Hours at 25 degrees C
Battery Capacity	At 25 degrees C, a 16-hour charge will operate the pump for at least 10 hours at 5.0 ml/hour with a 60 ml syringe.
Alarms/Alerts	Near Empty, Empty, Volume Limit, Occlusion Low Battery, Depleted Battery, Battery In Use, Battery Charging System Malfunction Syringe Pops Out, Check Clutch, Battery Depleted/Plug In AC Invalid Size, Invalid Number Stop/Program, Deliver, Priming, Standby
Total Volume Delivered	000.00 to 999.99 ml, increments of 0.01 ml
Volume Limit	00.0 to maximum capacity of syringe size selected increments of 0.1 ml
KVO	0.1 to 9.9 ml/hour, increments of 0.1 ml/hour

SPECIFICATIONS (2010)

Overall Size	4.5" wide X 3.0" high X 7.5" long
Weight	2.5 Pounds
Accuracy	+/- 3%, excluding syringe variations
Infusion Modes	Body-weight (mcg/kg/min,mcg/kg/HR,MG/kg/min,MG/kg/HR) MG/HR, ML/HR, Volume/Time
Flow Rate	0.1 to 378 ml/hour dependent on syringe size selected
Bolus Rate	Up to 378 ml/hour
Syringe Selection	Three Manufacturers: Becton-Dickinson (B-D); Monoject (Mono); Terumo (Terumo) Syringe Sizes: B-D 1, 3, 5, 10, 20, 30, 60 ml Mono 1, 3, 6, 12, 20, 35, 60 ml Teru 1, 3, 5, 10, 20, 30, 60 ml (Fill Volume: 1,3,6,12,25,35,60) B-D (GLASS) 1, 3, 5, 10 ml Special request available for other syringe manufacturers
Syringe Fill Volume	All syringe sizes will fill to maximum stated volumes
Power	AC 95-135V, 60Hz; International voltages available DC internal rechargeable batteries
Syringe Programming	The pump automatically senses the syringe size when loaded
Recharge Time	With Pump ON: 16 Hours at 25 degrees C
Battery Capacity	At 25 degrees C, a 16-hour charge will operate the pump for at least 10 hours at 5.0 ml/hour with a 60 ml syringe.
Alarms/Alerts	Near Empty, Empty, Bolus Delivery, Occlusion Low Battery, Depleted Battery, Battery In Use, Battery Charging System Malfunction Syringe Pops Out, Check Clutch, Battery Depleted/Plug In AC Invalid Size, Invalid Number Stop/Program, Deliver, Priming, Standby
Total Volume Delivered	0000.0000 to 9999.9999 mg or 0000.00 to 9999.99 ml

SECTION 3. THEORY OF OPERATION

3.1 INTRODUCTION

The Model 2001/2010 syringe pump consists of three major sub-assemblies (S/A): Top Housing S/A, Slide Housing S/A, and Bottom Housing S/A. These three sub-assemblies simply snap together and are held in place with five(5) screws. They fit together using tongue and groove construction which makes the pump resistant to fluid entry. These housings are injection-molded with high impact resistant polycarbonate.

3.1.1 Top Housing S/A

The Top Housing S/A consists of the Top Housing, Keypad, LCD display, and Main Electronic Board:

A membrane keypad with tactile keys is used to program the pump. The LCD display has 4 lines by 20 characters and a wide viewing angle. It is used to provide menu-driven programming, to display all programmed parameters and information, and to provide flexibility for future improvements. The LCD display is equipped with an LED backlight for low light viewing. The backlight is always on whenever AC power is used. When on battery power, the backlight is normally off. It can be turned on for approximately 15 seconds by pressing any key on the keypad.

Most of the electronics are contained on the Main Board attached to the top housing. The other small Auxiliary board is mounted on the slide housing. The brain of this pump is a single chip Micro-Controller with 32K bytes of non-volatile memory. The memory spaces for the program and the data are dynamically partitioned without any change in the hardware. This feature provides for maximum flexibility, thus allowing future software upgrades. Also, bi-directional serial communication with other computer equipment is possible via the DIN connector.

3.1.2 Slide Housing S/A

The Slide Housing S/A consists of the Slide housing, Mechanical pumping mechanism, Syringe barrel retainer, Sensors, and Auxiliary board:

The mechanical pumping mechanism consists of a stepper motor, a worm gearing system, a precision leadscrew, and a pair of fully engaged clutch nuts to propel the Track and the syringe plunger driver.

The syringe barrel retainer consists of a syringe barrel saddle and a syringe clamp. They are carefully designed so that virtually all types of syringes (1 cc to 60 cc) can be accommodated. The loading of the syringe is simplified by using the same procedure for all size syringes. The syringe barrel clamping system provides for syringe size sensing. By properly sensing syringe size one can prevent over/under-delivery caused by programming a syringe size different from the one actually being used. The barrel saddle position minimizes the overhang beyond the pump housing of the syringe plunger and the syringe barrel when a 60cc syringe is used.

The Model 2001/2010 syringe pump is equipped with an array of sensors for monitoring: the rotation of the motor shaft, the movement of the syringe plunger driver, the force at the end of the syringe plunger, the size of the syringe, and the internal battery voltage. The outputs of the sensors are monitored by the Micro-Controller via Analog-to-Digital (A/D) converter to assure proper pump operation.

The back pressure inside the syringe develops a force (at the end of the syringe plunger) which is sensed by a strain gauge force sensor. The Micro-Controller uses the reading of this sensor and the size of the syringe detected by the size sensor to determine the allowable force at the end of the syringe plunger. An occlusion alert is signaled if the trip force for the specific syringe size is exceeded.

The Auxiliary board has an amplifier for amplifying the signal from the strain gauge, and an optical device to detect the rotation of the motor shaft. This board provides a convenient connection point for cables simplifying the integration of the sub-assemblies.

3.1.3 Bottom Housing S/A

The Bottom Housing S/A consists of the Bottom housing, Battery pack, Audio Alarm, Power switch, and DIN connector.

Normally, the pump is powered by external AC power via the external plug-in AC adaptor. However, there is an internal battery pack to backup the operation of the pump in case of a power outage or during transportation. The battery is always being charged as long as the external AC power is applied. The charging circuit automatically switches to a trickle charging mode whenever the battery is fully charged.

The power switch is protected by a pair of switch guards to protect against being turned off accidentally. The DIN receptacle mates with the AC charger plug and has additional pins for future expansion (e.g., serial communication).

3.1.4 Safety features

Many safety features are carefully built into the pump. They are: the Watchdog circuit, Stepper motor control, Sensors, and System self-test.

The watchdog circuit monitors the proper operation of the Micro- Controller. The Micro-Controller must send at least a pulse to the watchdog circuit within a pre-set time interval, otherwise, the watchdog circuit activates the SYSTEM MALFUNCTION alert (LED & alarm) and disables the power to the stepper motor.

The stepper motor for driving the syringe plunger is directly controlled and driven by the Micro-Controller. The Micro-Controller must send out a proper sequence of waveforms to each of the four motor coils to turn the shaft of the motor. It is very unlikely that the motor can run away as long as the Micro-Controller is operating properly. If the Micro-Controller is not working properly, the watchdog circuit would activate an alert to stop the motor. If the motor driver fails, the motor will not run properly. When the rotation sensor detects this failure, an alert will be activated. If the motor is running, but the syringe plunger driver does not move (maybe due to defective clutch nuts or an improper engagement), the position sensor will detect this problem. If the syringe plunger is manually moved during delivery, the position sensor will detect this problem and sound an alarm.

The accuracy of the pump delivery rate depends mainly on the accuracy of the leadscrew and the system clock. There is no need for any adjustment or calibration for the delivery rate as long as the program inside the Micro-Controller is accurate. The integrity of the program is verified by performing a checksum test on the program after the pump is turned on.

3.2 MECHANICAL SYSTEM

3.2.1 Introduction

The Model 2001/2010 syringe pump consists of three major sub-assemblies: Top Housing S/A, Bottom Housing S/A, and Slide Housing S/A. These sub-assemblies are supported by 8 major injection molded plastic parts: Top Housing, Bottom Housing, Slide Top, Slide Bottom, Syringe Saddle, Syringe Clamp, Track, and Syringe Plunger Holder (or Driver). The Slide Housing S/A, the most complex assembly, hosts the entire pumping mechanism and all the pump sensors.

3.2.2 Top Housing S/A (P/N 1-68-20A00-0-X, Appendix A.2)

The Top Housing S/A holds the Keypad, the LCD display, and the Main board. The groove around the Top housing matches the tongue of the Bottom housing and Slide housing. This tongue and groove construction improves the resistance to fluid entry.

3.2.3 Bottom Housing S/A (P/N 1-68-20A01-0-X, Appendix A.3)

The Bottom housing holds the Battery pack, the Alarm, the Power switch, and the DIN connector. The battery pack is secured to the bottom housing by a strip of double-side tape. The tape has a very aggressive adhesive which can only be removed with a knife. The Power switch together with a pair of switch guards snaps into the bottom housing. The DIN connector is secured to the bottom housing with a ring nut.

The bottom housing also has a sliding guide and acts as a mechanical stop for the syringe clamp. There are two threaded inserts on the outside surface of the bottom housing for mounting the pole clamp. There is a recess on one exterior surface for placing the brief instruction label.

3.2.4 Slide Housing S/A (P/N 1-68-20A02-0-X, Appendix A.4)

The Slide Housing S/A is made up by the Slide S/A (1-68-20A03-0-X, Appendix A.5), the Track / Plunger holder S/A (1-68-20A04-0-X, Appendix A.6), the Pumping mechanism, and various sensors.

The Slide S/A is assembled by bonding the Slide Top housing, the Slide Bottom housing, and the Syringe Saddle together with a clamping fixture. After bonding, a worm bushing is inserted using a special tool. The Slide S/A can not be disassembled after bonding.

The Track / Plunger holder S/A consists of the Track, the Plunger holder, the Force sensor, and the Mounting hardware. Metal inserts are molded into both the Track and the Plunger holder to provide a solid support for the force sensor. The force sensor is made of a strain gauge reed and a blank reed. Two reeds are used to reduce the variation of the gauge output when the force is not applied at the center point of the strain gauge. Special surface treatment and tight dimensional tolerances for the mounting hardware are specified to improve the linearity and the stability of the final force sensor assembly.

Building this sub-assembly is not an easy task, caution and care should be taken and the proper tools must be used. Otherwise, the strain gauge can be easily damaged, or the performance of the force sensor will be adversely affected.

* Note the orientation of the nut plate holes during assembly.
* The reeds must be mounted perpendicular to the top surface of the plunger holder. A clamp should be used to assist the assembly.
* Shims should be used when assembling the plunger holder to the track to control the gaps between them. The gaps should be symmetrical on either side of the plunger holder. The front gap should be the same thickness as the front shim.

* The proper amount of torque must be applied to the socket head screws to assure the stability of the force sensor.
* There should be no mechanical interference between the plunger and the track.

3.2.4.1 Pumping Mechanism

The mechanical pumping mechanism is the heart of the syringe pump. This mechanism uses a stepper motor coupled to a worm gearing system to turn a precision leadscrew. The turning of the leadscrew propels the Track (via a pair of fully engaged clutch nuts) and advances the plunger driver (mounted on the Track) which pushes the syringe plunger thus expelling the fluid inside the syringe barrel.

3.2.4.1.1 Mechanical Resolution

The stepper motor's step angle is 7.5 degrees. The worm gearing ratio is 1:44. The leadscrew has a pitch length of 20 threads per inch. Thus each step of the motor advances the syringe plunger 0.00002368 inches.

3.2.4.1.2 Driving mechanism

The stepper motor is mounted on a bracket on the slide housing. The bracket must be aligned with the worm bushing hole by using a special alignment tool. As long as this bracket is not removed, there is no need for re-alignment. The motor shaft couples to the worm via a shaft driver on the motor shaft and a shaft coupler on the worm. The black/white markings on the shaft coupler are used to detect motor shaft rotation. A small amount of grease (Dow Corning 111 Valve Lubricant & Sealant) is placed inside the shaft coupler to dampen the hammering noise generated by the shaft driver at low speeds. The worm tip is supported by a worm bushing inserted inside the slide housing.

The worm is coupled to the leadscrew via a 44-tooth worm gear. One end of the leadscrew is supported by a bushing and the other end is supported by a bearing. E-clips are used to retain the leadscrew in position. The following cautions should be taken to minimize any friction which may reduce the pump output torque:

* Follow the procedure carefully to provide for an adequate gap between the leadscrew and the thrust bushing on the motor side. This gap is necessary to assure that there is no unwanted load on the leadscrew. The leadscrew should turn freely when there is no load (e.g., the clutch is opened).
* Be careful not to damage the teeth of the worm gear or the surface of either the leadscrew threads and the worm threads during assembly or disassembly.

A pair of spring-loaded half clutch nuts engage the leadscrew to the track. The pair of half clutch nuts form a 360 degree engagement onto the leadscrew and transform the rotation of leadscrew to a linear movement of the track. There is a clutch key next to the clutch nuts to secure the engagement of the clutch nuts to the track. A clutch actuator rod links a clutch lever to the clutch nuts and is secured by a clutch rod cover and two screws. Thus, by pinching the clutch lever, the clutch nuts open and the track is disengaged from the leadscrew. The track can be manually moved in and out.

A syringe plunger driver is mounted on the track. The movement of the track causes the syringe plunger driver to push the plunger of the syringe to expel the fluid inside the syringe.

There is a molded gear rack inside the track which engages a potentiometer via a cluster gear train. The linear movement of the track rotates the potentiometer shaft so that the track movement can be monitored.

3.2.4.2 Syringe retaining and size sensing

The syringe barrel retaining system consists of a syringe barrel saddle and a syringe clamp. The syringe saddle is bonded to the Slide S/A. The syringe clamp is a clear plastic clamp with a gear rack. It is inserted into a chimney-like slot on the Slide top and the gear rack is engaged with a spur gear located on the shaft of the size sensing potentiometer. A rubber boot is installed around the syringe clamp to discourage fluid entry.

The engagement (timing) between the gear rack and the spur gear must be carefully adjusted so that the center tab of the potentiometer always stays within the electrical range of the potentiometer for the lowest and highest useful positions of the clamp. The potentiometer spur gear is spring loaded with a torsion spring so that the syringe barrel is automatically held down in place when the clamp is released. The pre-loading amount should be carefully controlled. The clamp does not spring down easily if there is not enough pre-loading of the spring. However, permanent damage might happen to the spring if there is too much pre-loading. After the adjustment of the timing and preloading, the potentiometer and the spring must be secured tightly with the clamps and screws for mechanical stability.

3.2.4.3 Position Sensing

A gear rack is molded into the inside wall of the track. This gear rack engages with the spur gear at the shaft of a position sensing potentiometer via a cluster gear inserted in the slide housing. The potentiometer is secured to a potentiometer holder with a nut. The holder is then secured to the slide housing with two screws. The engagement (timing) of the spur gear with the cluster gear should be carefully adjusted so that the center tab of the potentiometer always stays within the electrical range of the potentiometer when the track is moved to the most inward or extended positions. The slot at the potentiometer holder is used to adjust the tightness of the engagement to obtain a smooth track movement with minimal backlash. The two screws must be tightly secured after the adjustment for mechanical stability.

3.2.4.4 Auxiliary board and force cable sealing

The force sensor flex cable is brought into the underside of the slide housing through an opening of the slide. This opening is sealed off with a pair of rubber cable seal plugs. The slide housing cable length should be carefully controlled since it affects the rolling action of the cable inside the track. Three wires are soldered to the end of the cable and to the Auxiliary board. The cable and the solder joints at the end of the cable should be carefully handled and secured to the slide housing with double-sided tape.

The Auxiliary board provides a convenient place for terminating sensor connectors and simplifies the cabling of the final assembly. The board is mounted to the slide housing by two screws. There is an opto-sensor on the board which detects motor shaft rotation. The force sensor signal is conditioned at the Auxiliary board before being converted by the A/D converter on the Main board.

3.2.4.5 Provision for cleaning

In other typically designed syringe pumps, a slot and a pair of rubber wipers are used to link the leadscrew to the plunger driver. This type of design has some disadvantages. A small object can easily fall into the slot and get trapped between the leadscrew and the clutch nut. The movement of the plunger might be blocked by this trapped object. Also, fluid can easily enter the slot and contaminate the leadscrew or possibly the electronic circuitry inside the pump. Cleaning a major spill is difficult.

The linkage of our pump between the track and the leadscrew is designed so that the leadscrew is almost inaccessible to the user. This design reduces the possibility for blockage of the track movement by a trapped object. The design of the leadscrew compartment also provides a better way for cleaning fluid spill and fluid entry into the pump. A door is provided for covering the leadscrew compartment. This door can be removed to clean the leadscrew compartment if there is a major spill.

3.3 ELECTRICAL SYSTEM

3.3.1 Introduction

The pump's electrical system resides on the Main board and the Auxiliary board. Most of the circuit is on the Main board. Refer to the system block diagram in Appendix B.1.

3.3.2 Main Board

The Main board consists of the following circuits: Power supply circuit, Watch-dog circuit, Micro-Controller, LED circuit, Input interface, Analog-to-Digital converter, Alarm circuit, Stepper motor driver, LCD & Backlight circuit, and the connectors for Keypad, LCD, Motor, Alarm, AC charger and the serial communication.

3.3.2.1 Power supply circuit

The requirements for the power supply circuit are: to convert the AC power input to a DC power so the pump can be operated regardless of the condition of the battery, to charge the battery regardless of the position of the power switch, and to switch the battery power whenever AC power input is interrupted. The power supply consists mainly of a rectifier, power switch, regulators, and the battery charging circuit.

* AC to DC conversion:

The AC power from the AC charger is fed to the Main board via the DIN connector. The AC voltage is converted to a rectified DC voltage (Vx) via a full-wave bridge rectifier CR1 and a 3300UF capacitor C32. A slo-blo fuse is inserted between the AC input and the rectifier for the over-current protection. The rectified DC voltage (Vx) (through the power switch J4B-1,2) provides the power for the LCD display backlight, and serves as the main power for the pre-regulated Voltage (Vm) via the regulator U8 (8.3V) and the diode D15. The voltage at Vx also feeds the power to the battery charging circuit.

* Battery charging circuit:

The Battery charging circuit will charge the battery at a rate of 1/10C (i.e., 150mA) when the battery power is low or depleted. The charging rate is automatically switched to a trickle charging rate as soon as the battery reaches the fully charged state (i.e, when the battery voltage is above approximately 8.5V). The charging circuit consists of regulator U11, comparator U9A and resistors R37, R38, R34 etc. Regulator U11 and resistor R37 (8.25 ohm) form a 145mA constant current source (i.e., 1.2V/8.25) for charging the battery if the battery voltage is less than a voltage set by the adjustment of VR1 (R32,VR1, and R33 form a voltage divider). This voltage is normally set to 8.5V. When the battery voltage exceeds the set voltage, pin 2 of the comparator (U9A) has a voltage higher than 2.5V at pin 3. The output of the comparator (pin 1) is switched to 0V, and the regulator U11 (combined with R38,R34) is then configured as a fixed voltage regulator to provide a trickle charging current to the battery. Capacitor C13 is to minimize the transient noise. Diode D17 and resistor R27 reduce the threshold voltage at pin 3 of the comparator to provide a latched condition to lock into the trickle changing mode after the set voltage is exceeded. The trickle charging mode will not be switched back to the normal charging mode unless the battery voltage drops to less than 6.8V, or the AC power input is turned OFF and then ON. Diode D16 prevents the battery from feeding the battery power back to the charging circuit if the AC power is absent. Diode D16 and resistor R37 also provide a sensing voltage for the transistor Q9 to indicate that charging current is flowing to the battery. If there is none or little current flowing through R37 and D16, the voltage between the base and the emitter of Q9 is so small that Q9 does not conduct. Hence, the green Charging LED would not light.

* Battery Detection:

There is a resistor R17 (750K ohm) connecting between pin 1 and 4 of the battery connector J4A. Both pin 1 and pin 4 of the battery pack connector are connected together to the positive terminal of the battery pack. If the battery pack connector is properly plugged into the connector J4A on the Main board, then R17 is shorted, and the normal charging current can be applied to the battery. If the connector of the battery pack is not properly plugged in, the pump can still be operated on AC power. However, the voltage drop at R17 helps the Micro-Controller detect the absence of the battery pack and to signal the low / depleted battery condition (LED & alarm).

* Power switch circuit:

Because the battery should always be charged regardless of the power switch position, the battery is always connected to the charging circuit. The charging circuit and the battery are directly connected to the AC input and will not be interrupted by the power switch. The power switch is a double-pole single-throw switch for providing two separate power pathways for the pre-regulated voltage (Vm) to operate the pump: one for the battery power and the other for the rectified power (Vx) from the AC input. Diodes D15 and D14 are used to isolate these two paths. The battery voltage can be monitored by the Micro-Controller via the Analog-To-Digital (A/D) converter (U6) and the voltage divider (R3,R4). The presence of AC power can be monitored by the Micro-Controller by detecting the voltage at Vx via the input multiplexer U4 and R11, D6, R13.

* Various DC Voltages (Vm, +5V, Vc, VA):

The regulator U8 (together with resistors R19,R18) regulates the rectified voltage Vx to 8.3V, and serves as the main source of the power for the pre-regulated voltage Vm via the diode D15. The voltage at Vm will be switched automatically to the battery voltage as soon as the output voltage at U8 is less than the battery voltage. This condition occurs when the AC power is interrupted, or the battery voltage has been over-charged (higher than 8.3V).

The rectified voltage Vx supplies the power to the LCD backlight via a power resistor R16. The backlight current is about 130mA when powered by Vx. The voltage drop at R16 is about 7.5V. The power resistor withstands heat better than a semiconductor. If there is no AC power, the backlight will not be lit unless the Micro-Controller turns on Q3 to supply current to the backlight from the regulated voltage +5V.

The pre-regulated voltage Vm provides the power to the rest of the circuits, i.e., the stepper motor, the alarm, and the regulated voltage +5V. The regulated voltage +5V is derived from Vm with a low drop-out voltage regulator U1. The majority of the IC's are powered by the +5V directly, i.e., LED latches (U2), Watch-dog circuit (U3), and the input multiplexer (U4). However, a de-coupling filter (R35,C30,C31) is inserted between +5V and the Micro-Controller. Another de-coupling filter (R9,C1,C2) is inserted between +5V and the LCD display (DP1). A switching transistor (Q4) provides a controlled voltage (VA) for the power to the Analog-To-Digital (A/D) converter and the sensors on the Auxiliary board via connector J5 (a 14 pin ribbon cable).

3.3.2.2 Watchdog circuit

An independent watchdog circuit is implemented to confirm that the Micro-Controller hardware is operating properly (i.e., not crashed). It is not the function of the watchdog to validate the software (i.e., to identify software bugs). If the Micro-Controller is crashed (i.e., not properly executing the software program), the watchdog signals alert and turns off the power to the motor.

The watchdog circuit is a simple R-C timing circuit consisting of R14,C10 and other supporting circuit (U3B, C9, R15, D8, Q6, U3A, Q5, LD7, D23, D4). Capacitor C9 blocks the DC signal allowing only the AC pulses to pass through. If the Micro-Controller fails to send a pulse to the watchdog circuit (via port pin P3.0) within a preset time interval (determined by R14 and C10), the voltage at C10 will be charged up and exceed the threshold voltage of the Schmitt-inverter U3A. The output at U3A becomes low thus turning on the SYS. MAL. LED (LD7) via transistor Q5. It also turns on the alarm via U3E, and disables the power to the motor via the diode D23 and an inverter at pin 1 of U10. This SYS. MAL. signal can be monitored from the outside of the pump via pin 7 of the DIN connector.

3.3.2.3 Micro-Controller

The brain of the pump is a Micro-Controller (DS5000-32 by Dallas Semiconductor). This 40-pin Micro-Controller (U5) consists of: a micro-processor (similar to Intel 8051), 32K-byte Non-volatile RAM (battery backup) which can be dynamically configured to different sizes for the Program ROM and/or the Data RAM, 32 parallel I/O ports, two 16-bit timers, and serial I/O ports. The usages and the definitions for these parallel I/O ports are described below and are also summarized in Appendix C.

Port 0 lines are pulled-up by 10K-ohm resistors. P0.0-P0.3 output the stepper motor waveform to the Driver (U10) to run the motor. P0.4 turns on /off the alarm. P0.5 and P0.6 are not used. P0.7 controls the power (VA) to the A/D converter and the sensors on the Auxiliary board via Q4.

Some lines of Port 1 have multiple usage. P1.0-P1.3 are used as input lines for the keypad scanning and for other input signals via the input multiplexer. P1.3 is also used to output a signal to the A/D converter. P1.4 controls the power for the stepper motor via an inverter (U10 pin 1) and an MOSFET transistor (U7). P1.5 and P1.6 output the control signals to the LCD display. P1.6 also controls the input multiplexer (U4). P1.7 outputs the clock signal for the LED latch/driver (U2).

Port 2 (P2) is used mainly as a slow data/control bus which supplies 8-bit data to the LCD display and the LED latch/driver (U2). P2.0-P2.3 output scanning signals for the keyboard. P2.4 and P2.5 are used to interact with the A/D converter (U6). P2.7 also controls the input multiplexer (U4).

Port 3 is used for miscellaneous controls. P3.0 outputs pulses to the watchdog circuit. P3.1 and P3.2 are reserved for the serial communication via the DIN connector. R20,R21,D26-D29 are used for the protection of the port lines against excessive voltage from the outside. P3.3 controls the READ/WRITE operation of the LCD display. P3.4 controls the Volume Limit LED. P3.5 turns ON/OFF the backlight when AC power is not present. P3.6 controls the loudness of the alarm. P3.7 outputs the Chip-Select signal for the A/D converter.

3.3.2.4 LED latches /Flasher

There are different LEDs to provide the visual signals for different kinds of alert conditions. The Micro-Controller stores the current status of the LEDs into an 8-bit latch (U2) via P2 port and P1.7 line. The Volume Limit LED (LD5) is directly controlled via P3.4. The

SYS. MAL LED (LD7) is directly controlled by the watchdog circuit. The Battery Charging LED (LD11) is controlled by the charging circuit. The blinking for some LEDs (Stop/Program, Deliver, and Battery-in-use) is implemented via a slow oscillator (U3B, R12, C11, D5, R10, Q7). D5 and R10 are added to the oscillator to reduce the "ON" blinking interval conserving the battery energy.

3.3.2.5 Input Multiplexer

Some input signals and sensors are detected by the Micro-Controller via a digital multiplexer (U4). Any of two banks of 4-input lines can be selected via Port P2.7. The output lines of the multiplexer (pin 4,7,9,12) are read by the Micro-Controller via P1.0 thru P1.3, if P1.6 is set to 0 (chip-enable for U4). When P2.7 is set to 1, the keypad column condition can be read. When P2.7 is set to 0, the motor shaft rotation sensor (pin 2), the presence of AC power (pin 5), and two other input signals (pin 11, 14) can be detected. The rotation sensor signal (from the Auxiliary board) is shaped by a schmitt inverter (U3C). The presence of AC power is detected via R11,R13, D6,D7 and pin 5 of RN1. If AC power is present, the rectified voltage Vx varies from 9V to 16V, the voltage at the junction of D6,D7,R13 is greater than 4.5V, the voltage at pin 5 of U4 is between 4.5V and 5V. If there is no AC input, pin 5 of U4 is about 0.6V. Thus the condition of the AC power can be detected by the Micro-Controller.

The keypad is configured as a matrix of 4 columns and 4 rows. The Micro-Controller sets up a 0V to only one of the rows sequentially via P2.0-P2.3 & D9-D12, and reads the condition of the corresponding column via pins 3,6,10,13 of U4 and P1.0-P1.3. If none of the keys of the scanned column is pressed, a logical '1' (5V) is sensed at each column line. On the other hand, a logical '0' (0.6V) is sensed for each depressed key of the scanned column. By scanning the column sequentially, the Micro-Controller can interpret the status of the keypad. Diodes D9-D12 are used to isolate the interference among P2.0-P2.3 lines when keys from different columns are depressed at the same time. Diodes D30-D45 are used to protect the port lines and U4 against any excessive static voltage.

3.3.2.6 Analog-to-Digital (A/D) converter

The converter U6 is a 4-channel Analog-to-Digital (A/D) Converter which converts the analog voltage of the selected channel to a digital reading. This reading can be retrieved by a series of pulses from the Micro-Controller (via pins 2,10,12,13 of U6). The digital section of the IC is powered by +5V. However, the reference voltage for the A/D (at pin 9) is powered by voltage VA which can be turned off by P0.7 via Q4 to conserve battery power. The assignments for the analog channels are:

Channel 1 (U6-3) : Force sensor
Channel 2 (U6-4) : Size sensor
Channel 3 (U6-5) : Position sensor
Channel 4 (U6-6) : Battery voltage

3.3.2.7 Alarm Circuit

The alarm circuit consists of an alarm (via connector J1), a switching transistor (Q1), the loudness control (Q2, R8), and some gating components (D3, D4, R7). The alarm supply voltage is the pre-regulated voltage Vm. The alarm is switched on/off by the control voltage at the gate of Q1. This control voltage is high if the Micro-Controller wants to turn on the alarm by setting P0.4 high, or if SYS. MAL. condition signal is low (i.e., System Malfunction occurs). The alarm can only be turned off if there is no SYS. MAL. signal. The loudness of the alarm is controlled by P3.6 via Q2 and R8. If P3.6 is high, Q2 is shorted and the alarm volume is loud. If P3.6 is low, then Q2 is turned off. Resistor R8 is in series with the alarm to make the alarm volume soft.

3.3.2.8 Stepper Motor and Controls

A 7.5 degree 4-phase unipolar stepper motor is used in the pump. Basically, the motor consists of a rotor with permanent magnetic poles, and a stator with 4 coils. The coils must be energized in a very specific sequence for the rotor to rotate properly. The waveforms needed to drive the coils of the motor are provided directly by the port lines of the Micro-Controller, i.e., P0.0-P0.3. U10 is a open-collector Darlington Driver and is used to convert the controlling waveform into the switching sequence to energize the motor coils. Pins 2-5 of the pull-up resistor pack RN2 provide the bias current for the Darlington drivers. Diodes D18-D22 are to protect port lines of the Micro-Controller from going negative due to the spike from the switching motor coils.

The motor supply voltage is the pre-regulated voltage Vm and is controlled by P1.4 (via U10 pin 1, U7 and R24) and the SYS. MAL. signal (via D23). A high current is supplied to the motor coils through U7 if U7 is turned on by P1.4. U7 can be turned off (if P1.4 is set to 0) to significantly reduce the motor current because of the insertion of R24.

The motor current control is very important for reducing the energy consumed by the motor to conserve the battery energy when running at low speeds, and to reduce the heat produced by the motor. The current reduction is made possible with the use of an uni-directional transmission system and a stepper motor. The pump's uni-directional transmission system consists of a leadscrew, a worm, and a worm gear. This system only allows the motor to deliver torque to drive the syringe, and prevents the reactional load (caused by driving the syringe) from generating enough torque to overcome the motor's holding torque thus preventing reverse rotation of the motor. Because of this unidirectional feature, when the motor is running at low speed, high current is only needed to advance the rotor to the next position. As soon as the rotor reaches and stops at the desired position (approximate 10ms), the current can be cut back to a lower level. This low current provides additional holding torque to the motor's residual holding torque and holds the rotor in the new position for the duration of the current step. Thus, the energy requirement for the motor during low speed operation can be significantly reduced. If a current meter is used to monitor the motor current, it can be observed that the current for the motor increases as the delivery rate increases. It reaches a maximum current within a speed range (B-D 60cc syringe, 80ml/hr through 200ml/hr, i.e., the motor pulse interval is less than 10ms). Beyond this range, the current decreases as the delivery rate increases. This decrease is realized because the motor is an inductive device and there is always a resistance to the current change in the motor coils. The current supplying the motor coils can not reach the maximum value (saturation) when they are switched on/off at high speed.

A low SYS. MAL. signal over-rides ,via diode D23, the control to the motor current by the P1.4 line and reduces the motor power to a low current mode. The motor does not have enough power to advance the rotor to the next position in the low current mode. Thus, the motor shaft would not turn as long as the SYS. MAL. signal remains low. It is very difficult for the motor to "run-away" due to a hardware failure. The reasons are:

* In order to turn the rotor of the motor, four sets of specific waveforms for four motor coils are required. These waveforms can not be generated if the Micro-Controller crashes.
* The watchdog will trigger a low SYS. MAL. signal to prevent the motor from running after the Micro-Controller crashes.
* The motor would not run properly if the motor driver U10 fails because the motor coil switching sequences would not be correct. The Micro-Controller will sense this problem by using the rotation detector and signal an alert.

3.3.2.9 LCD display / backlight

The LCD display requires an 8-bit data line (D0-D7), and 3 control signals (E,RS,and R/W). The data lines are supplied by P2.0-P2.7. The E (Enable) line is P1.5. R/W (Read/Write) line is P3.3 which is always low to write to the LCD. RS (Register Select) line is P1.6 which also controls the input multiplexer. The LCD display can be backlit by turning on the LED backlight (BL pins). The backlight is always turned ON when the AC power is present, and can be "on demand" turned ON for a short period of time when battery power is used. This requirement is accomplished by connecting the rectified voltage Vx to the LCD backlight via a current limiting power resistor R16. The Micro-Controller can turn on the backlight by supplying +5V through the transistor Q3 with a control signal form P3.5. R1 provides additional current limiting to the backlight. Diodes D1 and D2 are used to isolate the two different power sources to the backlight.

3.3.2.10 Interface Connectors

The Main board provides connectors for interfacing the different hardware components, i.e., Alarm(J1), Motor(J7), LCD display(J2), Auxiliary board(J5), Keypad(J3), battery & power switch (J4), AC charger and serial communication (J6). Both J4 and J6 are 8-pin connectors but J6 has a key at pin 2. J6 consists of a 3-pin connector (for the charger) and a 5-pin connector (for serial communication etc.). J8 consists of two 4-pin connectors for the power switch and the battery. Make sure that the polarity and orientation of the connectors are correctly installed after the pump is serviced. Otherwise, the Main board could be damaged. Also, the cables must be properly routed to prevent them from being pinched between the Main board, the Auxiliary board, the battery, the motor, the power switch, and the DIN connector.

3.3.3 Auxiliary Board

An Auxiliary board is mounted on the Slide housing S/A to provide a base for connecting the different sensors inside the pump, i.e., the force sensor form the plunger driver, the size potentiometer from the syringe clamp, the position potentiometer from the Track, and the motor shaft rotation sensor.

3.3.3.1 Rotation sensor

The rotation sensor is a reflective opto-sensor OP1 consisting of a photo-diode and a photo-transistor mounted on the Auxiliary board. The photo-diode emits light to the motor shaft coupler. The reflected light is sensed by a photo-transistor inside OP1. The shaft coupler has 4 sides. Two opposite sides are painted black. Thus, there are 4 transitions for each motor shaft rotation. The quality of the signal at the collector of the photo-transistor depends on the focal distance of the OP1 and the light intensity of the photo-diode. The seating height of the opto-sensor OP1 to the Auxiliary board is pre-calibrated for the best focused condition between OP1 and the shaft coupler. A single-turn trim pot R102 is used for adjusting the light intensity emitted by the photo-diode.

3.3.3.2 Size sensor

The size sensor is a single-turn potentiometer VR3 engaged to the syringe clamp via a rack and pinion arrangement. When the syringe clamp is lifted, the potentiometer shaft turns. Thus, for each syringe size, there is a corresponding angular position of the potentiometer shaft, and the syringe size is converted to the voltage at the potentiometer center tab. The engagement (timing) between the pinion on the potentiometer shaft and the molded gear rack on the syringe clamp must be properly adjusted so that, for all syringe sizes, the potentiometer center tab always stays within the electrical range of the potentiometer.

Capacitor C104 minimizes any high frequency transient noise picked up by the potentiometer. Due to linearity variations of the potentiometer, a calibration process uses the sizes of known syringes to establish a formula to convert the resistance value for unknown syringe sizes resulting in size recognition for these syringes.

3.3.3.3 Position sensor

The track's linear displacement is converted to a voltage via the position potentiometer. The spur gear on the potentiometer shaft engages with a cluster gear and then to a molded gear rack inside the track. The engagement (timing) between the spur gear and the gear rack must be properly adjusted so that the potentiometer center tab remains within the electrical range of the potentiometer when the track is at its maximum extended position or at the most inward position. Capacitor C103 minimizes any high frequency transient noise picked up by the potentiometer. Due to linearity variations of the potentiometer, a calibration process uses the most extended position and the most inward position to establish a formula to convert a resistance value to a position reading to check the track movement. This method is also used to monitor the remaining fluid volume inside the syringe. An alert signal will be given if the Micro-Controller detects no track movement.

3.3.3.4 Force sensor

A strain gauge sensor is attached to the plunger driver mounted on the track to sense the force required to push the plunger of a syringe during delivery. The signal generated at the gauge is transmitted to the Auxiliary board via a flat cable, and is conditioned by the amplifier circuit on the Auxiliary board. The amplifier consists of U101 and the associated resistors. The capacitors C101,C102, and C105 are used for limiting the bandwidth of the amplifier and reducing the high frequency transient noise. U101A is an inverted amplifier with an approximate gain of 14. R107 and R108 provide the bias voltage for the amplifier. The voltage difference between the gauge's center tab and the bias voltage, as well as the voltage changes generated by the applying force are amplified by U101A. It is very important to make sure that R107 and R108 are closely matched to prevent the difference in bias voltages from saturating the amplifier. The amplified signal at pin 1 of U101A is amplified again by another inverter U101B with a gain of 39. R109, R110 and VR2 are used to adjust the combined offset voltage from U101A and U101B. The adjustment brings the voltage at pin 7 of U101B to a lower voltage so that the amplifier U101B will not be saturated by the gauge signal when a very high force is applied to the gauge.

3.3.3.5 Controlled Voltage VA

The supply voltage for all the sensors and the amplifiers is voltage VA (a gated +5V), the same voltage for the reference voltage of the A/D converter. VA is turned off to conserve energy when the sensors are not active. The digital ground (pin 12 at J103) for the rotation sensor is separated from the analog ground (pin 14 at J103) for other sensors. They are joined together at the A/D converter. The unused connector at J014 is for future expansion.

3.3.4 Battery pack

The battery pack consists of 6 rechargeable Ni-Cad battery cells in series. Each battery cell is a SC size cell with 1.5AH capacity. A 4-pin connector is used to link the battery pack to the Main board. The negative terminal of the battery (black wire) is connected to pin 3. Two red wires are attached to the positive terminal of the battery pack. They are connected to pins 1 and 4. Upon plugging the connector into the Main board, the two red wires short-circuit the resistor R17 on the Main board to let the Micro-Controller know that the battery pack is properly connected. The battery is designed as a back-up power supply when AC power is interrupted. The pack is always in the charging mode as long as AC power is applied regardless of the power switch position. When the battery is not fully charged, the charging current is about 145mA. When the battery reaches full charge, the charging circuit automatically switches to the trickle charge mode (50mA).

Some specifications from the battery manufacturer deserve attention:

* The majority of the battery energy lies between 7.6V and 7.3V.
* The battery can supply more than 500 charge/discharge cycles (conservative number, 2000 cycles according to the chart) when used repeatedly.
* The shelf life of the battery: The capacity retention of the battery depends on the storage temperature. It will retain 50% capacity after 6 months of storage at 20 degree C. The charging acceptance of the battery is temporarily decreased after long-term storage, but returns to normal condition after 1-3 charge/discharge cycles.
* The battery cell is sealed and leakproof thus providing safety and maintenance-free service.

3.4 NOTES AND CAUTIONS FOR ASSEMBLING THE PUMP

3.4.1 Top Housing S/A (P/N 1-68-20A00-0-X) (Appendix A.2)

In order to assemble the Main board to the top housing, the keypad connector from the top housing must be plugged into the right-angle 9-pin connector of the Main board. Then the connector for the LCD display is engaged and the Main board is mounted onto the top housing, assuming that the LEDs on the Main board are properly aligned into the holes on the top housing. Three long spacers (brass & nylon) and three screws secure the Main board to the top housing.

The following inspections should be performed after assembling:

* The keypad connector should be "fully" engaged with the pin. (i.e., minimum exposure of the pin can be observed). The connector and pins can be inadvertently slightly disengaged when trying to engage the LCD connector to the pins on the Main board. If the keypad connector is not fully engaged, the pump could have intermittent keypad problems, or if totally disengaged due to mechanical shock the keypad would not function.
* Each of the three long spacers is made of a short brass spacer and a nylon spacer bonded with thread lock adhesive. The two parts should be tightly engaged and bonded because the combined length of the spacer affects the final assembly of the three major assemblies (i.e., Top, Slide, and Bottom). Also, the three spacers must be tightly threaded, with a tool, into the top housing screw studs. The threads of these spacers receive three flat head screws during the final assembly. If the engagement between the spacer and the Main board is loose before disengaging the flat head screw and the nylon spacer, the bottom housing can not be separated from the slide housing.

The only Top Housing S/A adjustment required is to set the trickle charge voltage. However, the Top Housing S/A must go through a calibration for monitoring the battery voltage if the Micro-Controller is replaced. (i.e., software update etc.) The adjustment and the calibration are discussed later in this manual (Tests and Calibration). Some earlier versions of the Top Housing S/A had a trim pot for adjusting the contrast of the display. It is no longer used with current production.

3.4.2 Slide Housing S/A (P/N 1-68-20A02-0-X) (Appendix A.4)

The Side Housing S/A is the most complex sub-assembly in the pump. Proper sequence must be followed to assure reliability and efficiency in assembling.

3.4.2.1 Assembling the Plunger Holder/Track S/A (P/N 1-68-20A04-0-X) (Appendix A.6)

To obtain mechanical stability adequate torque must be applied to tighten the reeds onto the plunger holder and the track.

The reeds on the plunger holder must be aligned (perpendicular) to the top surface of the plunger. Note the orientation of the nut plates. The hole of the plates should be biased downward.

Shims must be used to ensure symmetrical gaps between the plunger holder and the track. Note the orientation of the nut plate for holding the screw, the hole should be biased upward. The plunger holder should be free from any mechanical interference from the track.

3.4.2.2 Assembling the Slide Housing S/A (P/N 1-68-20A02-0-X)

3.4.2.2.1 Assembling the Syringe clamp etc. to the Slide S/A:

The torsion spring for the syringe clamp gear must not be over-tightened since the spring could be damaged permanently when the clamp is lifted up.

Follow the procedure to properly engage the size potentiometer gear with the syringe clamp so that the minimum and maximum positions of the clamp fall within the potentiometer's mechanical range. A final adjustment is needed (see Tests and Calibrations) to bring both positions within the potentiometer's electrical range.

The hardware (clamp, screws) for securing the potentiometer and the torsion spring must be tightened after the calibration. A torque seal must be applied to the screws to discourage tampering.

3.4.2.2.2 Assembling the Plunger Holder/ Track S/A to the Slide S/A:

EXTREME CAUTION should be exercised during the removal or installation of the Clutch Nuts and the clutch spring. Wear safety eye-glasses because the clutch spring could spring out and cause physical harm to the operator or someone near-by.

The tab at the end of the clutch nuts must be oriented correctly so that the nuts can be properly engaged into the track slot.

The length of the force gauge cable inside the track must be closely controlled to avoid any interference due to the rolling movement of the cable inside the track.

The bending and termination of the force gauge cable must be carefully handled because the cable copper trace can be broken very easily by bending it back and forth, especially at the end of the cable where the wires are soldered. Caution should be taken not to stress these soldering joints (i.e., wires soldered onto the end of the cable) during the removal of the Auxiliary board.

3.4.2.2.3 Assembling the Position Potentiometer to the Slide S/A:

The hex nut on the potentiometer must be tightened to prevent the potentiometer from turning with the Pot holder.

Make sure that proper timing is followed to engage the Position Potentiometer (pot) gear to the cluster gear (and the track) so that the potentiometer center tab stays within the electrical range at both extreme track positions.

Control the engagement tightness between the pot gear and the cluster gear by adjusting the slot on the pot holder to obtain smooth track movement and minimum backlash between the gears.

The screws for the Pot holder must be secured to avoid mechanical drifting of the pot holder when operating the track.

3.4.2.2.4 Assembling the motor mount to the Slide housing:

A special alignment tool must be used for aligning the motor mount bracket to the slide housing to minimize side loading between the worm and the motor shaft. As long as this motor mount bracket has not been disturbed, there is no need to re-align if the motor is removed.

3.4.2.2.5 Assembling the leadscrew etc. to the Slide S/A:

CAUTION must be taken to avoid causing burrs to the polished surfaces of the worm, and the leadscrew. Burrs cause a reduction of the overall output torque of the motor / transmission system.

Follow the procedure very carefully when assembling the leadscrew and bearings / bushings into the slide housing. Press the bearing inward to seat the leadscrew and bushing firmly into the housing. After E-clips are installed, press the leadscrew towards the motor to re-seat the washer and the bearing. Check the rotation of the leadscrew. Make sure little friction is detected. Also make sure that no damage is done to the teeth of the worm gear during installation or removal.

3.4.2.2.6 Assembling the Auxiliary board to the Slide S/A:

When soldering the wires connecting the force gauge cable, make sure that the force cable is properly secured by the double-sided tape and the end of the cable is not under stress. Also, note the polarity of the wires when they are soldered to the Auxiliary board. The Auxiliary board should have previously been properly checked and preliminarily adjusted.

3.4.2.2.7 Assembling the worm and the motor to the Slide S/A:

Make sure that a small amount of grease is applied inside the shaft coupler on the worm for reducing motor noise (generated by the motor shaft driver and the coupler) at certain speeds. Also, clean the excess grease on the shaft coupler to minimize contamination (on the markers of the coupler) which might prevent the rotation sensor from properly sensing the motor shaft rotation.

3.4.2.3 Adjustments and Calibrations:

The Slide Housing S/A needs both mechanical and electrical adjustments, as well as final calibrations for the sensors: (Refer to Tests and Calibrations for detailed procedures)

Mechanical adjustments involve setting the timing for both the size and position potentiometers.

Electrical adjustments involve the two trim pots on the Auxiliary board. The pot near the motor is used for adjusting the current for the photo-diode to obtain the best rotation signal. The other pot is used to adjust the voltage offset of the force sensor signal when no force is applied to the sensor.

Final calibrations are required for the force, the position, and the size sensors. All calibration information is stored inside the Micro-Controller. Thus, if the Slide Housing S/A is replaced, or the sensors are serviced, then all calibrations need to be performed or checked.

3.4.3 Bottom Housing S/A (P/N 1-68-20A01-0-X) (Appendix A.3)

The battery pack is secured by double-sided adhesive tape. Since the gap between top of the battery and the underside of the Main board is small, it is very important that the battery pack is pushed down towards the bottom housing as far as possible.

A tool should be used to tighten the ring nut for securing the DIN S/A to the bottom housing. Use an 8-pin strain relief to join the two connectors from the DIN S/A. Note the polarity.

Note the power switch orientation when it is installed into the bottom housing so that the legend on the switch is correctly positioned.

Note the orientation or the polarity of the two 4-pin connectors from the power switch and the battery when they are combined into an 8-pin connector with a strain relief. Use the tie-wrap to obtain a good cable routing.

3.4.4 System integration (Refer to Appendix A.1, P/N 1-72-20010-0-1)

The complete system is integrated together by: inserting the Slide Housing S/A into the Bottom Housing S/A, connecting all the cables to the Top Housing S/A, and securing the three sub-assemblies together with five (5) flat head screws. Since the space left inside the pump is tight, the following cautions should be exercised to assure reliable pump operation.

Carefully match the tongue and groove between the Slide Housing S/A and the Bottom Housing S/A when putting them together. If an unusual amount of force is needed, it is very likely that the tongue and groove are not lined up properly. Forcing them together could cause damage to the housing.

The cable tie-wrap should be used to assist cable routing and to avoid inserting the connectors into the wrong receptacles. It is very important to follow the factory cable routing so that the cables / wires are not caught in the wrong places. Noticeably, the wires from the battery pack and DIN connector could be pinched between the Main board and the DIN connector if the wires are not bundled together with the cable tie. The Flat ribbon cable between the Main board and the Auxiliary board could be pinched between the battery and the Main board if the cable is not bent in the correct direction. The battery cable could be trapped under the syringe clamp if it is not properly tied to other cables with the cable tie. Observe the original cable routing and cable tie placement before disassembling the cables. Do not force the sub-assemblies together since this is an indication that there might be some interference caused by the cables.

Through the bottom housing holes and the holes at the legs of the slide housing, three flat head screws are threaded into the long nylon spacers on the Main board of the Top Housing S/A. If the spacers are not tightly threaded into the Main board, they can become loose before the flat head screws can be removed. If this happens, the nylon spacers and the flat head screws prevent the separation of the slide housing and the bottom housing. In this case, continue turning the flat head screws until the Top Housing S/A is separated. Then, using a plier hold the spacer to assist the removal of the flat head screw from the spacer. Do not force the separation between the Slide Housing S/A and the Bottom Housing S/A, because the legs of the slide housing can be broken off. This breakage is very expensive, because the Slide Housing S/A must be completely disassembled in order to replace the slide housing.

If the bottom housing DIN receptacle is loose due to the repeated insertion of the charger plug, the ring nut of the DIN receptacle should be tightened with a tool. Apply some thread lock adhesive. Do not over-tighten the DIN connector ring nut (due to the use of the tool). Check by connecting the locking nut on the charger plug into the DIN receptacle. Screw the connector into its full length.

3.5 SOFTWARE SYSTEM (2001)

(Refer to Appendix D.1 for the software flow diagrams)

After the power is turned on, the Micro-Controller performs a system initialization and scans the keypad for any special access request. If no such special access is requested, the Micro-Controller operates normally. There are three special accesses available by pressing and holding the appropriate keys when turning the power switch on:

* OFF-LINE Programming: Select & Enter keys
* SYSTEM CALIBRATIONS: Stop/Program & Select keys
* BATTERY CHARGING TIMER: Stop/Program & Deliver keys

The operation of these special accesses is discussed later.

3.5.1 Normal Operation

The Micro-Controller starts normal operation by signing on the software version number. It then checks the non-volatile data areas to see: if the options are properly selected in offline programming, and if the integrity of the calibration data is valid. If any error is detected, the corresponding error message is displayed on the LCD and the system malfunction alarm is triggered. This type of error indicates that the non-volatile memory inside the Micro-Controller is questionable. If everything is OK, then, the option code is displayed and decoded on the LCD display. The battery voltage is measured while supplying current into two motor coils. This battery voltage is displayed on the LCD. If the battery voltage is less than 7.3V, the pump LCD display will state "PLUG IN AC". AC power must be supplied in order to continue operation. Then, a SYSTEM SELFTEST is performed. If an error is detected, "SYSTEM ERROR" is indicated on the LCD display and the SYSTEM MALFUNCTION alert is triggered. If the SYSTEM TEST is passed, the Micro-Controller performs another system initialization and proceeds to the routine SELMD (select mode) to determine which infusion mode is to be used. The Micro-Controller then jumps to the respective routine for the selected infusion mode.

The structure for each infusion mode is very similar. There is a PGM loop for handling the programming activity in the Stop/Program mode, and a RUN routine to go to when the delivery command is activated. The RUN routine controls the running of the motor at the programmed speed until the delivery is completed or interrupted. Afterwards, the Micro-Controller returns to the PGM loop for the Stop/Program activities.

3.5.1.1 System Selftest (SELFTS)

The SYSTEM SELFTEST checks the proper functions of: the registers inside the microprocessor, the different banks of the working registers, the Random-Access-Memory (RAM), and the Non-volatile program memory area. Both timers inside the microprocessor are checked for proper counting function and interrupting mechanism. The Micro-Controller turns on/off the LEDs and the audio alarm for the user to verify if they are functioning properly. The SYSTEM MALFUNCTION LED and audio alarm are triggered by the Micro-Controller by not sending pulses to the watchdog circuit.

3.5.1.2 Selection of the infusion mode (SELMD)

If only one infusion mode is pre-selected during off-line programming, then, the LCD displays the pre-selected mode, and the Micro-Controller continues to the Stop/Program loop for the selected infusion mode. However, if multiple choices are selected during off-line programming, the Micro-Controller requests the user to choose one of the pre-selected modes as the current infusion mode. The Micro-Controller continues to the Stop/Program loop of the selected infusion mode.

3.5.2 Stop/Program loop (Continuous Mode): (MODE0, PGM0LP)

After entering the Continuous Mode (MODE0), the Micro-Controller initializes the LCD, and displays the current occlusion force selection next to the syringe size. It asks for the selection of the syringe manufacturer if it is not pre-programmed by the off-line option. The confirmation for the syringe size is then requested. The Volume Limit (VL) and KVO rate will be asked if they are enabled during the off-line programming. KVO will not be asked for if VL is not selected (i.e., VL is set to 0). Then the continuous infusion rate is asked. If an invalid rate is entered, two audio beeps are given and the Micro-Controller suggests a new rate. The user can accept the suggested rate or re-enter another valid rate. All settings are now valid and the pump enters the PGM0LP loop ready to deliver.

3.5.2.1 PGM0LP

During the PGM0LP loop, the Micro-Controller continuously checks the syringe size, monitors the AC power and the battery voltage, and scans the keypad. If it detects the removal of the syringe, a confirmation of the syringe size is requested. If the syringe size is changed, then the volume limit / KVO and the infusion rate will be asked. If the status of AC power or battery is changed, the proper alert / LED will be indicated. If a valid key is pressed, the corresponding routine is called to service the key. The Micro-Controller returns to PGM0LP when the service is completed. The following routines handle the keys for Continuous Mode (MODE 0):

* SEL0 (select key): This routine allows the user to modify the Volume Limit / KVO rate and the continuous infusion rate sequentially.

* RT30,RT20,RT10,RT00 (rate keys): These routines allow the user to modify only the continuous infusion rate.

* DEL0 (deliver key): This routine uses the routine CALTB to prepare all the parameters needed to run the motor based on the programmed settings, and calls the RUN routine to run the motor to deliver the fluid.

The following routines are the same for different infusion modes:

* TOT0 (reset total key): This routine resets the total delivered.

* PRM0 (prime key): This routine allows the user to drive the syringe plunger at the maximum rate to purge the air from the tubing set and to remove mechanical slack from the driver/syringe hook-up. The primed volume is not added to the total delivered volume. The prime key must be continuously pressed to prime. The primed volume displayed on the LCD will not be reset until another key is pressed. If the prime key has been held down for 15 seconds, an alarm will be signaled. This provides an additional warning against the danger caused by a collapsed prime key.

* FNC01 (function key): This routine allows the user to setup a standby timer and put the pump in a standby mode. The Function key is used for a different purpose for the Intermittent Modes (Modes 2A,2M).

* SLOOP (side loop, stop & enter keys): This routine provides selections for the different occlusion force level. The new selection will remain in effect until another selection is made.

3.5.3 Stop/Program loop (Volume / Time Mode): (MODE1, PGM1LP)

After entering the Volume/Time Mode (MODE1), the Micro-Controller initializes the LCD, and displays the current occlusion force selection next to the syringe size. It requests a selection for syringe manufacturer if it is not pre-programmed by the off-line option. The confirmation for the syringe size is then requested. The KVO rate will be asked if it is enabled by the off-line option. The dose volume (DV) and the delivery time (DT) are asked. If the dose volume is greater than the maximum volume for the selected syringe, warning beeps are given and the maximum volume is suggested. If the resulting infusion rate (DV/DT) is invalid, two audio beeps are given and the Micro-Controller suggests a new delivery time (DT) based on the given dose volume (DV). The user can enter any other valid number. All settings are now valid, and the Micro-Controller calculates and displays the equivalent infusion rate and then enters into the PGM1LP loop ready for delivery.

3.5.3.1 PGM1LP

During the PGM1LP loop, the Micro-Controller continuously checks syringe size, monitors AC power, battery voltage, and scans the keypad. If it detects the removal of the syringe, a confirmation of the syringe size is requested. If the syringe size is changed, then the dose volume and the delivery time will be asked. If the status of AC power or battery is changed, the proper alert / LED will be indicated. If a valid key is pressed, the corresponding routine is called to service the key. The Micro-Controller returns to PGM1LP when the service is completed. The following routines handle the keys for Volume/Time Mode (MODE 1):

* SEL1 (select key): This routine allows the user to modify the KVO rate, the dose volume, and the delivery time sequentially.

* RT31,RT21,RT11,RT01 (rate keys): These routines allow the user to modify the dose volume and the delivery time directly.

* DEL1 (deliver key): This routine uses the dose volume (DV) as the volume limit (VL). The Volume Limit is enabled and the rest of the operations are identical to DELO.

3.5.4 Stop/Program loop (Intermittent Modes): (MODE2A,MODE2M)

There is little difference between Mode 2A (Intermittent, Automatic) and Mode 2M (Intermittent Manual) except that at the end of the Time-Between period, Mode 2A automatically continues with a new dose infusion, while Mode 2M only signals an alert and the new dose can only be activated manually by pressing the deliver key. Except for some slight difference during the execution of the routine DEL2, the software routines for these two modes are identical .

After entering either of the Intermittent modes, the Micro-Controller initializes the LCD ("A" or "M" is added to the display for identifying the infusion mode), and displays the current occlusion force selection next to the syringe size. It requests a selection for syringe manufacturer if it is not pre-programmed by the off-line option. The confirmation for the syringe size is then requested. The Volume Limit (VL) and KVO rate will be asked if they are enabled by the off-line option. KVO will not be asked if VL is not selected (i.e., VL is set to 0). The dose volume (DV) and the delivery time (DT) are then asked. If the dose volume is greater than the maximum volume of the selected syringe, warning beeps are given and the maximum volume is suggested. If the resulting infusion rate (DV/DT) is invalid, two audio beeps are given and the Micro-Controller suggests a new delivery time based on the given dose volume. The user can enter any other valid number. Then, the Time-Between (TB) is asked. Time-Between must be larger than the delivery time (DT), or error beeps would be signaled. All settings are now valid, and the Micro-Controller calculates and displays the equivalent infusion rate, and enters into the PGM2LP loop ready for delivery.

3.5.4.1 PGM2LP

During the PGM2LP loop, the Micro-Controller continuously checks syringe size, monitors AC power, battery voltage, and scans the keypad. If it detects the removal of the syringe, a confirmation of the syringe size is requested. If the syringe size is changed, then the dose volume, the delivery time, and the time-between will be asked. If the status of AC power or battery is changed, a proper alert / LED will be indicated. If a valid key is pressed, the corresponding routine is called to service the key. The Micro-Controller returns to PGM2LP when the service is completed. The following routines handle the keys for the Intermittent Modes (MODE 2A, 2M):

* SEL2 (select key): This routine allows the user to modify the Volume Limit, the KVO rate, the dose volume, the delivery time , and the time-between sequentially.

* RT32,RT22,RT12,RT02 (rate keys): These routines allow the user to modify the dose volume, the delivery time, and the time-between directly.

* FNC23 (function key in mode 2A,2M): This function key is used to reset the working time-between timer RTBW (indicating the time left until the next dose delivery) to 0, so that the operator can start the next dose delivery immediately.

* DEL2 (deliver key): This routine calls CALTB to prepare parameters for the dose delivery as in the Volume/Time mode. This routine also uses a working timer RTBW to control the standby timing after the dose delivery is completed. If a KVO rate is programmed, the pump continues the delivery at the KVO rate during the standby mode. The green deliver LED blinks during the KVO delivery. However, if the KVO rate is set to 0, the pump stops the delivery during the standby period and the deliver LED will be turned off. When the working timer RTBW is up (i.e., time for the next dose), the Micro-Controller starts the next dose delivery for Mode 2A and initiates a new Time-Between cycle. However, for Mode 2M, the Micro-Controller returns to stop/program mode at the end of the standby period. The slow beeping alarm signals the user that the end of the cycle has been reached.

3.5.5 CALTB routine:

CALTB is responsible for calculating all the parameters for controlling the running of the motor. It uses tables containing the characteristics of the syringe in use, to derive the following parameters:

* VINC (volume increment per motor step),
* T (time interval between pulses),
* EMPCNT (syringe empty position),
* NECNT (Near empty position),
* TKVO (time between pulse for KVO), and
* OCCNUM (occlusion force).

Armed with these parameters, the Micro-Controller knows how fast to run the motor, how to update the total volume and running volume, when to signal a near empty alert, when to stop the motor to signal an alert for syringe empty, and when to interrupt the delivery to signal an occlusion alert. Although the resolution of the volume displayed on the LCD is only to 0.01ml, the resolution of VINC is 0.001ml / (256 * 256). These digits (after 0.01ml) are not revealed (truncated) on the LCD display.

3.5.6 RUN routine:

The RUN routine uses all the parameters generated by the CALTB routine to control the running of the motor. Upon entering this routine, the LEDs, internal flags and counters are initialized. The stepper motor waveform is set up and the timer for controlling the motor speed is loaded with the contents in parameter T and then activated. When the timer count is up, a new waveform is setup and the timer is re-loaded. This process is repeated for each motor step. During each motor step, a pulse is sent to the watchdog circuit to prevent the SYS. MAL. signal from being activated, and the following routines are called:

- UPVOL: This routine updates total volume and running volume on the LCD display. The running volume is compared with the volume limit or the dose volume. In Mode 2A, 2M (intermittent mode), another running volume counter is used to compare with the dose volume for each time-between interval. If the volume limit or the dose volume is reached, the motor is stopped or switched to a KVO delivery rate.

- SERKEY: This routine scans the keypad. The keys recognized during delivery are: Stop/program, alarm, backlight, and deliver keys. If the stop/program key is pressed, the motor is stopped and the RUN routine is terminated. The alarm key silences the near empty alarm, and the backlight key or any other key turns on the LCD display backlight temporarily when the pump is on battery power.

- RCKSYR: This routine monitors the syringe size to determine if the syringe is properly seated during the delivery. If the syringe size reading has been significantly changed, an alert signal is triggered and the delivery is interrupted.

- CKOCC: This routine monitors the force gauge reading to detect the force encountered at the syringe plunger during the delivery. If the reading exceeds the parameter OCCNUM, (the occlusion threshold for the syringe generated by CALTB), the delivery is interrupted and the Occlusion alert is signaled.

- CKPOS: This routine monitors the position of the track to assure that the pump is really advancing the track. "Check Clutch" alert is given if the track does not move at the expected speed.

- RCOND: This routine reads the condition of some external sensors for further analysis such as AC power and rotation sensor.

- CKAC: This routine updates the Battery-in-use LED based on the condition of AC power as determined by RDCOND.

- CKROT: This routine analyzes the rotation sensor signal determined by RDCOND to see if the motor is running as expected. Note that there are four transitions per motor shaft revolution. Thus, if the count in the transition counter does not fall within the expected range after the motor has advanced the pre-determined number of steps, then the "SYSTEM ERROR U" alert is signaled for under-delivery and "SYSTEM ERROR O" for over-delivery.

* ROUTR: This routine performs all the necessary housekeeping routines such as updating the LEDs, the alarm, the backlight, the watchdog circuit, monitoring the battery voltage as well as the syringe size, and scanning the keypad. This routine is performed approximately every 0.06 seconds.

3.5.7 Resume/Restart after interruption

It should be noted that the pump recognizes two distinctive types of delivery when the deliver key is pressed: the Restarted delivery, and the Resumed delivery. The Restarted delivery re-initializes all counters and flags so that a fresh new delivery is restarted. The Resumed delivery assumes that the current delivery is to resume the previously interrupted delivery (probably due to occlusion, syringe pops out, or the stop/program key). In this case, the RUN routine does NOT initialize all the counters and flags. This situation is noticeable in the intermittent delivery mode because of the running volume and the time-between delivery timer. The running volume is reset to zero and the running time-between timer (RTBW) is reloaded with the time-between time (TB) for a Restarted delivery. For the Restart delivery, the dose delivery starts immediately after the delivery key is pressed. For the Resumed delivery, the time left in timer RTBW must expire before the dose delivery can be given again. Normally, the delivery after an interruption is considered a Resumed delivery. However, there are some conditions which imply that the next delivery should be a Restarted one. For example: the previous infusion is completed because the volume limit is reached, or the syringe has been emptied. The situations explained below are also considered Restarted deliveries: priming a syringe, changing syringe size, and changing Dose volume, Delivery time, or Time-between. For more specific details, please refer to the operator's manual.

3.5.8 Additional detailed discussions:

3.5.8.1 Motor Power control

In order to conserve battery energy and prevent overheating the stepper motor, a subroutine CKTO is called repetitively during each motor step to check if the motor current can be cut back. High current must be applied to the motor for a sufficient time period to assure that the stepper motor has advanced to the new position. After that period, the motor current can be cut back to a lower level for holding the motor at the new position. The length of this timing interval varies with the motor type. The pump allows approximately 10ms before switching the motor to a low power setting. By switching the motor to the low power mode, battery power can be greatly conserved. In other words, if the motor pulse interval (i.e., T as calculated in CALTB) is greater than 10ms (i.e., 100 steps per second), high power is applied to the motor for the first 10ms and low power is used for the rest of the motor pulse interval. No energy saving can be realized if the motor is running faster than 100 pulses per second.

3.5.8.2 Occlusion detection

During system calibration, the A/D converter readings for 0LB and 16LB are stored in the Micro-Controller. There is an occlusion force table, in the program area of the Micro-Controller, which stores the occlusion force (in LBs) for any syringe manufacturer and size. During the CALTB routine, this force is converted to a corresponding A/D converter reading from the interpolation calculation with the A/D readings of 0LB and 16LB. This calculated number is stored in OCCNUM. The amplified force sensor voltage for the applied force is converted to a digital reading by the A/D converter. This reading is compared with OCCNUM by the routine CKOCC during the delivery. If the A/D reading is higher, the occlusion alert is triggered. However, if the A/D reading exceeds OCCNUM within a small window before the syringe empty point, then it is considered an empty syringe condition. An empty syringe alarm is indicated instead of the occlusion alarm. This method is employed to compensate for the non-linearity and tolerance of the size potentiometer.

3.5.8.3 Rotation detection

There are four transitions and 48 motor steps per motor shaft revolution. Thus, in theory, 72 transitions (4*18) should be detected for every 18 motor revolutions (or 864 steps). Due to the rotation sensor resolution, the Micro-Controller expects to see the transition counts between 69 and 75 every time the motor advances 864 steps. Otherwise, the alarm "SYSTEM ERROR U" for under-delivery or "SYSTEM ERROR O" for over-delivery will be signaled.

3.5.8.4 Size sensing

During system calibration, the corresponding A/D readings of the size potentiometer for the known syringe sizes are remembered by the Micro-Controller and stored in non-volatile memory. There is a size table inside the program area of the Micro-Controller storing a number (proportional to the outside diameter) for each specific syringe manufacturer and size. During the syringe size confirmation, the Micro-Controller takes the size reading of the unknown syringe from the A/D converter and tries to determine the syringe size by searching the size table for the specified syringe manufacturer. If the size reading of the unknown syringe falls within +/- 0.045" (except for 1cc syringes whose tolerance is +/-0.030") of a number in the size table, the size of the unknown syringe will be recognized. If a match can not be found, the "invalid size" alert is given. After a successful recognition, the current size A/D reading is stored in a variable SIZENM which is used for comparison during syringe size monitoring. If the A/D reading of the size sensor deviates significantly from SIZENM, the Micro-Controller will indicate that the current syringe has been removed or disturbed. If this condition is detected during delivery, the "Syringe Pops Out" alarm is given. If detected in the stop/program mode, the "Load syringe / press enter" message is given to request the user to again confirm the syringe size.

3.5.8.5 Position sensing

During system calibration, the A/D converter readings for position 0 (most inward) and position 99 (most outward) are stored in the non-volatile memory of the Micro-Controller. The distance between the two positions is 4.836 inches. From the two readings, the Micro-Controller can calculate how many motor steps are required to produce a change in the A/D reading of the position sensor. (STEPN=4.836*20*44*48/(POS99-POS0)). At any time, the current track position can be monitored by reading the A/D converter for the position potentiometer reading. The Micro-Controller assumes, after advancing 2*STEPN motor steps, that the difference in the A/D readings for the two different positions should be 2. However, due to the potentiometer non-linearity, and the gearing system backlash, the reading differences can be from 1 to 4. The "Check Clutch" alarm is given if there is no change or too large a change when the motor advances the pre-determined number of steps. Thus, if the track fails to drive the syringe plunger due to a broken gearing system, broken clutch, or if the track is manually moved, the condition is detected by the position sensor.

The Position sensor is also used to signal the empty syringe alarm. There is a table (EMPTB) ,inside the Micro-Controller program area, which stores the track position for each syringe manufacturer and size when the syringe is empty. During the routine CALTB calculation, the syringe empty position is converted to a corresponding A/D reading (stored in EMPCNT) by interpolating the A/D readings of position 0 and 4.836. If the current position sensor reading is less than EMPCNT, the alarm for an empty syringe is given. This empty syringe alarm is also indicated if an occlusion condition is detected while the current position is between 0.080 inches and the theoretical empty position. This approach compensates for the non-linearity and the position sensing system variation.

3.5.8.6 Delivery accuracy

As described above, the array of sensors are used mainly to confirm proper pump behavior during delivery. The absolute delivery accuracy depends on three factors: the system clock, the accuracy of the leadscrew, and the correct software. All these factors do not need calibration and do not wear with time and usage. A rigorous validation process before the software release, and the program integrity test during the system selftest at power-up eliminate error due to the software program. The error in the system clock is negligible. The majority of the error is attributed to the leadscrew tolerance. This tolerance is less than 0.4%.

3.5.9 Offline Programming

The User can enter the Offline programming mode by pressing and holding both the stop/program and the deliver keys when turning on the pump. When the keys are released, "1234" must be entered to access the offline mode. Off-line programming allows the user to customize his/her pump to better fit the needs of the user. The features to be customized by the user are:

* Customizing the selections of the infusion modes:
  Use the select key to remove and the enter key to add the displayed infusion mode from the selection list. If only one mode is in the list, then, no mode selection is asked during the normal operation (refer to SELMD).

* Maximum infusion rate:
  A two-digit (XX) number can be entered to establish a maximum allowable infusion rate (XX ml/hr). This maximum rate is applicable only in the Continuous Mode. If XX is a non-zero number, the pump will not accept an infusion rate higher than XX ml/hr.
  This option can also be used to change the delivery rate resolution for larger size syringes (larger than 6cc). If XX is non-zero, the infusion rate resolution for larger size syringes will have an increment of 0.01ml/hr.
  However, if a zero limit (i.e.,XX=00) is entered, there is no such additional limit on the infusion rate. The highest programmable infusion rate is limited by the syringe manufacturer and size. The infusion rate resolution for larger syringes is 0.1 ml/hr. The resolution for small size syringes (1,3,5,6cc) remains 0.01ml/hr.

* Option code:
  The user calculates the option code to customize the following features for his applications: Volume limit, KVO, Pre-programmed syringe manufacturer, Temporary alarm off time, Alarm Loudness, and Alarm type. See appendix E for more detailed descriptions.

The Micro-Controller stores the offline programmed parameters and the associated checksum into a non-volatile memory area. These parameters are checked and used during normal pump operation. The features not selected during offline programming never appear during normal operation and can significantly simplify programming steps.

3.5.10 Software routine CALMD for system calibrations:

Please refer to section 4.4 (Tests and Calibration) for further details.

3.5.11 Battery Charging Timer

By pressing both the stop/program and deliver keys when turning on the pump, a battery charging timer routine CHARGE is entered. This routine will update every minute the charging time and the battery voltage every minute. The charging timer is incremented when AC power is detected. If AC power is not detected, the timer is decremented.

3.6 SOFTWARE SYSTEM (2010)

(Refer to Appendix D.2 for the software flow diagrams)

The major differences between the software for 2010 and 2001 are:
-Different infusion modes (different user interface)
 * Addition for 2010:
    Body-weight (mg/kg/hr,mg/kg/min,mcg/kg/hr,mcg/kg/min), MG/HR
 * Deletion for 2010:
    Intermittent Automatic, Intermittent Manual
-Added features for 2010:
 * Infusion rate can be modified without stopping the pump,
 * Bolus delivery,
 * Decimal point position for the delivery rate (also concentration, weight) can be adjusted,
 * The previous settings are remembered even after the power is turned off,
 * MG to ML conversion
-Deleted features for 2010:
 * Volume Limit and KVO are not available for 2010

The software structure for 2010 is similar to 2001. Additional modules are added to support the new infusion modes to convert the programmed infusion rate from mg/kg/min to ml/hr. Some software modules for 2001 are modified to support the new requirements (e.g., rate modification during delivery, bolus delivery, etc.).

The power-on sequence is identical to 2001. Three special modules can be accessed by pressing and holding the appropriate keys when turning the power switch on:

* OFF-LINE Programming: Select & Enter keys
* SYSTEM CALIBRATIONS: Stop/Program & Select keys
* BATTERY CHARGING TIMER: Stop/Program & Deliver keys

The operations of SYSTEM CALIBRATIONS and BATTERY CHARGING TIMER are identical to those in the 2001 (Refer to Sections 3.5.10 and 3.5.11).

3.6.1 Normal Operation (2010)

If no special access is requested, the Micro-Controller proceeds to Normal Operation. The first part of the normal operation (i.e., sign-on, checking non-volatile memory, displaying options, checking battery, System Selftest) is identical between the 2010 and 2001. The integrity of the previous settings is verified. "Invalid Settings" message is displayed if the settings are questionable. Then, the previous infusion mode is displayed. The user can confirm this infusion mode or slect a new mode. If the infusion mode is not changed, then the previous settings are displayed. The user can press the enter key to confirm the previous settings to prepare the pump ready for infusion. Otherwise, the user must reprogram the new pump settings by following the instructions on the LCD display.

The two new infusion modes, i.e., Body-weight and MG/HR, share the same software modules. The body weight is automatically set to 1.00 kg for MG/HR and ML/HR modes. The concentration is set to 1.00 mg/ml for ML/HR mode. The software modules for Volume/Time mode are identical to those in the 2001. All these infusion modes use similar software structure. There is a PGM loop for handling the programming activity in the Stop/Program mode, and a RUN routine to go to when the delivery command is activated. The RUN routine controls the running of the motor at the programmed speed until the delivery is completed or interrupted. Afterwards, the Micro-Controller returns to the PGM loop for the Stop/Program activities.

3.6.2 Stop/Program loop (MODE0,MODE1,MODE2; PGM0LP: Body-weight, MG/HR, ML/HR)

The Micro-Controller initializes the LCD, and displays the current occlusion force selection next to the syringe size. It asks for the selection of the syringe manufacturer if it is not pre-programmed by the off-line option. The confirmation for the syringe size is then requested. Concentration, Weight, Bolus, and Infusion rate must be confirmed or entered. If an invalid rate is entered, two audio beeps are given and the Micro-Controller suggests a new rate. The user can accept the suggested rate or re-enter another valid rate. The decimal point "." key can be used to change the decimal point position. If there is no acceptable infusion rate for the selected syringe size, concentration, and weight, the Micro-Controller will request the user to confirm the syringe size. Ater a valid infusion rate is entered, all settings are now valid and the pump enters the PGM0LP loop ready to deliver. The user can use the "enter" key to ask the Micro-Controller to display the equivalent rate in ML/HR and total volume in ML.

3.6.2.1 PGM0LP (2010)

During the PGM0LP loop, the Micro-Controller continuously checks the syringe size, monitors the AC power and the battery voltage, and scans the keypad. If the status of the AC power or the battery is changed, the proper alert / LED will be indicated. If a syringe removal is detected, a confirmation of the syringe size is requested. If the syringe size is changed, then the concentration, weight, bolus, and infusion rate must be reconfirmed. If the concentration is changed, the previous bolus and infusion rate become invalid (are reset to 0). The user must enter new numbers. If a valid key is pressed, the corresponding routine is called to service the key. The Micro-Controller returns to PGM0LP when the service is completed. The service routines for handling the keypad are:

* SELO (select key): This routine allows the user to modify the concentration, weight, bolus, and infusion rate sequentially.

* RT30,RT20,RT10,RT00 (rate keys): These routines allow the user to directly modify the infusion rate.

* DELO (deliver key): This routine converts the programmed infusion rate into ML/HR and calculates the total bolus (bolus x weight) to be delivered. The routine CALTB (similar to 2001) is called to prepare all the parameters needed to run the motor based on the converted rate and the other programmed settings. The RUN routine is called to run the motor to deliver the fluid. The routine also provides the necessary controls for supporting the two special features in the 2010: changing infusion rate and viewing the equivalent ML/HR (or ML) during delivery.

* ENTO (enter key): This routine allows the user to view the programmed rate in ML/HR and the total volume in ML. This key is inactive for the ML/HR mode.

* FNC01 (protocol/. key): When the pump is in the "Ready to Deliver" state, this key serves as protocol key and calls the FNC01 routine to change the rate mode (e.g., mg/kg/hr or mcg/kg/min in Body-weight mode) and the bolus feature. When the pump is not ready to deliver (i.e., the setting is being modified), this key serves as the decimal point key (".") and can be used to change the decimal point position of the setting being modified.

* BOLO (bolus key): This routine allows the user to change the bolus amount directly.

The following routines are the same for different infusion modes:

* TOTO (reset total key): This routine resets the total delivered.

* PRMO (prime key): This routine allows the user to drive the syringe plunger at the maximum rate to purge the air from the tubing set and to remove mechanical slack from the driver/syringe hook-up. The primed volume is not added to the total delivered volume. The prime key must be continuously pressed to prime. The primed volume displayed on the LCD will not be reset until another key is pressed. If the prime key has been held down for 15 seconds, an alarm will be signaled. This provides an additional warning against the danger caused by a collapsed prime key.

* SLOOP (side loop, stop & enter keys): This routine is used to set-up a stand-by timer or to select a different occlusion force level. The new occlusion level remains in effect until another selection is made.

3.6.3 Stop/Program loop (Volume / Time Mode): (XMODE1, XGM1LP)

This routine is identical to the routine for Volume/Time in the 2001. Refer to Section 3.5.3 for further details.

3.6.4 CALTB routine (2010):

CALTB is responsible for calculating all the parameters for controlling the motor. It uses tables containing the characteristics of the syringe in use, to derive the following parameters: (This routine is basically the same as CALTB in the 2001 with some minor modifications.)

* VINC (volume increment per motor step),
* T (time interval between pulses),
* EMPCNT (syringe empty position),
* NECNT (Near empty position),
* OCCNUM (occlusion force).

Volume Limit (VL) and KVO are not available in 2010. Thus, the calculation for TKVO is not needed. The calculation for NECNT is based on time (10 minutes) for the Body-weight, MG/HR, and ML/HR modes due to the absence of a Volume Limit. However, in the Volume/Time mode, the physical near empty position is used for NECNT.

The resolution of VINC is 0.001ml/(256 x 256). This number is converted to MGINC in the Body-weight, MG/HR, ML/HR modes. MGINC is represented as XXYY.ZZZZZZ x .0001mg. XXYY are BCD digits. ZZZZZZ are 3-byte binary in .0001/(256 x 256 x 256) mg.

3.6.5 RUN routine: (2010)

This routine is basically the same as the RUN routine in the 2001. However, the following routines are modified to support the additional features in the 2010 (i.e., bolus delivery, changing infusion rate and viewing equivalent ML/HR & ML during delivery):

* SERKEY: This routine scans the keypad. The keys recognized during delivery are: Stop/program, alarm, select, enter, bolus & prime keys, and rate keys. If the stop/program key is pressed, the motor is stopped and the RUN routine is terminated. The alarm key silences the near empty alarm. Select key simplifies the contents shown on the LCD display. The enter key lets the user examine the equivalent infusion rate in ML/HR and the total volume in ML without stopping the delivery. Holding down both bolus and prime keys will initiate a preprogrammed bolus delivery. Rate keys are used to initiate and modify the infusion rate. Enter key must be pressed to confirm the desired rate change. If the new rate is not acceptable, then, the current infusion rate will be retained.

* UPVOL: This routine updates total volume, bolus volume (during bolus delivery), and the running volume (Volume/Time) on the LCD display. When bolus delivery is initiated by the bolus & prime key, the motor is driven at the maximum rate and the bolus volume is displayed. This bolus volume is compared with bolus x weight. If the bolus volume exceeds bolus x weight, then the normal delivery resumes. In the Volume/Time mode, the running volume is compared with the dose volume (DV). If the dose volume is reached, the delivery is terminated.

3.6.6 Offline Programming (2010)

The User can enter the Offline programming mode by pressing and holding both the stop/program and the deliver keys when turning on the pump. When the keys are released, "1234" must be entered to access the offline mode. Off-line programming allows the user to customize the pump to better fit his/her needs. The features to be customized are:

* Customizing the selections of the infusion modes:
  Use the select key to remove and the enter key to add the displayed infusion mode from the selection list. If only one mode is in the list, no mode selection is asked for during the normal operation. If only the Body-weight mode is selected, then the user can optionally lock the pump in a desired infusion rate mode (e.g., mcg/kg/min).

* Bolus feature: The user can disable the bolus feature if it is not needed in the normal operation.

* Option code:
  This option is basically the same as that in the 2001 except that VL and KVO are not applicable. The user calculates the option code to customize the following features for his applications: Pre-programmed syringe manufacturer, Temporary alarm off time, Alarm Loudness, and Alarm type. See appendix E for more detailed descriptions.

The Micro-Controller stores the offline programmed parameters and the associated checksum into a non-volatile memory area. These parameters are checked and used during normal pump operation. The features not selected during offline programming never appear during normal operation and can significantly simplify programming steps.

SECTION 4. MAINTENANCE

4.1 INTRODUCTION

This section discusses general pump maintenance including procedures for tests and calibrations. A performance test procedure is included in Appendix E which can be used as part of a routine preventive maintenance schedule. The test equipment required for performance tests and calibration procedure is indicated in each respective procedure.

4.2 PREVENTIVE MAINTENANCE

A routine preventive maintenance schedule should be followed according to the policy defined by the individual hospital. Presently, Medfusion recommends that these procedures be performed at least once every year. Additional routine cleaning and inspections should be performed on an as needed basis (i.e., droppage, fluid contamination, suspect malfunction etc.,).

4.2.1 Performance Test

The performance test procedures in Appendix E can be used as a reference for preventive maintenance pump testing. As discussed in previous sections, the pump's delivery accuracy does not require adjustment or calibration, and does not change with wearing caused by normal usage. The accuracy does not rely on the sensors. The sensors are used for confirmation only. Thus, the flow rate accuracy is maintenance-free. However, the sensors must be checked periodically or as often as necessary to prevent false alarms. If the sensors fail to meet the specifications, any calibration should only be performed by qualified personnel. The calibration procedures should be carefully followed. Otherwise, the pump will not perform properly. Also, the disassembly /assembly procedures should be followed when pump repair is needed.

4.2.2 Cleaning and Miscellaneous:

Cleaning is performed as part of a disinfection procedure or to remove contamination due to an inadvertent spill. However, the chemical used to clean the pump should be carefully selected because some chemicals attack and weaken the pump's plastic housing. Please refer to the operator's manual for a list of recommended chemicals, or consult with our customer service department. The list is updated on a periodic basis.

The pump is designed to RESIST fluid entry. However, it is NOT WATER-PROOF. Do not apply excessive cleaning agents. Remove residue agent as soon as possible, and immediately clean the pump following accidental contamination.

There are several moving parts in the pump. Efforts should be made to avoid hindering the operation of these parts (e.g. adhesive tape etc). For examples:

* Syringe Clamp: a smooth sliding operation of this part is very important for size recognition and to ensure proper seating of the syringe. Do not apply any tape or adhesive material on the clamp's sliding surface. Try to keep the sliding surface as clean as possible. If the sliding of the clamp becomes sluggish, it can be improved by applying a very small amount of silicon lubricant (such as Dow Corning 111 Valve Lubricant & Sealant) on its sliding surface.

* The track must be able to move in and out easily when the clutch nut is disengaged by the clutch lever. Do not apply any chemical which might bond the track to the slide housing.

Although the housing of the pump is made of high impact resistant polycarbonate, dropping the pump can cause breakage or chipping. Care should be taken in handling the pump during transportation.

There is a locking nut on the connector of the charger so the user can lock the AC connector to the pump. Unscrew this lock nut before pulling the AC connector from the pump.

4.3 DISASSEMBLING THE PUMP

CAUTION:

1. **It is very important that the person disassembling the pump should be properly grounded to avoid possible electrostatic discharge (ESD) damage to the electronic components.**

2. **We recommend that the person(s) responsible for repairing the pump should attend a training class available by Medfusion to familiarize himself/herself with the details of disassembling and assembling the pump so that the reliability and the performance of the pump can be assured.**

Turn the pump off. Remove the charger connector. Remove the Pole clamp by removing the two flat head screws. Remove the five(5) flat head screws which hold the major sub-assemblies of the pump together. One of the screws is covered with a tamper-proof label.

4.3.1 Disconnect the cables from sub-assemblies:

Note the cable routing, the polarity and the positions of the connectors. The pump can now be separated into three major sub-assemblies: Top Housing S/A, Bottom Housing S/A, and Slide Housing S/A.

4.3.2 Disassembling the Top Housing S/A:

Remove the three long spacers and three screws. The Top Housing S/A can be further disassembled into the Main board S/A and the Top housing. The LCD display can be removed from the Top Housing by removing two brass spacers. The Micro-Controller can be removed from the socket of the Main board. The internal fuse can be replaced by de-soldering it from the Main board.

4.3.3 Disassembling the Bottom Housing S/A:

The Bottom Housing S/A can be further disassembled into the DIN connector S/A, Power switch S/A, Alarm S/A, Battery S/A, and the Bottom Housing, by disengaging the securing hardware and cable ties. Note the cable routing and the positioning of the cable ties. The battery S/A can only be removed by cutting off the adhesive tape between the battery pack and the bottom housing with a knife. The Power switch S/A along with the switch guards can be pulled out of the bottom housing by depressing the clips on the switch. The connectors for the battery S/A and power switch can be separated by removing the joint strain relief. Note the power switch green wire is always located at the most outside position.

4.3.4 Disassembling the Slide Housing S/A:

The Slide Housing S/A is the most complex sub-assembly. Disassembling the Slide Housing S/A by the user is **NOT RECOMMENDED.** However, the following descriptions describe replacing particular parts in the Slide Housing S/A. The User should understand the pump in depth before attempting to service this sub-assembly.

4.3.4.1 Replacing Motor S/A or the worm:

The removal of the motor and the worm can be done by removing the supporting bracket and hardware for the motor. IMPORTANT: DO NOT loosen the two brass spacers holding down the motor alignment bracket underneath the motor. If the motor alignment bracket is disturbed, a special alignment tool is required.

4.3.4.2 The Position Sensor:

The position sensor can be detached from the Slide S/A by removing the two holding screws and the Auxiliary board connector. The difficult part in reassembly is to ensure that proper timing between the potentiometer spur gear and the cluster gear is maintained.

4.3.4.3 Size Sensor:

The size potentiometer, gear, spring, and syringe clamp can be disengaged by removing the four(4) holding screws. However, the difficulty in reassembly is to ensure that proper timing between the potentiometer gear and the gear rack on the clamp is maintained. Also, the preloading amount for the torsion spring must be properly adjusted. Removal of the position sensor might be necessary in order to apply proper preloading of the torsion spring.

4.3.4.4 Auxiliary board:

To remove the Auxiliary board, three(3) wires connecting the force sensor cable to the Auxiliary board must be de-soldered first. Then the size and the position potentiometer connectors must be disconnected. Remove the two holding screws to disengage the Auxiliary board from the Slide S/A. Note the trim pots on the Auxiliary board must be adjusted if the force sensor is replaced. Adjustment of the photo-diode current is needed only if the rotation sensor on the Auxiliary board is replaced.

4.3.4.5 Replacing the worm gear and the leadscrew:

The E-clips on both ends of the leadscrew must be removed first. The leadscrew can be removed by opening the clutch nuts with the clutch lever and pushing the leadscrew from the clutch lever end toward the direction of the motor. Remove the worm gear with a proper tool. DO NOT damage the worm gear teeth. The leadscrew, bushing, and bearing can now be removed while the clutch nuts are opened. Handle the leadscrew with care. DO NOT damage the threads. Proper reassembly procedures must be followed to obtain a specified gap so that the rotation of the leadscrew is free from any binding.

4.3.4.6 Disengaging the Track S/A from the Slide S/A:

The size sensor, Auxiliary board, and leadscrew must be removed first. Move the track to the most extended outward position and turn over the Slide S/A so that the bottom of the track faces upward. Remove the clutch actuator rod cover by removing the two(2) holding screws. Sightly move the clutch actuator rod inward to disengage the actuator rod from the clutch lever. Swing the lever 90 degrees so that it can be removed from the track. The clutch actuator rod can then be pulled out. Remove the clutch key next to the clutch nuts by pulling it out with a plier. The clutch nuts can then be removed by pulling them sideways and forward. **CAUTION** should be exercised when removing the clutch nuts from the Slide S/A because of the clutch spring. Remove the double sided tape for the force cable underneath the slide housing. The track S/A can then be disengaged from the slide housing.

4.3.4.7 Disassembling the plunger holder S/A from the track S/A:

To disengage the force sensor / plunger holder from the track, remove the socket head screw visible through the clutch lever hole. A threaded nut plate will fall off. After the plunger holder S/A is pulled out of the track, the force sensor can be removed from the plunger holder by removing the holding socket head screw. Two plates (one with threads) will fall off.

4.4 TESTS AND CALIBRATIONS

4.4.1 Tests

There are many test levels at different assembly stages: Board level, Sub-assembly level, and Final system level. Board level tests are performed by Medfusion. The sub-assembly level tests are required after a sub-assembly has been taken apart. Special tools and fixtures are needed to perform these tests. Refer to Medfusion Production Testing Procedure available upon special request.

The final system level can be tested by following the Performance Tests in Appendix E. The sensor calibrations can be checked using the QC inspection mode described in the following sections.

4.4.2 System Calibrations:

The pump provides a Calibration Mode for handling the inspection and the calibration of the sensors. There are different levels of calibrations: Battery Calibration, Sensor Calibration, and QC inspection. The Sensor calibration as well as the QC inspection can be performed by the user when the pump is completely assembled. However, the battery calibration can only be performed at the Top Housing S/A level. There is also an adjustment of the set voltage for the battery trickle charging at the Top Housinge S/A. Both adjustments require special test fixtures and are performed at Medfusion. The battery calibration is needed only when the Micro-Controller on the Main board is replaced. Under normal condition, there is no need for further adjustment. Thus, the procedures for both adjustment are not discussed in this section. They are available upon special request.

The system calibration mode can be accessed by pressing and holding the stop/program key and the select key while turning on the pump. When released, the Micro-Controller displays "LOCK---> " and waits for a valid access code to be entered.

4.4.2.1 Sensor Calibration:

This calibration mode can be accessed by entering code "8021". This mode is used for calibrating the force sensor, position sensor, and size sensor.

During each calibration stage, the enter key is used to instruct the Micro-Controller to accept the A/D reading for the calibration point. The program key is used to skip the current calibration stage. All other keys can be used to go back to the previous calibration point.

- Force Sensor Calibration:

  There are three stages: 0LB calibration, 16LB calibration, and the force sensor calibration test.

0LB calibration:

The Micro-Controller displays "ADJ. FORCE 0LB=XX" where XX is the A/D reading for the amplified force sensor voltage. The operator should make sure that there is no force being applied to the plunger holder. Press the enter key to instruct the Micro-Controller to store the current A/D reading for the 0LB force. The A/D reading for the 0LB force should be between 0A and 18. If an A/D reading is out of this range, then the variable resistor VR2 (near the size pot) on the Auxiliary board needs to be adjusted until this range is obtained.

16LB calibration:

After the 0LB force is calibrated, the Micro-Controller displays "ADJ. FORCE 16LB=XX" and waits for the operator's response. The operator should use a special force gauge fixture to apply 16LB force to the plunger holder. Press the enter key to instruct the Micro-Controller to store the A/D reading for the 16LB force. Special force gauges can be purchased from Medfusion, Inc.

Force sensor calibration test:

After the 16LB force calibration, the Micro-Controller displays "FORCE(LB) Y.YYY =XX" where Y.YYY is the calculated force reading in pounds and XX is the A/D reading for the force sensor. The Micro-Controller continuously takes the A/D reading from the force sensor and converts the reading to a force reading in pounds. The conversion is done by using the interpolation calculation based on the two pre-calibrated readings for the 0LB and 16LB. The operator should apply different forces to the plunger holder and verify that the displayed force reading falls within the acceptable range.

- Position Sensor Calibration

  There are three stages: POS. 0 calibration, POS. 99 calibration, and Position sensor calibration test:

POS. 0 calibration:

After pressing the enter key to exit the force sensor calibration, the Micro-Controller displays "ADJ. POS. 0=XX" where XX is the A/D reading for the current track position. The operator should move the track to the most inward position, do not release the clutch lever, and press the enter key. If the clutch lever is released prior to pressing the enter key, the engagement of the clutch nut and the leadscrew might change the A/D reading. The Micro-Controller stores this A/D reading as POS 0.

POS. 99 calibration:

Then the LCD displays "ADJ. POS. 99=XX". The operator moves the track to the most extended position and presses the enter key while holding the clutch lever open. The Micro-Controller stores this A/D reading for POS. 99. The displacement between the two points is 4.836 inches.

Position sensor calibration test:

The LCD displays "POS. (INCH) Y.YYY=XX" where XX is the A/D reading for the current track position and Y.YYY is the calculated position (in inches) corresponding to the A/D reading. The formula is: Y.YYY=(ADC-AD0)*4.836/(AD99-AD0) ; where AD0,AD99, and ADC are the A/D readings for POS.0, POS.99, and the current position.

- Size sensor calibration:
  There are five stages: 4 calibration stages for TERU 1, TERU 6, TERU 25, TERU 60, and Size sensor calibration test:

Size calibrations with TERUMO syringes 1cc, 6cc, 25cc, and 60cc:
After pressing the enter key to exit the position sensor calibration, the Micro-Controller displays "ADJ. TERU 1 =XX" where XX is the A/D reading for the size sensor. By lifting up and then releasing the syringe clamp several times, it can be seen that the A/D reading varies slightly from time to time for the same syringe due to the syringe clamp tension applied by the torsion spring. The most common reading should be used as the calibration reading. The operator should now correctly load a TERUMO 1cc syringe. Press the enter key to instruct the Micro-Controller to use the most common A/D reading for the syringe. Continue this process for obtaining the calibrated A/D readings for TERUMO 6cc, 25cc, and 60cc syringes. These calibrated A/D readings are stored in the Micro-Controller non-volatile memory.

Size sensor calibration test:
The Micro-Controller displays "SIZE(INCH) Y.YYY=XX" where Y.YYY is the calculated size for the corresponding A/D reading XX. Y.YYY is derived from the interpolation of the current A/D reading with the stored calibrated A/D readings of the 4 TERUMO syringes to compensate for the size sensor's non-linearity. The user should sequentially load the four TERUMO syringes and inspect the size sensor calibration. Refer to the size recognition data sheet in the attached procedure (Appendix E).

The reason for using TERUMO syringes for size calibration is the TERUMO 60cc syringe has the largest outside diameter (O.D.) when compared to B-D or Monoject syringes. These four syringe sizes were selected to evenly spread the calibration points over the entire range of the size sensor.

4.4.2.2 QC inspection:

The QC inspection access code is "1000". This mode allows the QC inspector to verify the calibration of all sensors without inadvertently modifying a calibration parameter and altering the system calibration.

- Force sensor calibration test:
  Once the correct QC access code is entered, the Micro-Controller displays "FORCE(LB) Y.YYY=XX". The operator can use the force gauge fixture to apply a known force to the plunger holder. Compare the force gauge readings with the LCD display readings. If the two readings are within the acceptable range, press the enter key to advance to the Position sensor calibration test. Several different force levels should be tested.

- Position sensor calibration test:
  The LCD displays "POS.(INCH) Y.YYY=XX". XX is the A/D reading in Hex code. Y.YYY is the calculated track position in inches. Hold down the clutch lever, move the track to its most inward position and to its most extended positions. Observe the readings

on the LCD display. Two readings "0.000+/-0.005" and "4.836+/-0.005" should be obtained. Record the corresponding hex readings of these two points. Move the track to both end positions, the hex codes displayed on the LCD should be within +/- 1 hex digit of the recorded hex codes. Press the enter key to advance to the size sensor calibration test.

- Size sensor calibration test:
  The Micro-Controller displays "SIZE(INCH) Y.YYY=XX". Y.YYY is a size height measurement (in inches) for the syringe to be measured. If no syringe is loaded, the nominal height is 0.100". Correctly load TERUMO 1, 6, 25, and 60 syringes. Verify the readings on the LCD display. Refer to data sheet in Appendix E for the acceptable range for each syringe.

4.5 TROUBLE-SHOOTING GUIDE

The Trouble-shooting Chart in the appendix G can be used as a guide to help locate the probable cause of a problem. The chart is not all inclusive, and the causes of some problems may be multiple or not in the chart. The success of the trouble-shooting depends largely on the user's knowledge and experience with the pump. Please call the Service Department at Medfusion if further assistance is needed.

4.6 RETURINING YOUR PUMP FOR SERVICE

Please call Medfusion for a Return Authorization Number (RA) before sending your pump to Medfusion for service. Use the original package to ship the pump if possible. Remove the Pole clamp and Charger form the pump. There is no need to return the pole clamp and charger with the pump unless they are questionable. Please include a description (as specific or detailed as possible) regarding the problem of the pump so that we can properly and quickly service the pump.

APPENDIX A. ASSEMBLY DRAWINGS

A.1 Final Assembly

A.2 Top Housing S/A

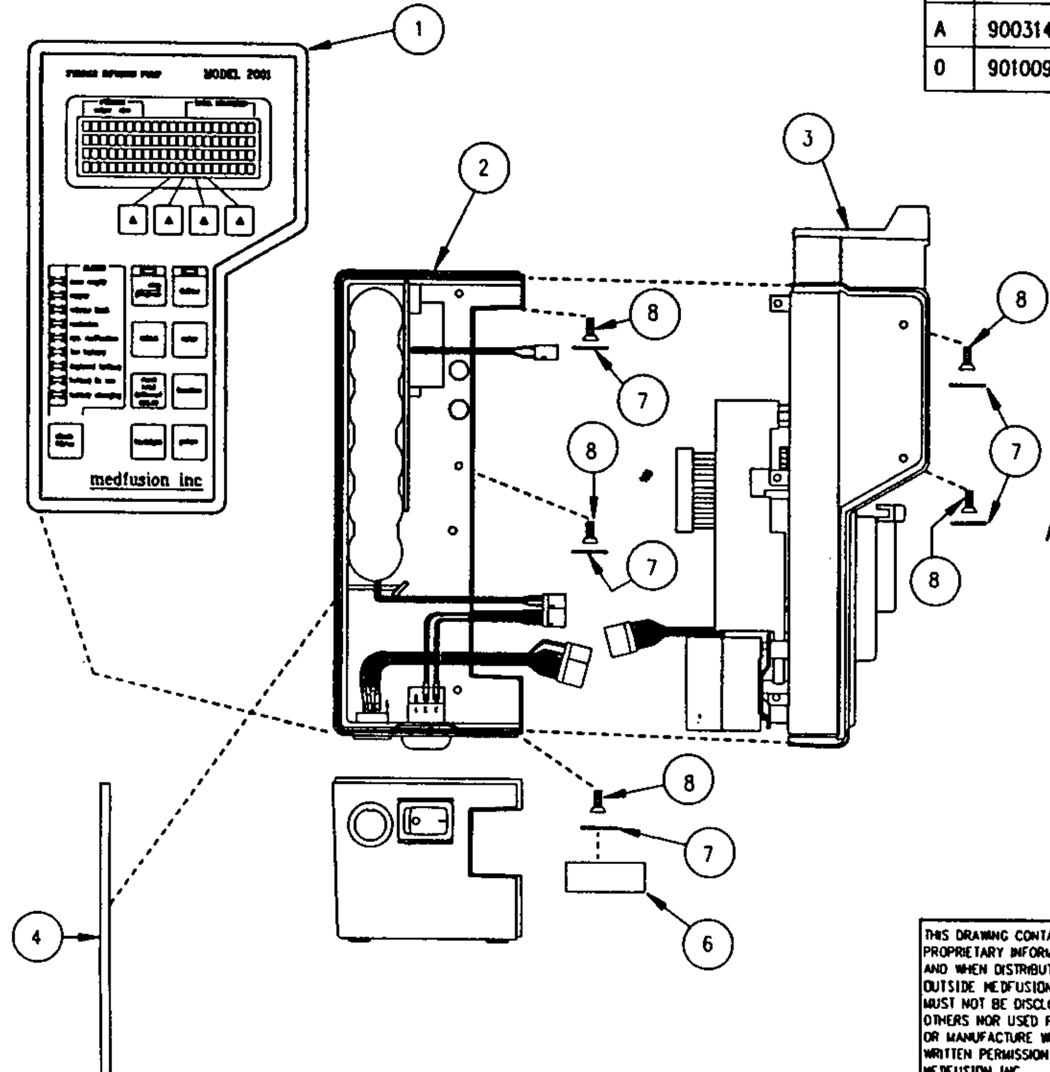
A.3 Bottom Housing S/A

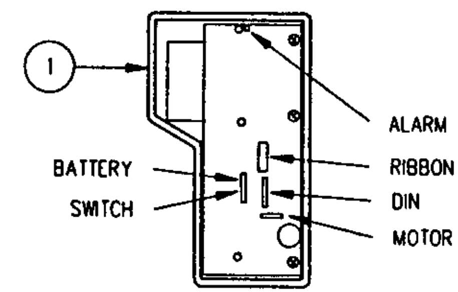
A.4 Slide Housing S/A

A.5 Slide S/A

A.6 Plunger Holder / Track S/A

REV	DCN#	DESCRIPTION OF REVISION	APPROVED	DATE
A	90031402	DELETE CHARGER AND LABEL	C. LEE	3-27-90
			R. BOOTH	3-28-90
0	90100901	ADDED INSTRUCTION LABEL	[signature]	12-20-90
			[signature]	1-7-91





PC BOARD CONNECTIONS

ASSEMBLY INSTRUCTIONS:

1. PLUG IN CONNECTORS FROM BOTTOM HOUSING (2) TO PCB ON TOP HOUSING. CONNECT ALARM TO PCB ON TOP HOUSING. CONNECT MOTOR AND RIBBON CABLE TO PCB ON TOP HOUSING.
2. ASSEMBLE SLIDE HOUSING SUB ASSEMBLY (3) TO TOP HOUSING SUB ASSEMBLY AND THEN ASSEMBLE INTO BOTTOM HOUSING SUB ASSEMBLY. BE SURE ROUTING WILL NOT INTERFERE WITH ASSEMBLY.
3. INSERT THREE SCREWS (8) FOR THE BOTTOM HOUSING STARTING WITH THE OUTSIDE SCREWS.
4. INSERT THE OTHER TWO SCREWS (8) INTO THE SLIDE HOUSING.
5. TIGHTEN ALL SCREWS.
6. PLACE SCREW HEAD COVERS (7) AND THE TAMPER RESISTANT LABEL (6) OVER SCREW HEAD HOLES.
7. PLACE INSTRUCTIONS (4) ON SIDE OF PUMP.

DWN.	D. AMMANN	1-5-90
ENGR.	J. STEMPFLE	1-5-90
CHK	D. AMMANN	1-5-90
PROD	B. KRATOFIL	1-5-90
APVD	R. BOOTH	1-5-90

MEDFUSION INC.

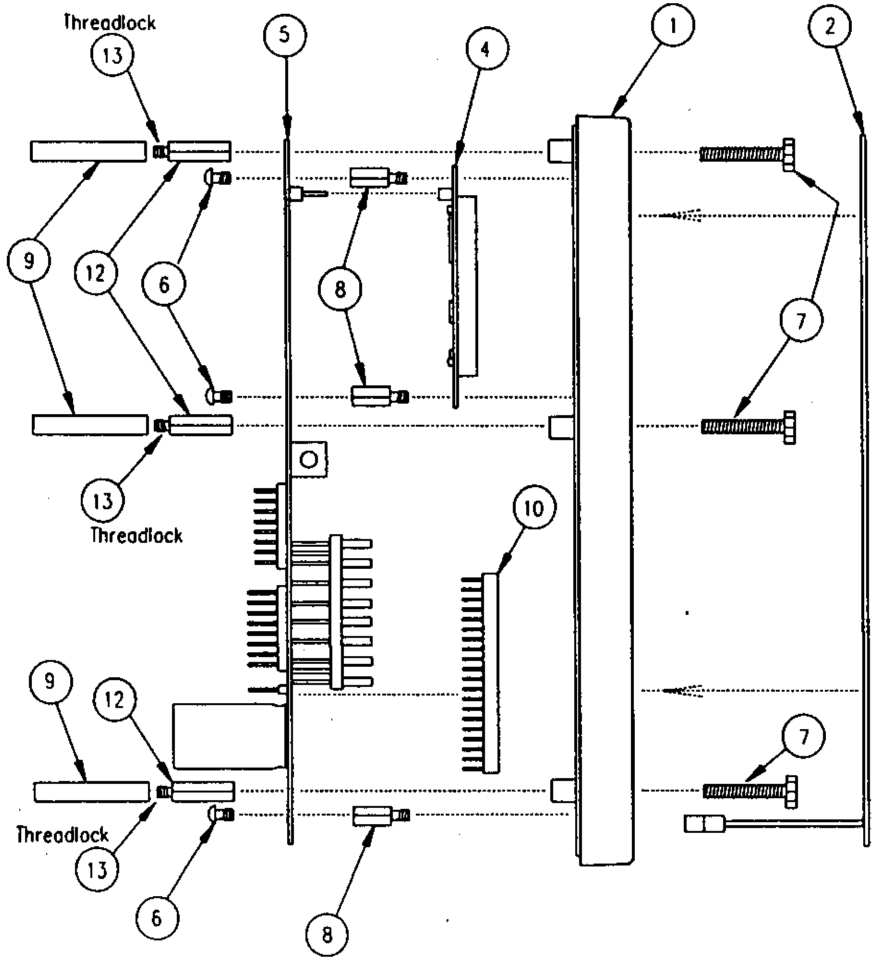
DIMENSIONS ARE IN INCHES — TOLERANCES UNLESS OTHERWISE NOTED DEC / ANGLE

FINISH N/A — MATERIAL N/A

TITLE FINAL ASSEMBLY

SIZE	SHEET	SCALE	PRODUCT REFERENCE	PART NO.	REV
B	1 OF 1	NONE	2001	1-72-20010-0--1	0

REV	DCN #	DESCRIPTION OF REVISION	APPROVED	DATE
1	90031402	CHANGED ITEM #9, ADDED ITEMS 12,13	C. LEE R.BOOTH	3-22-90 3-23-90
2	90060101	ELIMINATED LCD INSERT & GLUE	J.STEMPFLE R.BOOTH	6-05-90 6-06-90
2B	90092701	ADD NOTE ON STEP 1.	[signature] [signature]	10-8-90 10/10/90

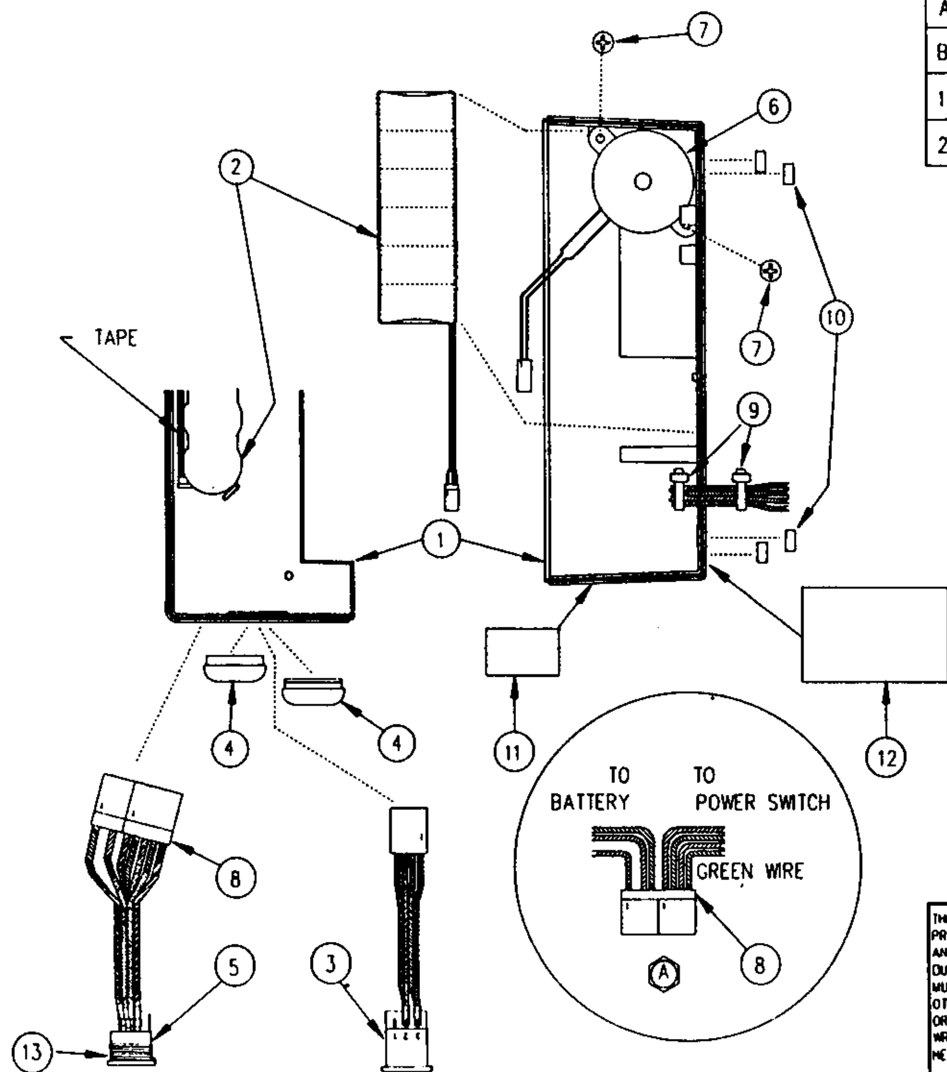


ASSEMBLY INSTRUCTIONS:

1. INSERT 3 HEX HEAD SCREWS IN TOP HOUSING
   REMOVE BACKING FROM KEYPAD AND INSTALL IN TOP HOUSING
   NOTE: IF SEIKO DISPLAY IS TO BE USED,
   TRIM KEYPAD/TOP AROUND LCD DISPLAY
2. INSTALL LCD INTO TOP HOUSING.
3. INSTALL THREE MALE-FEMALE STANDOFFS
4. INSTALL PROGRAMMED MPU INTO MAIN PC BOARD
5. CONNECT KEYPAD TAIL TO MAIN PC BOARD
   INSTALL MAIN PC BOARD TO TOP HOUSING S/A
6. INSTALL THREE ROUND NYLON FEMALE STANDOFFS TO THREE BRASS HEX STANDOFFS WITH THREADLOCK. INSTALL ASSEMBLY TO HEX HEAD SCREWS. INSTALL PAN HEAD SCREWS.

THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.	DWN D.AMMANN	12-11-89	MEDFUSION INC.	
	ENGR. L.GARCIA	12-12-89		
	CHK D.AMMANN	1-05-90	DIMENSIONS ARE IN INCHES DEC NA	TOLERANCES UNLESS OTHERWISE NOTED ANGLE
	PROD B.KRATOFIL	1-05-90	FINISH NA	MATERIAL NA
	APVD R.BOOTH	1-05-90	TITLE TOP HOUSING S/A	
SIZE B / SHEET 1 OF 1	DCN # NA	NONE	PRODUCT REFERENCE 2001	PART NO. 1-68-20A00-0-2 / M REV B

REV	REF	DESCRIPTION OF REVISION	APPROVED	DATE
A	90031402	ADD LABEL	C. LEE / R. BOOTH	3-27-90 / 3-28-90
B	90060401	DELETE ADHESIVE; ITEM 5 HAD 2 WIRES	D. AMMANN / R. BOOTH	6-20-90 / 6-21-90
1	90091404	ADDED LABEL (11)	D. AMMANN / R. BOOTH	9-17-90 / 9-17-90
2	91042504	REVISED ASSEMBLY INSTRUCTIONS	[signatures]	5-31-91 / 6-10-91



ASSEMBLY INSTRUCTIONS:

1. ATTACH TWO SWITCH GUARDS (4) TO BOTTOM HOUSING.
2. INSTALL DIN RECEPTACLE SUB-ASSEMBLY (5) THROUGH THE BOTTOM OF THE BOTTOM HOUSING, AND ADD SMALL AMOUNT OF LOCTITE (13) TO THREADS. ATTACH RETAINING RING TO DIN RECEPTACLE (NOTCHES TOWARD CENTER). TIGHTEN WITH SPECIAL TOOL.
3. PRESS POWER SWITCH (3) INTO BOTTOM HOUSING. BE SURE O (OFF) ON SWITCH IS CLOSEST TO DIN RECEPTACLE.
4. PEEL OFF TAPE BACKING ON BACK OF BATTERY PACK (2), AND PLACE INTO BOTTOM HOUSING WITH CABLE ON BOTTOM OF BATTERY PACK.
5. ATTACH ALARM (6) TO BOTTOM HOUSING (1) WITH 2 SCREWS (7).
6. ADD STRAIN RELIEF (8) TO THE THE POWER SWITCH AND BATTERY CONNECTOR (BE SURE GREEN WIRE IS ON THE OUTSIDE). ADD STRAIN RELIEF (8) TO THE TWO DIN CONNECTORS.
7. USE 2 WIRE TIES (9) TO TIE THE WIRES FROM THE POWER SWITCH, DIN RECEPTACLE AND BATTERIES TOGETHER.
8. ADD FOUR FEET (10) TO BOTTOM HOUSING IN RECESS PROVIDED.
9. ADD LABELS (11) & (12)

DWN	D. AMMANN	1-5-90
ENGR	C. J. LEE	1-5-90
CHK	D. AMMANN	1-5-90
PROD	B. KRATOFIL	1-5-90
APVD	R. BOOTH	1-5-90

MEDFUSION INC.

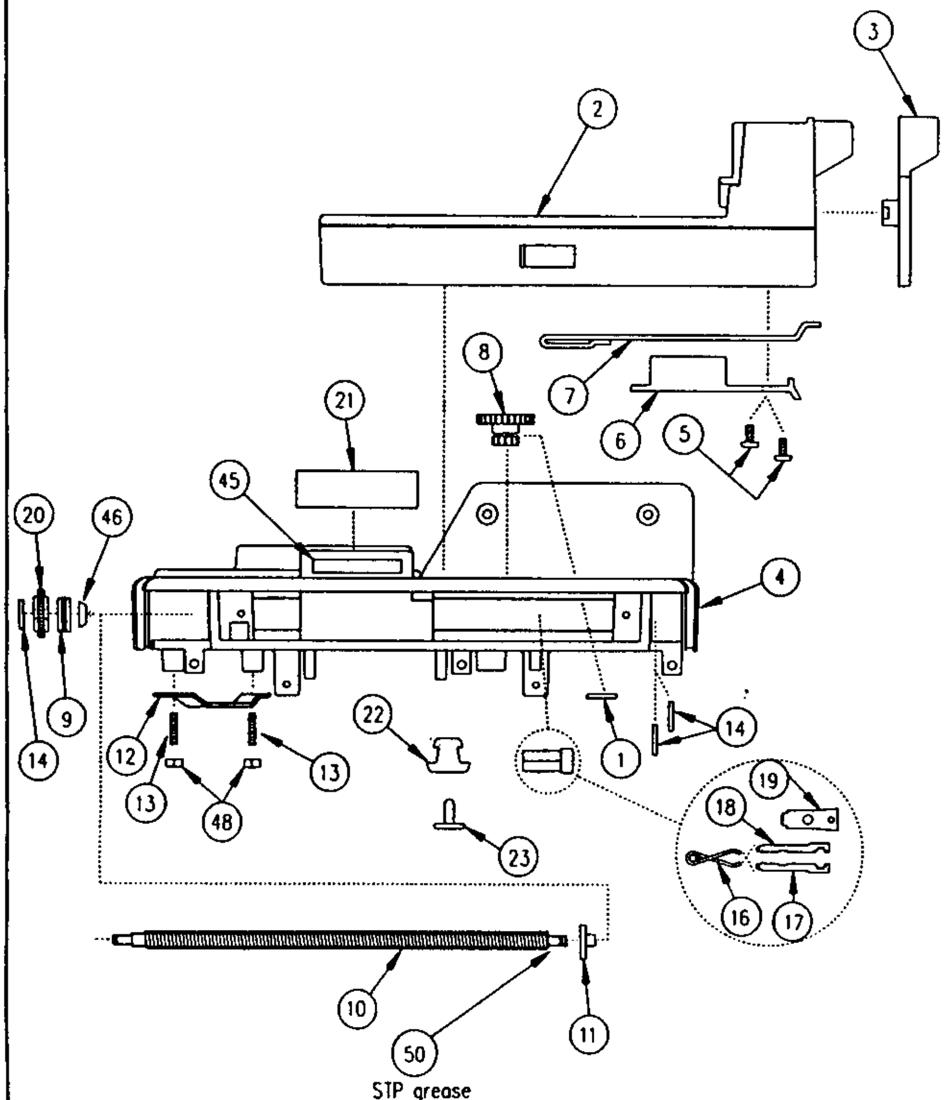
DIMENSIONS ARE IN INCHES — TOLERANCES UNLESS OTHERWISE NOTED — DEC — ANGLE

FINISH: N/A — MATERIAL: N/A

TITLE: BOTTOM HOUSING S/A

SIZE	SHEET	SCALE	PRODUCT REFERENCE	PART NO.	REV
B	1 OF 1	NONE	2001	1-68 20A01 0-2	0

REV	DCN#	DESCRIPTION OF REVISION	APPROVED	DATE
A	90072601	MADE ITEM 37 A SUB ASSEMBLY	D. AMMANN R. BOOTH	8-6-90 8-6-90
5	90110501	ADDED ADDITIONAL ITEM 14	R.BOOTH D.AMMANN	12-10-90 12-10-90
A	91060302	SAFETY WARNING ADDED	[signature] [signature]	6-14-91 6-14-91



ASSEMBLY INSTRUCTIONS:

* SAFETY GLASSES REQUIRED

NOTE: All 2-56 screws are to be torqued 10 in/oz.
All 4-40 screws are to be torqued 16 in/oz.

*1. Press the cluster gear (8) through the slide top housing (4) and secure with an E-clip (1).

2. Feed transducer cable through cable seal (22), then position in slide housing. Cable length after cable seal is 1.5 inch. Secure with cable plug (23).

*3. Wearing safety glasses, assemble the clutch spring (16) onto the lower clutch (17) then onto the upper clutch (18). Do not let go of this assembly as it may spring apart. Insert this assembly through the slot in the slide top housing and into the square hole in the track assembly (2) making sure the cable does not interfer with clutch. The tabs face away from the plunger holder. Slide the clutch assembly towards the tab side and insert the clutch key (19).

4. Insert clutch actuator (7) into clutch assembly. Attach clutch lever (3) and slide clutch actuator into clutch lever. Attach clutch cover (6) and attach with two pan head screws (5).

5. Attach the motor mount (12) with two set screws (13) and two 1/4 hex female standoffs (48). Align with fixture (0-66-20003-0-X) and tighten to 10 in-lb torque.

*6. Open the clutch and insert feed screw (10). Grease (50) and install thrust washer (11) and slide the assembly till end of feed screw comes through the slide bottom. Secure with two E-clips (14).

*7. Insert water seal (46) (note orientation) then bearing (9). With bearing insertion tool (0-66-20004-0-X), press the leadscrew bearing into the slide bottom. Check turning of feed screw with tool (0-66-20005-0-X). Press the worm gear (20) over the square end of the leadscrew and secure it with an E-clip (14). Check manual operation of plunger track movement.

8. Attach the rubber boot (21) with tape (45) 1 inch long to the upper slide assembly.

DWN	D. AMMANN	1-5-90
ENGR.	J. STEMPFLE	1-5-90
CHK	D. AMMANN	1-5-90
PROD	B. KRATOFIL	1-5-90
APVD	R. BOOTH	1-5-90

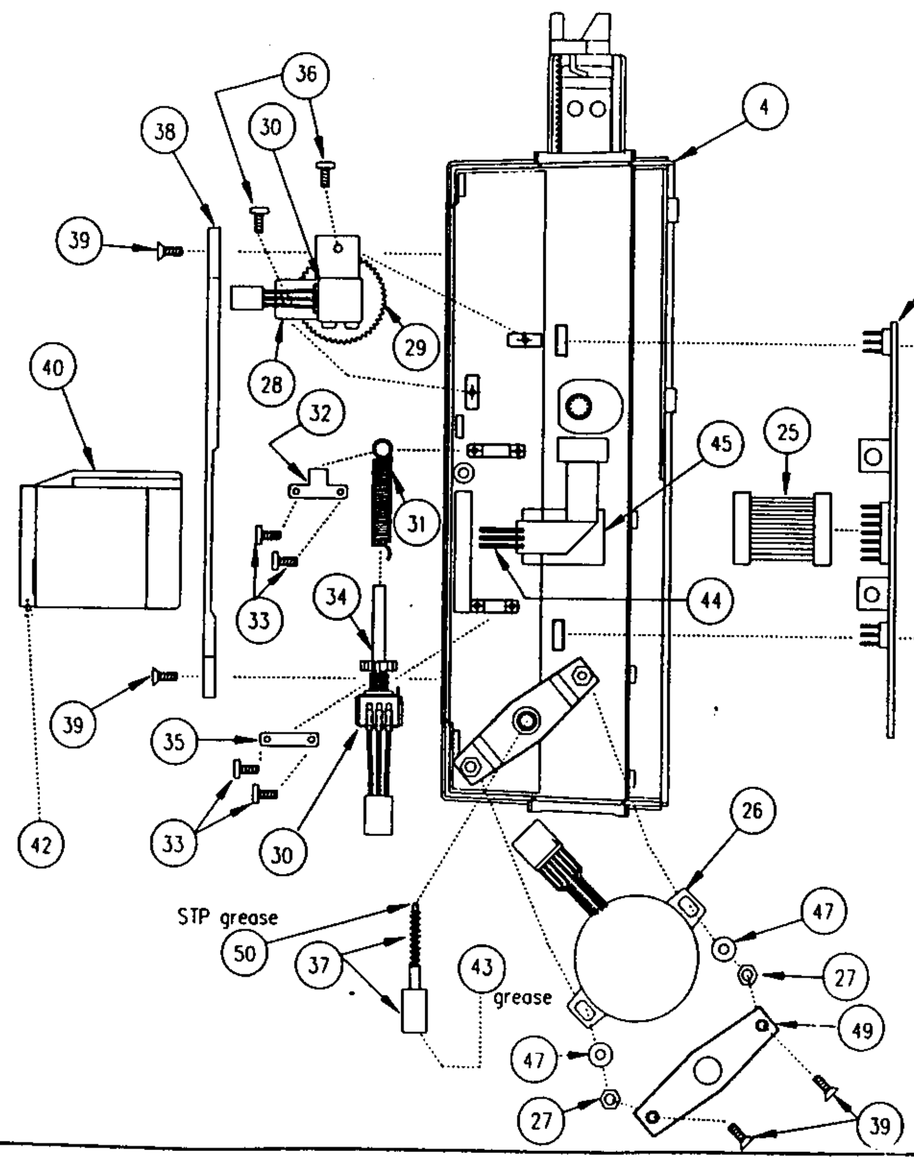
MEDFUSION INC.

DIMENSIONS ARE IN INCHES — TOLERANCES UNLESS OTHERWISE NOTED: DEC / ANGLE

FINISH: N/A — MATERIAL: N/A

TITLE: SLIDE HOUSING S/A

SIZE	SHEET	SCALE	PRODUCT REFERENCE	PART NO.	REV
B	1 OF 2	NONE	2001	1-68-20A02-0-5	A



ASSEMBLY INSTRUCTIONS:

* SAFETY GLASSES REQUIRED

NOTE: All 2-56 screws are to be torqued 10 in/oz.
All 4-40 screws are to be torqued 16 in/oz.

1. Take clamp gear (34) and slip onto potentiometer shaft (30). Slide torsion spring (31) over gear shaft and engage open loop of torsion spring in slot of clamp gear.

   Place all of above assembly into both half-round recesses of slide housing (4) with the pot. body toward motor side. Take pot. clamp (35) and two pan head screws (33) and secure around pot. neck, but do not tighten screws.

   Rotate clamp gear counter-clockwise with torsion spring as seen looking at closed loop spring end until it stops.

   While maintaining stop out, rotate potentiometer with gear and spring together until closed spring loop is parallel with mounting surface of slide housing. The pot's cable should point away from circuit board. Now tighten both screws of pot clamp.

   Take clear syringe clamp (40) and enter gear rack side through rubber seal and engage with clamp gear while maintaining stop out and push syringe clamp all the way.

   * Using the winding tool, engage the closed loop end and rotate the spring just past one full turn counter-clockwise until the loop is again parallel with the mounting surface. Secure the closed loop by placing the spring-end-clamp (32) through the loop and tighten with two pan head screws (33).

   Now loosen the pan head screws on the potentiometer and rotate the pot counter-clockwise about 20° to prevent the clear syringe clamp from disengaging with the gear. Final potentiometer position will be done later at calibration.

2. Attach the position pot holder (28) to a pot sub-assembly (30) with hardware supplied with pot. Push the position gear (29) onto the pot. Be sure the hub on the gear is towards the pot. Rotate the gear to the full counter clockwise position. Slide plunger/track to empty position. Reset the gear 5 teeth, then install the pot assembly to the slide bottom with two screws (36). Ensure clearance between the gears.

*3. Solder the three wires (44) to the force cable, then to the auxiliary PCB. Attach the PCB assembly (24) to the slide bottom with screws (5). Plug in both pots to the PCB.

4. Place worm gear into housing assembly.

5. Add grease (43) to coupling. Attach the worm/coupling to motor and secure it with the two 3/16 hex female standoffs (27) and two flat washers (47). Be sure motor is aligned with bracket and tighten securely.

6. Secure motor with motor mount back (49) and two pan head screws (5).

7. Snap slide door (38) into slide housing and secure with two screws (39).

8. Connect ribbon cable (25) to PC board.

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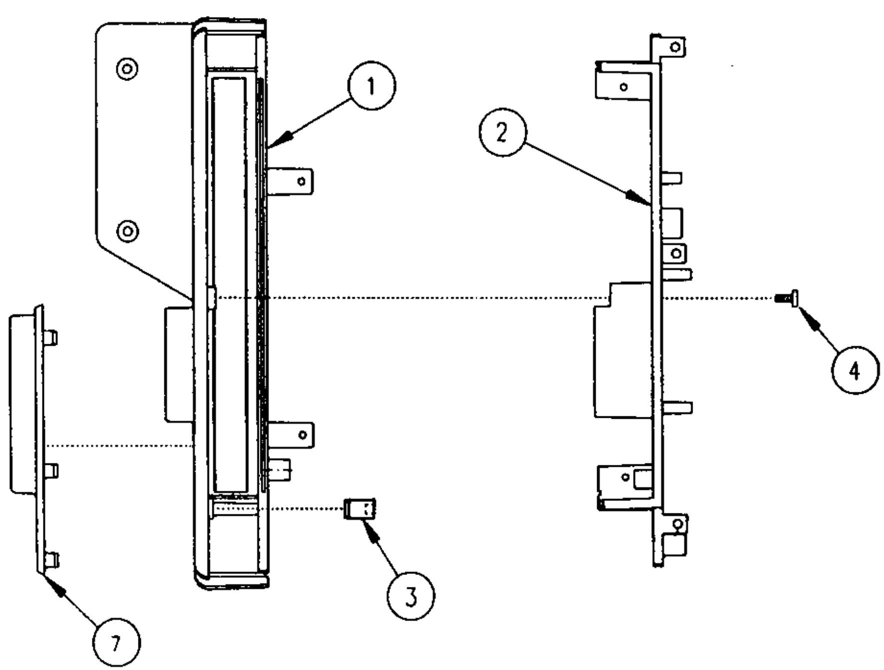
	ENGR. J. STEMPFLE	1-5-90	DIMENSIONS ARE IN INCHES	TOLERANCES UNLESS OTHERWISE NOTED DEC ANGLE
	CHK D. AMMANN	1-5-90	FINISH N/A	MATERIAL N/A
	PROD B. KRATOFIL	1-5-90	TITLE SLIDE HOUSING S/A	
	APVD R. BOOTH	1-5-90		
SIZE B / SHEET 2 OF 2	SCALE NONE		PRODUCT REFERENCE 2001	PART NO. 1-68-20A02-0 5 / REV A

REV	REF	DESCRIPTION OF REVISION	APPROVED	DATE
1	90060101	REMOVED BALL BEARING	J.STEMPFLE R.BOOTH	6-5-90 6-6-90
A	91060302	SAFETY WARNING ADDED	[signature] [signature]	6-14-91 6-14-91



8 SILICONE ADHESIVE

6 SOLVENT GLUE

ASSEMBLY INSTRUCTIONS:

SAFETY GLASSES REQUIRED

1. APPLY GLUE (6) BETWEEN THE PRONGS OF THE SYRINGE SADDLE (7) AND SNAP THE SYRINGE SADDLE INTO THE SLIDE TOP (1). GLUE (8) THE SIX PRONGS ON THE BACK SIDE.
2. PRESS THE THRUST BEARING INTO THE SLIDE TOP
3. GLUE (ITEM#6) ALL THE EDGES OF THE SLIDE BOTTOM THAT CONTACT THE SLIDE TOP. PRESS THE SLIDE BOTTOM INTO THE SLIDE TOP AND SECURE THE ASSEMBLY WITH THE PAN HEAD SCREW (4). CLAMP (WITH SOLVENT BONDING FIXTURE #0-66-20001-0-0) ASSEMBLY UNTIL DRY

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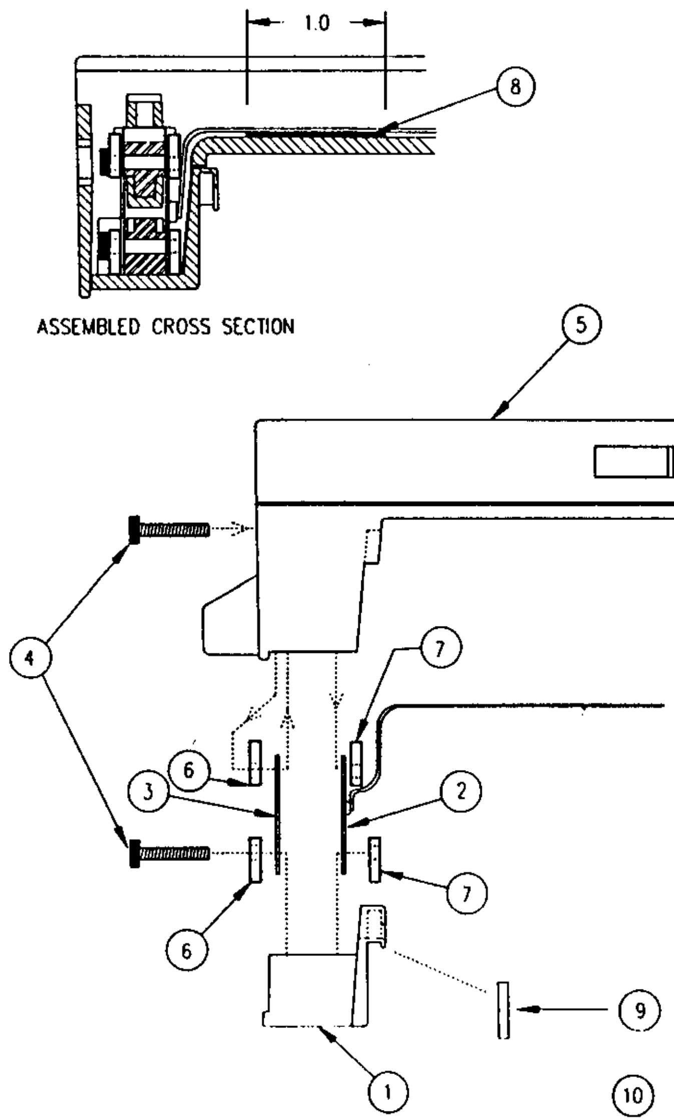
	ENGR. J. STEMPFLE	1-5-90	DIMENSIONS ARE IN INCHES DEC	TOLERANCES UNLESS OTHERWISE NOTED ANGLE
	CHK D. AMMANN	1-5-90	FINISH N/A	MATERIAL N/A
	PROD B. KRATOFIL	1-5-90	TITLE SLIDE S/A	
	APVD R. BOOTH	1-5-90		
SIZE B / SHEET 1 OF 1	SCALE NONE		PRODUCT REFERENCE 2001	PART NO. 1-68-20A03-0-1 / REV A

REV	DCN #	DESCRIPTION OF REVISION	APPROVED	DATE
1	90103101	ITEMS 9 & 10 WERE ADDED	R. BOOTH D.AMMANN	11-1-90 11-1-90
A	91060302	SAFETY WARNING ADDED	[signatures]	6-14-91 5-14-91



ASSEMBLY INSTRUCTIONS:

* **SAFETY GLASSES REQUIRED**

1. Insert transducer nut plate (7) (note orientation) into plunger holder (1).
2. Insert force sensor plate with cable (2) between transducer nut plate (7) (note cable orientation) and plunger holder (1).
3. Insert blank sensor plate (3) and screw plate (6) (note orientation) into plunger holder (1). Align (2) & (3) before tightening socket head screw (4). Torque to a screwdriver setting of 20 in/lb.
4. Place plunger holder assembly into track.
5. Insert transducer nut plate (7) (note orientation) into assembly. Do not press into the ribbon cable. Holding the nut plate with one hand, tilt the assembly upright and place the transducer screw plate (6) (note orientation)into position. Ensure alignment of all parts. Secure remaining socket head screw (4) into position.
6. Insert shims to center plunger holder. Tighten remaining socket head screw to 20 in/lbs.
7. Place about one inch of double sided tape (8) on inside of track (5).
8. Press on cable to secure to tape.

*9. Glue plunger retainer (9) to plunger holder (1) with glue (10).

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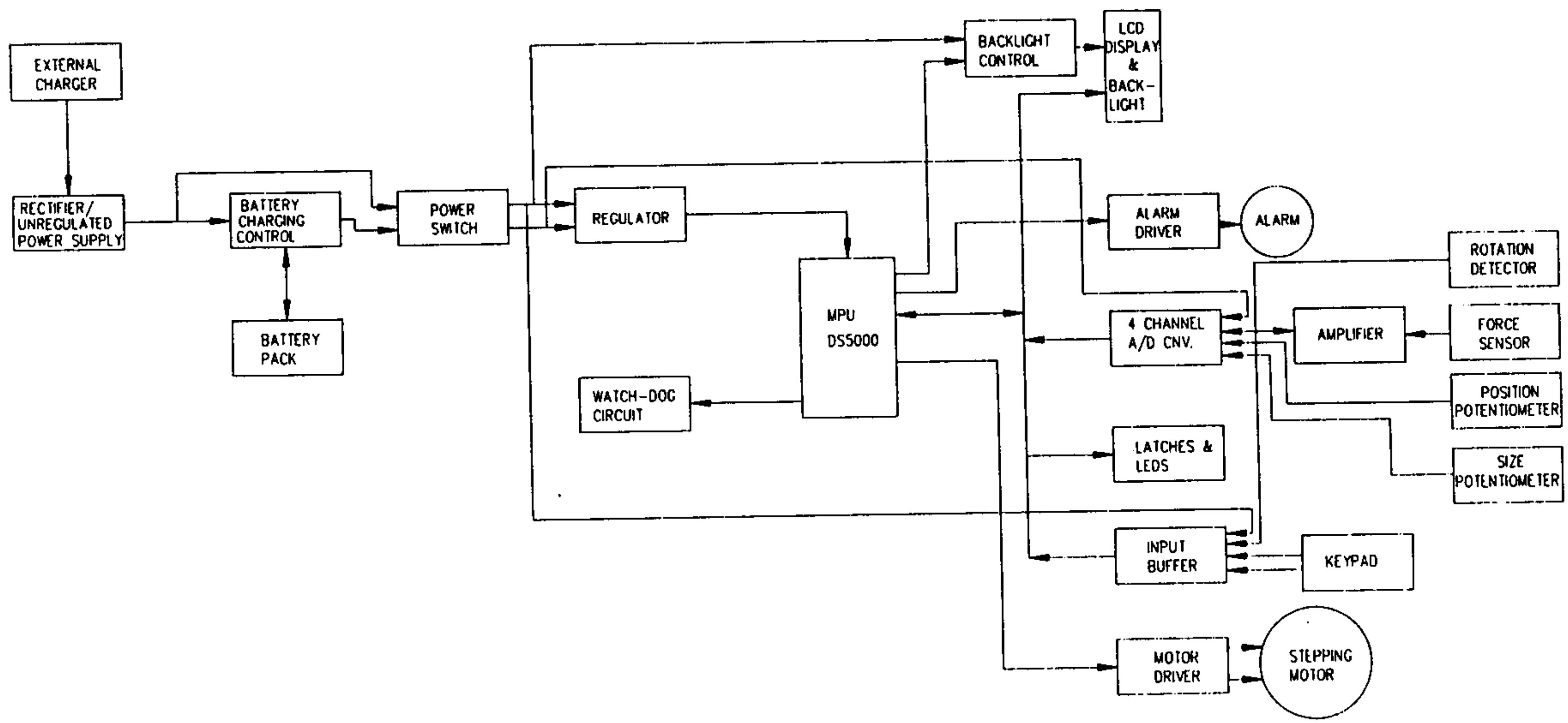
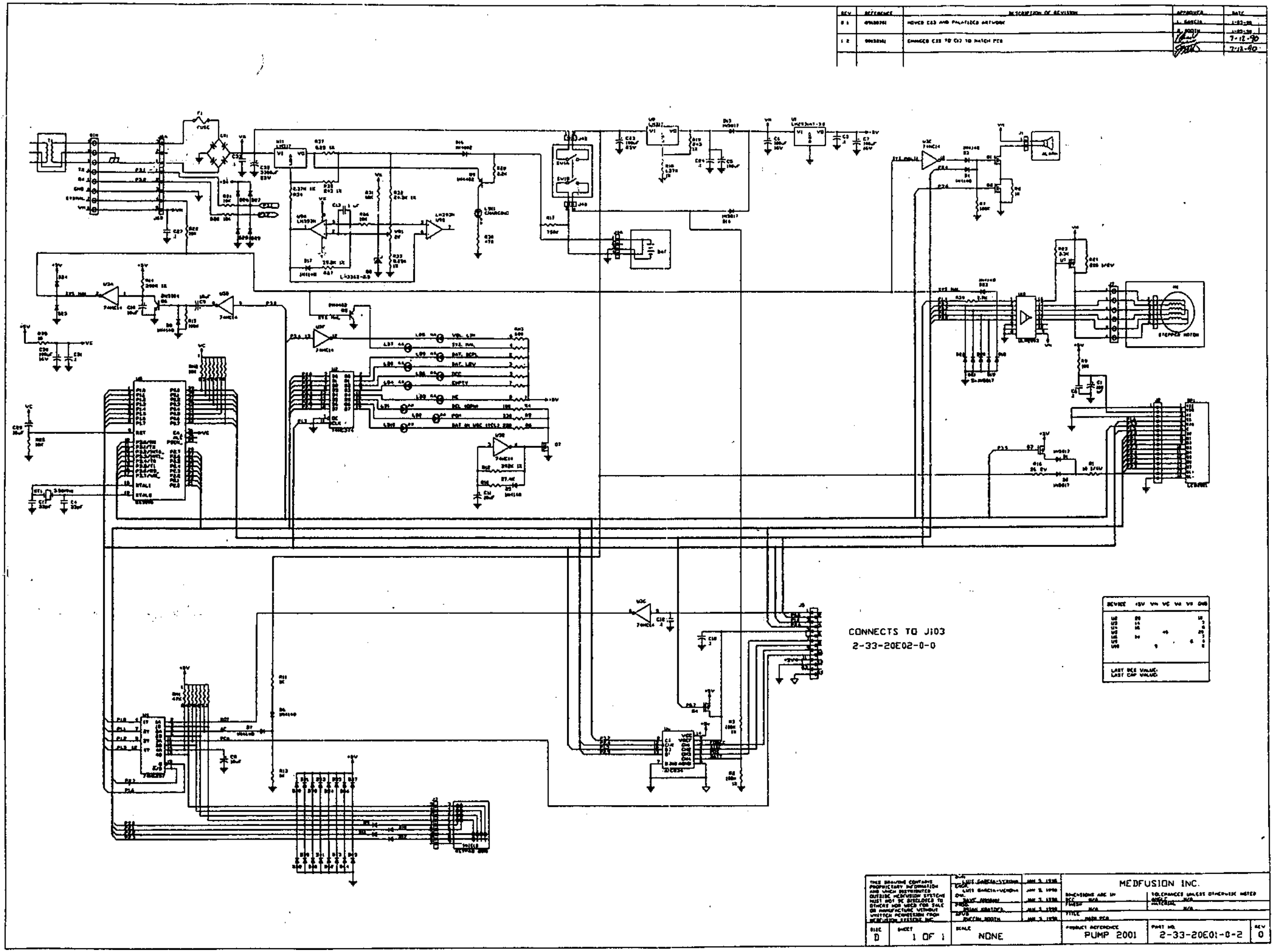
	ENGR L.GARCIA	12.12.89	DIMENSIONS ARE IN INCHES DEC NA	TOLERANCES UNLESS OTHERWISE NOTED ANGLE NA
	CHK D.AMMANN	1.05.89	FINISH NA	MATERIAL NA
	PROD B.KRATOFIL	1.05.90	TITLE PLUNGER HOLDER/TRACK S/A	
	APVD R.BOOTH	1.05.90		
SIZE B · SHEET 1 OF 1	DCN # NA	SCALE NONE	PRODUCT REFERENCE 2001	PART NO. 1-68-20A04-0-1 · REV A

APPENDIX B. SCHEMATIC DIAGRAMS

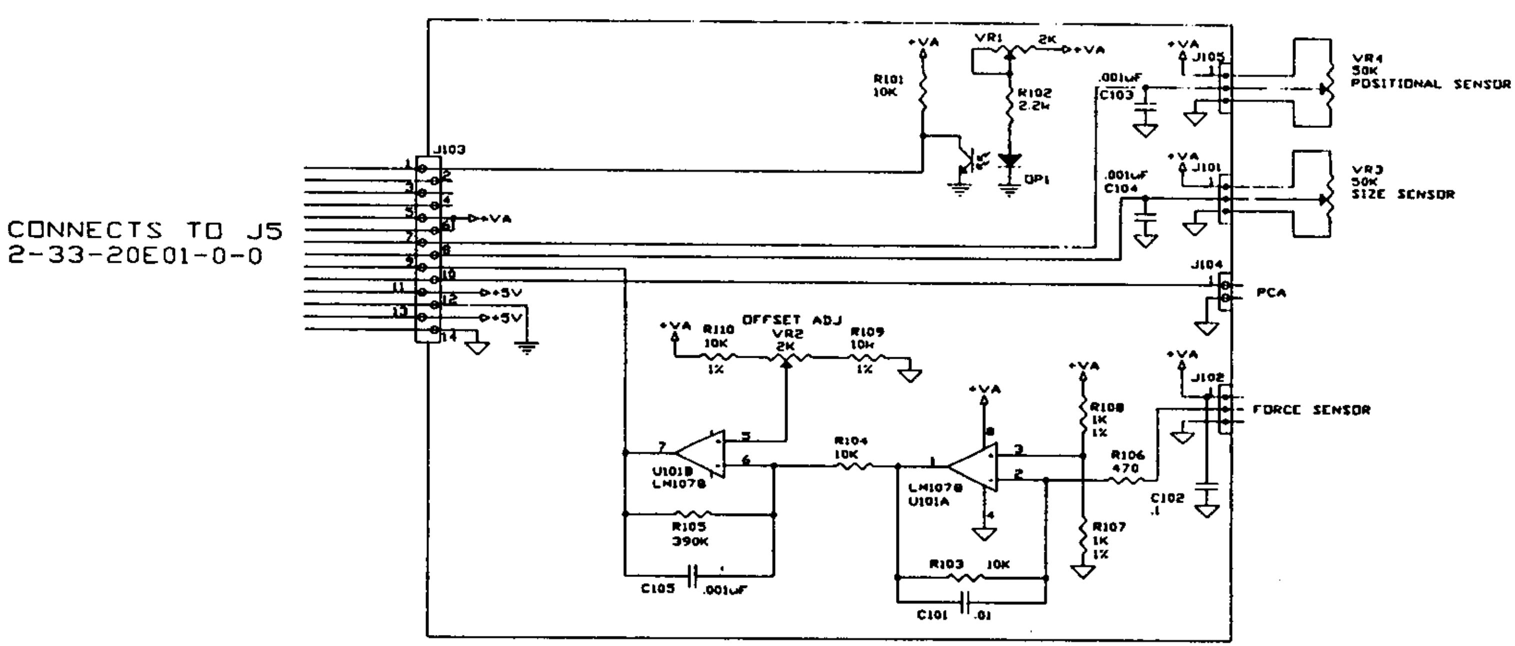


SYSTEM BLOCK DIAGRAM, 2001/2010



CONNECTS TO J103
2-33-20E02-0-0
STEPPER MOTOR
ALARM
MEDFUSION INC.
PUMP 2001
2-33-20E01-0-2
NONE
1 OF 1
D
0

REV	REFERENCE	DESCRIPTION OF REVISION	APPROVED	DATE
0 1	90052101	Added C103, C104, C105	L Garcia V	7-12-90
			[illegible]	7-12-90



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DWN.	LUIS GARCIA-VERONA	JAN 5, 1990
ENGR.	LUIS GARCIA-VERONA	JAN 5, 1990
CHK.	DAVE AHMANN	JAN 5, 1990
PROD.	BRIAN KRATOFIL	JAN 5, 1990
APVD.	RUFFIN BOOTH	JAN 5, 1990

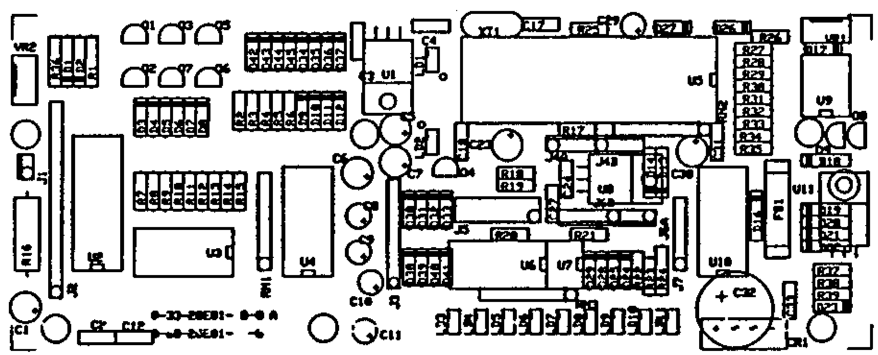
MEDFUSION INC.

DIMENSIONS ARE IN DEC. N/A
FINISH N/A
TITLE AUX PCB
TOLERANCES UNLESS OTHERWISE NOTED
ANGLE N/A
MATERIAL N/A

SIZE	SHEET	SCALE	PRODUCT REFERENCE	PART NO.	REV
B	1 OF 1	NONE	PUMP 2001	2-33-20E02-0-1	0

REV	REF	DESCRIPTION OF REVISION	APPROVED	DATE

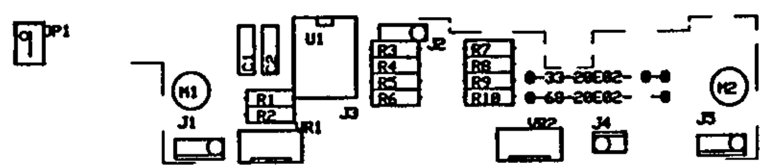
PART NO. 1-68-20E01-0-0 REV 0



THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.	DWN. L. GARCIA-VERONA	1.5.90	MEDFUSION INC.	
	ENGR.	1-5-90		
	CHK	1-5-90	DIMENSIONS ARE IN INCHES DEC N/A	TOLERANCES UNLESS OTHERWISE NOTED ANGLE N/A
	PROD	1-5-90	FINISH N/A	MATERIAL N/A
	APVD	1/5/90	TITLE 2001 MAIN PCB S/A	
SIZE B / SHEET 1 OF 1	SCALE NONE		PRODUCT REFERENCE PUMP 2001	PART NO. 1-68-20E01-0-0 / REV 0

REV	REF	DESCRIPTION OF REVISION	APPROVED	DATE

PART NO. 1-68-20E02-0-0 REV 0



DWN.	L. GARCIA-VERONA	1.5.90
ENGR.	[signature]	1-5-90
CHK	[signature]	1-5-90
PROD	[signature]	1-5-90
APVD	[signature]	1/5/90

MEDFUSION INC.

DIMENSIONS ARE IN INCHES
DEC N/A

TOLERANCES UNLESS OTHERWISE NOTED
ANGLE N/A

FINISH N/A

MATERIAL N/A

TITLE 2001 AUX PCB S/A

SIZE	SHEET	SCALE	PRODUCT REFERENCE	PART NO	REV
B	1 OF 1	NONE	PUMP 2001	1-68-20E02-0-0	0

APPENDIX C. MICRO-CONTROLLER I/O PORT DEFINITIONS

Port 0:

P0.0-P0.3:	(output) stepper motor waveform
P0.4:	(output) alarm ON(1) / OFF(0)
P0.5-P0.6:	not used
P0.7:	(output) A/D REF power(VA)* ON(0) / OFF(1)

Port 1:

P1.0-P1.3:	input from Multiplexer	
	: Keypad input;	if P3.7=1, P1.6=0, P2.7=1
	: P1.0-ROT, P1.1-AC;	if P3.7=1, P1.6=0, P2.7=0
P1.3:	input from A/D	if P3.7=0, P1.6=1, P0.7=0

P1.4:	output, Motor power High (1), Low (0)
P1.5:	output, LCD control E
P1.6:	output, LCD control RS or Mutiplexer OE* (0-enabled)
P1.7:	output, LED latch clock

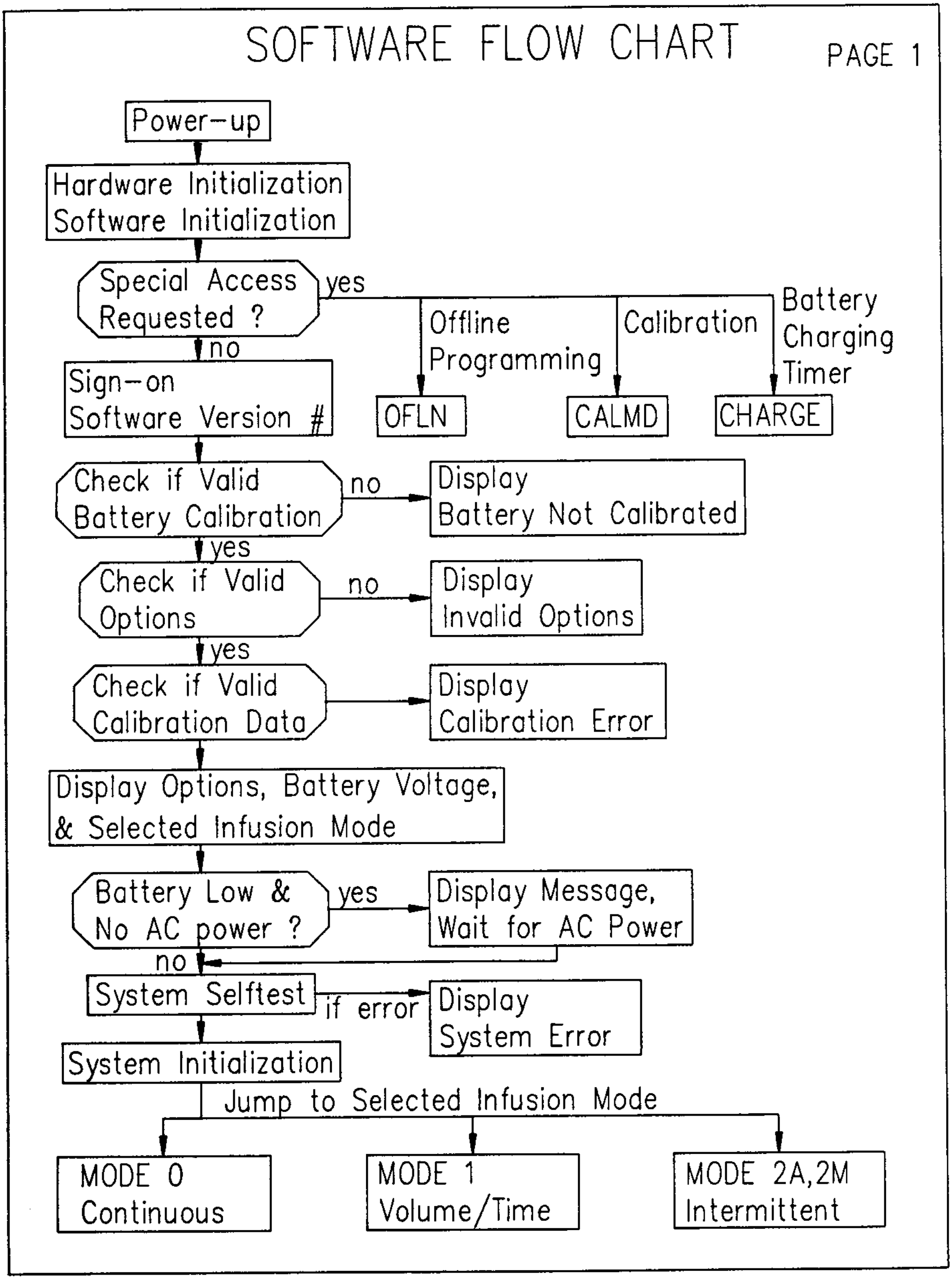
Port 2:

P2.0-P2.7:	8-bit data bus to LCD display and LED latch
P2.0-P2.3:	output scanning signals for the keyboard
P2.4:	output, A/D CLK
P2.5:	output, A/D DI (data input)
P2.7:	output, select one set of inputs from multiplexer.

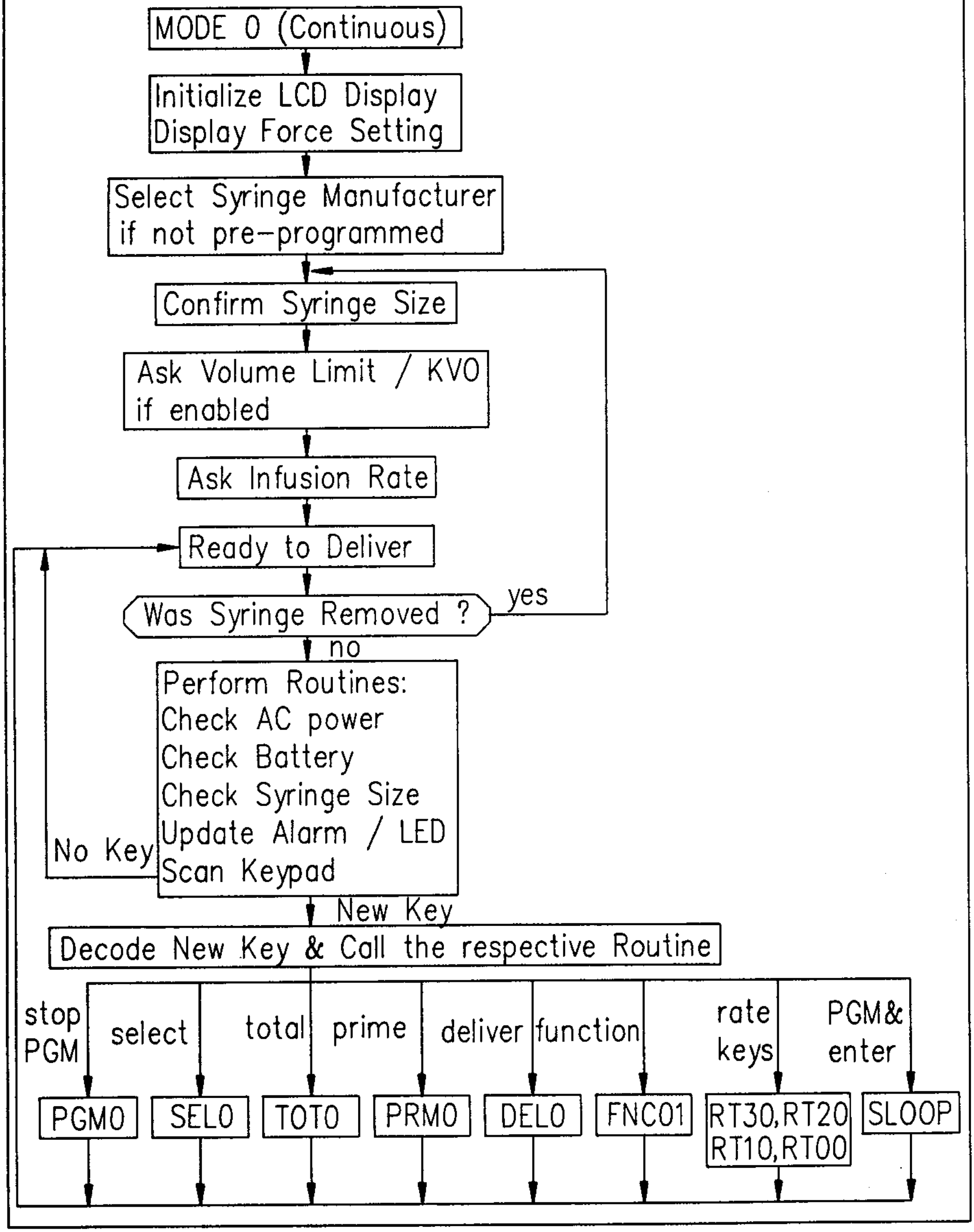
Port 3:

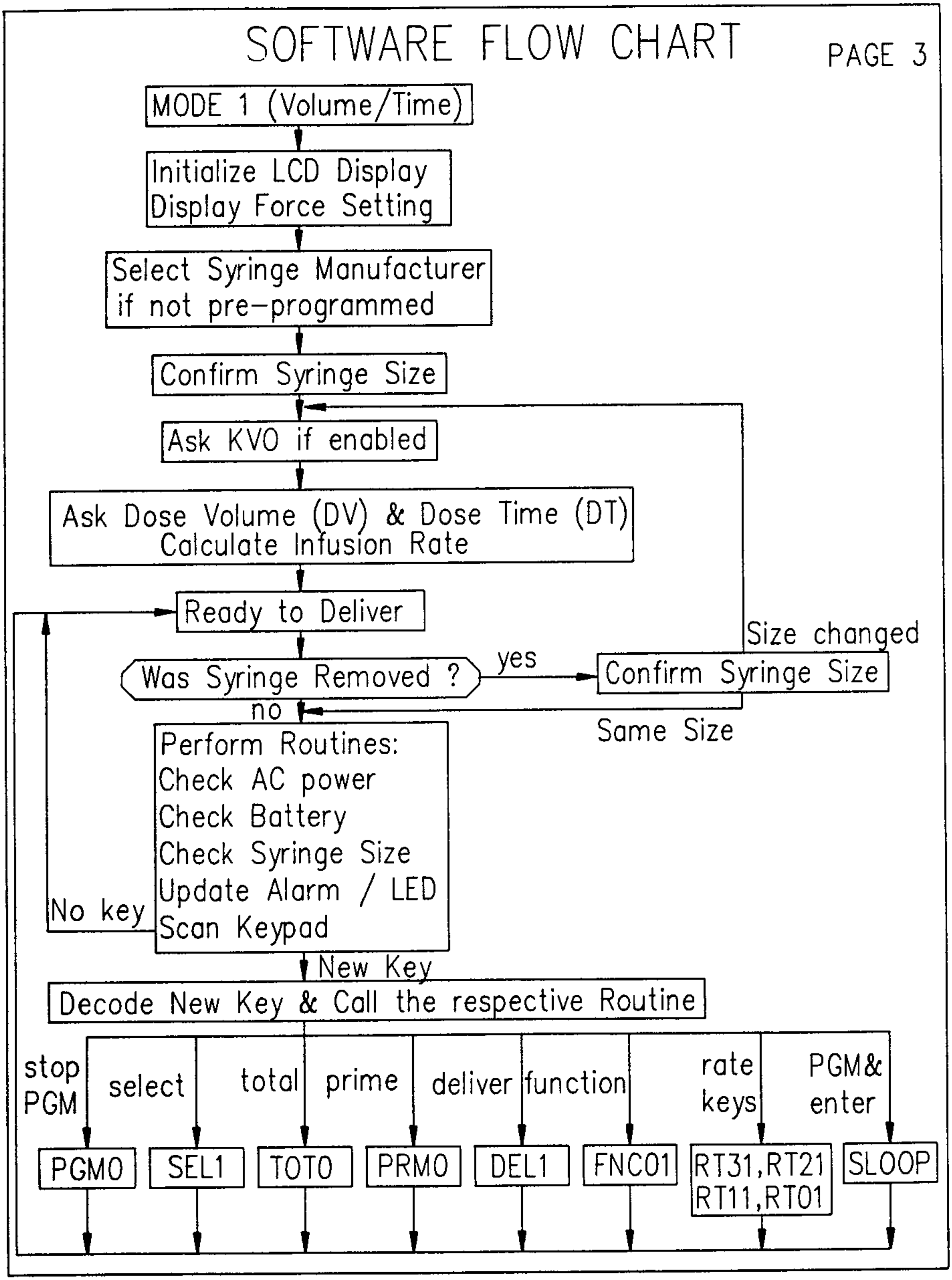
P3.0:	output, send pulses to the watchdog circuit
P3.1-P3.2:	reserved for serial communication
P3.3:	output, control LCD display Read(1) / Write(0)
P3.4:	output, Volume Limit LED ON(1) / OFF(0)
P3.5:	output, LCD backlight* ON (0) / OFF(1)
P3.6:	output, Alarm Volume Loud(1) / Soft(0)
P3.7:	output, CE* control for A/D (0-enabled)

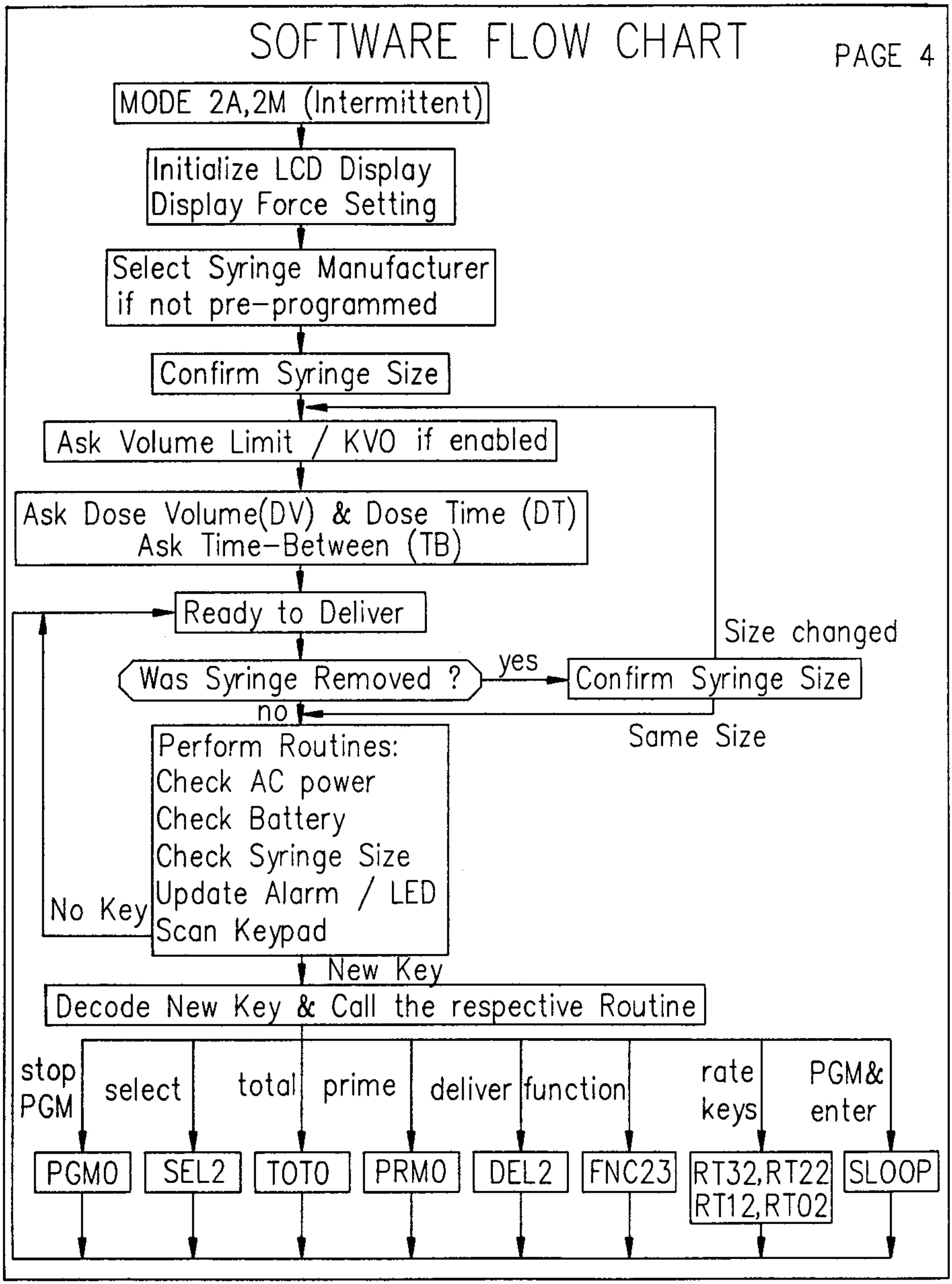
APPENDIX D.1 SOFTWARE FLOW CHARTS (2001)


SOFTWARE FLOW CHART
PAGE 1
Power-up
Hardware Initialization
Software Initialization
Special Access Requested ?
yes
no
Offline Programming
Calibration
Battery Charging Timer
OFLN
CALMD
CHARGE
Sign-on
Software Version #
Check if Valid Battery Calibration
no
Display
Battery Not Calibrated
yes
Check if Valid Options
no
Display
Invalid Options
yes
Check if Valid Calibration Data
Display
Calibration Error
Display Options, Battery Voltage, & Selected Infusion Mode
Battery Low & No AC power ?
yes
Display Message, Wait for AC Power
no
System Selftest
if error
Display
System Error
System Initialization
Jump to Selected Infusion Mode
MODE 0
Continuous
MODE 1
Volume/Time
MODE 2A,2M
Intermittent

SOFTWARE FLOW CHART

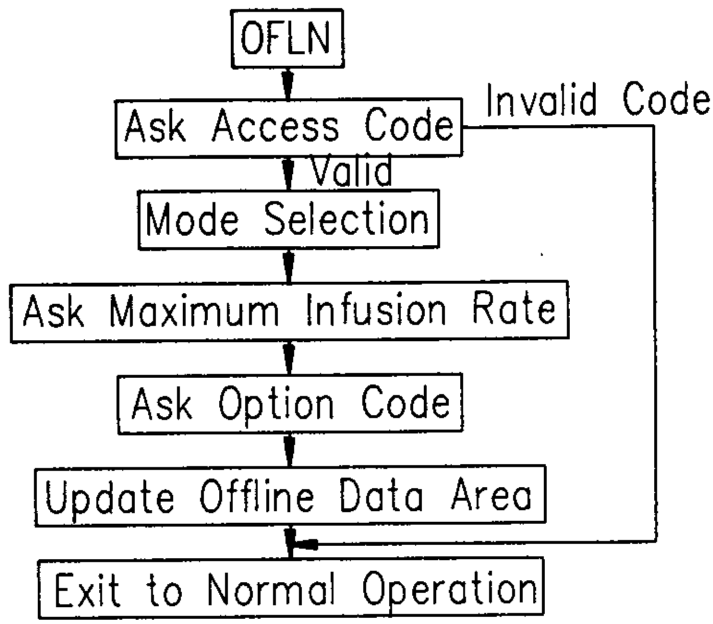



SOFTWARE FLOW CHART
PAGE 3
MODE 1 (Volume/Time)
Initialize LCD Display
Display Force Setting
Select Syringe Manufacturer
if not pre-programmed
Confirm Syringe Size
Ask KVO if enabled
Ask Dose Volume (DV) & Dose Time (DT)
Calculate Infusion Rate
Ready to Deliver
Was Syringe Removed ?
yes
Confirm Syringe Size
Size changed
Same Size
no
Perform Routines:
Check AC power
Check Battery
Check Syringe Size
Update Alarm / LED
Scan Keypad
No key
New Key
Decode New Key & Call the respective Routine
stop PGM
select
total
prime
deliver
function
rate keys
PGM& enter
PGM0
SEL1
TOT0
PRM0
DEL1
FNC01
RT31,RT21
RT11,RT01
SLOOP

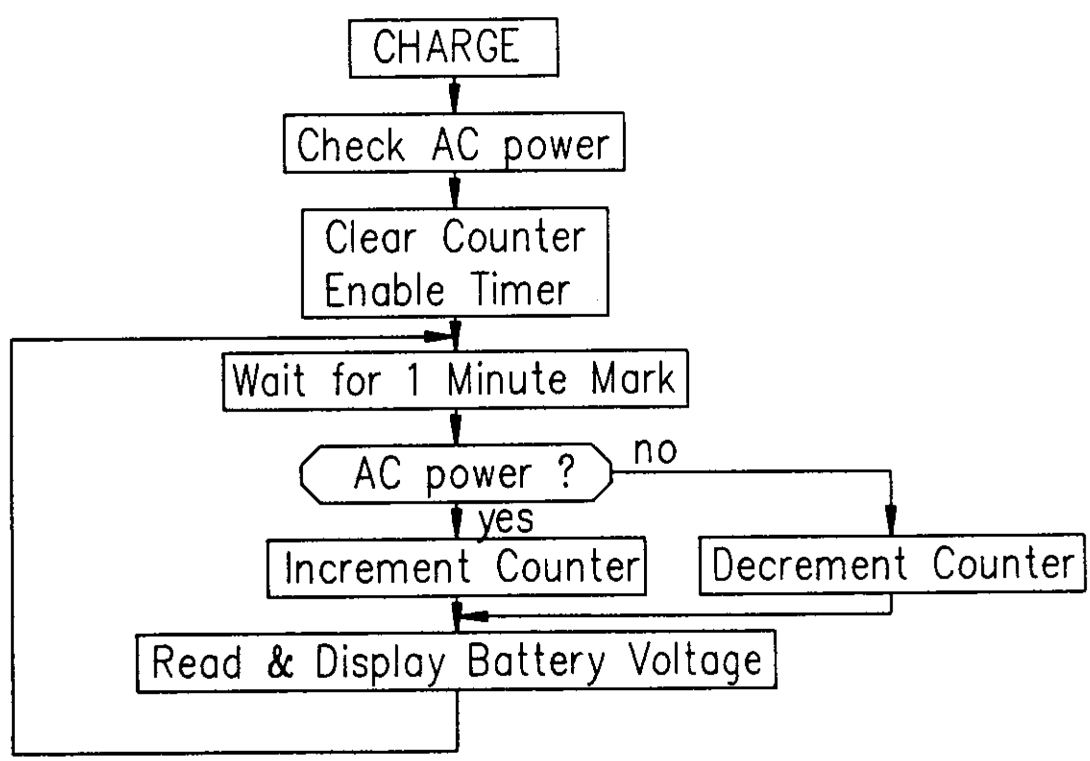

SOFTWARE FLOW CHART
PAGE 4
MODE 2A,2M (Intermittent)
Initialize LCD Display
Display Force Setting
Select Syringe Manufacturer
if not pre-programmed
Confirm Syringe Size
Ask Volume Limit / KVO if enabled
Ask Dose Volume(DV) & Dose Time (DT)
Ask Time-Between (TB)
Ready to Deliver
Size changed
Was Syringe Removed ?
yes
Confirm Syringe Size
no
Same Size
Perform Routines:
Check AC power
Check Battery
Check Syringe Size
Update Alarm / LED
Scan Keypad
No Key
New Key
Decode New Key & Call the respective Routine
stop PGM
select
total
prime
deliver
function
rate keys
PGM& enter
PGM0
SEL2
TOT0
PRM0
DEL2
FNC23
RT32,RT22
RT12,RT02
SLOOP

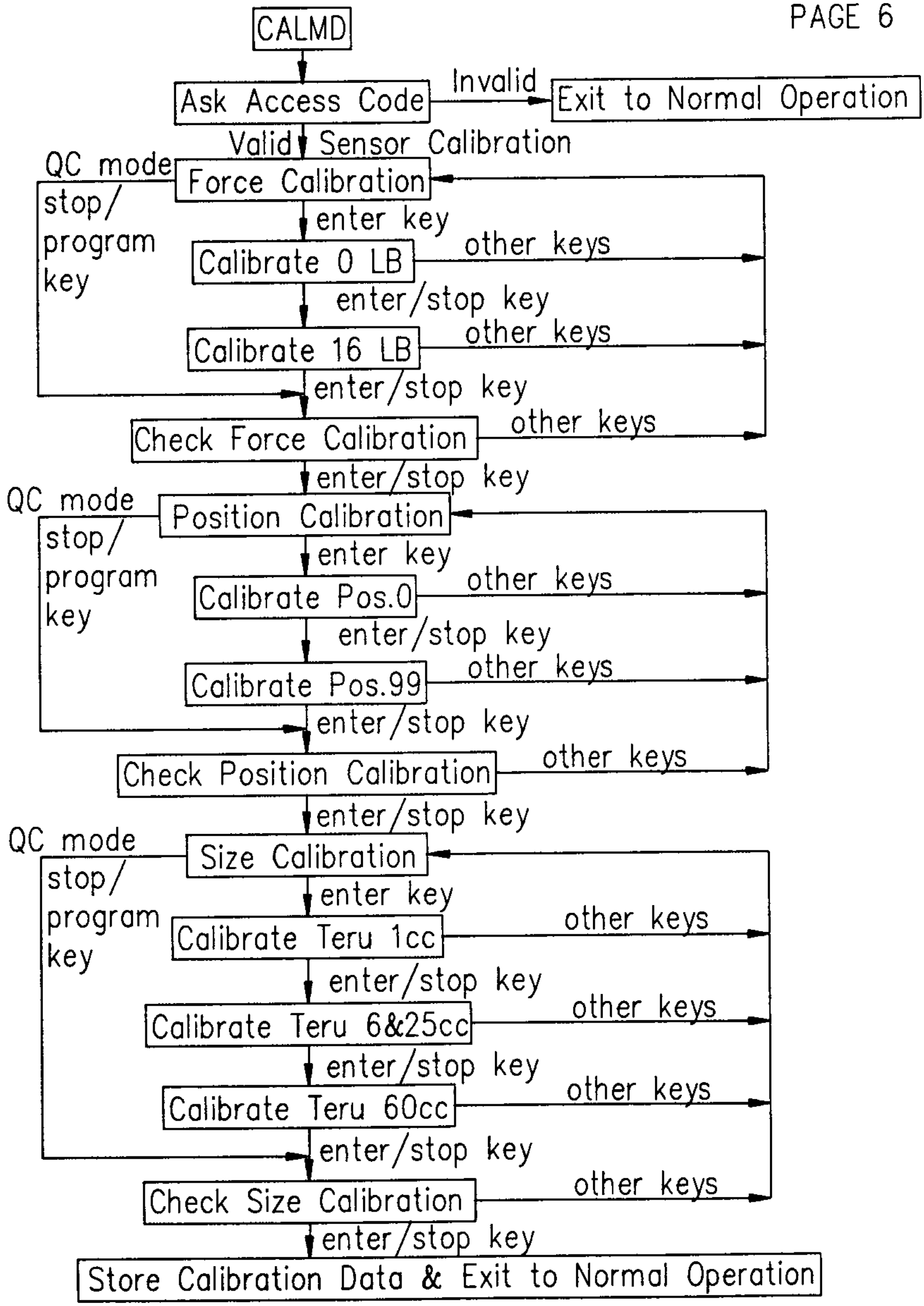
SOFTWARE FLOW CHART

OFFLINE PROGRAMMING

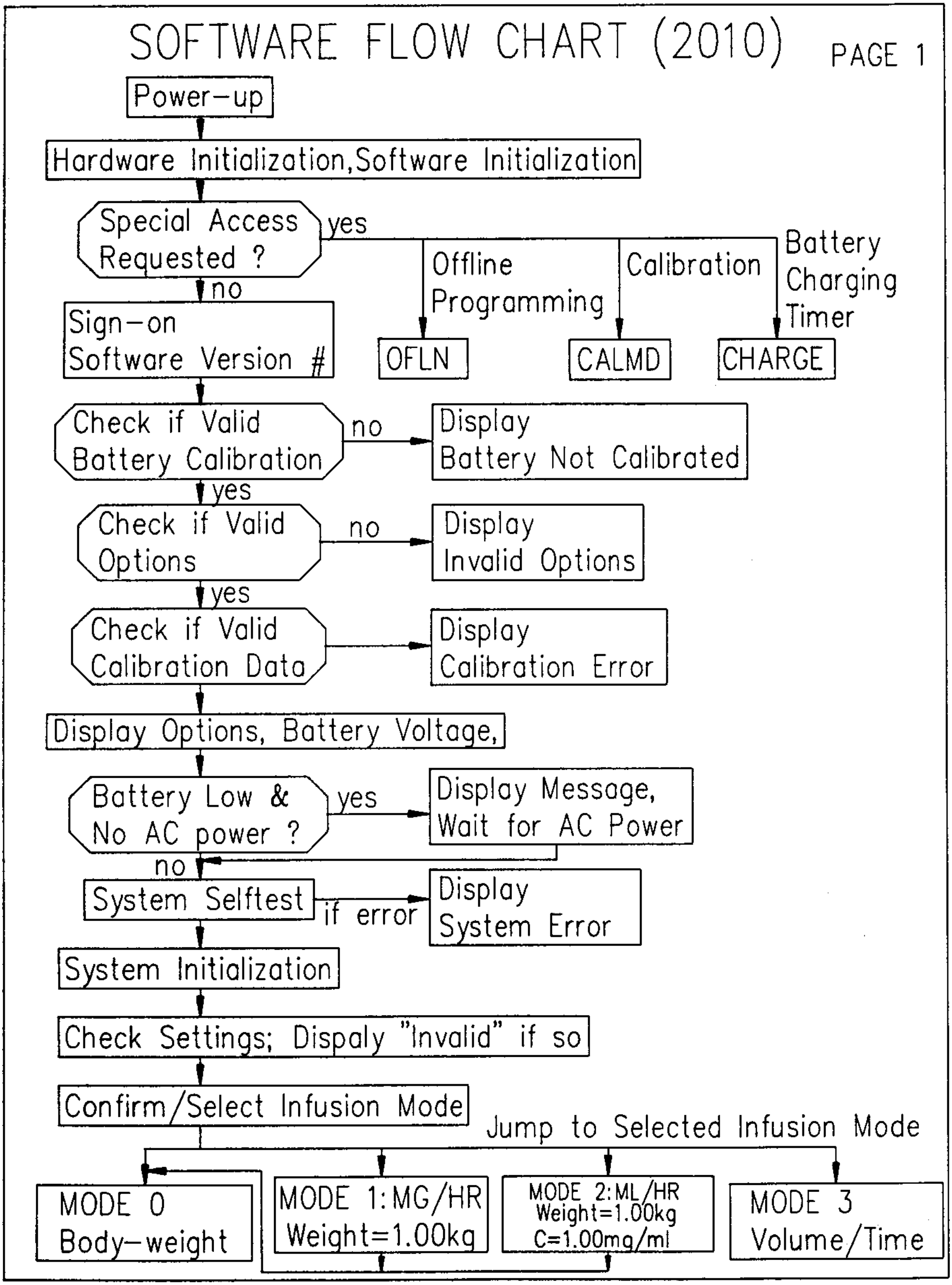


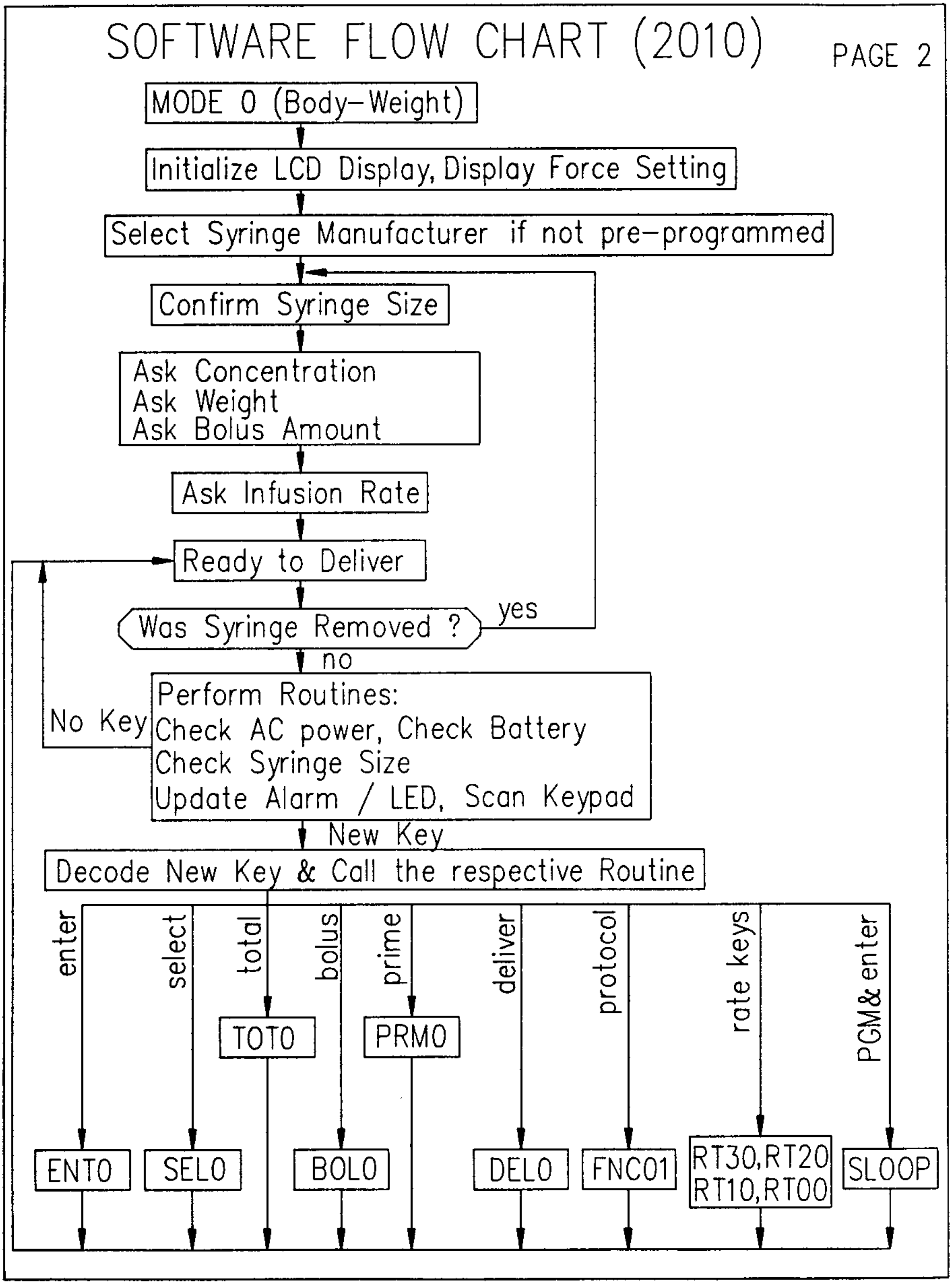
BATTERY CHARGING TIMER




CALMD
Ask Access Code
Invalid
Exit to Normal Operation
Valid
Sensor Calibration
QC mode
Force Calibration
stop/
program
key
enter key
Calibrate 0 LB
other keys
enter/stop key
Calibrate 16 LB
other keys
enter/stop key
Check Force Calibration
other keys
enter/stop key
QC mode
Position Calibration
stop/
program
key
enter key
Calibrate Pos.0
other keys
enter/stop key
Calibrate Pos.99
other keys
enter/stop key
Check Position Calibration
other keys
enter/stop key
QC mode
Size Calibration
stop/
program
key
enter key
Calibrate Teru 1cc
other keys
enter/stop key
Calibrate Teru 6&25cc
other keys
enter/stop key
Calibrate Teru 60cc
other keys
enter/stop key
Check Size Calibration
other keys
enter/stop key
Store Calibration Data & Exit to Normal Operation

APPENDIX D.2 SOFTWARE FLOW CHARTS (2010)


SOFTWARE FLOW CHART (2010)
PAGE 1
Power-up
Hardware Initialization,Software Initialization
Special Access Requested ?
yes
no
Offline Programming
Calibration
Battery Charging Timer
OFLN
CALMD
CHARGE
Sign-on Software Version #
Check if Valid Battery Calibration
no
Display Battery Not Calibrated
yes
Check if Valid Options
no
Display Invalid Options
yes
Check if Valid Calibration Data
Display Calibration Error
Display Options, Battery Voltage,
Battery Low & No AC power ?
yes
Display Message, Wait for AC Power
no
System Selftest
if error
Display System Error
System Initialization
Check Settings; Dispaly "Invalid" if so
Confirm/Select Infusion Mode
Jump to Selected Infusion Mode
MODE 0 Body-weight
MODE 1:MG/HR Weight=1.00kg
MODE 2:ML/HR Weight=1.00kg C=1.00mg/ml
MODE 3 Volume/Time


SOFTWARE FLOW CHART (2010)
PAGE 2
MODE 0 (Body-Weight)
Initialize LCD Display, Display Force Setting
Select Syringe Manufacturer if not pre-programmed
Confirm Syringe Size
Ask Concentration
Ask Weight
Ask Bolus Amount
Ask Infusion Rate
Ready to Deliver
Was Syringe Removed ?
yes
no
Perform Routines:
Check AC power, Check Battery
Check Syringe Size
Update Alarm / LED, Scan Keypad
No Key
New Key
Decode New Key & Call the respective Routine
enter
select
total
bolus
prime
deliver
protocol
rate keys
PGM& enter
TOTO
PRMO
ENTO
SELO
BOLO
DELO
FNC01
RT30, RT20
RT10, RT00
SLOOP

APPENDIX E. QC Test Procedure

(System Performance Tests)

1.0 PURPOSE:

1.1 To establish a detailed test procedure to demonstrate that the Model 2001 meets inspection specifications.

2.0 SCOPE:

2.1 The Q.A. Inspector is responsible for the inspection, acceptance/rejection and notifying accounting.

2.2 The electronics technician will test the pumps prior to sampling by Q.C.

2.3 The Director of Quality Assurance (or designate) is responsible for assuring compliance with this procedure.

3.0 RELATED PROCEDURES AND DOCUMENTS:

3.1 Form P-72-20001-0-X, Q.C. Test Report Form (X = Latest revision)

3.2 Associated Assembly Specifications

3.3 Model 2001 Operator's Manual

3.4 Form P-72-20002-0-X, Batch Functional Test

3.5 Form P-72-20003-0-X, P-72-20004-0-X or P-72-20005-G-X Syringe Recognition Test

3.6 GMP Regulations

3.7 MIL-STD-105D

3.8 Syringe Infusion Pump Flow Test Procedure, 4-72-FLOW1-0-X

4.0 ASSOCIATED MATERIALS:

4.1 Hand tools

4.2 AC power source

4.3 Force transducer test gauge

5.0 PROCEDURE:

5.1 Pumps are delivered to Q.C. by production in batches. Several batches may make up a work order. Record on inspection forms: P-72-20001-0-X and P-72-20002-0-X (where appropriate). See 4-61-20010-G-X for German Screen Translations (if applicable).

5.1.1 Identify pump model/serial number.

5.1.2 Record the work order on the inspection form.

5.1.3 The Q.C. Inspector will test per forms P-72-20001-0-X and P-72-20002-0-X.

5.2 Inspection procedure

5.2.1 Visual Inspection

5.2.1.1 Inspect for presence of S/N-UL label and Charger label on pump's rear panel, checking for legibility and record serial number on the Inspection Form.

5.2.1.2 Rubber bumpers are attached to the bottom (4 each).

5.2.1.3 Check for front panel's printing and legibility.

5.2.1.4 On/off switch is oriented with the "1" towards the slide.

5.2.1.5 Check overall cosmetic appearance. No finger print on LCD window.

5.2.1.6 Turn unit on all sides and check for any loose parts both internal and external.

5.2.2 Operational Checks: Battery Mode

5.2.2.1 Check syringe slide operation. With clutch disengaged, carriage must slide freely along it's full travel with no appreciable friction or binding. Clutch should freely disengage and spring back into engagement.

5.2.2.1.1 Syringe Plunger Retainer should be firmly attached to Syringe Driver.

5.2.2.2 Check for proper lift and function of the syringe clamp. For German Pump, use German syringes. Clamp must lock onto syringe tabs.

5.2.2.3 With unit unplugged from AC power, turn the power switch on. After checks, unit should be in program mode with audio alarm and "battery in use" (German: "BATT. Betrieb") light illuminated. Record on the top of the form the software version, the battery voltage, the alarm delay and the number of the options. Use overlay and manual with German displays added for German version.

Observe for:

5.2.2.3.1 Proper software revision
5.2.2.3.2 Proper power-up system check
5.2.2.3.3 Alarms sound quality and volume
5.2.2.3.4 LED's function
5.2.2.3.5 LCD display contrast

5.2.2.4 Programming - Select mode (continuous, volume/time, intermittent-auto or intermittent-manual, if programmed), syringe manufacturer, load syringe, volume limit and Keep Vein Open (KVO) (if applicable), rate, and cancel audio alarm. Verify operation of all keys used during this sequence. The pumps may be preprogrammed to exclude certain options. Vary the modes, manufactures and rates for different pumps.

5.2.2.5 Push and hold "prime" key until continuous audio alarm sounds (about 16 seconds). (Display should indicate PRIME VOL = XX.XX ML.) Verify visually syringe cradle movement.

5.2.2.6 Press "deliver" key. Unit should begin moving the syringe cradle, and incrementing the Running Volume display and the Total Volume delivered display.

5.2.2.7 Test the occlusion alarm as follows:

5.2.2.7.1 While in the deliver mode apply hand pressure to the end of the slide that meets the syringe plunger to activate the occlusion alarm. The pressure required to activate the alarm will vary with the syringe size, less is needed for the small syringe sizes and more is needed for the larger sizes.

5.2.2.8 Resume the deliver mode, run cradle through "near empty" to "empty" alarms and verify alarm function.

5.2.2.9 After empty alarm, pressing "reset total volume" button should change the "Total Volume" display to 0.00.

5.2.2.10 Pressing the "backlight" button, or any key in the DC mode, should cause the LCD back-light to illuminate. You may need to turn off the room lights to check this.

5.2.2.11 Check motor for noise using a B-D 60cc at 60 ml/hr for 1 minute. Reject pump if excessive noise is observed.

5.2.3 Operational Checks: AC Mode

5.2.3.1 Plug unit in AC receptacle, and turn power switch off, then on. Unit should go through power up sequence as in 5.2.2.3, except that "battery in use" LED should be off, and "battery charging" LED should be on.

5.2.3.2 Verify unit programs properly, as in 5.2.2.4. Place in deliver mode.

5.2.3.3 Verify backlight to illuminate in the AC mode. You may need to turn off the room lights to check this.

5.2.3.4 Turn the AC power off, leaving the unit's power switch on. No interruption in function should occur, but the "battery in use" LED should illuminate.

5.2.3.5 Turn the unit's power switch off. Plug unit in AC receptacle, depress and hold "stop/program" and "deliver" keys simultaneously while turning the units power switch to on. Unit should display "BATTERY TIME=00.00". After one minute the LCD will display "BATT.V= X.X".

5.2.3.6 The inspector performing the testing signs and dates the form.

5.2.4 Transducer Calibration Check

5.2.4.1 Press stop/program and select key at the same time, turn pump on, hold for approximately one second and release. Lock = 000.0 will appear on the display. Key in 100.0 onto the display. Press enter. Access complete. Display will show "Force (lb) 00.XX=XX".

5.2.4.2 Test the occlusion pressure using the 2001 force gauge. Place gauge on the pump, and set gauge to the values stated on the "Q.C. Final Test Report, Model 2001". The 2001 Pump display should read within the stated tolerances.

5.2.4.2.1 The tolerances are as follows:
$1.5 \pm .5$,
$8.0 \pm .75$,
15.0 ± 1.5.

5.2.5 Position Sensor Test (This test should be done with the clutch disengaged.)

5.2.5.1 Press the stop/program key once. Pos. (inch) appears on display. For the first readings, move track so that 0.000 is shown on the display. Record this number and its corresponding HEX number. Move track so that $4.836 \pm .005$ is shown on the display. Record this number and its corresponding HEX #. For the second readings, move the track to the lowest point possible. Record this # and its corresponding HEX #. Move the track to the highest point possible. Record this # and its corresponding HEX #. Verify that the lowest point HEX # is equal to or less than the 0 reading HEX # by one HEX digit only. Verify that the highest point HEX # is equal to or greater than the 4.836 reading HEX # by one HEX digit only.

5.2.5.2 The inspector performing the testing signs and dates the form.

5.2.6 Syringe Recognition Test

5.2.6.1 Press the stop/program key once again. Size (inch) will appear on the display. Insert syringes listed on "Syringe Recognition Report, P-72-20003-0-X or P-72-20004-0-X, if applicable. Read number on display between high and low for each syringe.

5.2.6.2 The inspector performing the testing signs and dates the form.

5.2.7 Flow Test

5.2.7.1 Perform flow testing as required on form P-72-20002-0-X or P-72-20001-0-X. Use any size syringe in the volume/time mode. Test should last 20 minutes mimimum using more than 70% of the pipette. Refer to Flow Test Procedure 4-72-FLOW1-0-X.

5.2.7.2 The inspector performing the testing signs and dates the form.

5.2.8 Final Check

5.2.8.1 Check for presence of screw covers over 4 screws. Two in line with the brass pole mount inserts and two screws closest to the face plates. Check for tamper evident label on screw on the back bottom center.

5.3 Inspection Forms

5.3.1 Fill in the Inspection Form, P-72-20001-0-X for Model 2001, for all test categories. Note any improper function in the reject column and comments section. Any reject must be separated and handled in accordance with the Q.A. Manager's instructions. The form must be signed and dated.

5.3.2 Form number P-72-20002-0-X, Batch Functional Test - Model 2001, should also be completed for each batch of pumps delivered to Q.C. Instructions are on the form.

Q.C. Final Test Report, Model 2001
Preprogrammed Settings:

(See Procedure 4-72-20001-0-X)

S/N________________________
Software Version_________
Work Order:_______________

_________	_________	_________	_________
Alarm Vol.	Alarm Delay	Batt. V.	Options

		Accept	Reject
5.2.1	**VISUAL:**		
5.2.1.1	S/N-UL Label and Charger Label attached	_______	_______
5.2.1.2	Rubber bumpers attached (4)	_______	_______
5.2.1.3	Face plate printing and I.D.	_______	_______
5.2.1.4	On/off switch properly oriented	_______	_______
5.2.1.5	Overall appearance	_______	_______
5.2.1.6	Loose parts - internal and external	_______	_______
5.2.2	**OPERATIONAL CHECKS:**		
5.2.2.1	Syringe slide function	_______	_______
5.2.2.1.1	Syringe plunger retainer attached	_______	_______
5.2.2.2	Syringe clamp function	_______	_______
5.2.2.3	Power switch function	_______	_______
5.2.2.3.1	Proper software revision	_______	_______
5.2.2.3.2	Proper power up system check	_______	_______
5.2.2.3.3	Alarms sound quality and volume	_______	_______
5.2.2.3.4	LED's function	_______	_______
5.2.2.3.5	LCD display contrast	_______	_______
5.2.2.4	Programmable	_______	_______
5.2.2.5	Priming function (Alarm at about 16 secs.)	_______	_______
5.2.2.6	Delivery function (RV displayed)	_______	_______
5.2.2.7	Occlusion alarm function (finger pressure)	_______	_______
5.2.2.8	Alarms		
5.2.2.8.1	Near Empty	_______	_______
5.2.2.8.2	Empty	_______	_______
5.2.2.9	Reset volume switch function	_______	_______
5.2.2.10	Light switch function	_______	_______
5.2.2.11	Motor noise B-D 60cc at 60 ml/hr for one min.	_______	_______
5.2.3	**OPERATIONAL CHECKS (in AC Mode):**		
5.2.3.1	Power Up	_______	_______
5.2.3.2	Programmable	_______	_______
5.2.3.3	Verify backlight to illuminate	_______	_______
5.2.3.4	Uninterrupted function when AC power is disconnected	_______	_______
5.2.3.5	Charging function	_______	_______
5.2.3.6	Sign/Date	________________	
5.2.4	**TRANSDUCER CALIBRATION CHECK:**		
5.2.4.1	Program in Q.C. Test Mode - Code 1000	_______	_______
5.2.4.2	1.5±.5_____, 8.0±.75_____, 15.0±1.5_____		
5.2.5	**POSITION SENSOR CALIBRATION**		

5.2.5.1 1st reading: 0=_______HEX=_________ 4.836±.005=________HEX=________
2nd reading: Lowest point = ______HEX=______ Highest point =_______HEX_____
Lowest point HEX number must be equal to or less than 0 reading HEX number, by 1 HEX digit only.
Highest point HEX number must be equal to or greater than 4.836 reading HEX number, by 1 HEX digit only. _______ _______

5.2.5.2 Sign/Date ________________

S/N ____________________

5.2.6 SYRINGE RECOGNITION TEST (SEE FORM P-72-20003-0-X, P-72-20004-0-X OR P-72-20005-G-X IF APPLICABLE)

5.2.6.1

MFG/SIZE	LOW	HI	ACCEPT	REJECT
No Syringe	088	115	______	______
TERUMO				
1 ML	145	171	______	______
5 ML	461	531	______	______
20 ML	790	860	______	______
60 ML	1188	1258	______	______

5.2.6.2 Sign/Date ____________________

5.2.7 FLOW TEST (See Flow Test Procedure, 4-72-FLOW-0-X)

5.1.7.1

Syr. Type	Syr. Size	Tubing Type	Rate	Elapsed Time	Predict Volume	Deliver Volume	± 3% Error

5.2.7.2 Sign/Date ____________________

5.2.8 FINAL CHECK:

5.2.8.1 Screw covers (4) and tamper label (1) attached — ACCEPT ______ REJECT ______

COMMENTS: ____

____

____

____

Accept Reject
(Circle One)

____
Inspector/Date

P-72-20001-0-6
DCN#: 91053002

RE U. Ammann 5-31-91 MFG B Keaton 6-14-91 QC [signature] 6/14/91

BATCH FUNCTIONAL TEST
MODEL 2001

Date(s) of Inspection:	PROCEDURE	List S/N No. By Software version:
Batch Size:	Inspect all pumps using form P-72-20001-0-X (Latest revision)	
Work Order No.:	Flow test a random sample using special level S4 reduced. IGNORE AQL. No. flow tested:	

Flow tests:

S/N	Syringe Type	Syringe Size	Tubing Type	Rate	Elapsed Time	Predicted Volume	Delivered Volume	± 3% Error

COMMENTS:

P-72-20002-0-1
DCN90070201

Approval [signature] Date 7/27/90

Approval V. Ammann Date 7-31-90

Accept / Reject (Circle)

Inspector ________ Date ________

Reviewer ________ Date ________

1.0 PURPOSE:

1.1 To establish a detailed test procedure to demonstrate that the Model 2010 meets inspection specifications.

2.0 SCOPE:

2.1 The Q.A. Inspector is responsible for the inspection, acceptance/rejection and notifying accounting.

2.2 The electronics technician will test the pumps prior to sampling by Q.C.

2.3 The Director of Quality Assurance (or designate) is responsible for assuring compliance with this procedure.

3.0 RELATED PROCEDURES AND DOCUMENTS:

3.1 Form P-72-21001-0-X, Q.C. Test Report Form (X = Latest revision)

3.2 Associated Assembly Specifications

3.3 Model 2010 Operator's Manual

3.4 Form P-72-21002-0-X, Batch Functional Test

3.5 Form P-72-20004-0-X or P-72-20005-G-X Syringe Recognition Test (if applicable)

3.6 GMP Regulations

3.7 MIL-STD-105D

3.8 Syringe Infusion Pump Flow Test Procedure, 4-72-FLOW1-0-X

4.0 ASSOCIATED MATERIALS:

4.1 Hand tools

4.2 AC power source

4.3 Force transducer test gauge

5.0 PROCEDURE:

5.1 Pumps are delivered to Q.C. by production in batches. Several batches may make up a work order. Record on inspection forms: P-72-21001-0-X and P-72-21002-0-X (where appropriate). See 4-61-20010-G-X for German Screen Translations (if applicable).

5.1.1 Identify pump model/serial number.

5.1.2 Record the work order on the inspection form.

5.1.3 The Q.C. Inspector will test per forms P-72-21001-0-X and P-72-21002-0-X.

5.2 Inspection procedure

5.2.1 Visual Inspection

5.2.1.1 Inspect for presence of S/N-UL label and Charger label on pump's rear panel, checking for legibility and record serial number on the Inspection Form.

5.2.1.2 Rubber bumpers are attached to the bottom (4 each).

5.2.1.3 Check for front panel's printing and legibility.

5.2.1.4 On/off switch is oriented with the "1" towards the slide.

5.2.1.5 Check overall cosmetic appearance. No finger print on LCD window.

5.2.1.6 Turn unit on all sides and check for any loose parts both internal and external.

5.2.2 Operational Checks: Battery Mode

5.2.2.1 Check syringe slide operation. With clutch disengaged, carriage must slide freely along it's full travel with no appreciable friction or binding. Clutch should freely disengage and spring back into engagement.

5.2.2.1.1 Syringe Plunger Retainer should be firmly attached to Syringe Driver.

5.2.2.2 Check for proper lift and function of the syringe clamp. For German Pump, use German syringes. Clamp must lock onto syringe tabs.

5.2.2.3 With unit unplugged from AC power, turn the power switch on. After checks, unit should be in program mode with "battery in use" (German: "BATT. Betrieb") light illuminated. Record on the top of the form the software version, the battery voltage, the alarm delay and the number of the options. Use overlay and manual with German displays added for German version.

Observe for:

5.2.2.3.1 Proper software revision
5.2.2.3.2 Proper power-up system check
5.2.2.3.3 Alarms sound quality and volume
5.2.2.3.4 LED's function
5.2.2.3.5 LCD display contrast

5.2.2.4 Programming - Select mode (ML/HR, volume/time, MG/HR or Body weight mode), Bolus amt (yes or no), syringe manufacturer, load syringe, bolus amt, rate. Verify operation of all keys used during this sequence. The pumps may be preprogrammed to exclude certain options. Vary the modes, manufactures and rates for different pumps.

5.2.2.5 Push and hold "prime" key until continuous audio alarm sounds (about 16 seconds). (Display should indicate PRIME VOL = XX.XX ML.) Verify visually syringe cradle movement.

5.2.2.6 Press "deliver" key. Unit should begin moving the syringe cradle, and incrementing the Total Volume delivered display. Pre-programmed Bolus amt should also be displayed.

5.2.2.7 Test the occlusion alarm. While in the deliver mode apply hand pressure to the end of the slide that meets the syringe plunger to activate the occlusion alarm. The pressure required to activate the alarm will vary with the syringe size, less is needed for the small syringe sizes and more is needed for the larger sizes.

5.2.2.8 Test Bolus function by pressing the "Bolus" and "Prime" keys. Bolus amt. and total vol. delivered should be displayed.

5.2.2.9 Resume the deliver mode, run cradle through "near empty" to "empty" alarms and verify alarm function.

5.2.2.10 After empty alarm, pressing "reset total volume" button should change the "Total Volume" display to 0.0000.

5.2.2.11 Check motor for noise using a B-D 60cc at 60 ml/hr for 1 minute. Reject pump if excessive noise is observed.

5.2.3 Operational Checks: AC Mode

5.2.3.1 Plug unit in AC receptacle, and turn power switch off, then on. Unit should go through power up sequence as in 5.2.2.3, except that "battery in use" LED should be off, and "battery charging" LED should be on.

5.2.3.2 Verify unit programs properly, as in 5.2.2.4. Place in deliver mode.

5.2.3.3 Verify backlight to illuminate in the AC mode. You may need to turn off the room lights to check this.

5.2.3.4 Turn the AC power off, leaving the unit's power switch on. No interruption in function should occur, but the "battery in use" LED should illuminate.

5.2.3.5 Turn the unit's power switch off. Plug in AC receptacle, and depress and hold "stop/program" and "deliver" keys simultaneously while turning the units power switch to on. Unit should display "BATTERY TIME= 00:00". After one minute the LCD will display "BATT.V= X.X".

5.2.3.6 The inspector performing the testing signs and dates the form.

5.2.4 Transducer Calibration Check

5.2.4.1 Press stop/program and select key at the same time, turn pump on, hold for approximately one second and release. Lock = 000.0 will appear on the display. Key in 100.0 onto the display. Press enter. Access complete. Display will show "Force (lb) 00.XX=XX".

5.2.4.2 Test the occlusion pressure using the 2001 force gauge. Place gauge on the pump, and set gauge to the values stated on the "Q.C. Final Test Report, Model 2010". The 2010 Pump display should read within the stated tolerances.

5.2.4.2.1 The tolerances are as follows:
1.5±.5,
8.0±.75,
15.0±1.5.

5.2.5 Position Sensor Test (This test should be done with the clutch disengaged.)

5.2.5.1 Press the stop/program key once. Pos. (inch) appears on display. For the first readings, move track so that 0.000 is shown on the display. Record this number and its corresponding HEX number. Move track so that 4.836±.005 is shown on the display. Record this # and its corresponding HEX #. For the second readings, move the track to the lowest point possible. Record this # and its corresponding HEX #. Move the track to the highest point possible. Record this # and its corresponding HEX #. Verify that the lowest point HEX # is equal to or less than the 0 reading HEX # by one HEX digit only. Verify that the highest point HEX # is equal to or greater than the 4.836 reading HEX # by one HEX digit only.

5.2.5.2 The inspector performing the testing signs and dates the form.

5.2.6 Syringe Recognition Test

5.2.6.1 Press the stop/program key once again. Size (inch) will appear on the display.

Insert syringes listed on "Syringe Recognition Report, P-72-20004-0-X or P-72-20005-G-X, if applicable. Read number on display between high and low for each syringe.

5.2.6.2 The inspector performing the testing signs and dates the form.

5.2.7 Flow Test

5.2.7.1 Perform flow testing as required on form P-72-21001-0-X or P-72-21002-0-X. Use any size syringe in the volume/time mode. Test should last 20 minutes mimimum using more than 70% of the pipette. Refer to Flow Test Procedure 4-72-FLOW1-0-X.

5.2.7.2 The inspector performing the testing signs and dates the form.

5.2.8 Physicial Test

(Inspection level S4 Ignore AQL) Access each mode, Volume/Time, ML/Hr, Mg/HR and Body weight.

5.2.8.1 Verify MG/Kg/min, MG/Kg/HR, Mcg/Kg/min and Mcg/Kg/HR are accessible.

5.2.9 Final Check

5.2.9.1 Check for presence of screw covers over 4 screws. Two in line with the brass pole mount inserts and two screws closest to the face plates. Check for tamper evident label on screw on the back bottom center.

5.3 Inspection Forms

5.3.1 Fill in the Inspection Form, P-72-21001-0-X for Model 2010, for all test categories. Note any improper function in the reject column and comments section. Any reject must be separated and handled in accordance with the Q.A. Manager's instructions. The form must be signed and dated.

5.3.2 Form number P-72-21002-0-X, Batch Functional Test - Model 2010, should also be completed for each batch of pumps delivered to Q.C. Instructions are on the form.

Q.C. Final Test Report, Model 2010
Preprogrammed Settings:

(See Procedure 4-72-21001-0-X)

S/N______________________

Software Version_________
Work Order:______________

_________	_________	_________	_________
Alarm Vol.	Alarm Delay	Batt. V.	Options

		Accept	Reject
5.2.1	VISUAL:		
5.2.1.1	S/N-UL Label and Charger Label attached	______	______
5.2.1.2	Rubber bumpers attached (4)	______	______
5.2.1.3	Face plate printing and I.D.	______	______
5.2.1.4	On/off switch properly oriented	______	______
5.2.1.5	Overall appearance	______	______
5.2.1.6	Loose parts - internal and external	______	______
5.2.2	OPERATIONAL CHECKS:		
5.2.2.1	Syringe slide function	______	______
5.2.2.1.1	Syringe plunger retainer attached	______	______
5.2.2.2	Syringe clamp function	______	______
5.2.2.3	Power switch function	______	______
5.2.2.3.1	Proper software revision	______	______
5.2.2.3.2	Proper power up system check	______	______
5.2.2.3.3	Alarms sound quality and volume	______	______
5.2.2.3.4	LED's function	______	______
5.2.2.3.5	LCD display contrast	______	______
5.2.2.4	Programmable	______	______
5.2.2.5	Priming function (Alarm at about 16 secs.)	______	______
5.2.2.6	Delivery function	______	______
5.2.2.7	Occlusion alarm function (finger pressure)	______	______
5.2.2.8	Bolus function	______	______
5.2.2.9	Alarms		
5.2.2.9.1	Near Empty	______	______
5.2.2.9.2	Empty	______	______
5.2.2.10	Reset volume switch function	______	______
5.2.2.11	Motor noise B-D 60cc at 60 ml/hr for one min.	______	______
5.2.3	OPERATIONAL CHECKS (in AC Mode):		
5.2.3.1	Power Up	______	______
5.2.3.2	Programmable	______	______
5.2.3.3	Verify backlight to illuminate	______	______
5.2.3.4	Uninterrupted function when AC power is disconnected	______	______
5.2.3.5	Charging function	______	______
5.2.3.6	Sign/Date	______________	
5.2.4	TRANSDUCER CALIBRATION CHECK:		
5.2.4.1	Program in Q.C. Test Mode - Code 1000	______	______

5.2.4.2 3.0±.5_____, 8.0±.75_____, 15.0±1.5_____

5.2.5 POSITION SENSOR CALIBRATION

5.2.5.1 1st reading: 0=_______HEX=_______4.836±.005=_______HEX=________
2nd reading: Lowest point =______HEX=______ Highest point______HEX=______
Lowest point HEX number must be equal to or less than 0 reading HEX number, by 1 HEX digit only.
Highest point HEX number must be equal to or greater than 4.836 reading HEX number, by 1 HEX digit only. ______ ______

5.2.5.2 Sign/Date ______________

S/N ____________________

5.2.6 SYRINGE RECOGNITION TEST (SEE FORM P-72-20003-0-X, P-72-20004-0-X OR P-72-20005-G-X IF APPLICABLE)

5.2.6.1

MFG/SIZE	LOW	HI	ACCEPT	REJECT
No Syringe	088	115	______	______
TERUMO				
1 ML	145	171	______	______
5 ML	461	531	______	______
20 ML	790	860	______	______
60 ML	1188	1258	______	______

5.2.6.2 Sign/Date ______________

5.2.7 FLOW TEST (See Flow Test Procedure, 4-72-FLOW-0-X)

5.2.7.1

Syr. Type	Syr. Size	Tubing Type	Rate	Elapsed Time	Predict Volume	Deliver Volume	± 3% Error
______	______	______	______	______	______	______	______
______	______	______	______	______	______	______	______

5.2.7.2 Sign/Date ______________

5.2.8 PHYSICAL TEST: Access modes (Special level 4 inspection, ignore AQL)

5.2.8.1 Verify 4 body weight Sub-modes ACCEPT ______ REJECT ______

5.2.9 FINAL CHECK:

5.2.9.1 Screw covers (4) and tamper label (1) attached ACCEPT ______ REJECT ______

COMMENTS: ____

____

____

____

Accept Reject
(Circle One)

____
Inspector/Date

P-72-21001-0-2
DCN #: 91053002

RE U. Ammann 5-31-91 MFG B. Keating 6-14-91 QC [signature] 6/14/91

1.0 PURPOSE:

1.1 To establish a detailed test procedure to demonstrate that the syringe infusion pumps meet the proper flow rate accuracy specifications.

2.0 SCOPE:

2.1 The Q.A. Inspector is responsible for the testing, acceptance/rejection.

2.2 The Director of Quality Assurance (or designate) is responsible for assuring compliance with this procedure.

3.0 RELATED PROCEDURES AND DOCUMENTS:

3.1 Form P-72-01001-0-X, P-72-20001-0-X or P-72-21001-0-X, Q.C. Test Report Forms (X = Latest revision)

3.2 Work order

3.3 Pumps Operator's Manual

3.4 Form P-72-01002-0-X, P-72-20002-0-X or P-72-21002-0-X, Batch Functional Test Forms (X = Latest revision)

4.0 ASSOCIATED MATERIALS:

4.1 BD, Monoject and Terumo Syringes

4.2 53-60-225 MFI Extension Sets

4.3 Distilled Water

4.4 Various sizes of calibrated pipets

5.0 PROCEDURE:

5.1 Pumps are delivered to Q.C. by production in batches. Several batches may make up a work order. Each batch must be tested on a Batch Functional. The number to be Flow tested will be determined by the batch size and the current Inspection Level.

5.1.1 Identify pump model/serial number.

5.1.2 Record the serial number on the inspection form.

5.1.3 Select any size syringe from BD, Mono, or Terumo. Plan to use more than 70% of the syringe. The size of syringe selected will determine the size of pipet you should use. Try to use at least 70% of the pipet. 3cc syringes should use a 2 ml pipet, 6cc syringes should use a 5 ml pipet. 20-35cc syringes should use a 25 ml pipet.

5.1.4 Record the syringe type, syringe size and tubing type on the inspection form.

5.1.5 To determine the rate you must decide on the dose volume and the delivery time. The dose volume should be more than 70% of the syringe volume. The delivery time should be no less than 20 minutes. To calculate the rate, you will divide the dose volume by the delivery time. (Delivery time must be in decimal form). With the Models 2001 and 2010 the rate will be calculated by the program within the unit after the dose volume and delivery time are entered.

$$\text{Rate} = \frac{\text{Dose Vol.}}{\text{Del. Time}}$$

5.1.6 Record the rate, elapsed time and predicted volume on the inspection form.

5.1.7 Fill the syringe with Distilled water and connect to the Extension set. All air bubbles must be removed to insure an accurate flow test. If bubbles are in the tubing, prime them out before attaching to the pipet.

5.1.8 Load syringe into the syringe cradle and program unit for delivery in the Volume/Time mode. Prime unit to the first significant number on the pipet. Set a timer for the correct delivery time. Start the timer and the delivery. At end of delivery, record the delivered volume on the inspection form.

5.1.9 To determine the % error you will take the actual delivered volume and subtract the predicted or dose volume. Divide the difference by the predicted or dose volume and then multiply by 100. [(Actual - Dose Volume) divided by dose volume] * 100.

5.2 Record the % error on the inspection form.

BATCH FUNCTIONAL TEST
MODEL 2010

Date(s) of Inspection:	PROCEDURE	List S/N No. By Software version:
Batch Size:	Inspect all pumps using form P-72-21001-0-X (Latest revision)	
Work Order No.:	Flow test a random sample using special level S4 reduced. IGNORE AQL. No. flow tested:	

Flow tests:

S/N	Syringe Type	Syringe Size	Tubing Type	Rate	Elapsed Time	Predicted Volume	Delivered Volume	± 3% Error

COMMENTS:

P-72-21002-0-0
DCN90110101

Approval Changjo Lee Date 12/20/90

Approval O. Parker Date 12-21-90

Accept / Reject (Circle)

Inspector ____ Date ____

Reviewer ____ Date ____

APPENDIX F. SPARE PART LIST & TEST FIXTURES

Notes:

1. Part Number format: 0-AA-BBBBB-C-X, X is revision #
   X will be changed due to revision.
   Consult manufacturer for the appropriate revision level.

2. Refer to Assembly Drawing for Item # in Sub-Assemmbly.

MEDFUSION, INC.
2001/2010 SPARE PARTS LIST

PART NUMBER	ITEM NUMBER	DESCRIPTION
0-68-20M00-0-X		Pole Clamp Kit
0-72-20C07-0-X		Charger S/A
0-68-20A00-0-X		**Top Housing S/A (specify Software Version #)**
0-84-K2001-0-X	2	Keypad 2001
0-84-K2010-0-X	2	Keypad 2010
0-68-20C00-0-X	4	LCD Display S/A
0-68-20E01-0-X	5	Main Board S/A
0-68-20 --	10	MPU, Programmed (specify Software Version #) Consult factory for exact part number
0-87-1P5SB-0-0	N/A	Fuse, 1.5A slo-blo (soldered on Main Board)
0-48-20000-0-X	1	Top Housing
0-68-20A01-0-X		**Bottom Housing S/A**
0-48-20001-C-0	1	Bottom Housing
0-68-20C09-0-X	2	Battery Pack S/A
0-68-20C01-0-0	3	Power Switch S/A
0-48-20025-0-0	4	Switch Guard (need 2pcs per pump)
0-68-20C02-0-X	5	DIN Receptacle S/A
0-68-20C06-0-X	6	Alarm S/A
0-28-EC100-8-0	8	Strain Relief 8-pin
0-39-TT102-0-0	9	Wire Tie
0-49-20003-0-0	10	Rubber Bumper
0-68-20A02-0-X		**Slide Housing S/A**
0-68-20A04-0-X	2	Plunger Holder/Track S/A
0-48-20008-0-0	1,9	Plunger Holder/Insert (Ref. Dwg 1-68-20A04-0-X)
0-68-20A03-0-X	4	Slide S/A
0-79-14280-0-0	25	Main Cable
0-68-20C08-0-X	26	Stepper Motor S/A
0-48-20006-0-0	40	Syringe Clamp
0-68-20C04-0-X	30	Pot. S/A
0-48-20013-0-0	34	Clamp Gear
0-50-20009-C-0	31	Torsion Spring
0-48-20019-0-0	35	Pot. Clamp
0-48-20020-0-0	32	Spring End Clamp
0-48-20024-0-0	28	Position Pot. Holder
0-48-20014-0-0	29	Position Pot. Gear
0-48-20015-0-0	8	Cluster Gear
0-39-13318-0-0	1	E-Clip
0-49-20001-0-1	22	Cable Seal
0-48-20031-0-0	23	Cable Seal Plug

MEDFUSION, INC.
2001/2010 SPARE PARTS LIST

PART NUMBER	ITEM NUMBER	DESCRIPTION
0-48-20011-0-0	18	Clutch, Upper Half
0-48-20012-0-0	17	Clutch, Lower Half
0-48-20018-0-X	19	Clutch Key
0-50-20008-0-0	16	Clutch Spring
0-50-20007-0-X	7	Clutch Actuator
0-48-20009-0-0	3	Clutch Lever
0-48-20016-0-0	6	Clutch Cover
0-50-20001-0-X	10	Leadscrew
0-48-20034-0-0	11	Leadscrew Thrust Bearing
0-48-20023-0-0	9	Leadscrew Bearing
0-48-20010-0-0	20	Worm Gear
0-39-13311-0-0	14	E-Clip, Leadscrew
0-68-20E02-0-X	24	Aux. Board S/A
0-48-20005-0-0	38	Slide Door
0-48-20027-0-0	46	Water Seal
0-49-20002-0-0	21	Clamp Seal
0-68-20A05-0-0	37	Worm/Coupling S/A
		Bottom Housing Hardware (REF 1-68-20A01-0-X)
0-42-90372-0-0	7	Screw, 4-40x3/8 Phil Pan HD SS
		Top Housing Hardware (REF 1-68-20A00-0-X)
0-42-90252-0-0	6	Screw, 4-40x1/4 Phil Pan HD SS
0-42-J1002-0-0	7	Hex Head, SS, 4-40x1.00
0-42-04503-0-0	8	Standoff, 3/16 Hex Male-Female
0-42-1653N-0-0	9	3/16 Round Female Standoff
0-42-4505B-0-0	12	3/16 Hex Male-Female Standoff
		Slide Housing S/A Hardware (REF 1-68-20A02-0-X)
0-42-80622-0-0	13	5/8 Set Screw 4-40x.625 SS
0-41-90502-0-0	33	Screw, Pan Phil HD, SS, 2-56x1/2
0-41-93122-0-0	36	Screw, Pan Phil HD, SS, 2-56x5/16
0-42-90252-0-0	5	Screw, Pan Phil HD, 4-40x1/4
0-42-G7701-0-0	27	3/16 Hex Female, Standoff
0-42-2098B-0-0	48	1/4 Hex Female Standoff
0-42-A0252-0-0	39	Screw, Flat HD Phil, SS 4-40
		Final Assembly Hardware (REF 1-72-20010-0-X)
0-42-A0502-0-0	8	4-40x1/2 Flat HD Ph SS
		Pole Clamp
0-43-A0372-0-0	N/A	Screw, 6x32x3/8 Flat HD, Ph, SS
	OTHER	
A-61-205M1-0-0		2001/2010 Syringe Infusion Pump Service Manual

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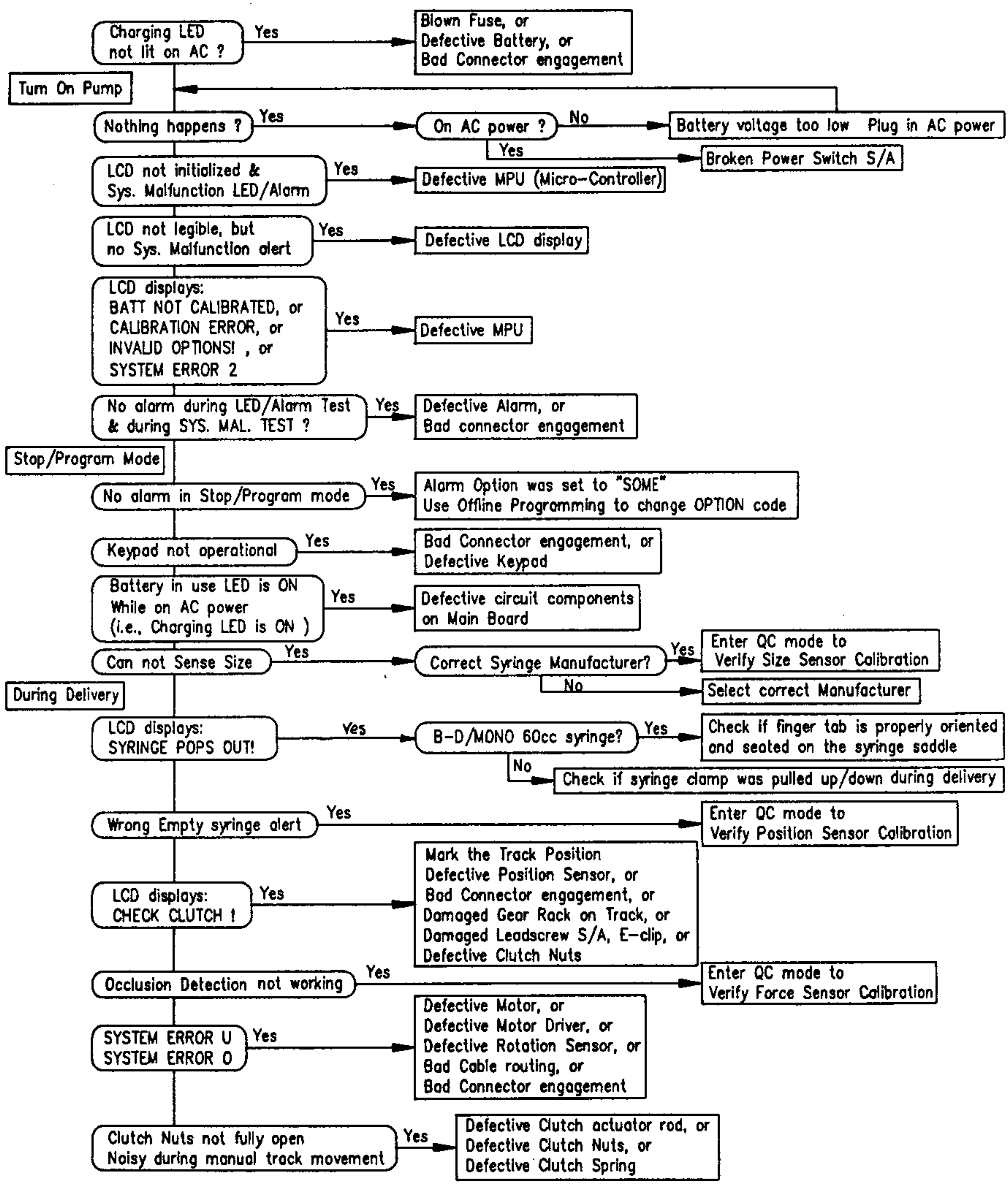
MEDFUSION, INC.
2001/2010 TOOLS - FIXTURES

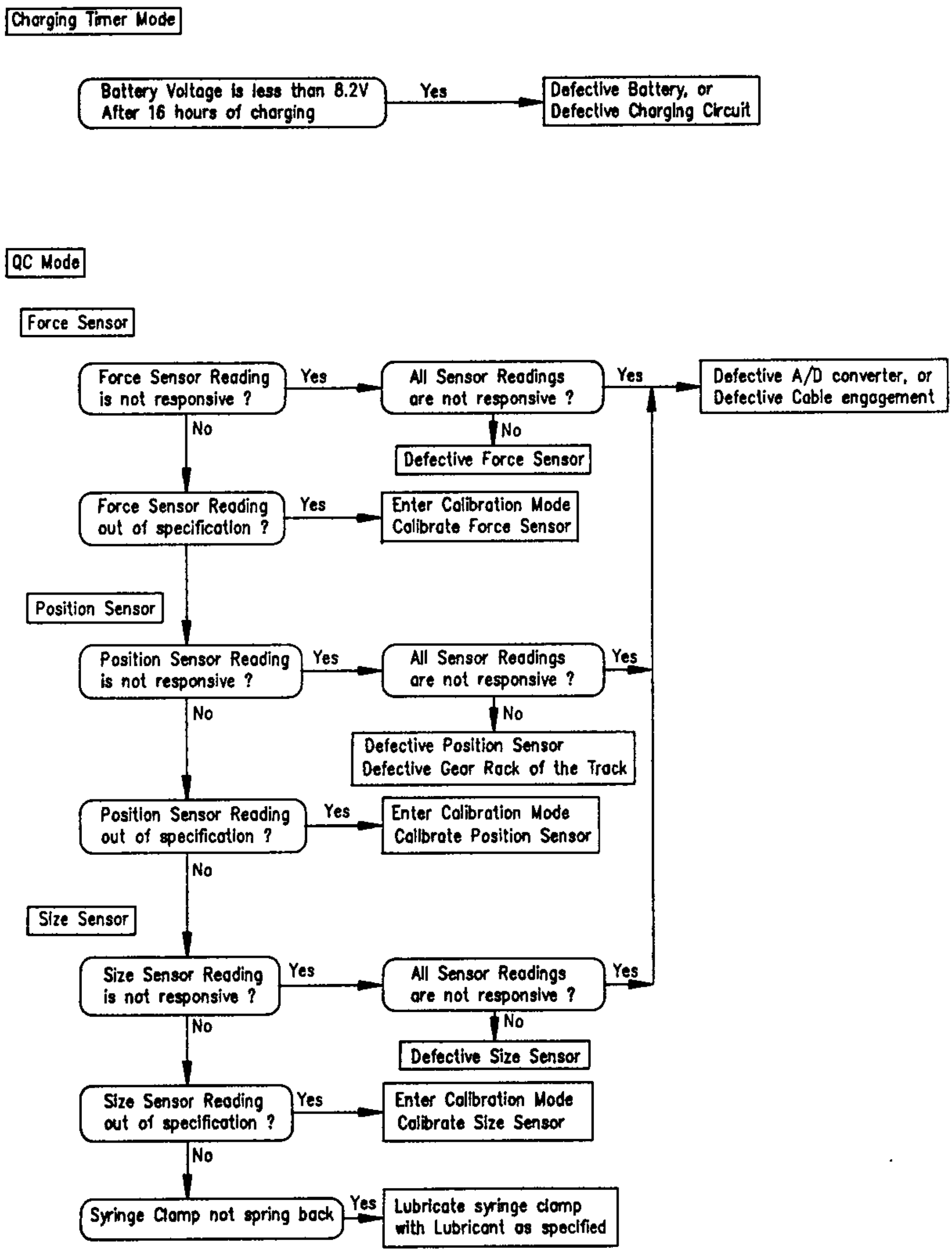
PART NUMBER	DESCRIPTION
TEST/CALIBRATION FIXTURES	
0-72-20003-0-X	Force Gauge
0-60-20001-0-X	Size Calibration Kit
TEST/REPAIR FIXTURES	
0-65-20002-0-X	Battery Calibration Fixture
0-65-20001-0-X	Charge Circuit Calibration Fixture
0-47-20001-0-X	Motor Bracket Alignment Tool
0-47-20002-0-X	Leadscrew Installation Tool
0-47-20003-0-X	DIN Ring Tool
0-47-20004-0-X	Torsion Spring Driver
0-47-20006-0-X	Front Shim, Plunger Holder
OTHER SUPPLIES: AVAILABLE FROM MANUFACTURERS AS LISTED	
CAL 36/4 Model #810587 TT#304TO034	Torque Screw Driver MFR: Sturtevant/Richmont DIST: Techni Tool 5 Apollo Road, Box 368 Plymouth Meeting, PA 19462 Phone: (215) 941-2400
TT#840TO020	Hex Key 3/32 (Need with Torque Screw Driver Above) Same Manufacturer
667-3 .003 Shim Stock	Side Shim, Plunger Holder MFR: Starrett DIST: Ziegler Tools 711 Marietta Street, P.O. Box 93958 Atlanta, GA 30318 Phone: (404) 892-7117

APPENDIX G. TROUBLE-SHOOTING CHART

TROUBLE-SHOOTING CHART



TROUBLE-SHOOTING CHART



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