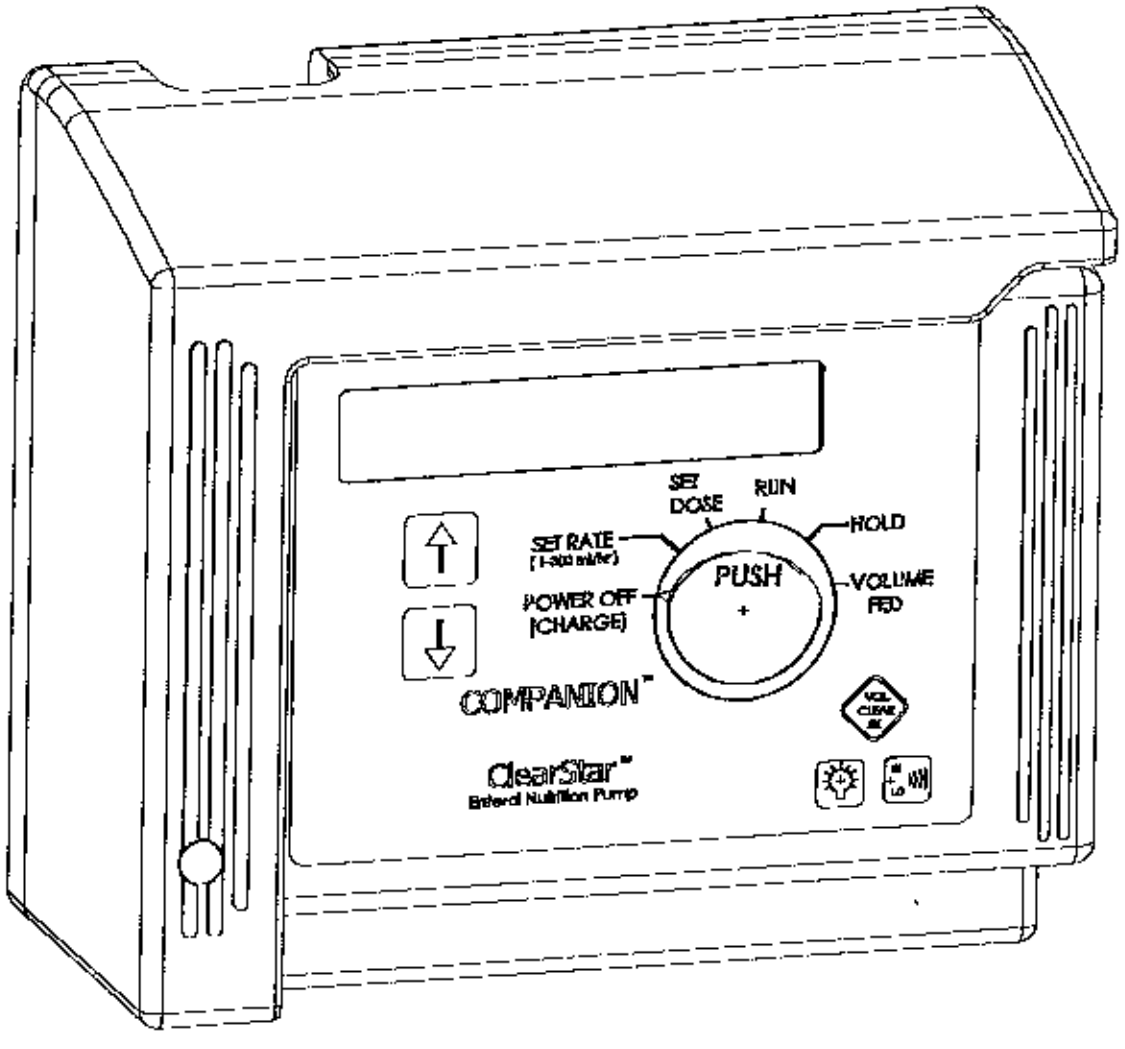
Companion™ ClearStar™ Enteral Pump

For Use With REF M771

SERVICE MANUAL

For Enteral Use Only
Not for Parenteral Use



62-1IF-0550-02 (10/2000)

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Section 1

INTRODUCTION

This manual was prepared for use as a reference document for personnel who will service the Companion™ ClearStar™ Enteral Nutrition Pump. It is important that this manual be read and understood before servicing the device.

The Companion™ ClearStar™ Enteral Nutrition Pump is a microprocessor controlled infusion pump which provides accurate delivery rates, easy-to-read displays, and simple controls. The pump will operate on AC power or battery (i.e.: the fluid delivery system and safety alarms function when the pump is used by an ambulatory patient or is mounted on an IV pole). The pump utilizes a specially designed administration set, including a cassette with bellows to deliver measured amounts of enteral fluid.

CAUTION: This pump is designed to deliver only liquid enteral feeding product (standard products, infant formula, or reconstituted powder that has been thoroughly mixed into solutions).

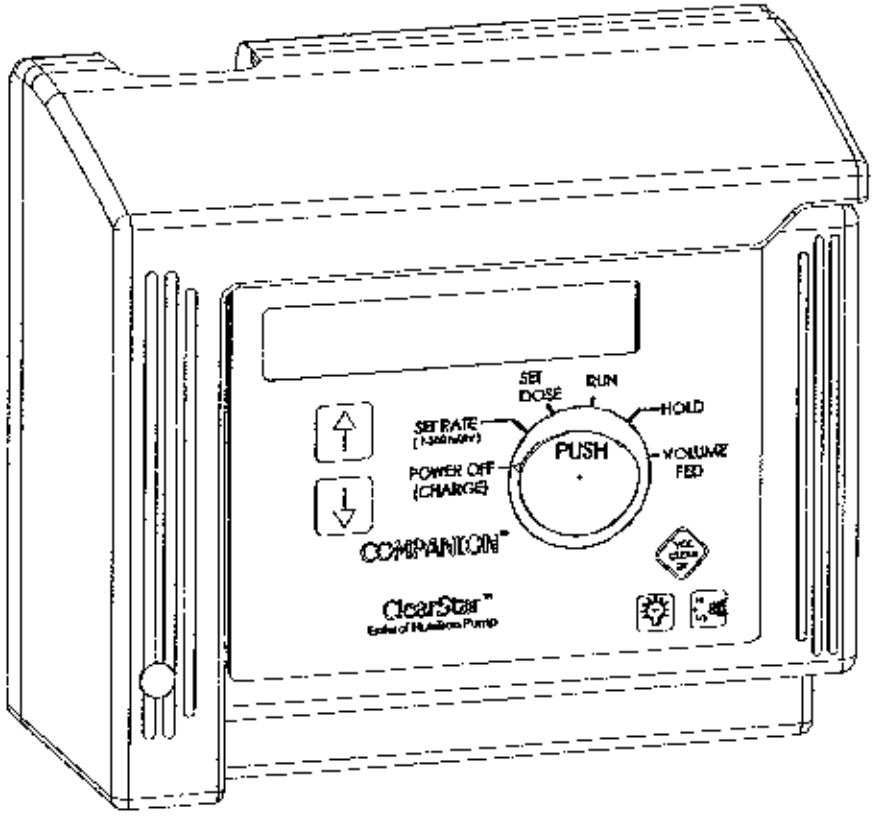

Figure 1-1, Companion™ ClearStar™ Enteral Nutrition Pump

1.1
INDICATIONS FOR USE

The Companion™ ClearStar™ pump can be used for adult and pediatric patients provided the patients can tolerate a feeding range within the pump operational specifications. Those specifications are:

- ❖ The flow rate is 1-300 ml/hr in 1 mL/hr increments
- ❖ The flow rate accuracy is ±10% or ±0.5 ml/hr, whichever is greater
- ❖ The occlusion pressure limit is 26-28 psi.

If these specifications are not appropriate for a given patient, the Clear Star pump should not be used.

Pediatric Use: Use of the Clear Star Pump for pediatric patients should only be done on the advice of a physician trained in pediatrics.

Intestinal tolerance and overall fluid balance of the individual pediatric patient should be considered when selecting the pump. In these patients, a volume of product no more than four times the hourly feeding rate should be hung.

1.2
PRECAUTIONS

WARNING

POSSIBLE EXPLOSION HAZARD EXISTS IF USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

Nonhazardous, low-level electrical potentials are commonly observed when fluids are administered by pumps. These potentials are well within accepted safety standards, but may create artifacts on voltage sensing equipment such as RCG, EMG, and EEG machines. These artifacts vary at a rate that is associated with the pumping rate. If the monitoring machine is not operating correctly or has loose or defective connections to its sensing electrodes, these artifacts may be accentuated so as to simulate actual physiological signals. To determine if the abnormality in the monitoring equipment is caused by the pump instead of some other source in the environment, set the pump so that it is temporarily not delivering fluid. Disappearance of the abnormality indicates that it was possibly caused by electronic noise generated by the pump. Proper setup and maintenance of the monitoring equipment should eliminate the artifact. Refer to the appropriate monitoring system documentation for setup and maintenance instructions.

All enteral pumps have the potential to bolus-feed or overdeliver, which is an important consideration in feeding volume-sensitive patents. In these patients, a volume of product no more than four times the hourly feeding rate should be hung.

This pump is designed to deliver only a liquid enteral feeding product: standard liquid product, infant formula, or reconstituted powder product that has been thoroughly mixed.

Not For Parenteral Use

Confirm proper placement and function of patient's enteral feeding tube (nasogastric, jejunostomy, gastrostomy, etc.). Failure to do so may result in vomiting and/or aspiration, Verify the following before initiating feeding:

1. A Companion™ ClearStar™ Pump Set is being used.
2. Cassette is properly seated in pump.
3. When on AC power, pump is fully seated in charger.
4. Flow rate is set at the prescribed mL/hr.
5. Pump dial is turned to RUN.

1.3
SCOPE

The material contained in this manual is limited to technical information necessary for performing preventive maintenance, periodic testing functions, various service tests, interpreting system alarms, and troubleshooting to the level of subassembly replacement. Replacement of parts is limited to those parts listed in *Section 6, Disassembly and Recalibration Instructions*. Specific instructions for operating this product are contained in the Companion™ ClearStar™ Enteral Nutrition Pump Operating Manual.

1.4
ABOUT THIS MANUAL

The purpose for this Service Manual is to provide instructions necessary for testing the Companion™ ClearStar™ Enteral Feeding Pump, troubleshooting alarms, and replacing field replaceable components and assemblies. Refer to the pump Operating Manual for detailed information on operating instructions.

This manual is organized into seven sections as follows:

Section 1:	Introduction
Section 2:	Specifications
Section 3:	Theory of Operation
Section 4:	Maintenance and Service Tests
Section 5:	Troubleshooting Guide
Section 6:	Disassembly and Recalibration Instructions
Section 7:	Parts List, Drawings and Electrical Schematics

1.5
USER QUALIFICATIONS

The Companion™ ClearStar™ Enteral Nutrition Pump is for use at the direction of or supervision of licensed physicians, and by licensed or certified health care professionals who are trained in the use of the pump and the administration of enteral fluids.

WARNING

SERVICE INSTRUCTIONS ARE FOR USE ONLY BY QUALIFIED BIOMEDICAL ENGINEERS (BME), BIOMEDICAL ELECTRONIC TECHNICIANS (BMET), ROSS OR ABBOTT FIELD SERVICE PERSONNEL. TO AVIOD PERSONAL INJURY OR INSTRUMENT DAMAGE, DO NOT PERFORM ANY REPAIR OR CORRECTIVE ACTION UNLESS FULLY TRAINED AND AUTHORIZED TO DO SO. USER-SERVICEABLE PARTS ARE LIMITED TO THOSE ITEMS LISTED IN SECTION 6.

1.6
WARNINGS, CAUTIONS, AND NOTES

Throughout this manual, three types of alert messages are used. They are warnings, cautions, and notes. Pay attention to all alert messages. They are described as follows:

WARNING

A WARNING CONTAINS A SPECIAL SAFETY EMPHASIS AND MUST BE OBSERVED AT ALL TIMES. FAILURE TO OBSERVE WARNING MESSAGES CAN BE DANGEROUS AND POTENTIALLY FATAL.

****

CAUTION: A CAUTION message usually appears in front of a procedure or statement. It contains information that could prevent irreversible damage or hardware failure. Neglecting a CAUTION message could result in serious injury.

****

NOTE: A NOTE message highlights information that helps explain a concept or a procedure.

1.7
INSTRUMENT INSTALLATION PROCEDURE

The Instrument Installation Procedure consists of three steps: unpacking, inspection, and pump operation test. It is recommended that these steps be followed in order to ensure that the pump has not been damaged during shipping. Procedures for performing these steps are provided below.

1.7.1
UNPACKING

Use care when unpacking the pump. Retain the packing slip and save all original packing material for returning pump to the Ross Products Division Service Center or Abbott International Service Center, in the event that the pump is damaged or fails the operational self-test.

NOTE: Product damage may occur unless proper care is exercised during the unpacking and installation process.

1.7.2
INSPECTION

Inspect the packing container thoroughly for possible damage. Do not use the pump if it appears to be damaged in any way. Verify that there is no damage to the pump or backpack enclosure, overlay, LCD, clamp arm assembly, power cord, etc. Ensure that all WARNING & CAUTION LABELS are present. Should the pump or backpack appear to be damaged, or labels are missing, contact the Ross Products Division Service Center or Abbott International Service Center for further instructions.

1.7.3
PUMP OPERATIONAL TEST

NOTE: Do not place in service if pump fails the operational self-test.

The following procedure is the minimal recommended level of testing that should be performed on all pumps to ensure that the unit has not been damaged during shipping and handling. A greater level of detailed testing may be performed, per Section 4.3 (Performance Verification Tests). Test is to be performed on battery power (i.e.: power cord not plugged into an AC outlet).

1. Rotate the pump control dial from POWER OFF (CHARGE) to the SET RATE position. Verify that the pump goes through a self-test sequence.
   a. Verify the following is displayed on the LCD:
      - ✓ Numeric digits display (**8888**).
      - ✓ All LCD indicators display (**RUN, ml/hr, LOW ALARM, OCCL, EMPTY, LOW BATTERY**, and **SELECT RUN**) or appropriate ICONs.
      - ✓ Backlighting is illuminated.
      - ✓ Buzzer (3 beeps).

b. Verify proper memory retention. The LCD displays the following information:
   - ✓ "**rATE**" and Set Rate "value".
   - ✓ "**dOSE**" and Set Dose "value".
   - ✓ "**FEd**" and Volume Fed "value".

c. When self test is completed, verify the following information is displayed on the LCD:
   - ✓ Set Rate "value" and "ml/hr"
   - ✓ "BATTERY"
   - ✓ Backlighting is OFF.

2. Depress the backlight keypad.
   a. Verify the backlighting illuminates for approximately 15 seconds.
3. Depress and hold the increment (↑) keypad.
   a. Verify that the Set Rate "value" increments (scrolls @ 3 speeds).

4. Depress and hold the decrement (↓) keypad.
   a. Verify that the Set Rate "value" decrements (scrolls @ 3 speeds).

NOTE: The lead-acid battery may not be fully charged upon receipt. Therefore, it is recommended that the battery be charged for a minimum of 8 hours before pump is placed into service.

Section 2

SPECIFICATIONS

The following is a list of specifications for the Companion™ ClearStar™ Nutrition Feeding Pump:

ELECTRICAL

Input:	85 - 264Vac, 47 - 63Hz Single Phase, 9 - 12 Watts.
Output:	Single, 0 - 1.3A @ 4.68+/- 0.02Vdc.
Fusing:	Hot & Neutral lines are current fused, Wickman, Type MXT, rated 2A, 250V, (non-serviceable).
Power Cord:	Listed or HAR, Type SJT, No. 18 AWG, 3 conductor, "Hospital Grade" plug, rated 125V, 15A (for 120 configuration) or tandem blade/pole grounding type plug, 250V, 15A configuration.
Leakage:	Less than 100 microamperes.

BATTERY

Type:	4V, 1Ah sealed lead-acid, marked 2A x 2K or WP1-4.
Charge:	Battery is considered fully charged within 8 hours.
Life:	Operating time of 24 hours @ 125ml/hr when fully charged.

MECHANICAL

General:	Two piece design, pump (with integral battery) separable from backpack assembly.
Size:	Pump - 4.25"x5.93"x1.62" [10.8cm x 8.5cm x 4.1cm]. Pump & Backpack - 6.00"x7.49"x3.67" [15.2cm x 19cm x 9.3cm].
Weight:	Pump - 1.30 pounds [0.6Kg]. Pump & Backpack - 3.52 pounds [1.6Kg].

OPERATIONAL

Flow Rate	
Range:	1 to 300ml/hr @ 1ml/hr increments.
Accuracy:	± 10% (or ± 0.5ml whichever is greater) with fluid head >30" above pump's cassette interface and distal set ≤10" below pump's cassette interface.
Pressure:	Pumps against a 28psi [193Kpa] maximum backpressure before occlusion alarm.

ENVIRONMENT

Temperature/ Humidity:	0 to 110 deg.F [-17.8 to 43 deg.C] @ 15 to 90%RH (storage). 60 to 90 deg.F [15.6 to 32.2 deg.C] @ 30 to 90%RH (operating).

REGULATORY

Standards:	Designed and manufactured to meet requirements of UL2601-1, IEC601-1, CSA 22.2 No.601.1, IEC601-1-2, and IEC601-1-4.
Classification:	Class 1 (type of protection against electrical shock). Type BF (degree of protection against electrical shock). Drip Proof (IPX1).

Section 3

THEORY OF OPERATION

This section describes the theory of operation for the Companion™ ClearStar™ Enteral Nutrition Pump. The theory of operation details the following major topics:

- ☐ General
- ☐ Charger Power Board
- ☐ Pump Controller Board
- ☐ Pump Display Board

3.1 GENERAL

The Companion™ ClearStar™ Enteral Nutrition Pump replaces conventional peristaltic rotor/silicone tubing combinations and syringe type infusion pump systems with a cassette containing a compressible membrane and a pressure actuated combination check valve. The disposable cassette is inserted into the pump cavity with the compressible membrane contacting the reciprocating piston (drive system). Control and measurement of the administration of enteral feedings, at rates of 1 to 300 ml/hr, is monitored by an 8-bit microcontroller. The pump also contains various sensors, in order to detect flow alert conditions, and a rechargeable sealed lead-acid battery, for use in portable operating modes.

Figure 3-1 illustrates the Functional Block Diagram for the Companion™ ClearStar™ Enteral Nutrition Pump. Sections 3.2 (Charger Power Board), 3.3 (Pump Controller Board) and 3.4 (Pump Display Board) all reference Figure 3-1 throughout and describe each block in great detail.

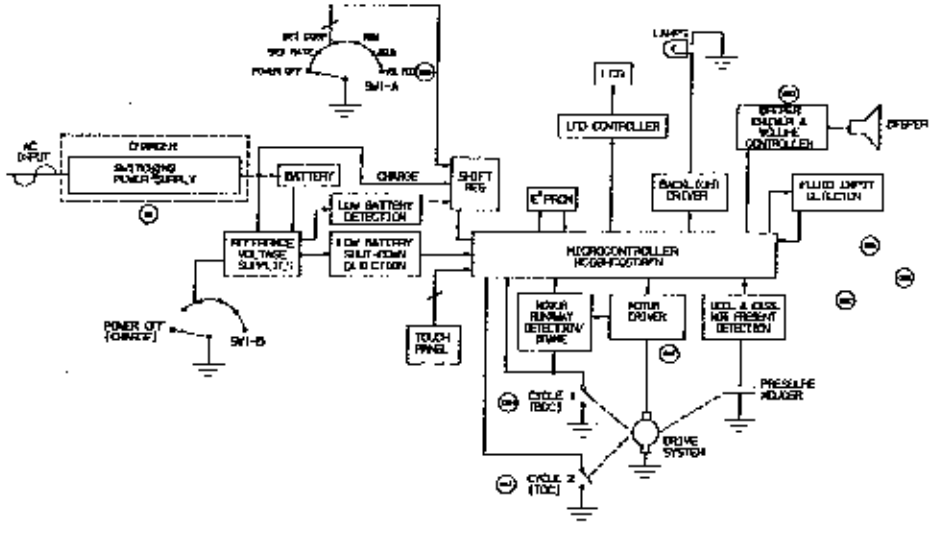

Figure 3-1, Functional Block Diagram

3.2
CHARGER POWER BOARD

3.2.1
GENERAL

The d.c. switching power supply is designed to meet UL2601 (IEC601-1) safety and EMC (IEC601-1-2) requirements. The power supply is designed to operate at line voltages ranging from 85 - 264Vac @ 47 - 63Hz single phase, while providing a regulated output voltage of 4.68Vdc. The charger provides enough power to simultaneously operate the pump and charge the 4V, 1Ah sealed lead-acid battery.

The power supply has two separate outputs. The first is the primary output, used to provide a constant 4.68 + .02Vdc, from 0 - 1.3A. The second output is called "LINE SENSE" and is only used as an indicator for battery charging. The primary output is fully protected against short circuit and output overload. Under an overload or short circuit condition the output voltage will foldback and eventually hiccup. The system will automatically recover once the fault has been removed.

Refer to Section 6.4.5 for the power supply calibration procedure.

3.2.2
AC INPUT/RECTIFICATION

The input voltage is applied to the EMI filter through the fuses (F1 & F2). The input voltage must be 85 to 264 Vac, of 47 to 63 Hz, with less than 5% distortion. The two 2A input fuses provide protection from fire hazard under catastrophic failure conditions. The fuses will not open on overload or short circuit output conditions.

Under normal conditions, the control circuits provide overcurrent protection. Moderate energy voltage transients on the input power are clamped by a metal oxide varistor (M1). The MOV clamps excessive non-repetitive voltage transients of less than 250 microseconds duration and limited to 10 Joules of total energy. Input current then passes through a common-mode EMI chokes (T1 & T3) with both common mode (C5 & C6) and differential filter capacitor (C1) from line-to-ground and line-to-line, respectively. These components attenuate switching frequency and rectifier harmonics to within the FCC and VDE class B limits for conducted emissions. The bleeder resistor (R22) across the AC mains is provided to discharge the EMI capacitors when the AC power is interrupted.

The input voltage is then rectified through a full-wave bridge rectifier (CR1, 7, 9 &10) and filtered by large electrolytic capacitors (C7) to provide DC voltage with a small ripple voltage at twice the input frequency. The peak ripple component is typically 0 to 20% of the peak-input voltage.

3.2.3
SWITCHING CONVERTER STAGE OPERATION

The switching converter stage chops and transforms the high voltage DC bus at C7 to multiple low voltage outputs. The DC bus voltage is always applied to one end of the primary winding of the power transformer (T2). The drain of the power MOSFET transistor is connected to the other of the primary winding. When the control circuit provides gate voltage to the power switch (Q1), the entire input voltage is applied across the primary winding. Current begins to ramp up from the initial level set by the flux remaining in the core at a rate proportional to the input voltage. Power is not transferred to the output windings during this portion of the switching cycle since the primary winding is out of phase with the secondary windings. Reverse current flow is blocked by the output rectifiers. Thus, the power to be transferred to the outputs must be stored by the power transformer.

Energy storage is possible since the power transformer is actually an inductor with multiple windings. Once the stored energy reaches a level determined by the control circuit, the gate voltage is rapidly removed from the power switch gates, switching them off. The interruption of the current flow in the power transformer forces the voltage across the primary to reverse almost instantaneously, rising to the level required to provide a discharge of the flux built up in the power transformer. Since the secondary windings are out of phase with the primary, the voltage across the windings must reverse and rise to the lowest clamping voltage of any winding. The action of the transformer is said to "fly back" to the clamping level, thus the popular term flyback converter. The clamping of the transformer primary is not perfect. The short time after the current in the primary is interrupted and before the secondary current has overcome the leakage inductance of the output windings leaves the primary unclamped to any voltage. The end of the winding attached to the power switches will rise rapidly, trying to discharge the energy stored in the power transformer. Left unclamped, the rising voltage could avalanche the power switches leading to their failure. A temporary path for current in the primary winding back to the DC bus exists through the primary snubber, (CR2 & C10). The snubber slows the rising voltage, allowing the output current to reach its peak value. Bleeder resistor (R16) discharge or reset C10. The result is a sawtooth waveform across C10 of approximately 80Vpk.

The primary current is sensed by a power resistor in series with the source of the switch (R1 & R11). The control circuit monitors the voltage analog of the primary current and shuts off the power switches early if excess current is detected (approximately 1V peak).

3.2.4
OUTPUT RECTIFIER AND FILTER

The output rectifier (CR6) clamps the transformer windings directly to the filter capacitor (C12) for the +4.68V output. The output capacitor receives charge from the power transformer during the power transistor "Off" time or flyback period. When the power transistor turns "On" again, the output capacitor must provide all the output current. The reversal of current flow into and out of the filter capacitor causes a small voltage ripple on the capacitors. The ripple filter (L1 & C11) is used to reduce switching spikes and ripple to acceptable levels. Small capacitance and inductance can cause

reverse voltage spikes in excess of the rating of the rectifier. To snub the spike voltages to acceptable levels, a dissipative snubber (R19 & C9) is connected across the anode to cathode of CR6.

3.2.5
CONTROL CIRCUITS

The output voltage is controlled directly and thus sets the transformer voltage for all other outputs. The output voltage is sensed through the resistor divider (R25, 17 & 9). The divider sets the voltage ratio applied to the reference of U4 (2.50V reference). When U4-R is above 2.5V, the cathode pin conducts current through the optocoupler photodiode (U2). The photodiode of U2 is connected to CR6 anode through CR5 to prevent current drawn from battery at the output. The current in the photodiode of U2 causes base current to flow in the output transistor of U2 which pulls down pin 1 of U1. At approximately 1V on U1-1, the output pulses are at minimum width. If the pulse width is too narrow (Output #1 too low) less collector current flows through the photo transistor of U2 allowing U1-1 to be pulled up to the 5.00V reference of U1 (Pin 8) by R7 increasing the pulse width to a maximum of approximately 47% "On" time. When mains power is not supplied to the power supply, reverse current flows back into the output terminal of the power supply is kept below 30µA by the implementation of Q3 & Q4.

Modulation of the pulse width occurs inside U1. A flip-flop is set as the timing cap (C13) begins to charge through R7. If the voltage at U1-1 is of sufficient magnitude, the output driver goes high at the same instant (U1-6), turning the power transistors "On". The primary current begins to ramp. The current signal is compared to a portion of the voltage at U1-1. When the ramp reaches the level of U1-1, the output drive is latched "Off". The timing capacitor continues to charge to approximately 3.3V. Once this level is reached, U1-4 switches to a rapid discharge mode back to 1.6V. The timing oscillator repeats the same cycle with the output driver latched "Off" by an internal flip-flop that is reset by the oscillator cap discharge. Thus, the oscillator operates at twice the actual power switching frequency and the maximum duty cycle cannot exceed 50% (typically less due to the discharge time of timing cap).

Excessive current (voltage at U1-3 more than 1V) causes the output driver to switch off and latch until the next normal "On" pulse. The driver pulses become so narrow that the transformer voltages fold back. The bias voltage also folds back (TP1 to TP5), to the under voltage lockout point of U1 (approx. 10V), turning U1 "Off". The startup capacitor begins to recharge through R2 until the startup threshhold is reached (approx. 16V). Normal switching operation will commence if the fault has been removed. If the fault is still present, the shutdown cycle will repeat. The power supply thus appears to be providing short bursts of power or "hiccuping".

If the voltage of the main output increases beyond safe limits, the overvoltage protection zener diode begins to conduct (CR8). When sufficient current is available to raise the gate of SCR1 to approximately 0.7V, the SCR latches "On", shorting the output causing a "hiccup" cycle that will repeat until the fault is removed or the power supply is repaired.

3.3
PUMP CONTROLLER BOARD

The following is an in-depth description of the various subsystems that make up the pump controller board assembly.

3.3.1
REFERENCE VOLTAGES / SUPPLIES

The pump is activated when the control dial (attached to rotary switch, SW1) is rotated to any position other than "POWER OFF (CHARGE)". Charger output or battery power is routed through rotary switch, SW1, activating four separate voltage supplies (V0, V1, V2, and 1.2VREF). Note, when the control dial is placed in the "POWER OFF (CHARGE)" position, all power is removed from the pump main board, except power used for battery charging.

As stated above, when the control dial is rotated to a position other than "POWER OFF (CHARGE), charger or battery power is routed through rotary switch, SW1, turning on the p-channel mosfet, SI2301DS, Q12. Q12 requires a minimum threshold voltage $V_{GS(th)}$ of 2V for current to flow from source to drain. This helps protect against conditions where the sealed lead-acid battery is completely discharged. The supply voltage V1 is produced at the drain of Q12. The 1μf capacitor, C17, provides filtering to eliminate contact bounce during switching of SW1. V1 supplies power to ICs (U6, U7 & U8), beeper, infrared emitter/detector, motor run and lcd backlight. V1 is monitored by the Low Battery & Low Battery Shutdown detection circuits.

A 1.2 volt voltage regulator LM385BM-1.2, D8, is used along with V1 to provide a stable 1.235 volt reference voltage source (1.2VREF). D8 maintains the load voltage at a constant 1.2 volts, independent of variations in load current or supply voltage, V1. 1.2VREF supplies a reference voltage to the empty, occlusion, cassette not present, clog clearing, motor run and Low Battery / Low Battery Shutdown detection circuits.

Supply voltage V0 is generated directly from supply V1, via 1A diode PRLL5817, D1, and a 680μf electrolytic capacitor, C4. V0 is required so as to maintain power during the saving operation, of critical operating information, to the EEPROM when main power is discontinued, via Low Battery Shutdown or rotation of control dial to the "POWER OFF (CHARGE)" position. V0 supplies power to the microcontroller (U3), reset supervisor (U1), EEPROM (U4), shift register (U5), and display board.

Supply voltage V2 is generated directly from supply V1, via 1A diode PRLL5817, D2. V2 is required so that the I/O lines going to the microcontroller are at the same potential as the V0 supply. V2 supplies power to the pull-up resistors for the rotary dial input (SW1:A), touch panel overlay, and the majority of inputs lines going to the microcontroller (U3).

3.3.2
BATTERY

A 4 volt, 1 ampere hour rechargeable, sealed lead-acid battery (Sonnenschein #2A x 2K or Long #WP1-4) is utilized during portable pumping operating modes. Lead-acid batteries have several unique features that help to simplify the charger circuitry. First, lead-acid batteries self regulate charge current automatically, therefore only requiring the implementation of a single level constant voltage charging circuit. Second, due to the pumps practical application (i.e.: operating temperature of 60 - 90 degree Fahrenheit), temperature compensation is not necessary. Third, the batteries have an extremely low rate of self-discharge, which is highly suitable for low or intermittent usage applications.

The 4V, 1Ah sealed lead-acid battery is constant voltage charged, with a constant voltage of 4.68 ± 0.02Vdc placed across it's terminals. This is the most suitable method to recharge a sealed lead-acid battery. Charging occurs directly through a 1A slo-blo fuse, with the battery regulating charge current. The 1A slo-blo fuse is utilized to protect against the following fault conditions: (1) shorted battery cell, (2) shorted input connector, and (3) shorted components on main board assembly.

3.3.3
LOW BATTERY / SHUTDOWN

There are two separate circuits. The first circuit detects when the battery voltage falls below 3.95 ± 0.2 volts, at which point the pump goes into an alarming condition (visual "LOW BATTERY" and audible beeper). This circuit is therefore called the Low Battery Detection Circuit. The second circuit, Low Battery Shutdown Circuit, goes into an alarming condition (audible beeper) and automatically shuts down the pump in a safe manner, whenever battery voltage falls below 3.65 ± 0.2 volts. This prevents excessive battery discharge and protects pumping circuitry.

The Low Battery Detection Circuit monitors V1 through a voltage divider, resistors R36 and R39. A CMOS voltage comparator TLC374CD, U7:A, compares the output of the voltage divider with reference voltage 1.2VREF. If the output of the voltage divider falls below 1.2 volts, the output of U1 goes HIGH and initiates a LOW BATTERY alarm. The 1 megaohm resistor, R26, provides hysteresis for proper triggering of U7:A.

The Low Battery Shutdown Circuit also monitors V1 through a voltage divider, resistors R38 and R40. A CMOS voltage comparator TLC374CD, U7:B, compares the output of the voltage divider with reference voltage 1.2VREF. If the output of the voltage divider falls below 1.2 volts, the output of U7:B goes HIGH and initiates a LOW BATTERY SHUTDOWN alarm. The comparator is latched in the HIGH state via positive feedback diode D5. The motor run circuit is also disabled via diode D5 and comparator U7:C.

3.3.4
CONTROLLER

The microcontroller utilizes high-density, complementary metal-oxide semiconductor (HCMOS) technology, which helps to minimize power requirements and provide maximum battery operating life. The microcontroller #MC68HC705C9A-CFN, U3, is initialized when power (V0) is applied to the circuit and a reset threshold of 2.93V is exceeded, via the microcontroller supervisory chip, U1. The microcontroller software then performs an initialization routine and a self test function, which includes visual, audible, RAM and I/O verification. If there should be an error associated with RAM, the message "F1" is displayed on the LCD.

The single chip microcontroller contains 15,932 bytes of EPROM and 352 bytes of RAM, SPI, and has 31 bi-directional I/O lines that control and monitor various pumping and user interfacing functions. The ClearStar pump also utilizes the onboard microcontroller watchdog timer, on-chip crystal oscillator connections, and power-saving stop function. Software was written in C-language and was compiled via the Byte Craft C6805 code development system.

3.3.5
MEMORY

Besides the 15,932 bytes of EPROM and 352 bytes of RAM that are onboard the microcontroller, the microcontroller communicates serially, via the serial peripheral interface (SPI), with a nonvolatile EEPROM device. The nonvolatile EEPROM, #NM93CS66LM8X, U4, contains 4096 bits of memory, internally organized 256 x 16 and can operate in all modes down to 2.7V. The device features an endurance of 10^6 data changes with 40 years data retention.

The nonvolatile EEPROM is used to save, the following information:

1. *general user operating information* - Set Rate, Set Dose and Volume Fed values,
2. *diagnostic recorder* - error event data (fault codes F1 - F21) used to identify errors encountered while in operation,
3. *occlusion event recorder* - event number & duration of clog clearing in seconds are saved,
4. *general default information* - when activated the diagnostic & occlusion event recorders are reset, Set Rate = 300ml/hr, Set Dose = 0ml, Volume Fed = 0ml, TDC & BDC delay values = 70ms, and XDUCER = 49, and
5. *TDC & BDC delay values* and the *XDUCER gain value* are stored in secured memory.

The nonvolatile EEPROM requires 15ms in order to erase and write a single 16 bit value. When the operating parameters are changed, or a fault condition occurs during normal pumping (excluding power shutdown), one to two 16 bit values are saved into non-volatile EEPROM. During power shutdown (POWER OFF, low battery shutdown, or motor runaway), the 680μf electrolytic capacitor, C4, maintains the supply voltage, V0, long enough (~ 80ms) to save the latest volume fed value, fault code (if any) and checksum (set rate + set dose + volume fed) information.

3.3.6
MOTOR DRIVER & SPEED CONTROL

The motor drive circuit consists of a motor voltage regulator, which regulates the voltage (Vm) supplied to the motor and driver. The motor drive circuit is activated when the /RUN line triggers LOW, through diode DAN202KT146, D6. The output of voltage comparator TLC374CD, U7:C, (pin 14) triggers LOW, allowing the pnp power transistor MJE371, Q10, to conduct. The collector voltage is feedback, through a digital controlled resistive voltage divider network (R10, R11, and U2), to the non-inverting input of comparator U7:C. The comparator is in effect turning the pnp power transistor, Q10, ON and OFF very quickly in order to maintain a constant (regulated) voltage at the collector. A 100μ electrolytic capacitor, C9, is needed for filtering to help reduce ripple.

Rotational speed of the dc gearmotor is directly dependent upon the input motor voltage, Vm, supplied to it. Motor speed is adjusted (i.e.: Vm applied to the gearmotor) so the piston travels from BDC to TDC in 900ms and from TDC to BDC in 900ms. Constant motor speed control was implemented in order to provide stability in transducer output due to changes in motor load (i.e.: normal feeding versus occluded conditions). The value of Vm is determined by the resistor values selected for R10, R11 and the value of the digital potentiometer, U2. Since R10 & R11 are fixed resistor values and the digital potentiometer may vary between 0 to 10K, Vm can vary between 2.03 to 3.15 volts. Timing feedback is monitored via CYCLE1 & CYCLE2 reedswitches, with the digital potentiometer controlled via the microcontroller.

The motor supply voltage, Vm, is current limited to 400mA. This assists in the minimization of electromechanical erosion of the motor commutator / brush system. Current limiting is achieved with pnp transistor, MMBT4403LT1, Q8, and 1.8Ω bias resistor, R15, controlling the base current of the pnp power transistor MJE371, Q10.

3.3.7
TDC/BDC POSITION DETECTION & MOTOR BRAKE

A normal pumping cycle consists of the piston stopping at the top dead center (TDC) position for 2.1 seconds (for flow rates between 250 - 300ml/hr) or 3.1 seconds (for flow rates between 1 - 249ml/hr) and at the bottom dead center (BDC) position for the remainder of the pumping cycle. The time at which the piston spends at the BDC position is determined by the flow rate setting that has been selected by the user.

The cycle begins with the piston at the BDC position. While at the BDC position, the microcontroller monitors the CYCLE2 reedswitch for an open condition. *Note, if the CYCLE2 reedswitch is activated (shorted) at the beginning of the motor cycle, the pump shutdown sequence is initiated.* The microcontroller enables the /RUN signal allowing the motor to rotate so the piston approaches the TDC position. Once the /RUN signal is enabled, the microcontroller monitors the CYCLE2 reedswitch for activation. When activated, the microcontroller initiates the TDC delay value (0 - 200ms, entered during pump calibration). The motor continues to rotate until the TDC delay value expires. The /RUN signal is disabled and the /BRAKE is enabled for 100ms, allowing the piston to stop at true TDC position (±.001").

After the 2.1 or 3.1 second idle time at TDC, the second part of the normal pumping cycle begins. While at the TDC position, the microcontroller monitors the CYCLE1 reedswitch for an open condition. *Note, if the CYCLE1 reedswitch is activated (shorted), the pump shutdown sequence is initiated.* The microcontroller enables the /RUN signal, allowing the motor to rotate so that the piston returns to the BDC position. Once the /RUN signal is enabled, the microcontroller monitors the CYCLE1 reedswitch for activation. When activated, the microcontroller initiates the BDC delay value (0 - 200ms, entered during pump calibration). The motor continues to rotate until the BDC delay value expires. The /RUN signal is disabled, a 30ms coast period is initiated, and the /BRAKE is enabled for 100ms, allowing the piston to stop at true BDC position (±.001").

The /BRAKE line is utilized in order to stop the rotation of the dc gearmotor abruptly. This helps the piston to stop at true TDC & BDC positions, which ensures overall pump delivery accuracy. When the /BRAKE line is enabled, pnp transistor MMBTA63LT1, Q5, is driven into saturation. This, in turn, forces npn power transistor, MJE521, Q6, to limit braking current from the motor. The back EMF induced by motor rotation allows it to stop very quickly. Note, the BRAKE line is LOW for 100 milliseconds in order to conserve power and prolong battery life.

3.3.8
MOTOR RUNAWAY DETECTION

The motor runaway detection (watchdog) circuit monitors the motor supply voltage, Vm, for conditions that may cause a motor runaway event. The watchdog circuit consists of an RC network (R37 and C20), comparator TLC374CD, U7:D, and latching diode MMBD914LT1, D11, to verify that Vm is activated for no longer than 10 seconds. If so, the output of comparator U7:D (pin13) is latched HIGH, enabling the beeper (constant tone) and shunting the motor supply voltage, Vm, via the n-channel mosfet, SI2302DS, Q13. The microcontroller, monitoring the RUNAWAY line, displays fault code F-07 on the liquid crystal display, initiates a constant audible alarm, forces the /RUN line HIGH, forces the /BRAKE line LOW, forces the SOFT_RUNAWAY line HIGH, and enters the STOP mode.

3.3.9
CLOG CLEARING, OCCLUSION & CASSETTE NOT PRESENT DETECTOR

A piezoelectric ceramic transducer is mounted at the end of the drive system cam follower (piston). During normal pumping, the piston remains in constant contact with the cassette bellows, thus producing an electric potential across the plates of the piezoelectric transducer. This signal varies in amplitude with the change in force required to compress and decompress the bellows. The Companion® ClearStar™ pump monitors the decompression cycle (from TDC to BDC piston position) of the *normal pumping mode* and *clog clearing mode*.

The transducer signal is fed directly to the input of a high impedance amplifier, TLC271CD, U8. R42 and C28 are used to set the voltage per unit force developed by the piezoelectric transducer and condition the input signal to a maximum voltage time duration. Resistor, R41 is for EMI protection.

A low pass filter (C21 & R27) conditions the transducer signal by eliminating unwanted noise caused by motion artifact. Diode, D13, prevents reverse voltage damage to the op amp. The gain of the amplifier is selected by digital potentiometer, AD8402, U2, and can only be accessed while the FORCE_CAL line is active. The output of the op amp is monitored by three different voltage comparators: (a) Occlusion - TLC347CD, U6:D, (b) Clog Clearing - TLC347CD, U6:B, and (c) Cassette Not Present - TLC347CD, U6:C. A detailed description of each circuit is as follows:

(a) Occlusion - The conditioned (amplified) transducer signal is compared, via TLC347CD, U6:D, with 1.2VREF. Under normal operating conditions, the transducer signal falls below the 1.2 volt reference, causing the output of comparator U6:D (pin 13) to remain high. If the transducer level is greater than 1.2VREF, the output of comparator will trigger LOW. After a reverification period, the pump will either enter the *clog clearing mode* or will result in a visual and audible "OCCL" alarm.

(b) Clog Clearing - Once in the *clog clearing mode* the conditioned transducer signal is monitored, via comparator TLC347CD, U6:B, to determine when the clog has been removed. The transducer signal is compared against 1.10V, which is generated via voltage divider R33 & R29 and 1.2VREF. Under an occluded condition, the transducer signal is greater than 1.10V, causing the output of comparator U6:B (pin 2) to remain LOW. The pump will remain in the clog clearing mode. However, if the clog has been cleared, the peak transducer signal will drop below the 1.10V threshold, causing the output of the comparator to trigger HIGH. After one additional verification stroke, the pump will return to the *normal pumping mode*.

(c) Cassette Not Present - The piezoelectric ceramic transducer is also used to detect the presence or absence of the disposable cassette within the pump cavity. During normal pumping or an occlusion condition, the piston makes contact with the bellows, thus generating a voltage potential across the plates of the piezoelectric transducer. This signal is monitored by comparator TLC374CD, U6:C. If there is no cassette positioned within the pump cavity, the output of the transducer is approximately 0 volts. Therefore, the output of comparator U6:C (pin 14), remains HIGH throughout the pumping cycle, thus indicating an "EMPTY" visual and audible alarm within two pumping cycles.

3.3.10
FLUID EMPTY DETECTION

A GaAlAs infrared emitter diode and a npn silicon phototransistor is used in a thru-beam configuration to detect the presence, or lack, of fluid (opaque or transparent) in the disposable cassette inlet chamber. In order to conserve battery energy the infrared emitting diode is activated only at the very end of each pumping cycle (to the user, it appears that the emitting diode is activated at the beginning of a pumping cycle). This is also done to take advantage of the time between pumping cycles to allow viscous fluids to dissipate from the side walls of the cassette inlet chamber.

A 20K potentiometer, P1, varies the collector current of the phototransistor, thus allowing for differences in emitter/detector pairs. Comparator TLC374CD, U6:A, compares the output of the phototransistor to 1.2VREF. The output of comparator U6:A (pin 1), is monitored by the

microcontroller. Therefore, when there is fluid in the inlet chamber of the cassette, the output of comparator, goes HIGH, indicating a normal operating condition. On the other hand, if the feeding set is pumped dry, there would be an absence of fluid in the inlet chamber of the cassette. This absence of fluid allows the phototransistor to detect the infrared beam of the infrared emitter diode. The output of the comparator goes LOW, indicating an abnormal operating condition, resulting in an "EMPTY" visual and audible alarm after two pumping cycles (for flow rate settings between 3 - 300ml/hr). For flow rates settings 1 and 2ml/hr, when a possible empty cassette condition is detected at the end of the first pumping cycle, the software activates the emitting diode and monitors comparator U6:A five minutes into the next pumping cycle. If a second empty condition is detected, the pump displays "EMPTY" on the LCD and an audible alarm sounds.

3.3.11
BEEPER CONTROLLER

When either the RUNAWAY or BEEP line goes HIGH, transistor NMBT4401LT1, Q2 conducts, enabling the piezo beeper. The volume can be selected by the user, via the touch panel overlay. If

the HI ALARM level is selected, the microcontroller enables the VOLUME line (HIGH), which forces transistor NMBT4401LT1, Q3, into saturation, thereby by-passing the 6.8K resistor, R5. The result is a 85-90dB sound level alarm, when activated. If the LO ALARM level is selected, the microcontroller disables the VOLUME line (LOW), which forces transistor Q3 into cutoff. The result is a 65-70dB sound level alarm, when activated.

3.3.12
BACKLIGHT DRIVER

The LCD backlight is activated when the microcontroller PC4 port is LOW. This drives pnp transistor NMBT4401LT1, Q7, into saturation, activating the LED edge lit backlighting (located on the display board assembly).

3.3.13
TOUCHPANEL KEYPAD

The touchpanel keypad is arranged such that the keypads logically reside in a row/column matrix. A row must be activated in order to read back the state of the keypads in that row (column intersection with that row). For the software to determine whether a specific keypad has been depressed, it must first activate the row that contains that key and then read back the column intersection for that key. The keypad interface is a 3 by 3 row/column matrix.

Microcontroller I/O lines PB5, PB6 & PB7 are used to select the keypad row for reading. When the software sets one of these lines LOW, it can read the PB2 - PB4 signals to see which keypads are being depressed along the selected row.

Microcontroller I/O lines PB2, PB3 & PB4 are read back by the software to see which keypads are being depressed along the selected row. A depressed keypad is indicated by the signal line being LOW. If no row is being selected, the values on these signals are invalid.

The table below identifies the logical location, with respect to the microcontroller I/O signal lines, fo the five keypads located on the touchpanel overlay:

ROW/COLUMN	PB4	PB3	PB2
PB7	BACKLIGHT	ALARM HI/LO	
PB6		VOL. CLEAR 2X	DECREMENT
PB5			INCREMENT

3.3.14
CONTROL DIAL

The pump control dial selects the mode of operation for the Companion™ ClearStar™ Enteral Nutrition Pump. The microcontroller reads the selected mode, along with the LOW-BATTERY and /CHARGING input signals, through the serial output of the parallel to serial shift register, MC74HC589, U5. The serial output of the serial shift register is read via the microcontroller serial interface line, PD2. Data is clocked in on the rising edge of the serial interface clock, SCK. The microcontroller selects the serial shift register to be read via the PC3 line. The software reads the completed byte of parallel data to determine which mode has been selected.

3.4
PUMP DISPLAY BOARD

A custom triplexed transflective liquid crystal display (LCD) is used to provide a visual verification of ongoing pumping modes and alert functions. Two liquid crystal display COP472MW-3 controllers (IC1 and IC2) are used, in a master / slave combination, to directly drive the LCD. Data generated by the microcontroller is loaded serially and is held in internal latches. The controllers, containing an on-chip oscillator, generate all multilevel waveforms for backplane and segment outputs for the triplexed LCD.

The main board assembly communicates serially with the display board assembly via a 7-pin connector, J2. The 7-pin connector is made up of serial data input, serial clock input, chip select lines (IC1 & IC2), LED+, V_{dd} & ground.

Section 4

MAINTENANCE & SERVICE TESTS

This section of the Companion™ ClearStar™ Enteral Nutrition Pump Service Manual contains preventative maintenance information, performance verification tests, and electrical safety tests.

4.1
EQUIPMENT REQUIRED

The following hand tools, test equipment, materials and consumables are necessary to disassemble and reassemble parts of the Companion™ ClearStar™ Enteral Nutrition Pump.

4.1.1
TOOLS REQUIRED

1. Phillips screwdriver - medium
2. Phillips screwdriver - small
3. Flat blade screwdriver - small
4. Nut driver - 5/16"
5. Nut driver - 1/4"
6. Needle nose pliers
7. Exacto blade
8. Strain relief insertion tool
9. Green stick

4.1.2
TEST EQUIPMENT & MATERIALS REQUIRED

1. Digital multimeter (DMM)
2. Oscilloscope
3. Stopwatch
4. Companion™ ClearStar™ Enteral Feeding Set
5. High-Pot Tester
6. Graduated Cylinder

4.1.3
CONSUMABLES

1. Isopropyl alcohol
2. Lint free cloth
3. Hot melt glue
4. Small screw threadlock (Loctite #222)
5. Torque seal
6. Water or enteral product

4.2
PREVENTATIVE MAINTENANCE

A preventative maintenance program will help promote longevity and trouble free operation of the Companion™ ClearStar™ Enteral Nutrition Pump. Such a program should include periodic inspection of the pump & backpack, exterior cleaning & sanitizing, verifying presence of important labels, and ensuring proper functional operation, per Performance Verification Tests (Section #4.3).

4.2.1
INSPECTING THE EXTERIOR

Periodically, the pump should be visually inspected for signs of defects such as worn or broken components, cracked enclosure, or damaged power cord. Inspection is applicable after any repair or during normal cleaning procedures.

Verify that the following items are present and inspect for any visual defects. Replace any missing or defective external parts.

- ✓ Control Dial (flip door)
- ✓ Touchpanel Overlay (keypads & LCD window)
- ✓ Cassette Retaining Latch
- ✓ Cassette Tube Cavity.
- ✓ AC Power Cord & Velcro® Strap
- ✓ Pole Clamp Assembly
- ✓ Enclosure
- ✓ External Screws
- ✓ Four (4) Rubber Feet
- ✓ Exterior Labels

4.2.2
CLEANING AND SANITIZING

As a minimum requirement, clean the pump and backpack after each use and establish a regular cleaning schedule while in use. The pump and charger are specially designed for easy cleaning. While cleaning, the pump should be turned off and unplugged. Do not submerge, autoclave, heat, steam, ETO or radiation sterilize the pump.

EXTERIOR

1. For general cleaning, the outside surfaces can be cleaned using a warm, soapy water (mild non chlorine based dish washing detergent) or isopropyl alcohol. For trouble-free operation, check pump frequently for signs of product spills. Clean immediately after spills occur. Dry thoroughly, making sure that no soapy film or residue remains.

CASSETTE CAVITY

1. The pump cassette tube cavity can be cleaned with a cotton swab or soft cloth and warm, soapy water (mild non chlorine based dish washing detergent). Dry thoroughly, making sure that no soapy film or residue remains.
2. The infrared optics (emitter & detector) can be cleaned using a small soft bristled child's toothbrush and warm, soapy water. Thoroughly scrub, getting in the optic openings. Immediately rinse well with warm water, ensuring water does not enter inside the pump through the cassette latch opening. Blow dry using deionized canned air. DO NOT clean the cassette tube cavity with alcohol.

DISINFECTANTS

Sanitizing is recommended for all external parts and surfaces. Allow to air dry after disinfecting. The following recommendations for sanitizing the pump are not substitutes for official procedures that may differ among institutions. Contact the local infection control officer to determine proper procedure in your institution.

1. For general disinfecting, the following chemicals may be used: Cidex® (Arbrook, Inc.), pHisoHex® (Winthrop-Breon Laboratories), Hibiclens® (Stuart Pharmaceuticals), or isopropyl alcohol.
2. For disinfecting after exposure to AIDS or hepatitis, use 10% concentration of 5.25% sodium hypochlorite (household bleach).
3. For disinfecting after exposure to Tuberculosis, use 70% concentration of isopropyl alcohol.

4.2.3
LABELS

Verify that all exterior labels are intact and legible, per Section #7.1 (Figures #1 & #2).

4.3
PERFORMANCE VERIFICATION TESTS

The following is a list of preventive maintenance tests that should be performed at regular intervals and after any repair. None of the checkouts or test procedures require disassembly of any part of the pump or backpack units. If any performance parameter is not met, or an obvious malfunction occurs, the pump should be removed from service and returned to an authorized repair facility.

4.3.1
SETUP

Prime a Companion® ClearStar™ Enteral Feeding Set with Ensure® Liquid Nutrition or Osmolite ® Isotonic Liquid Nutrition until the distal tubing is free from air entrapment. Insert the feeding cassette into the pump's cassette tube cavity until the cassette locks into position. Note, all testing shall be performed with the pump operating on AC power, unless otherwise specified.

4.3.2
POWER ON SELF-TEST

Rotate the pump control dial to the SET RATE position and immediately start timer (stopwatch). Verify the following:

1. All 7 of the 4 LCD numeric segments are displayed (8888).
2. All LCD indicators/ICONs are displayed (LOW BATTERY, SELECT RUN, EMPTY, OCCL, ml/hr, LOW ALARM, and RUN).
3. Backlighting illuminates.
4. Audible buzzer activates 3 consecutive beeps.
5. Directly following the 3 beeps, the LCD displays the following:
   (a) the word "rAtE", followed by the value & "ml/hr";
   (b) the word "doSE", followed by the value & "ml";
   the word "FEd", followed by the value & "ml". (c)
6. After Self Test is completed, the flow rate value & "ml/hr" is displayed on the LCD.

4.3.3
AC/BATTERY POWER

With the pump control dial in the SET RATE position, remove the pump from the backpack assembly. Verify that the "BATTERY" icon is displayed and that the LCD backlighting is discontinued.

4.3.4
TOUCHPANEL KEYPAD

With the pump operating in the battery mode, verify proper keypad operation by performing the following:

1. Press the increment (↑) keypad. Verify that the SET RATE value scrolls upwards.
2. Press the decrement (↓) keypad. Verify that the SET RATE value scrolls downwards.
3. Press the backlight (LIGHT BULB) keypad. Verify that the LCD backlight illuminates for approximately 15 seconds. Note; the LCD backlight will turn off if the backlight keypad is pressed again.
4. Press the (AUDIO HI/LO) keypad. Verify that the LOW ALARM icon toggles on.
5. Rotate pump control dial to the VOLUME FED position. Press the VOL. CLEAR 2X keypad quickly two times. Verify that the volume displayed on the LDC now reads "0 ml".

4.3.5
INACTIVITY ALARM

Place the pump back into the backpack assembly to resume battery charging. The "BATTERY" icon should be disabled. The inactivity alarm can be verified by performing the following steps:

1. Rotate the pump control dial to the SET RATE position.
2. Allow the pump to remain inactive for 5 minutes. Verify that the "SELECT RUN" icon is displayed on the LDC and that the audible alarm is enabled.
3. Rotate the pump control dial to the HOLD position. Verify that the "SELECT RUN" icon and audible alarm are both disabled.

4.3.6
CASSETTE NOT PRESENT ALARM

The cassette not present alarm can be verified by performing the following steps:

1. Rotate the pump control dial to the SET RATE position and enter in a rate of 300ml/hr.
2. With no cassette in the pumping chamber, rotate the pump control dial to the RUN position. Verify that directly following two complete pump cycles (~12 seconds), the "EMPTY" icon flashes on the LCD display and that the audible alarm is enabled.
3. Rotate the pump control dial to the HOLD position. Verify that the audible alarm is disabled but that the "EMPTY" icon continues to flash on the LCD displayed.

4.3.7
EMPTY ALARM

The empty cassette alarm can be verified by performing the following steps:

1. Rotate the pump control dial to the SET RATE position and ensure that a flow rate setting of 300ml/hr has been entered.
2. Place an unprimed cassette into the pumping chamber.
3. Rotate the pump control dial to the RUN position. Verify that directly following two complete pump cycles (~12 seconds), the "EMPTY" icon flashes on the LCD display and that the audible alarm is enabled.
4. Rotate the pump control dial to the HOLD position. Verify that the audible alarm is disabled but that the "EMPTY" icon continues to flash on the LCD displayed.

4.3.8
CLOG CLEARING MODE

The clog clearing operating mode may be achieved by performing the following steps:

1. Rotate the pump control dial to the SET RATE position and ensure that a flow rate setting of 300ml/hr has been entered.
2. Place a primed cassette into the pumping chamber and rotate the pump control dial to the RUN position. Verify that the "RUN" icon flashes on the LCD display.
3. Occlude the distal tubing of the feeding set just above the feeding adapter. Verify that after approximately 60 seconds, the "RUN" icon discontinues flashes and remains activated. This is an indication that the pump is in the clog clearing operating mode.

4.3.9
DISTAL OCCLUSION ALARM

The downstream occlusion alarm can be verified by performing the following steps:

1. Complete Section #4.3.8, verifying that the pump is in the clog clearing operating mode.
2. Allow the pump to continue functioning in the clog clearing operating mode for approximately 10 minutes. Verify that after 10 minutes, the "OCCL" icon flashes on the LCD display and that the audible alarm is enabled.
3. Rotate the pump control dial to the HOLD position. Verify that the audible alarm is disabled but that the "OCCL" icon continues to flash on the LCD displayed.

4.3.10
AUDIBLE ALARM VOLUME

With the pump alarming (per Section #4.3.5, #4.3.6, #4.3.7 or #4.3.9), press the AUDIO HI/LO keypad to change the audible alarm intensity. Press repeatedly to toggle between the high and low audible levels. The LCD will display the "LOW ALARM" icon when the low audible alarm level is selected.

4.3.11
OCCLUSION EVENT RECORDER

The occlusion event recorder is used to track and record all clog clearing and occlusion events. The event recorder will store two values for each event into EEPROM, they are:

(a) the **event number** - the number of the occlusion event (E-0 through E-99), and
(b) the **occlusion length** - the length of time, in seconds, pump spent in the clog clearing mode. (Note: maximum of 600 seconds: 10 min. x 60 sec./min).

The occlusion event recorder can be verified by performing the following steps:

1. The occlusion event recorder can be accessed via the control dial and touchpanel keypad, as follows:
   (a) Rotate the pump control dial to the HOLD position, and
   (b) Simultaneously press both the increment (↑) & VOL. CLEAR 2X keypads until a constant low audible beep sounds. Continue pressing both keypads for six consecutive seconds to initiate the occlusion event recorder read back mode.

2. Once in the event recorder read back mode, the last **event number** will be flashing on the LCD display (i.e.: "E-99" if 99 events occurred, "E-10" if 10 events occurred, "E-0" if no clog clearing events occurred, etc...). Note, only the ten most recent occlusion events will be stored into the EEPROM (i.e.: if ten occlusion events [E-1 through E-10] exist at the time the next event occurs, that event is saved as event E-11, dropping the first event E-1).

3. While in the event recorder read back mode, press the decrement (↓) keypad. Verify that the last **occlusion length** recorded is "600", per Sections #4.3.8 & #4.3.9. Note, "600" should be flashing, indicating that this is the last occlusion occurrence.

4. Continuing to press the decrement (↓) keypad will allow the operator to index backwards, displaying the previous **event number** and **occlusion length** "value". Note, the **event number** and **occlusion length** "value" should no longer be flashing.

5. Press the VOL. CLEAR 2X keypad twice in a five second period will clear all stored occlusion event data (both **event number** and **occlusion length** "values"). Verify that the LCD displays an **event number** of "E-0" and an **occlusion length** of "0".

6. Rotate the pump control dial to another position other than HOLD to toggle back to the normal pumping mode.

4.3.12
DELIVERY ACCURACY

The flow rate accuracy of the Companion™ ClearStar™ Enteral Nutrition Pump can be verified by performing the following procedure:

1. Using Ensure® Liquid Nutrition or Osmolite® Isotonic Liquid Nutrition, fill the container of a new feeding set to 1 Liter and suspend such that the fluid level in the sight chamber is 20 inches [50.8cm] above the pump cavity (*see Figure 4-1, Typical Pump Setup for Delivery Accuracy Test*). Note, fluid head height and viscosity are two variables that can affect flow rate.

2. Place the distal end of the feeding set into a graduated cylinder. The distal end should be placed 10 inches [25.4cm] below the pump cavity. Note, be sure to use a graduated cylinder for volume measurements, not an enteral feeding container.

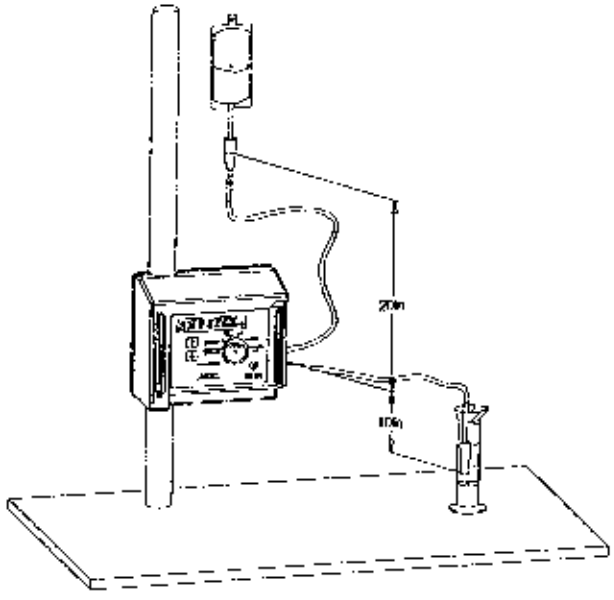

Figure 4-1, Typical Pump Setup for Delivery Accuracy Test

3. With the pump running on AC power, setup the pump according to instructions for a feeding rate of 300ml/hr and dose of 0ml. Start the pump and let run for a 15 minute break-in period.

4. Rotate the pump control dial to the SET RATE position and enter a flow rate setting of 100 ml/hr. Rotate the pump control dial to the SET DOSE position and enter a dose limit value of 100 ml.

5. Rotate the pump control dial to the RUN position and allow to run for 1 hour. Verify that the fluid delivered is between 90 - 110 ml (within 10% accuracy). Note, if flow rate is incorrect, try a new pump feeding set and repeat procedure.

4.4
ELECTRICAL SAFETY TESTS

Leakage current and grounding impedance shall be tested in accordance with Underwriters Laboratories Standard for Medical Electrical Equipment, Part 1: General Requirements for Safety, UL2601-1. The maximum allowable leakage current is 100 microamperes (AC RMS). Perform the electrical safety test, as follows:

4.4.1
LEAKAGE CURRENT

Perform the leakage current testing, as follows:

1. The pump shall be properly installed into the backpack (charger).
2. Since there are no exposed metal parts in the case which is likely to become energized, the leakage current is to be measured using the "metal foil" technique.
3. A piece of metal foil with an area not exceeding 10 by 20 centimeters (200 square centimeters) shall be placed in intimate contact with an accessible surface of the charger case. The foil shall be located by experimentation so that the current to ground is maximum.
4. The leakage current is to be measured between power (earth) ground and the foil in contact with the enclosure for any combination of the following:
    a) electrical supply polarity normal and reverse;
    b) power switch on and off;
    c) ground open and intact.
5. The maximum allowable leakage current, under any of the above condition, is 100 microamperes (AC rms).

4.4.2
GROUND IMPEDANCE

Since there is no externally accessible ground, no ground impedance measurement is mandated.

4.4.3
DIELECTRIC WITHSTAND TEST

Perform the dielectric withstand testing, as follows:

1. Connect one lead of the High-Pot Tester (Red) across the HOT & NEUTRAL terminals of the power cord assembly. Note, a jumper may be used to short both terminals of the power cord.
2. Connect the other lead of the High-Pot Tester (Black) to the GROUND terminal of the power cord assembly.
3. Turn AC High-Pot Tester power switch "ON". Ensure that "HIGH VOLTAGE / ON" indicator(s) illuminate.
4. Slowly increase voltage to 1500 VAC and hold for 5 seconds.

5. Verify that voltage does NOT drop and that the "FAILURE" light and audible alarm does NOT activate. Note, if a failure occurs, send the Companion™ ClearStar™ Enteral Nutrition Pump back to the Ross Products Division or Abbott International Service Center for repair.
6. Turn voltage down to zero and turn power "OFF".
7. Disconnect the High-Pot Tester leads from the power cord assembly.

Section 5

TROUBLESHOOTING GUIDE

This section contains information on obtaining technical assistance from the Abbott International Ltd. Service Center and/or the Ross Products Division Service Center, on malfunction error codes, alert and other miscellaneous problems.

5.1
TECHNICAL ASSISTANCE

For technical assistance or to order parts, accessories, or manuals, please contact Abbott International Ltd. or the Ross Products Division. Do not return the Companion™ ClearStar™ Enteral Nutrition Pump without first obtaining return authorization from either Abbott International Ltd. or the Ross Products Division.

5.2
DIAGNOSTIC MODE RECORDER

The Companion™ ClearStar™ Enteral Nutrition Pump has a feature, called the diagnostic mode recorder, which can retain into internal memory a number of pump fault conditions. At the time the pump detects a fault condition (failure mode event or alarm condition), both a two digit fault code and a sequence number are stored into the EEPROM:

(a) **sequence number** - the number (1-50) at which the failure or alarm condition occurred. A zero (0) denotes a cleared register.

(b) **error code** - an error code, "F-XX", representing a pump failure or an alarm condition. Refer to Table 5-1 for a listing and description of fault codes.

The diagnostic mode recorder archives the most recent 50 failure events (fault codes) into EEPROM. The information is stored and retrieved LIFO (last in first out). If more that 50 events occur prior to the clearing the diagnostic mode recorder, the first event is deleted and the new event is saved.

A qualified service technician can access the diagnostic mode recorder by performing the following steps:

1. Remove the pump from the backpack assembly.
2. Remove the battery door, using a medium Phillips head screwdriver. Remove the 4V, 1Ah sealed lead-acid battery.
3. Attach one end of a small jumper cable to the DIAGNOSTIC_REC LINE, pin #5 of connector, J5. Attach the other end of the small jumper cable to GROUND, pin #1 of connector, J5.

4. Utilizing a 2 ft long dc power cable assembly, apply power to the pump from the backpack assembly.
5. Rotate the pump control dial from the POWER OFF (CHARGE) position to the HOLD position. *Note, if the DIAGNOSTIC_REC line is pulled LOW prior to the pump first powering up, the pump will by-pass the self test diagnostic mode.* Data from the diagnostic mode recorder can now be accessed.

The error codes can be retrieved as follows:

1. The LCD displays the first sequence number saved into EEPROM.
2. Pressing the increment (↑) keypad will allow the technician to index forward, displaying the 1st error code, then 2nd sequence number, then 2nd error code, then 3rd sequence number, etc...
3. Pressing the decrement (↓) keypad will allow the technician to index backwards (i.e.: last error code, then last sequence number, then second to last error code , then second to last sequence number, etc...).
4. Once in the diagnostic retrieval mode, depressing the VOL. CLEAR 2X keypad for five (5) consecutive seconds will clear all stored sequence numbers and error codes.
5. Disconnecting the jumper cable between the DIAGNOSTIC_REC LINE (pin #5 of connector, J5) and GROUND (pin #1 of connector, J5) will allow the pump to return to the *normal pumping mode*.

Refer to Table 5-1 for a complete listing and description of fault codes (F-01 through F-21), audible & visual alert conditions, and microcontroller I/O line status.

Table 5-1: FAULT CODES & ALERT STATUS

DISPLAYED FAULT CODE	POSSIBLE FAULT CONDITION	ALERT CONDITION		MICROCONTROLLER I/O LINE STATUS			
		LCD DISPLAY	AUDIBLE ALERT	/RUN LINE	/BRAKE LINE	SOFT_ RUNAWAY LINE	CRYSTAL STATUS
F-01	RAM TEST	F-01	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-02	CYCLE_1 OPEN	F-02	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-03	CYCLE_1 SHORTED	F-03	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-04	CYCLE_2 OPEN	F-04	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-05	CYCLE_2 SHORTED	F-05	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-06	SOFT RUNAWAY	F-06	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-07	HARD RUNAWAY	F-07	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-08	LOW BATTERY SHUTDOWN	F-08	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-09	SOFT WATCHDOG	F-09	CONSTANT ON	HIGH	LOW	HIGH	STOP

DISPLAYED FAULT CODE	POSSIBLE FAULT CONDITION	ALERT CONDITION		MICROCONTROLLER I/O LINE STATUS			
		LCD DISPLAY	AUDIBLE ALERT	/RUN LINE	/BRAKE LINE	SOFT_ RUNAWAY LINE	CRYSTAL STATUS
F-10	CASSETTE NOT PRESENT	F-10	BEEPING	N/A	N/A	N/A	RUNNING
F-11	OCCLUSION	F-11	BEEPING	N/A	N/A	N/A	RUNNING
F-12	EMPTY	F-12	BEEPING	N/A	N/A	N/A	RUNNING
F-13	CHECKSUM ERROR (TDC + BDC + REDUCER)	F-13	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-14	2 REEDS SHORTED	F-14	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-15	FLOW RATE OUT OF RANGE	F-15	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-16	DOSE OUT OF RANGE	F-16	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-17	VOL. FED OUT OF RANGE	F-17	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-18	TDC DELAY OUT OF RANGE	F-18	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-19	BDC DELAY OUT OF RANGE	F-19	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-20	Invalid Rotary Switch Position Time-out >2.5s	F-20	CONSTANT ON	HIGH	LOW	HIGH	STOP
F-21	CHECKSUM ERROR (SET RATE + SET DOSE + VOL FED)	F-21	CONSTANT ON	HIGH	LOW	HIGH	STOP

5.3
SELF TEST PROBLEMS

This section is dedicated to the identification and solving of those problems detected during the pump's power on self-test mode. Repeat the Power On Self-Test performance verification test, per Section #4.3.2. Refer to Table 5-2 to remedy specific problems.

Table 5-2: SELF-TEST PROBLEMS & CORRECTIVE ACTION

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
1. Audio Failure (no audio)	Poor connection onto piezo beeper or connector, J1.	Inspect for proper solder connection between beeper lead wire. Inspect and reseat connector, J1, onto main board assembly
	Faulty piezo beeper.	Replace beeper assembly.
	Faulty piezo beeper drive circuit on main board assembly (Q2, Q3, etc.)	Replace main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.
	Low or dead battery.	Recharge (insert the pump into backpack) or replace battery. Note, replace only with battery marked 2Ax2K or WP1-4 (4V, 1Ah).
2. LCD Failure (one or more segments and/or indicators fail to be displayed).	Poor connection between display board assembly and main board assembly.	Reseat display board assembly onto the main board assembly connector, J2.
	Faulty display board assembly.	Replace display board assembly.
	Low or dead battery.	Recharge (insert the pump into backpack) or replace battery. Note, replace only with battery marked 2Ax2K or WP1-4 (4V, 1Ah).
3. Backlight Failure (backlight fails to illuminate).	Poor connection between display board assembly and main board assembly.	Reseat display board assembly onto the main board assembly connector, J2.
	Faulty backlight driver circuit on main board assembly (D4, Q7, etc.)	Replace main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.
	Faulty display board assembly.	Replace display board assembly.
	Low or dead battery	Recharge (insert the pump into backpack) or replace battery. Note, replace only with battery marked 2Ax2Kkk or WP1-4 (4V, 1Ah).

5.4
ALERT PROBLEMS

This section is dedicated to the identification and solving of those problems caused by nuisance alert alarms (i.e.: empty, occlusion, cassette not present, low battery, and select run). Refer to Table 5-3 to remedy specific problems.

Table 5-3: ALERT PROBLEMS & CORRECTIVE ACTION

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
1. "OCCL" alarm does not activate when a downstream occlusion is present.	Faulty feeding set.	Replace feeding set.
	Poor connection between occlusion sensor and connector, J7, located on the main board assembly.	Reseat the occlusion sensor connector, J7, onto the main board assembly. Inspect mating connector for damage.
	Occlusion sensor is in need of calibration.	Recalibrate the occlusion detection circuit on the main board assembly, per Section #6.5.2.
	Faulty occlusion sensor.	Replace defective occlusion sensor. Recalibrate the occlusion detection circuit on the main board assembly, per Section #6.5.2.
	Faulty occlusion detection circuit on main board assembly (U2, U6:D, U8, etc.).	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.
2."OCCL" alarm activates when a downstream occlusion is NOT present.	Faulty feeding set.	Replace feeding set.
	Occlusion sensor is in need of calibration.	Recalibrate the occlusion detection circuit on the main board assembly, per Section #6.5.2.
	Faulty occlusion sensor.	Replace defective occlusion sensor. Recalibrate the occlusion detection circuit on the main board assembly, per Section #6.5.2.
	Faulty occlusion detection circuit on main board assembly (U2, U6:C, U8, etc.).	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.
3. "EMPTY" (cassette not present) alarm fails to activate when the cassette is not present within the pump cavity.	Occlusion sensor is in need of calibration.	Recalibrate the occlusion detection circuit on the main board assembly, per Section #6.5.2.
	Faulty occlusion sensor.	Replace defective occlusion sensor. Recalibrate the occlusion detection circuit on the main board assembly, per Section #6.5.2.
	Faulty occlusion detection circuit on main board assembly (U2, U6:D, U8, etc.).	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
4. "EMPTY" (cassette not present) alarm activates when there is a cassette present within the pump cavity.	Faulty feeding set.	Replace feeding set.
	Poor electrical connection between occlusion sensor and connector, J7, located on the main board assembly.	Reseat the occlusion sensor connector, J7, onto the main board assembly. Inspect mating connector for damage.
	Occlusion sensor is in need of calibration.	Recalibrate the occlusion detection circuit on the main board assembly, per Section #6.5.2.
	Faulty occlusion sensor.	Replace defective occlusion sensor. Recalibrate the occlusion detection circuit on the main board assembly, per Section #6.5.2.
5. "EMPTY" alarm fails to activate when the feeding set is empty of enteral product.	Faulty feeding set.	Replace feeding set.
	Enteral product visible within the cassette's inlet tubing.	Allow enteral product to be pumped totally beyond the cassette. No product should be visible within the inlet tubing of the cassette.
	Optic ports are blocked (i.e.: enteral product, dust/dirt, cleaning contaminates, etc.).	Clean both optic ports with warm soapy water, rinse thoroughly, & dry with canned air.
	Poor electrical connection between optical sensors and connector, J8, located on the main board assembly.	Reseat the occlusion sensor connector, J8, onto the main board assembly. Inspect mating connector for damage.
	Faulty optical sensor.	Replace defective optics. Recalibrate the optical sensor circuit on the main board assembly, per Section #6.5.4.
	Faulty optical sensor circuit on main board assembly (Q1, LED1, U6:A, P1, etc.).	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.
6. "EMPTY" alarm activates when enteral product is present within the feeding set.	Air is entrapped in the optics path of the cassette.	Remove cassette from pump and reprime in order to dislodge air bubble. Reinsert cassette into pump.
	Faulty feeding set.	Replace feeding set.
	Optical sensor is in need of calibration.	Recalibrate optical sensor circuit located on the main board assembly, Section #6.5.4.
	Faulty optical sensor circuit on main board assembly (Q1, LED1, U6:A and P1).	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
7. "LOW BATTERY" alarm does not activate when battery is low (battery capacity below ~40%).	Faulty low battery detection circuit located on main board assembly (U3, U7:A, etc.).	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.
8. "LOW BATTERY" alarm activates when battery has been charged.	No power at AC receptacle during charging.	Verify AC is present (100 - 240V, 50/60Hz).
	Poor connection between AC power cord and appliance receptacle (international models).	Reseat AC power cord into appliance receptacle.
	Low or dead battery.	Replace battery. Replace only with battery marked 2Ax2K or WP1-4 (4V, 1Ah).
	No dc power (4.68 +/- .02V) at dc power connector. Faulty dc power plug, located on backpack assembly.	Replace faulty dc power plug assembly.
	Faulty dc power socket, located on pump assembly.	Replace faulty dc power socket assembly.
	Poor connection between battery terminals and dc power clips.	Inspect and reseat battery terminals onto dc power clips.
	Poor connection between dc power plug assembly and 3-pin connector, J2, located on the dc switching power supply assembly.	Reseat 3-pin connector onto dc switching power supply assembly. Inspect connector for damage.
	Faulty dc switching power supply assembly.	Replace defective dc switching power supply. Recalibrate dc output voltage to 4.68 +/- .02V, per Section #6.5.5.
	Blown fuse, F1, located on main board assembly.	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.
9. When battery is low, pump goes directly into low battery shutdown (by-passing the LOW BATTERY alarm).	Low or dead battery. Battery is at the end of it's useful life.	Replace battery. Replace only with battery marked 2Ax2K or WP1-4 (4V, 1Ah).
	Faulty low battery or low battery shutdown detection circuit(s) located on the main board assembly (U7:A, U7:B, U3, etc.).	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
10. Pump fails to enter low battery shutdown when battery is very low (battery capacity below 15%).	Faulty low battery shutdown detection circuit(s) located on the main board assembly (U7:B, U3, etc.).	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.
11. Motor rotates without a pause and pump goes into a shutdown mode.	Poor connection between DC gearmotor and 2-pin connector, J4, located on the main board assembly.	Reseat the 2-pin dc gearmotor connector, J4, onto the main board assembly. Inspect mating connector for damage.
	Faulty dc gearmotor assembly.	Replace defective dc gearmotor assembly.
	Faulty main board assembly.	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.

5.5
MISCELLANEOUS PROBLEMS PROBLEM

This section is dedicated to the identification and solving of a number of miscellaneous problems (other than problems identified during self test or caused by nuisance alert alarms). Refer to Table 5-4 to remedy specific problems.

Table 5-4: MISCELLANEOUS PROBLEMS & CORRECTIVE ACTION

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
1. Nothing happens when the control dial is in a position other than "POWER OFF (CHARGE)".	Low battery power level.	Recharge by inserting pump into backpack (charging unit). Plug power cord into AC outlet.
	Dead battery.	Replace defective battery. Replace only with battery marked 2Ax2K or WP1-4 (4V, 1Ah).
	No power at AC receptacle during charging.	Verify AC is present (100 - 240V, 50/60Hz).
	Poor connection between AC power cord and appliance receptacle (international models).	Reseat AC power cord into appliance receptacle.
	No dc power (4.68 +/- .02V) at dc power connector. Faulty dc power plug, located on backpack assembly.	Replace faulty dc power plug assembly.
	Faulty dc power socket, located on pump assembly.	Replace faulty dc power socket assembly.

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
	Poor connection between battery terminals and dc power clips.	Inspect and reseat battery terminals onto dc power clips.
	Poor connection between dc power plug assembly and 3-pin connector, J2, located on the dc switching power supply assembly.	Reseat 3-pin connector onto dc switching power supply assembly. Inspect connector for damage.
	Faulty dc switching power supply assembly.	Replace defective dc switching power supply. Recalibrate dc output voltage to 4.68 +/- .02V, per Section #6.5.5.
	Blown fuse, F1, or faulty power switch, SW1:B, located on main board assembly.	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.
2. One or more keypads do not respond when pressed.	Poor connection between touchpanel overlay and connector, J6, located on the main board assembly.	Inspect and reseat touchpanel overlay connector onto main board assembly. Inspect for damaged or cracked overlay ribbon cable.
	Faulty touchpanel overlay.	Replace defective touchpanel overlay.
	Faulty keypad decoder circuit located on the main board assembly (U3, etc.).	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.
3. Short battery life (less than 24 hours of run time @ 125ml/hr, or lower).	Insufficient battery recharge time.	Allow battery to charge for 24 hour period.
	Faulty battery.	Replace defective battery. Replace only with battery marked 2Ax2K or WP1-4 (4V, 1Ah).
	Low dc power (< 4.68 +/- .02V) at dc power connector.	Recalibrate the dc switching power supply assembly, per Section #6.5.5.
	Poor connection between battery terminals and dc power clips.	Inspect and reseat battery terminals onto dc power clips.
	Poor connection between dc power plug assembly and 3-pin connector, J2, located on the dc switching power supply assembly	Reseat 3-pin connector onto dc switching power supply assembly. Inspect connector for damage.
	Faulty low battery detection circuit located on main board assembly (U3, U7:A, etc.).	Replace defective main board assembly. Recalibrate all alarm detection circuits, per Section #6.5.

Section 6

DISASSEMBLY AND RECALIBRATION INSTRUCTIONS

6.1
DISASSEMBLY AND RECALIBRATION INSTRUCTIONS

CAUTION: The warranty is rendered null and void if the case housing is opened by other than Ross Products Division and Abbott International service personnel.

6.1.1
GENERAL

Disassembly and reassembly of the Companion™ ClearStar™ Enteral Nutrition Pump is accomplished with the hand tools indicated in Section 4, Maintenance & Service Tests. Unless otherwise noted, reverse disassembly procedure for assembly.

CAUTION: Remove all power from the charger prior to disassembly or reassembly. Prior to returning a repaired pump or charger for patient use, both units must undergo all checkout procedures outlined in Section 4.4 and the appropriate recalibration outlined in Section 6.5.

NOTE: Due to static sensitive components, it is recommended that service personnel wear an anti-static wrist strap (or other grounding means) while servicing the Companion™ ClearStar™ Enteral Nutrition Pump.

6.2
PUMP DISASSEMBLY PROCEDURE

6.2.1
REMOVING BATTERY ACCESS DOOR, (ITEM 3)

a. Remove Phillips screw (Item 1) and washer (Item 2) on battery access door and remove door.

6.2.2
REMOVE BATTERY (ITEM 4)

a. Remove battery access door (Item 3).
b. Slide battery out through access hole.

6.2.3
REMOVING CONTROL KNOB ASSEMBLY (ITEM 27)

a. Push control knob to the open position.
b. Pull the control knob door in order to remove control knob assembly.

6.2.4
REMOVE BACK CASE SUBASSEMBLY (ITEM 5)

a. Remove control knob assembly (Item 27).
b. Remove 5/16" nut (Item 26) and washer (Item 25) from rotary dial switch.
c. Remove battery (Item 4).
d. Remove (2) remaining Phillips screws (Item 1) and separate back case assembly to expose connectors.
e. Disconnect the 7-pin ribbon cable (PL6) from the main pc board connector (J6).
f. Disconnect the 7-pin MTA connector (PL8) from the main pc board connector (J8).
g. Disconnect the 2-pin MTA connector (PL7) from the main pc board connector (J7).
h. Fully separate the back and front case (Item 23) while carefully sliding the motor and power wires from between the main and display pc board assemblies.
i. Disconnect the display pc board from the main pc board by squeezing the ends of each of the (4) stand-offs while lifting up on the four corners of the display pc board.
j. Disconnect the 2-pin MTA connector (PL4) from the main pc board connector (J4).
k. Remove the positive (+) battery clip from the front case by sliding it off the locating boss.

6.2.5
REMOVING PIEZO BUZZER SUBASSEMBLY (ITEM 6)

a. Remove back case (Item 5).
b. Disconnect the 2-pin MTA connector (PL1) from the main pc board connector (J1).
c. Gently remove the piezo buzzer by peeling it off the main pc board assembly (Item 9).

6.2.6
REMOVING BATTERY CLIP ASSEMBLY (ITEM 8)

a. Remove back case (Item 5).
b. Remove the negative (-) battery clip from the back case by sliding it off the locating boss.
c. Disconnect the 2-pin MTA connector (PL3) from the main pc board connector (J3).

6.2.7
REMOVING MAIN PC BOARD ASSEMBLY (ITEM 9)

a. Remove back case (Item 5).
b. Remove piezo buzzer (Item 6).
c. Remove Battery Clip Assembly (Item 8).
d. Remove (5) Phillips screws/washers (Item 10).
e. Lift main pc board from back case.
f. The display pc board (Item 11) can be separated from the main pc board by depressing the (4) standoff tabs and lifting.

6.2.8
REMOVING DRIVE SYSTEM (ITEMS 12-19)

a. Remove back case (Item 5).
b. Remove cassette latch (Item 7).
c. Lift pump cavity and slide drive system from front case.

6.2.9
REMOVING REED SWITCH BRACKET ASSEMBLY (ITEM 18)

a. Remove back case (Item 5).
b. Remove drive system (Items 12-19)
c. Remove (2) flat head screws (Item 19) holding the reed switch bracket assembly to the motor bracket.
d. Remove (3) reed switch wires from 7-pin MTA Connector. (Brown, Blue, and Gray wires).

6.2.10
REMOVING PISTON & CAP ASSEMBLY (ITEM 14)

a. Remove drive system (Items 12-19).
b. Detach cassette tube (Item 12) from motor bracket by twisting 90 degrees and pulling apart.
c. Remove (2) Phillips screws (Item 16) holding the adapter bracket (Item 15) to the cassette tube (Item 12) and spacer (Item 13).
d. Separate adaptor bracket and remove the piston & cap assembly.

6.2.11
REMOVING FRONT TOUCH PANEL OVERLAY (ITEM 24)

a. Peel front touch panel from the front case (Item 23).
b. When reassembling, clean front case (bonding surface) with alcohol in order to remove old adhesive.
c. Clean LCD window with alcohol.
d. Replace with a new front touch panel.

6.3
CHARGER DISASSEMBLY PROCEDURE

WARNING

ELECTRICAL SHOCK HAZARD. HIGH VOLTAGE PRESENT AT FLYBACK CIRCUIT LOCATED ON THE DC SWITCHING POWER SUPPLY ASSEMBLY.

6.3.1
REMOVING REAR COVER (ITEM 5) - DOMESTIC

a. Remove (4) corner Phillips screws (Item 3) on rear cover and separate from front housing (Item 11).
b. Disconnect the dc power subassembly 3-pin MTA connector from the power pc board connector (J2).

REMOVE REAR COVER (ITEM 5) - INTERNATIONAL

a. Remove (4) corner Phillips screws (Item 3) on rear cover and separate from front housing (Item 11).
b. Disconnect the DC power Subassembly 3-pin MTA connector from the power pc board connector (J2).
c. Disconnect the 1/4" push on receptacles from the main indicator.

6.3.2

REMOVE SWITCHING POWER SUPPLY BOARD (ITEM 6) - DOMESTIC

a. Remove rear cover (Item 5).
b. Disconnect the power cord, white wire, 1/4" push-on receptacle, from the power pc board 1/4" tab marked N.
c. Disconnect the power cord, black wire, 1/4" push on receptacle from the power pc board 1/4" tab marked L.
d. Disconnect the appliance receptacle, yellow/green wire, 1/4" push on receptacle from the power supply board 1/4" tab marked Ground.
e. Remove (4) Phillips screws (Item 7) from power pc board.

REMOVING SWITCHING POWER SUPPLY BOARD (ITEM 6) - INTERNATIONAL

a. Remove rear cover (Item 5).
b. Disconnect the appliance receptacle, blue wire, 1/4" push-on receptacle, from the power pc board 1/4" tab marked N.
c. Disconnect the appliance receptacle, brown wire, 1/4" push on receptacle from the power pc board 1/4" tab marked L.
d. Disconnect the appliance receptacle, yellow/green wire, 1/4" push on receptacle from the power supply board 1/4" tab marked Ground.
e. Remove (4) Phillips screws (Item 7) from power pc board.

6.3.3

REMOVING POWER CORD (ITEM 1) - DOMESTIC

a. Remove rear cover (Item 5).
b. Remove power pc board (Item 6).
c. Remove strain relief (Item 2) from rear cover, using strain relief insertion tool.
d. Slide power cord from rear cover.

6.3.4
REMOVING APPLIANCE OUTLET ASSEMBLY (ITEM 2) - INTERNATIONAL

a. Remove rear cover (Item 5).
b. Remove power pc board (Item 6).
c. Depress the 3 tabs located on the appliance receptacle, while simultaneously pushing out of the appliance receptacle opening in the rear cover.

6.3.5
REMOVING POLE CLAMP (ITEMS 14-19)

a. Remove rear cover (Item 5).
b. Remove (2) Phillips screws (Item 4), centrally located on rear cover.
c. Lift clamp channel (Item 13), containing the pole clamp mechanism, from rear cover.
d. Slide pole clamp mechanism (Items 14-19) from clamp channel.

6.3.6
REMOVING DC POWER CONNECTOR SUBASSEMBLY (ITEM 10)

a. Remove rear cover (Item 5).
b. Remove Phillips screw (Item 8) on plate (Item 9).
c. Lift plate from front housing (Item 11) and carefully remove the DC power connector subassembly.

6.4
RECALIBRATION

6.4.1
GENERAL

Various elements of the Companion™ ClearStar™ Enteral Nutrition Pump and Charger must be recalibrated if parts affecting those elements are replaced or become out of adjustment due to wear or mishandling. If adjustments beyond those covered in this section are required, or cannot be accomplished in-house, the pump and backpack should be returned to an authorized repair facility for recalibration and/or repair.

6.4.2
DISTAL OCCLUSION DETECTOR

The distal occlusion sensor may be calibrated using two alternative methods, both methods are described in this section. The first method described, does not require Standard Pumps, the second method described does require the use of Standard Pumps.

6.4.2.1
RECALIBRATION USING NO STANDARD PUMPS:

EQUIPMENT:

- (1) ClearStar Companion Enteral Feeding Set
- (1) Ross Flexiflo Enteral Feeding Tube, #8 french (p/n 472)
- Degassed water
- (1) XDUCER_CAL / OPTIC_CAL Calibration Box, #701181
- (1) Oscilloscope or Multimeter with MIN/MAX feature

RECALIBRATION SETUP:

a. The following constraints shall be followed when selecting a *presorted feeding set* meant for calibration of the downstream occlusion sensor:

   i. Avoid using a cassette containing a bellows with a soft bottom, in which the tip of the bellows collapses.

   ii. Avoid using a cassette containing a bellows that is rigid between ribs 3 and 5, in which the bellows does not collapse between the 4th & 5th ribs.

   iii. Avoid using a cassette containing a bellows that the material is unevenly distributed, causing the bellows to collapse unevenly.

   iv. Note, optimal bellows should have rigid bottoms and exhibit even collapse, in which all ribs touch when collapsed. It is acceptable if there is not a total collapse between the 4th & 5th rib.

RECALIBRATION PROCEDURE:

a. Attach the Flexiflo 8F ng-tube to the orange distal connector of the *presorted feeding set*.

b. Fill the container of the *presorted feeding set* with degassed room temperature water and prime set. Ensure that all air has been removed from the cassette and

tubing. Note, water can be degassed using a vacuum chamber or water may be placed in uncovered containers and allowed to set for 24 - 72hrs.

c. Measured from the pump cassette tube opening, the fluid head height is +30", while the extreme distal tubing is -10".

d. Insert the *presorted feeding set* into the pump cassette tube opening until it is physically latched into position, then clamp the distal end of the 8F ng-tube to form a total downstream occlusion.

e. Connect the oscilloscope to the XDUCER_CAL / OPTIC_CAL Calibration Box as follows:

   i. Attach the o'scope ground to the terminal marked "GND" and the o'scope probe to the terminal marked "XDUCER".

   ii. Set the oscilloscope to the 0.2V/DIV setting.

f. The ClearStar pump shall be placed in the XDUCER_CAL mode, as follows:

   i. Attach the calibration plug from the XDUCER_CAL / OPTIC_CAL Calibration Box to connector J5 on the main board assembly. Note, verify proper plug orientation (line/dot on connector facing operator with pump facing up).

   ii. Rotate pump control dial from POWER OFF (CHARGE) to the SET RATE position. Note, self test should be by-passed and 150ml/hr flow rate displayed.

   iii. Rotate pump control dial to HOLD position. Note, control of the XDUCER_CAL and OPTIC_CAL modes are toggle via the HI/LO keypad.

   iv. While in HOLD, toggle the E-SAVE switch to the "on" position.

g. Rotate pump control dial to the RUN position and allow the pump to stroke until the transducer output has stabilized.

h. Using the "increment" or "decrement" keypads, adjust the pump transducer signal conditioning / amplifier circuit until an output of **1.60Vp** is achieved. Note, if the output is not stable (within +/- 0.02V), replace the *presorted feeding set* with a new set.

i. Record the "digital pot value" of the pump transducer signal conditioning / amplifier circuit.

j. Once the pump transducer signal conditioning / amplifier circuit has been calibrated, rotate the pump control dial to the HOLD position.

k. Toggle the E-SAVE switch to the "off" position.

l. Rotate the pump control dial to the POWER OFF (CHARGE) position.

m. Rotate the pump control dial back to the HOLD position to verify that the "digital pot value", displayed on the LCD, matches the value from i above.

n. Rotate the pump control dial to the POWER OFF (CHARGE) position.

o. Remove the *presorted feeding set* from the pump.

p. Disconnect the dc power supply from SK1.

q. Unplug the XDUCER_CAL / OPTIC_CAL Calibration Box from main board connector, J5.

6.4.2.2
RECALIBRATION USING STANDARD PUMPS:

EQUIPMENT REQUIRED:

- Oscilloscope
- (2) Production Feeding Sets
- (2) Needle Valves (Brooks Instrument, P/N 8504)
- Canola Oil
- (2) Standard Pumps

RECALIBRATION SETUP:

Per form the following steps a-c to select and adjust both the Transducer Calibration Set and Transducer Verification Set:

a. Fabricate the Transducer Calibration Set and the Transducer Verification Set by selecting a standard production feeding set which contains a bag or rigid feeding container.

   i. Pour 500ml of canola oil into the feeding container. (Note: Do not reuse the canola oil for more than one month).

   ii. Prime feeding set and make sure all air is purged from the cassette and feeding set assembly.

   iii. If the set is new, burn-in set for a minimum of 15 minutes at 300ml/hr. (Note: Do not use the Standard Pumps to burn-in the feeding sets).

   iv. Cut the orange connector off the end of the feeding set and attach the needle valve onto the pvc tubing.

   v. Fluid head height is 28 $\pm$ 3". Needle valve is placed on edge of table approximately 2" below pump.

b. Place the Transducer Calibration Set and the Verification Set into a Standard Pump, with pump set to 150ml/hr, and adjust the needle valve until a transducer voltage reading of 1.00 ± .02 volts peak is obtained on the oscilloscope. Allow the pump to cycle a minimum of (6) cycles and verify that the reading has stabilized.

c. Place the Transducer Calibration Set and the Transducer Verification Set into another Standard Pump, with pump set 150ml/hr, and verify that the transducer voltage reading of 1.00 ± 0.02 volts peak is indicated on the oscilloscope. Again, allow the pump to cycle a minimum of (6) cycles and verify that the reading has stabilized.

EQUIPMENT REQUIRED:

- Oscilloscope
- Transducer Calibration Set
- Transducer Verification Set
- (2) Standard Pumps
- Backpack Power Supply (4.68 vdc)
- Calibration Box w/ Connector Plug

RECALIBRATION PROCEDURE:

Note: Transducer readings shall be taken, using (2) Standard Pumps, on both the Transducer Calibration Set & Transducer Verification Set, every 30 minutes. Transducer voltage readings of 1.00 ± 0.02 volts peak must be verified. If readings fall outside of the acceptable range the Calibration and Verification Set must be recalibrated and all pumps within the last 30 minutes are to be checked and calibrated, if necessary.

a. Place an anti-static wrist band onto a convenient wrist and attach the grounding cord to the grounded anti-static mat at the work station.

b. Ensure the oscilloscope is "ON" and has warmed up for at least 10 minutes. Focus and adjust intensity as required. Set "AC, GND, DC" switch to "GND" Adjust position knob to line trace with baseline. Ensure 10x probe is connected.

c. Connect a jumper cable between the dc connector, on the charger, and the dc power jack on the pump.

   Note: A 4.68 Volt regulated direct current power supply may be used.

d. Attach calibration plug from the calibration box to connector J5 (on the Main Board assembly), with access through the battery door opening.

e. Attach the oscilloscope ground to the "GND" terminal on the calibration box and the scope probe to the "TRANSDUCER" terminal on the box.

f. Set the scope to the 0.2V/DIV setting.

g. Turn the rotary switch on the calibration box to the "TRANSDUCER/OPT" position.

h. Rotate the control dial of the pump from the POWER OFF (CHARGE) position to the SET RATE position.

- The self test should be by-passed and a 150ml/hr flow rate setting displayed on the LCD.
- If the flow rate setting is not at 150ml/hr, please do so at this time by depressing the increment or decrement keypads.

i. Rotate the pump dial to the HOLD position.

j. Control of the XDUCER_CAL/OPTIC_CAL modes is controlled through the HI/LOW keypad. Depression of the HI/LOW keypad will toggle between the XDUCER_CAL mode and the OPTIC_CAL mode.

k. While the pump is in HOLD, turn the "E SAVE" switch on the calibration box to the "ON" position.

l. Insert the Transducer Calibration Set cassette into the pump and verify that the cassette is latched into place.

m. Rotate the pump control dial to the RUN position.

- Allow the pump to stroke several times, allowing the motor speed control circuitry to stabilize. While this is taking place, monitor the oscilloscope and begin course adjustment of the transducer output.
- If the peak transducer signal is below 0.98 volts, adjust the output using the increment keypad to 1.00 ± 0.02 volts.
- If the peak transducer signal is above 1.02 volts, adjust the output using the decrement keypad to 1.00 ± 0.02 volts.

n. Once transducer calibration has been made, allow the pump to continue pumping for several strokes to ensure system has stabilized. Rotate the pump control dial to the HOLD position. Record the actual transducer setting and the digital pot value (indicated earlier on the LCD).

o. Remove the Transducer Calibration Set and replace with the Transducer Verification Set.

p. Rotate the pump control dial back to the RUN position.
- Verify that the transducer reading is 1.00 ± 0.02 volts peak.

q. Rotate the pump control dial to the HOLD position.

r. Turn the "E SAVE" switch on the calibration box to the "OFF" position.

s. Rotate the pump control dial to the POWER OFF (CHARGE) position.

t. Rotate the pump control dial to the HOLD position and verify that the digital pot value on the pump LCD display matches the value recorded.

Note: If the values do not match repeat the calibration procedure.

u. Rotate the pump control dial to the OFF position. Remove Set. Disconnect the dc power supply and calibration plug from the pump.

6.4.3
OPTICS

Perform the following steps if the optical detection circuit is in need of calibration.

a. Connect a jumper cable between the dc connector on the charger and the dc power jack on the pump.

Note: A 4.68 volt regulated direct current power supply may be used.

b. Attach calibration plug from the calibration box to connector J5 (on the Main Board assembly), with access through the battery door opening.

c. Ensure that the optical sensor path is unobstructed.

d. Using an oscilloscope, attach the oscilloscope ground to the "GND" terminal on the calibration box and the scope probe to the "OPTIC" terminal on the box.

e. Turn the rotary switch on the calibration box the "TRANSDUCER/OPT" position.

f. Set VOLTS/DIV switch on scope to 0.5 and set the "AC, GND, DC" switch to "DC".

g. Rotate the pump control dial to the HOLD position, depress the HI/LOW keypad to place the pump into the OPTIC_CAL mode. The microcontroller will force the optic I/O line to generate a square wave output signal (i.e.: 200ms HIGH, 500ms LOW, 200ms HIGH, 500ms LOW, etc.)

Note:
Depression of the HI/LOW keypad will toggle between the XDUCER_CAL mode and the OPTIC_CAL mode.

Note: The default position is the XDUCER_CAL mode.

h. Rotate P1 so that the photodector just begins to come out of saturation. This should occur at approximately 3.6 - 3.7 volts.

i. Set VOLTS/DIV switch on scope to 0.1.

j. Insert a primed Companion™ ClearStar™ Pump Set, filled with room temperature water, into the pump cavity. Ensure that the cassette tube latch is engaged.

Note: The pump set should be primed free of air bubbles to achieve proper optical readings during calibration.

k. Observe the reading on the scope. It must be between 0.1 and 0.5 volts peak.

Note: If reading is not as specified above, repeat steps h - k and raise or lower the saturation reading as necessary.

l. Torque seal P1.

m. Rotate the pump control dial to the POWER OFF (CHARGE) position. Remove the Optic Test Set.

n. Disconnect the dc power supply and calibration plug from the pump.

6.4.4
TDC/BDC POSITION DETECTOR

Perform the following steps if the reed switches have been replaced.

EQUIPMENT REQUIRED:

- TDC/BDC Calibration Fixture Assembly, P/N 700840
- PF5 Power Supply, Test Backpack
- Calibration Box w/Connector Plug

RECALIBRATION PROCEDURE:

a. With the pump control dial in the POWER OFF (CHARGE) position, attach the calibration plug to connector J5 on the main board. Ensure plug is in the proper position on the connector.

b. Connect a jumper cable between the dc connector, on the charger, and the dc power jack on the pump.

Note: A 4.68 Volt regulated direct current power supply may be used.

c. Place the pump to be calibrated in the fixture and tighten side plate of fixture to hold pump securely.

d. Insert the properly set-up gage/adaptor system into the pump. Ensure gage fits into pump. Reposition pump and secure if required. Remove gage/adaptor system from pump.

e. Rotate the rotary switch on the calibration box to the TDC/BDC position.

f. Rotate the pump control dial to the "RUN" position and allow pump to stroke once, then rotate the control dial on the pump to the "HOLD" position. Pump display should read "tdc". This indicates the calibration mode.

g. Press the "HI/LOW" switch on the overlay to change to BDC mode. Pump display should read "bdc".

h. Turn the Micro code unit on, set the measurement mode to INCHES and the function to read NORMAL. Zero out gage.

i. Lower the gage/adaptor system into the pump until the target displacement value $\pm$.001" appears on the digital gage of the Micro code unit. Lock the gage in place using the lever on the side of the fixture and zero out the gage display.

j. Turn the "E SAVE" switch on the calibration box to the "ON" position.

k. Rotate the pump control dial to the RUN position and allow the pump to run at least five strokes to stabilize.

Note: The digital read-out must be zeroed between each stroke at BDC to obtain accurate values in the DIFF, MAX and MIN modes.

l. Rotate the switch on the digital read-out to the "MIN" mode and observe the value recorded. If the value in the "MIN" mode is other than 0 ± .0005", increment or decrement the BDC delay value by using the "arrow buttons" on the pump overlay as needed to find the lowest value on the digital read-out ± .0005".

Pump display should read a value between 0 and 200.

Record pump display value.

m. Once the lowest value is found, rotate the pump control dial to the HOLD position. Make sure the switch on the digital read-out is in the "NORM" mode and zero out the gage display.

n. Press the "HI/LOW" switch on the pump overlay to change to TDC mode. Pump display should now read "tdc".

o. Rotate the pump control dial to the RUN position. Observe the displacement at TDC. Turn the switch on the digital read-out to DIFF mode and observe the displacement. The DIFF value and the NORM value must be the same ± .0005". Increment or decrement the TDC delay value by using the "arrow buttons" on the pump overlay as needed until both the DIFF value and the NORM value are the same

± .0005". Pump display should read a value between 0 and 200. Record pump display value.

p. Once the TDC value is reached, rotate the pump control dial to the HOLD position.

q. Turn the "E SAVE" switch on the calibration box to the "OFF" position.

r. Rotate the pump control dial to the POWER OFF (CHARGE) position.

s. Rotate the pump control dial to the HOLD position to reactive the TDC/BDC mode.

t. Rotate the pump control dial to the RUN position and verify that the TDC value is the same as the TDC value recorded.

u. Rotate the pump control dial to the HOLD position and press the HI/LOW switch on the overlay to change to BDC mode.

v. Rotate the pump control dial to the RUN position and verify that the BDC value is the same as the BDC value recorded on the Cal Sheet.

w. Rotate the pump control dial to the POWER OFF (CHARGE) position.

x. Remove the calibration plug and dc power plug from the pump.

y. Unlock the gage by turning the lever on the side of the fixture and remove the gage from the pump.

z. Loosen side plate of fixture and remove pump from fixture.

6.4.5
DEFAULT VALUE CALIBRATION MODE

During first time power-up of the main board assembly, the manufacturer initiates what known as the default value calibration mode. By activating the default value calibration mode, **default** values are stored into both the secured and non-secured area of EEPROM.

A service technician should activate the default value calibration mode feature if one or more of the following fault condition(s) occur:

- F-13: CHECKSUM ERROR
- F-18: TDC DELAY OUT OF RANGE
- F-19: BDC DELAY OUT OF RANGE

The default value calibration mode can be activated by performing the following steps:

a. Attach the FORCE_CAL (J5:3), TDC/BDC_CAL (J5:2) and DIAGNOSTIC_REC (J5:5) lines to ground (J5:1).

b. Activate ESAVE by attaching a jumper between J5:4 and J5:8.

c. Apply power to the pump via backpack power supply.

d. Rotate the control dial from the POWER OFF (CHARGE) position to the SET RATE position.

e. Verify that the word "dOnE" is displayed on the display board.

f. Rotate the pump control dial back to the POWER OFF (CHARGE) position and disconnect jumpers.

The following values will be loaded into EEPROM:

- SET RATE = 300
- SET DOSE = 0
- VOL FED = 0
- BDC = 0
- TDC = 0
- XDUCER = 49
- Diagnostic Recorder Cleared to 0
- Occlusion Event Recorder Cleared to 0

NOTE: As a direct result of a initiating the default value calibration mode, the distal occlusion detector and TDC/BDC position detector MUST undergo recalibration, per Section 6.4.2 and 6.4.4 respectively.

6.4.6
POWER SUPPLY (CHARGER)

WARNING

ELECTRICAL SHOCK HAZARD. HIGH VOLTAGE PRESENT AT FLYBACK CIRCUIT LOCATED ON THE DC SWITCHING POWER SUPPLY ASSEMBLY.

Perform the following steps if the output of the charger power supply is in need of calibration.

a. Separate the front housing and rear cover, leaving all connectors located on the power pc board connected.

b. Plug the charger's AC power cord into a 120 volt, 50/60 hertz power receptacle for Domestic, or into a 220-240 Volt, 50 hertz power receptacle for International.

c. Monitor the output of the power supply, using a digital multimeter (DMM), connected to the Backpact Output Test Fixture. Slide Test Fixture into charger until fully engaged.

d. Rotate R17 (100 ohm potentiometer) so that the open circuit output is between 4.66 and 4.70 VDC.

e. Torque seal R17.

f. To verify that the charger is regulated, depress and hold push-button switch on Backpack Output Test Fixture. Do not maintain load for more than (10) seconds. The charger is functioning properly if the output voltage lies between 4.50 and 4.70 volts. If the output voltage falls below 4.50 volts, the power pc board must be replaced.

g. Remove Test Fixture from charger. Unplug charger. Reassemble charger.

Section 7

PARTS LIST, MECHANICAL DRAWINGS AND ELECTRICAL SCHEMATICS

7.1
LABEL PLACEMENT

This section of the Companion™ ClearStar™ Enteral Nutrition Pump Service Manual contains labeling description and placement information for the domestic and international version pumps and backpacks.

7.1.1
PARTS LIST - CANADA (Code 13)

For most current revision please refer to Label Summary LM771-13.

7.1.2
PARTS LIST - GERMAN (Code 15)

For most current revision please refer to Label Summary LM771-15.

7.1.3
PARTS LIST - SPANISH (Code 22)

For most current revision please refer to Label Summary LM771-22.

7.1.4
PARTS LIST - AUSTRALIA (Code 27)

For most current revision please refer to Label Summary LM771-27.

7.1.5
PARTS LIST - EUROPE (Code 36)

For most current revision please refer to Label Summary LM771-36.

7.1.6
PARTS LIST - ITALIAN (Code 42)

For most current revision please refer to Label Summary LM771-42.

7.1.7
PARTS LIST - UK (Code 54)

For most current revision please refer to Label Summary LM771-54.

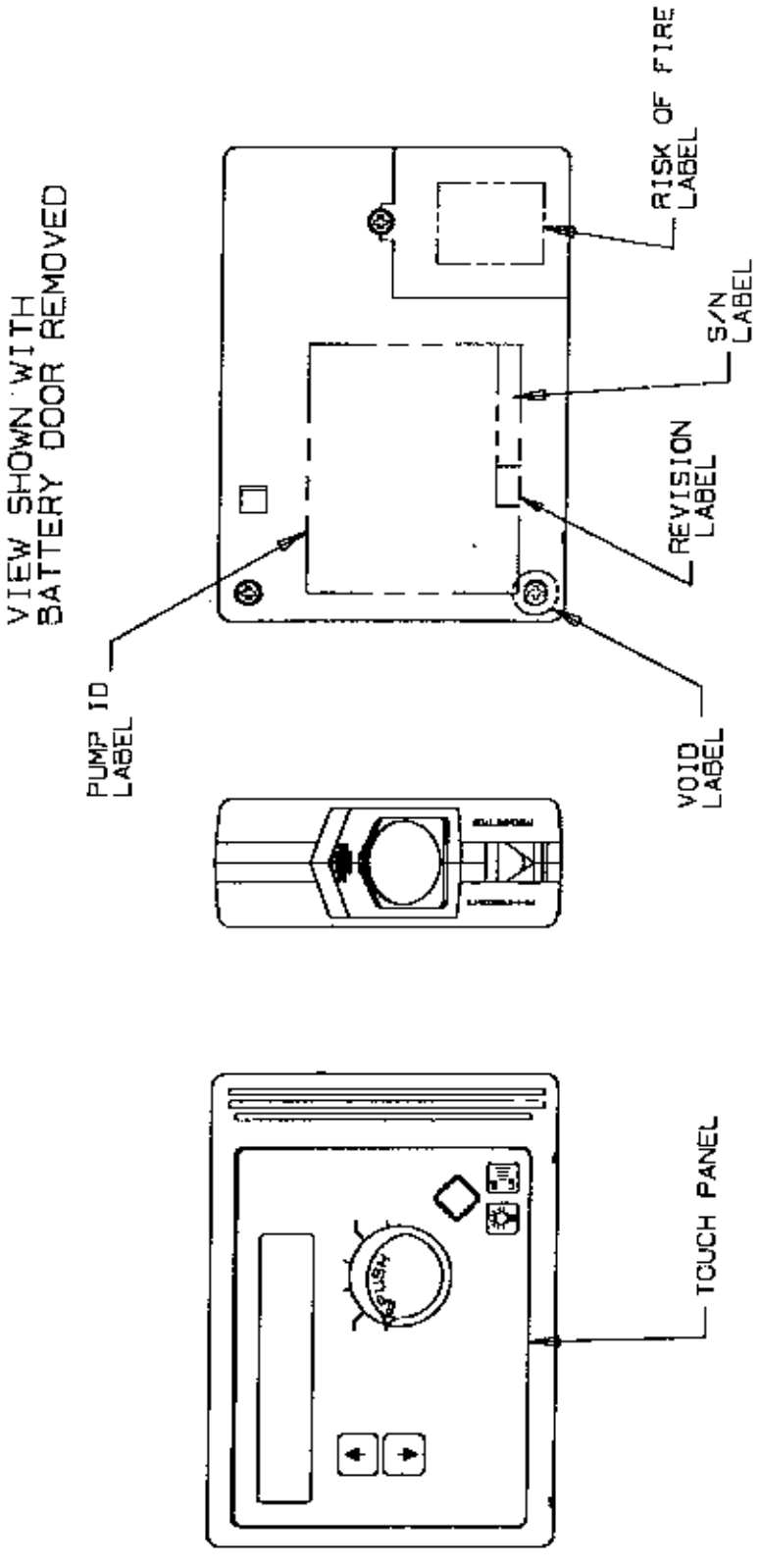

Figure 7-1, Pump - Label Placement

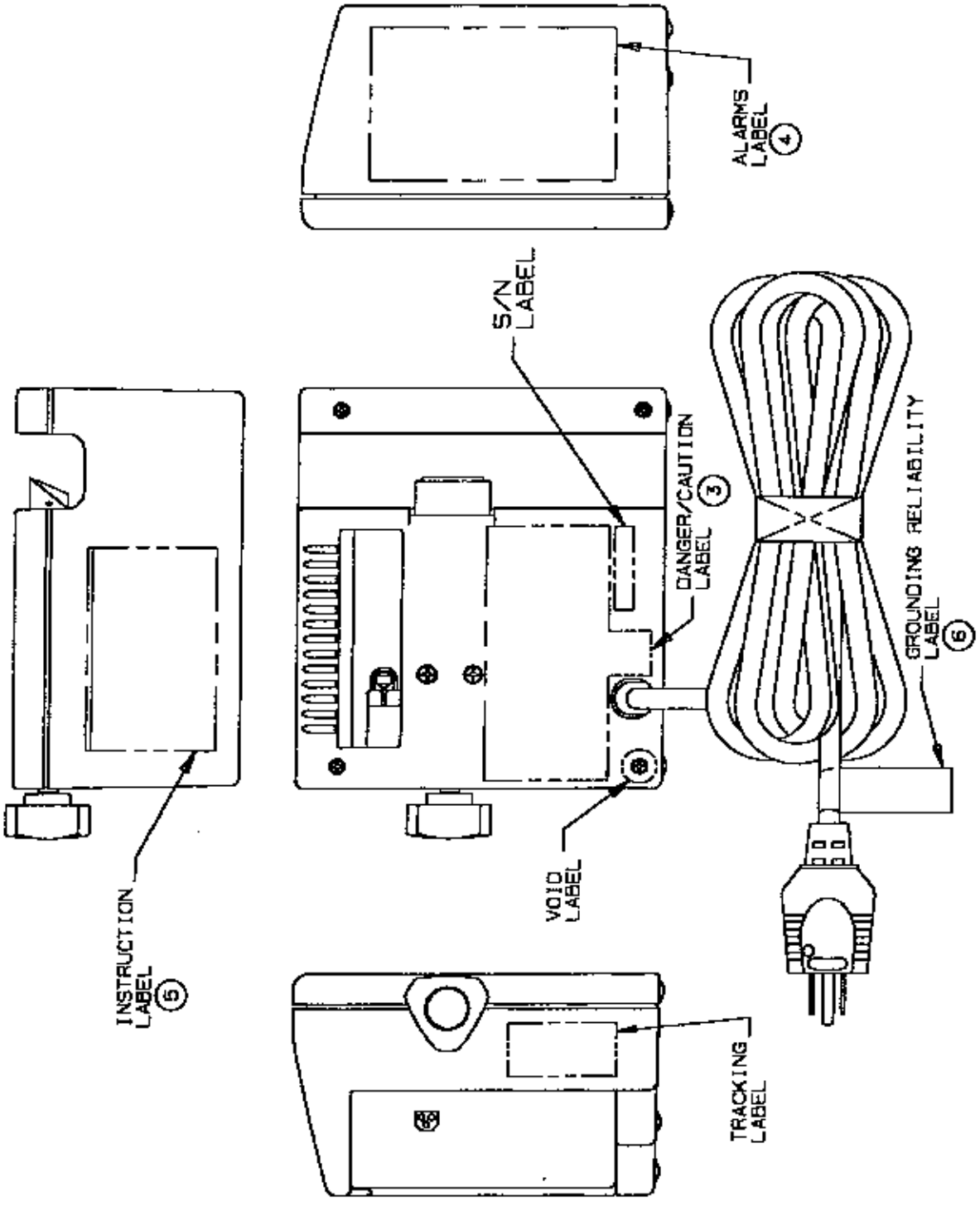

Figure 7-2, Domestic Backpack - Label Placement

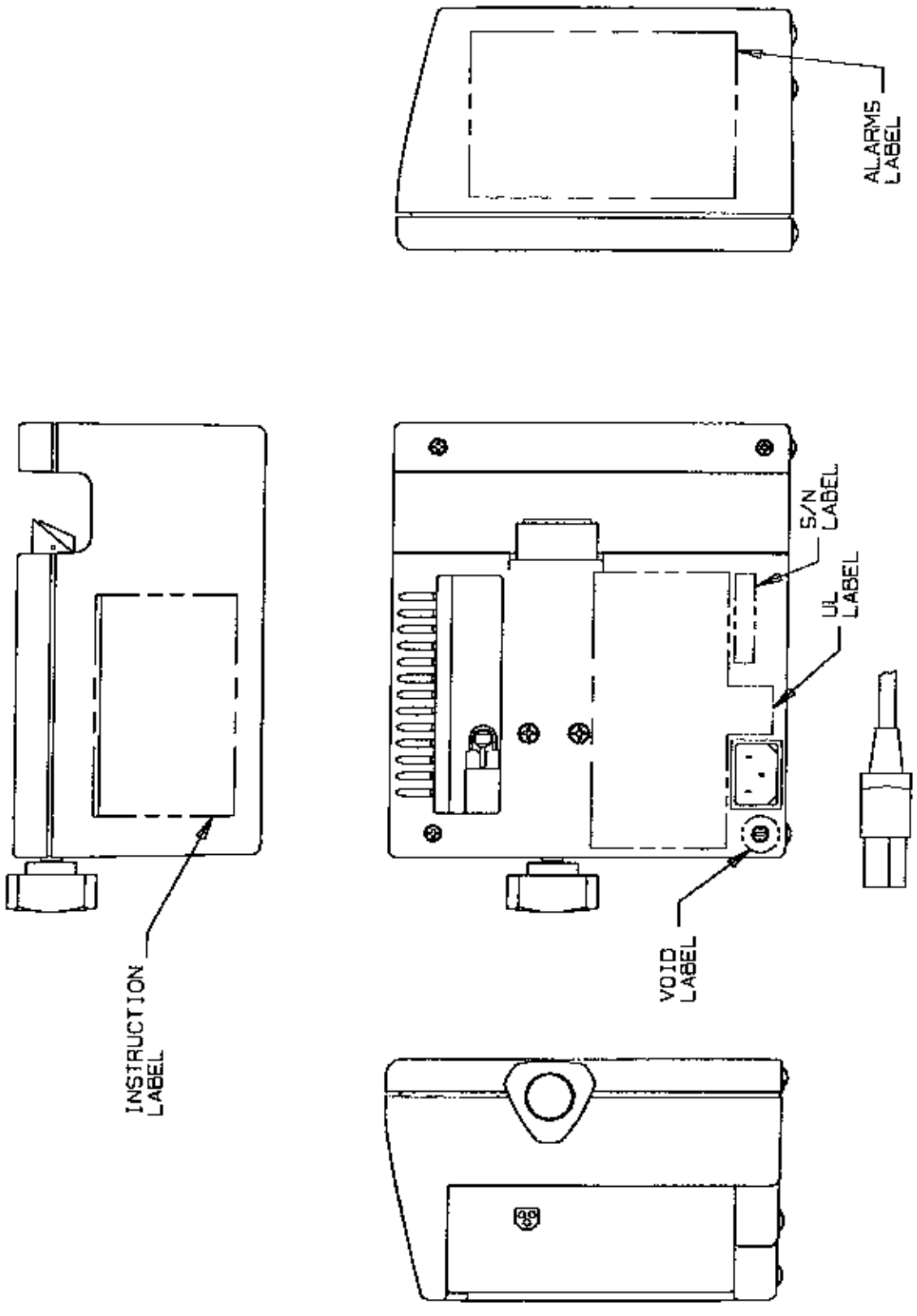

Figure 7-3, International Backpack - Label Placement

7.2
EXPLODED MECHANICAL VIEWS

This section of the Companion™ ClearStar™ Enteral Nutrition Pump Service Manual contains exploded views for the domestic and international pump (Figure 4) and backpack (Figures 5 & 6), item number, part description, part number and quantity required.

Domestic & International
Companion™ ClearStar™ Enteral Feeding Pump

Item Number	Part Description	Part Number	Quanity
1	Screw Pan Hd. #6-32 x 1"lg.	200015	3
2	Washer	200046	1
3	Battery Door	400014	1
4	Battery	500018	1
5	Backcase Sub-Assembly	800175A	1
6	Piezo Buzzer Sub-Assembly	800014	1
7	Cassette Latch	400019	1
8	Battery Clip Assembly	800221	1
9	Main Board Assembly	500274C	1
10	Screw Pan Hd. w/ Starwasher	200016	5
11	Display PCB Assembly - Domestic	500700	1
11	Display PCB Assembly - International	500720	1
12	Cassette Tube / Optics Subassembly	800233	1
13	Spacer	300155	1
14	Piston/Cap Sub-Assembly	800011	1
15	Adapter Bracket	400185	1
16	Screw Pan Hd. #2-28 x ½ lg	200571	2
17	Motor/Cam Assembly	800162B	1
18	Reed Switch bracket Assembly	800178A	1
19	Screw Machine Flat Hd. #2-56 x 3/16 lg	200219	2
20	Gasket, Rubber	200053	1
21	Washer, Rubber	400078	1
22	Bumper, Drive	400707	1
23	Frontcase Sub-Assembly	800307	1
24	Touchpanel Overlay - Domestic	500477	1
24	Touchpanel Overlay - European, Canada, Australia, and	500639	1
24	Touchpanel Overlay - German	500640	1
24	Touchpanel Overlay - Spanish	500642	1
24	Touchpanel Overlay - Italian	500641	1
25	Lockwasher External tooth	200042	1
26	5/16 Nut	200054	1
27	Control Knob Assembly	800010	1

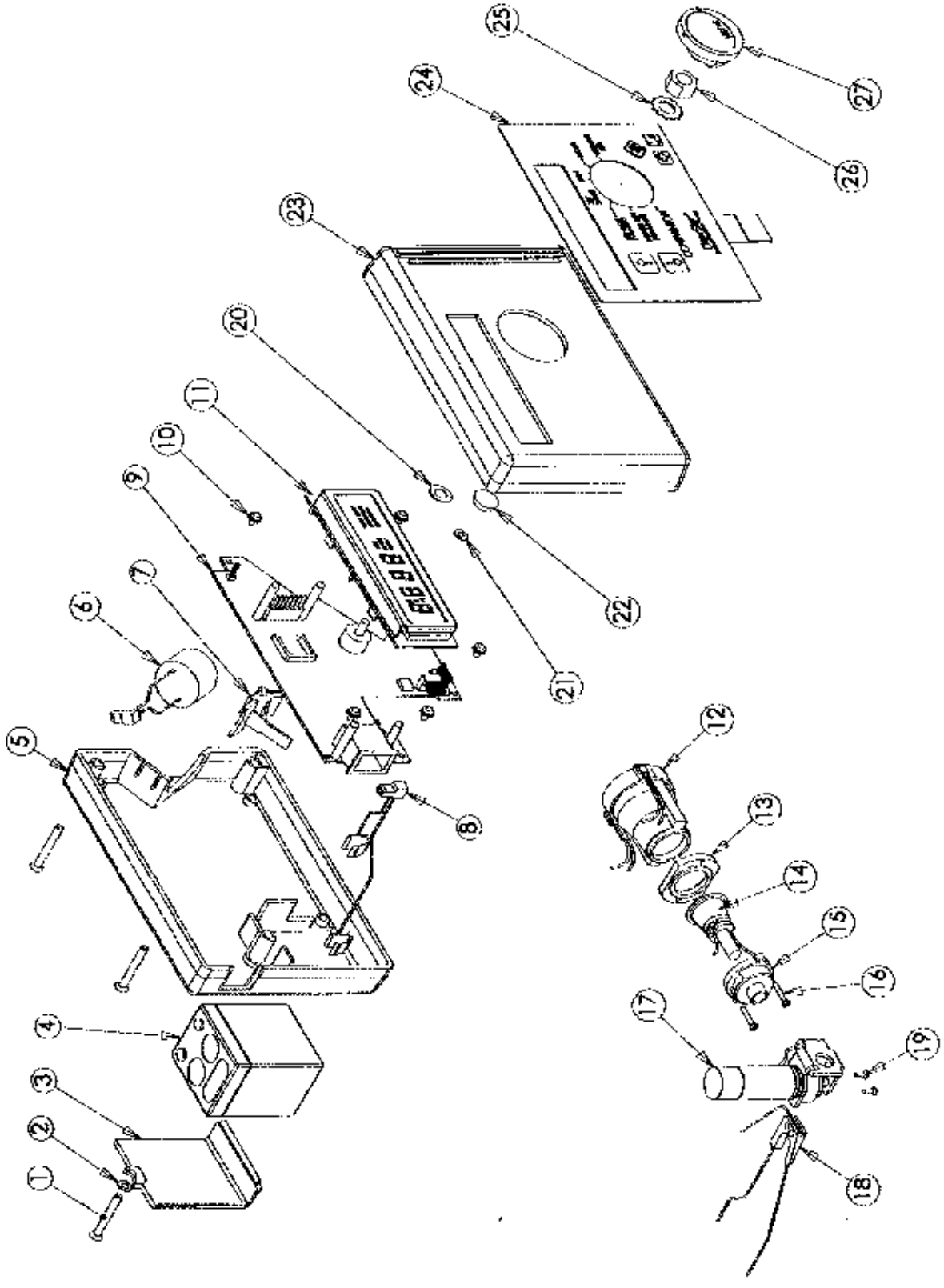

Figure 7-4, Pump - Exploded View

Domestic Companion™ ClearStar™ Backpack

Item Number	Part Description	Part Number	Quantity
1	Power Cord Assembly	600110	1
2	Strain Relief	500315	1
3	Screw, plastite #4 x 2 3/8 lg.	200029	4
4	Screw, Plastite #6-32 x 3/8 lg.	200105	2
5	Rear Cover / Insert Subassembly	800234	1
6	Switching Power Supply	500586C	1
7	Screw Pan Hd. #6-32 x ¼ lg	200497	4
8	Screw, Plastite #4 x 3/8 lg.	200111	1
9	Plate	400363	1
10	DC Power Sub-Assembly	800306B	1
11	Front Housing	400362A	1
12	Feet	400027	4
13	Channel	400031	1
14	Clamp Arm Sub-Assembly	800019	1
15	Clamp Support Block	400039	1
16	Clamp Screw	300007	1
17	Washer	200047	1
18	Retaing Ring	200049	2
19	Triangular Knob	600109	1

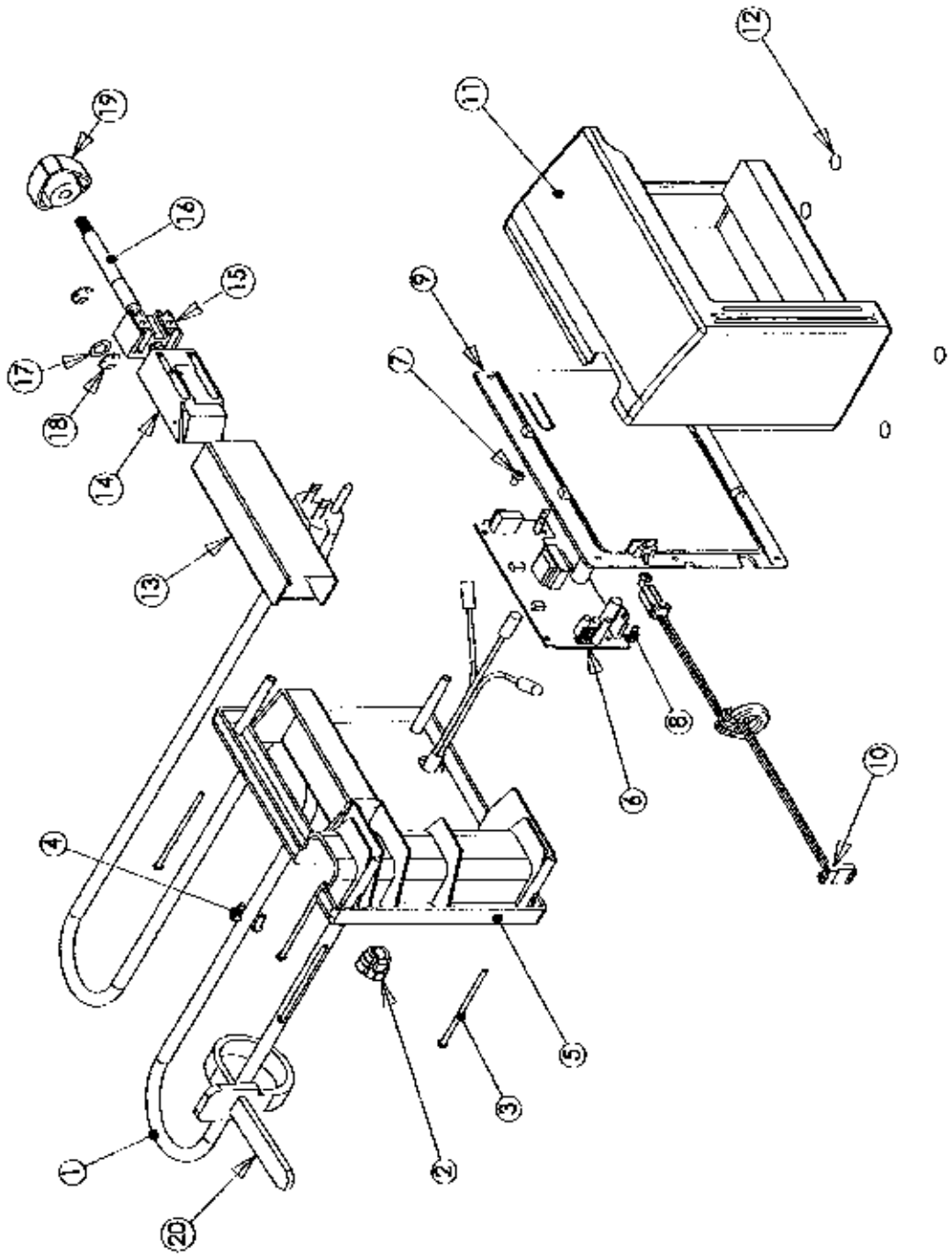

Figure 7-5, Domestic Backpack - Exploded View

International Companion™ ClearStar™ Backpack

Item Number	Part Description	Part Number	Quanity
1	AC Power Cord Assembly	800037	1
2	Appliance Outlet Assembly	800223	1
3	Screw, Plastite #4 x 2 3/8 lg.	200029	4
4	Screw, Plastite #6-32 x 3/8 lg.	200105	2
5	Rear Cover / Insert Subassembly	800234	1
6	Switching Power Supply	500586C	1
7	Screw Pan Hd. #6-32 x ¼ lg	200497	4
8	Screw, Plastite #4 x 3/8 lg.	200111	1
9	Plate	400363	1
10	DC Power Sub-Assembly	800306B	1
11	Front Housing / Mains Indicator Subassembly	800235	1
12	Feet	400027	4
13	Channel	400031	1
14	Clamp Arm Sub-Assembly	800019	1
15	Clamp Support Block	400039	1
16	Clamp Screw	300007	1
17	Washer	200047	1
18	Retaing Ring	200049	2
19	Triangular Knob	600109	1

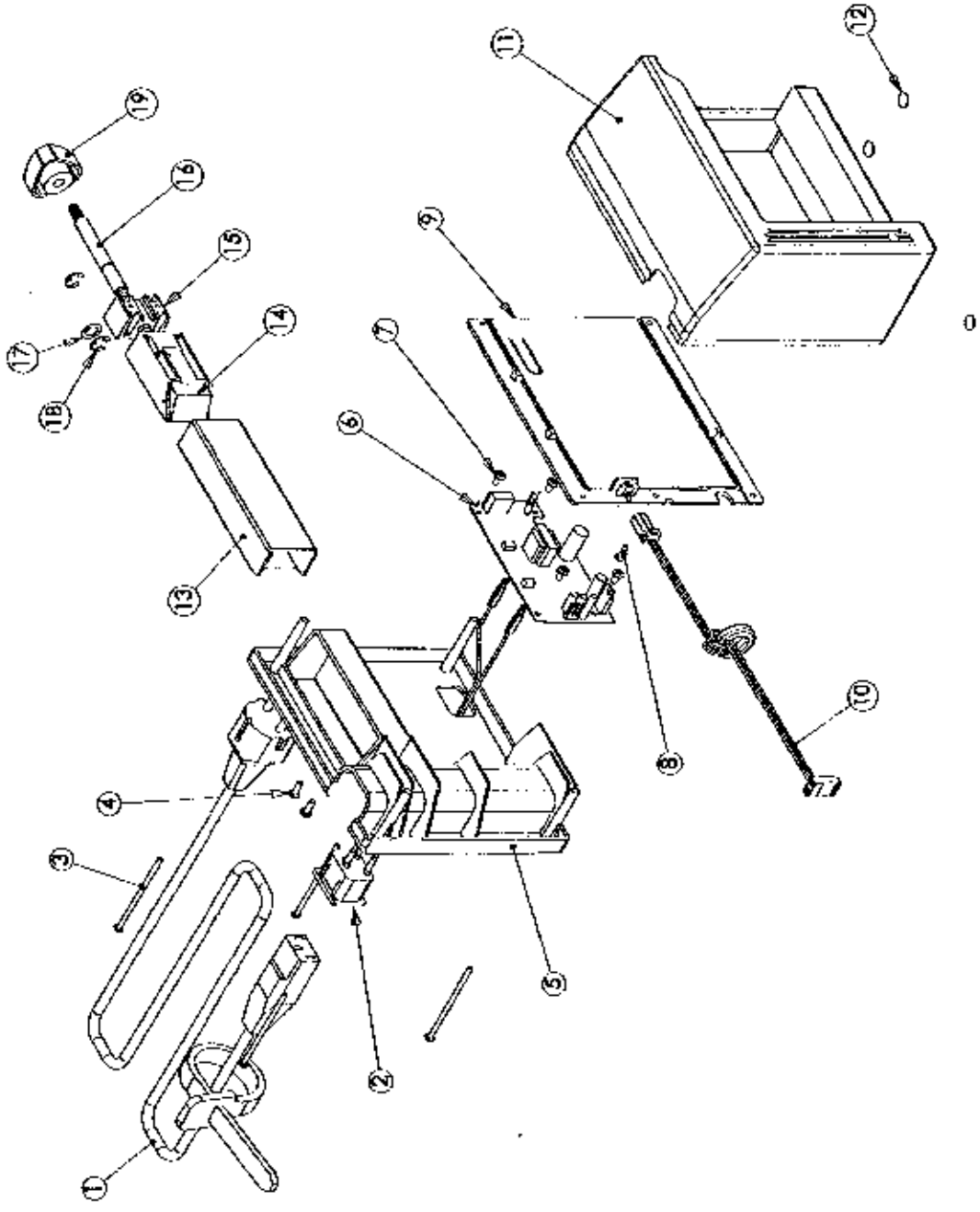

Figure 7-6, International Backpack - Exploded View

7.3
ELECTRONICS

This section of the service manual contains the functional block diagram, electrical schematics and pcb layouts (main, display and power board assemblies) for the domestic and international Companion™ ClearStar™ Enteral Nutrition Pump and Backpack.

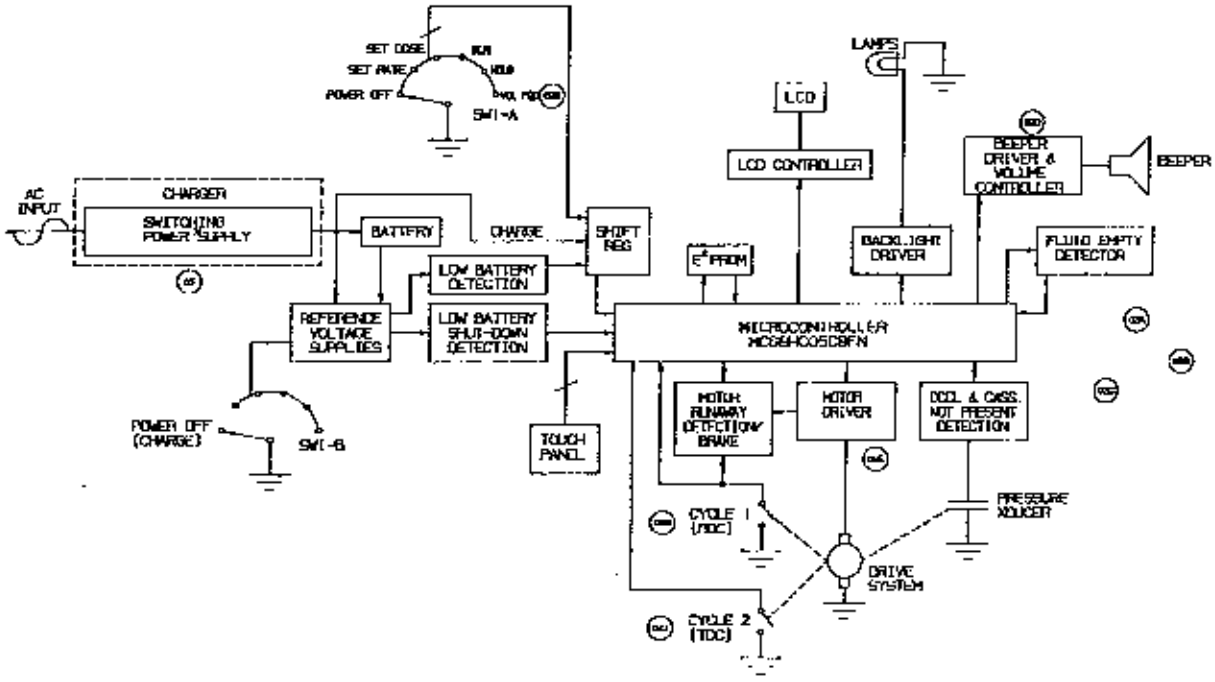

Figure 7-7, Electrical Block Diagram

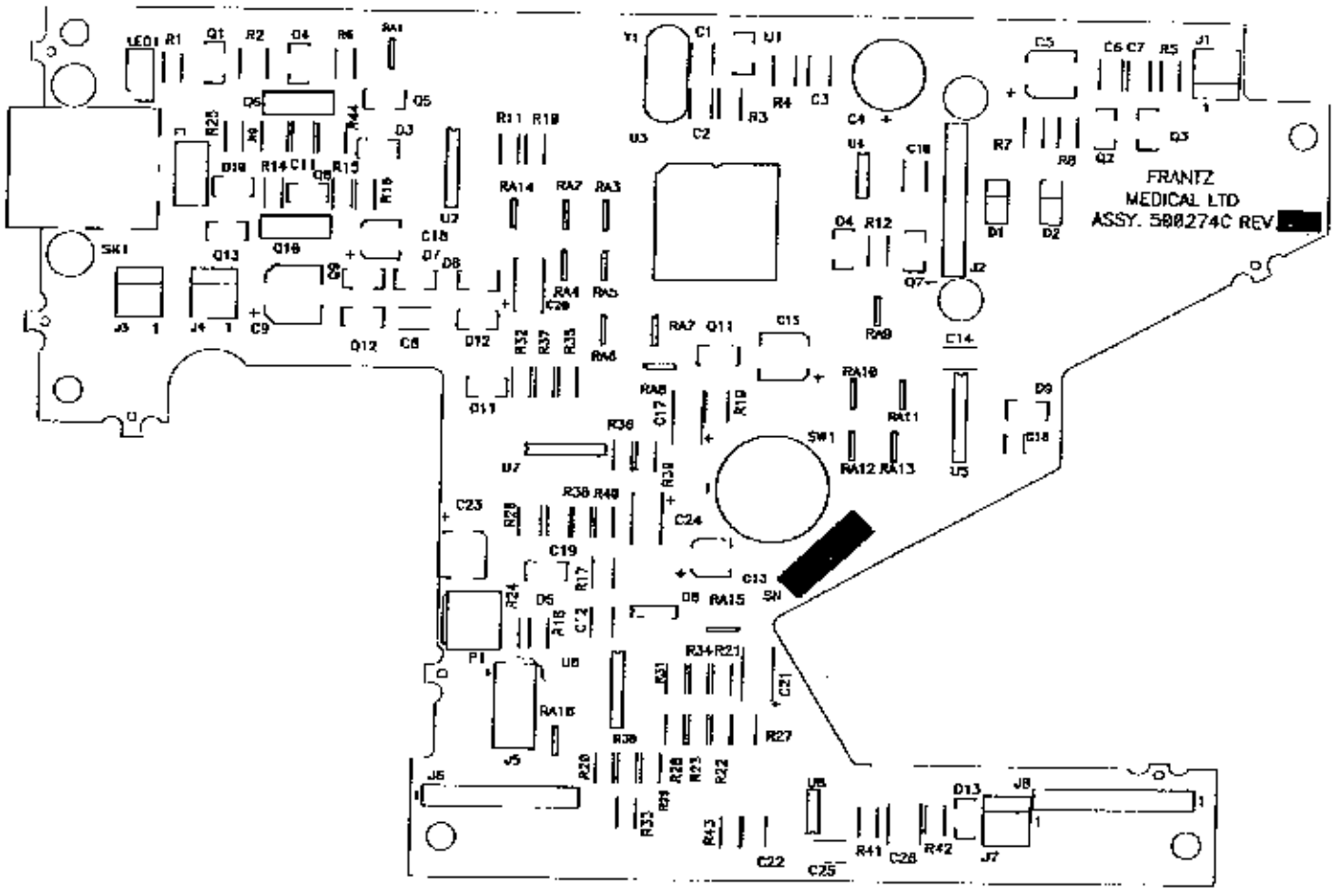

Figure 7-8, Main Board Assembly

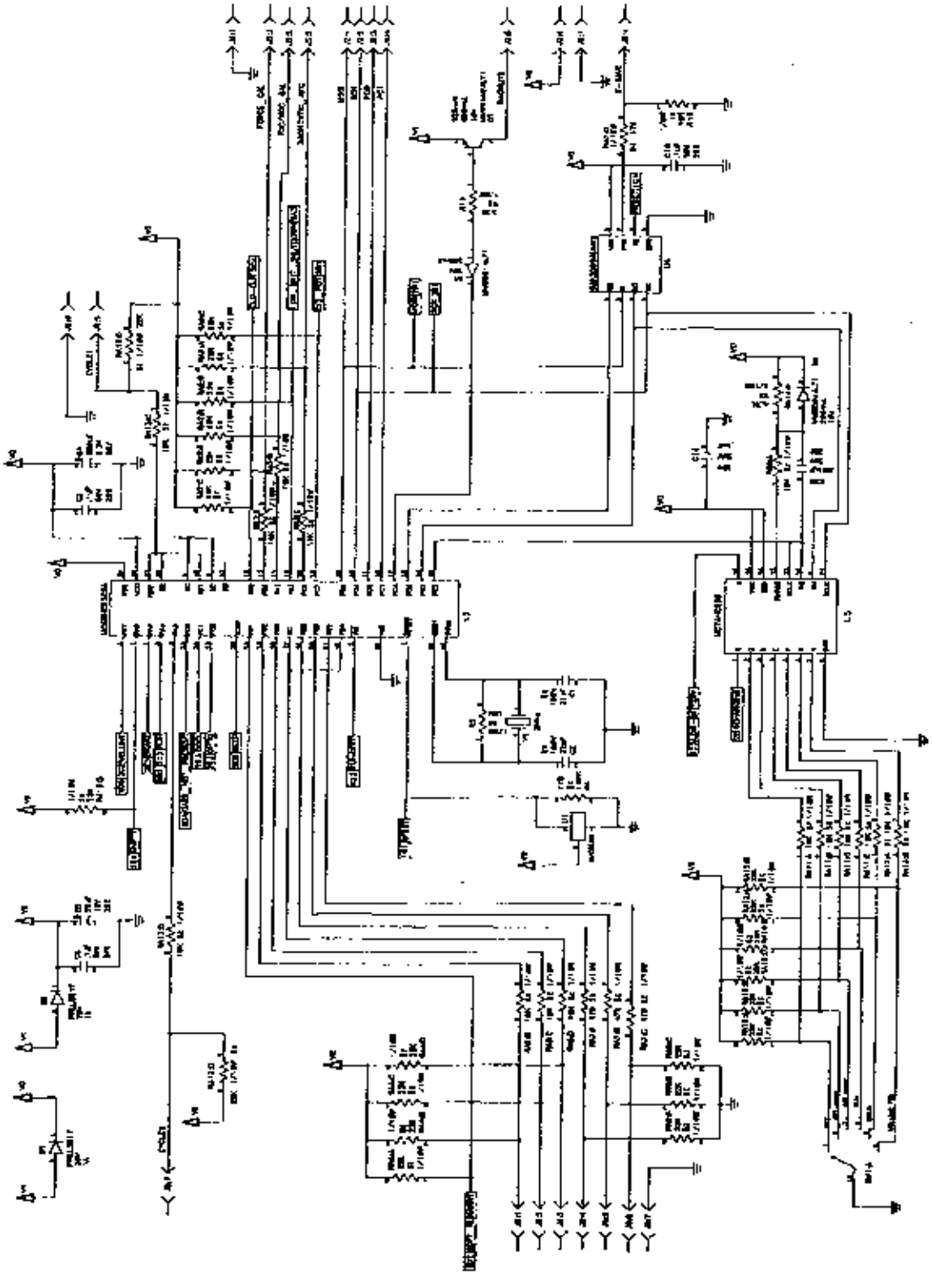

Figure 7-9, Main Board - Electrical Schematic (Digital)

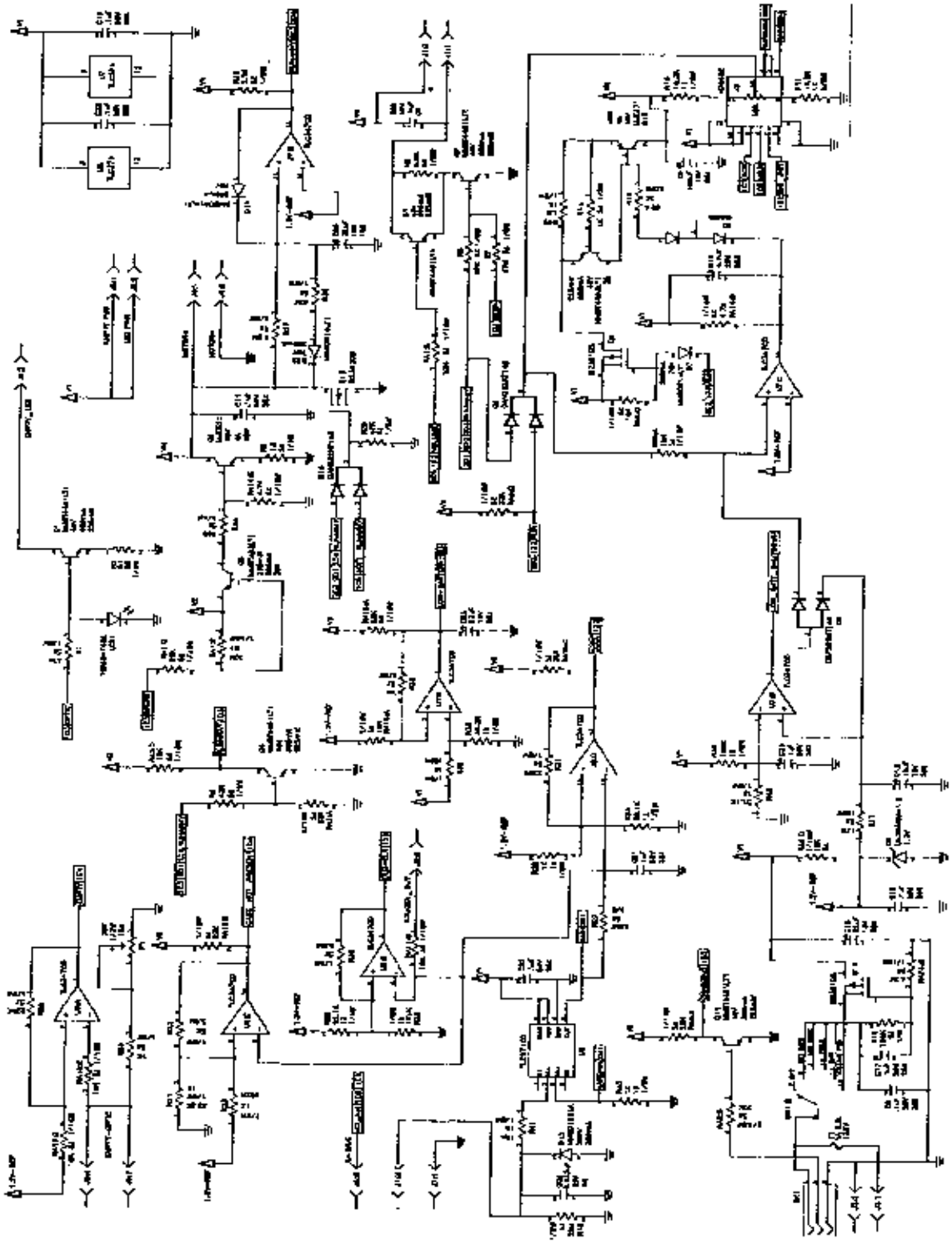

Figure 7-10, Main Board - Electrical Schematic (Analog)

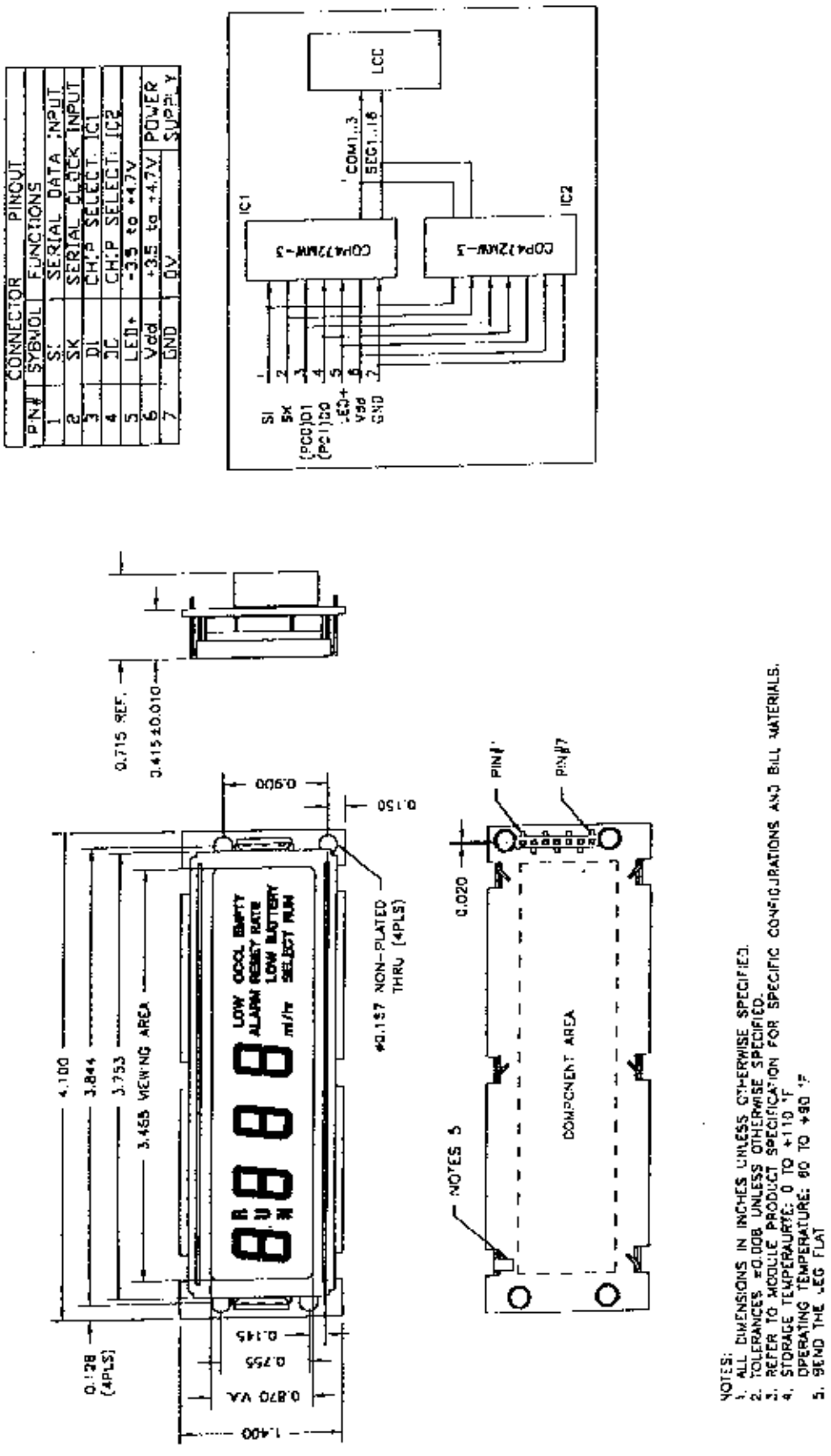

Figure 7-11, Domestic Display Board Assembly

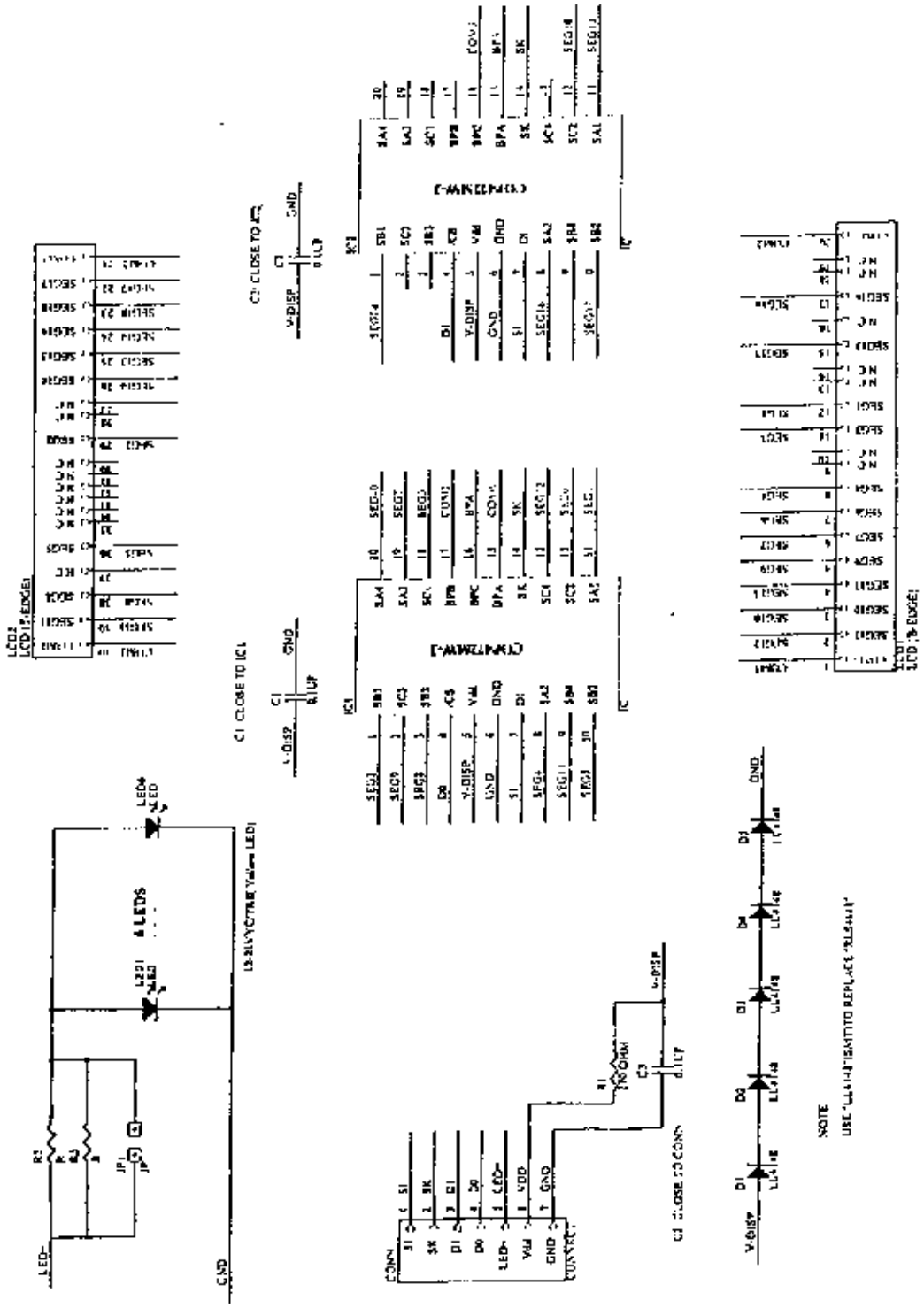

Figure 7-12, Domestic Display Board Assembly - Electrical Schematic

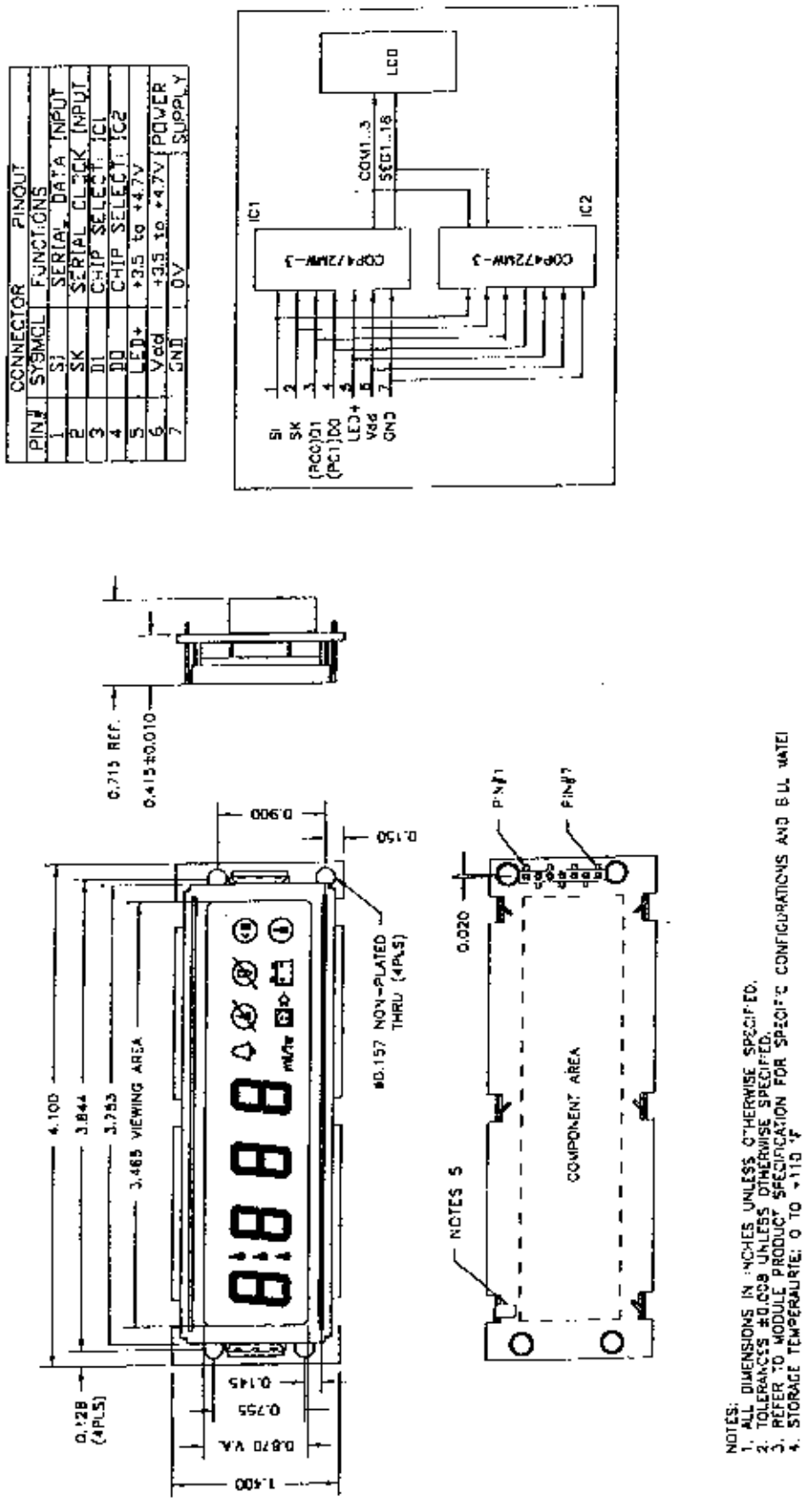

Figure 7-13, International Display Board Assembly

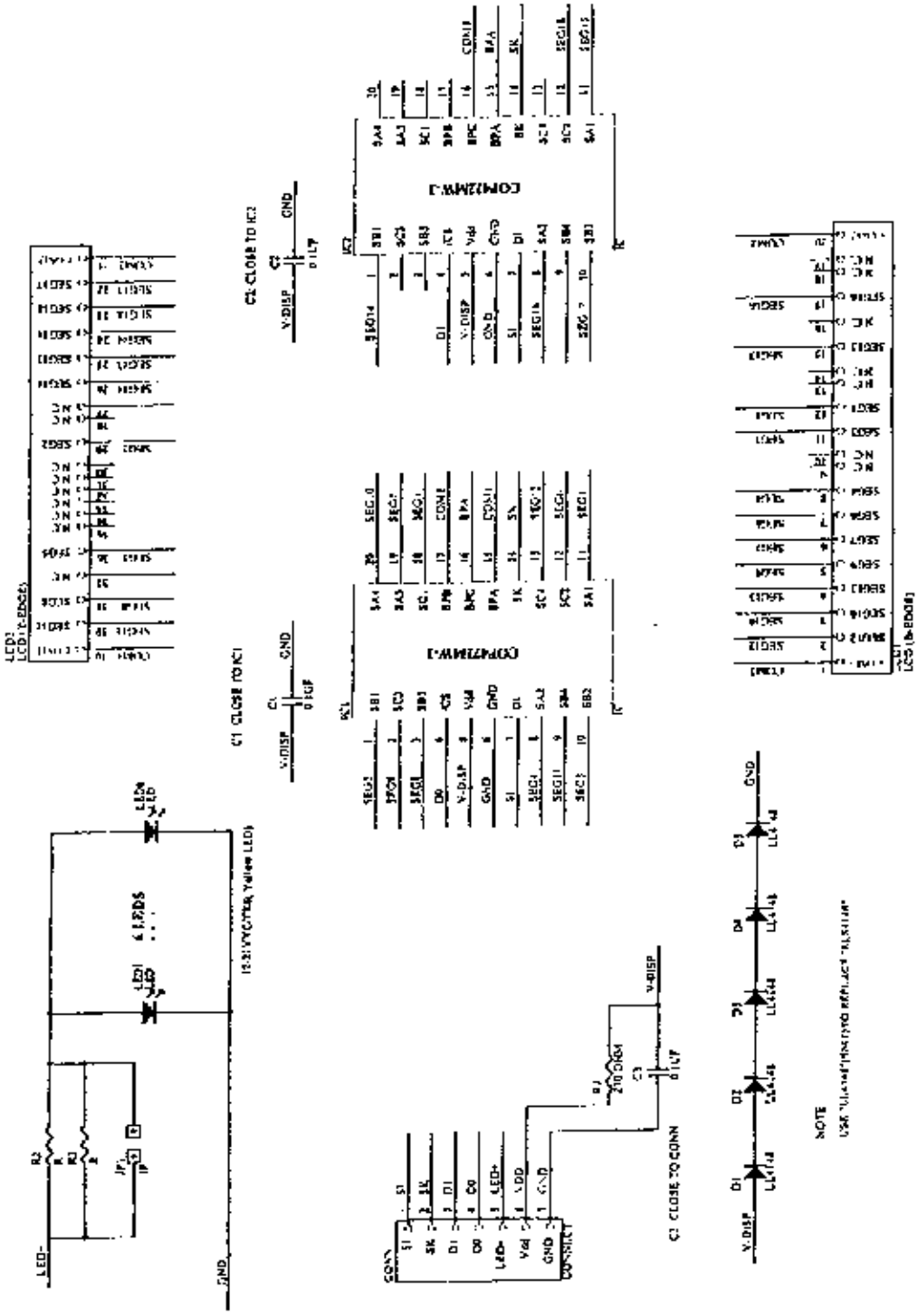

Figure 7-14, International Display Board Assembly - Electrical Schematic

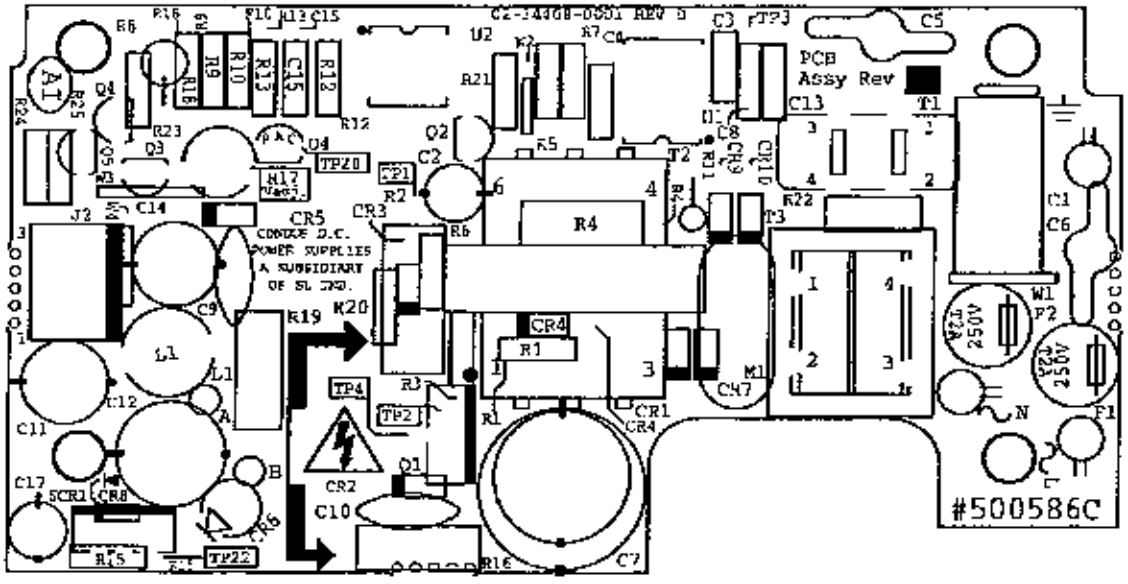

Figure 7-15, Power Board Assembly

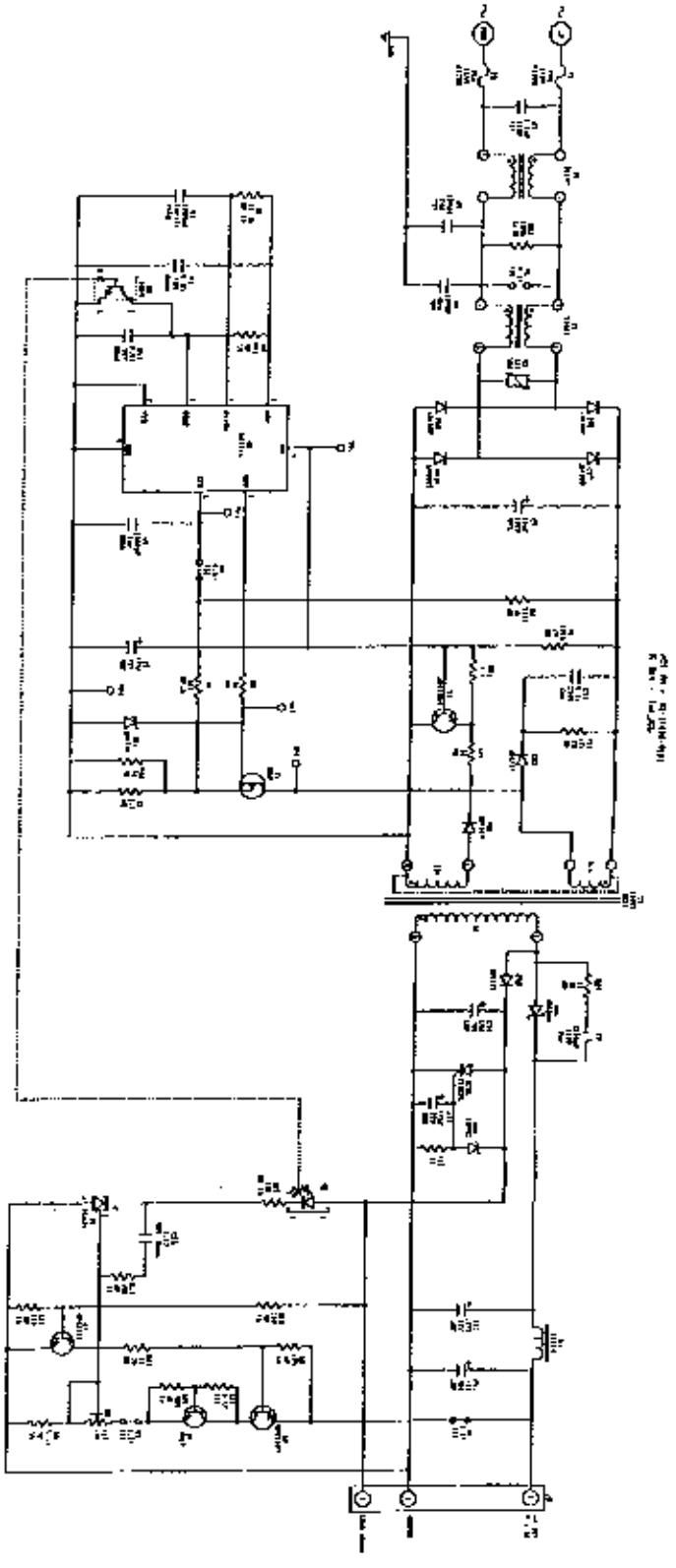

Figure 7-16, Power Board Assembly - Electrical Schematic