Service Manual

ABC Syringe Infusion Pump Model 4100

Atlanta BioMedical Corporation

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Always **B**est **C**are

ABC Model 4100 Service Manual Table of Contents

Section 1: ABC Model 4100 Service Manual
Introduction / Warnings / Cautions

This manual contains the technical service information for the ABC Model 4100 Syringe Infusion Pump. The purpose of this manual is to provide the necessary technical information for servicing, troubleshooting and repair of the Model 4100.

This manual is intended for use by trained biomedical technicians, who are authorized by their medical facility to perform service and repair of medical devices.

Do not modify the Model 4100, perform any repairs not contained in this manual, or install substitute parts. Unauthorized modifications or repairs will void the warranty.

All information contained in this service manual is current as of the effective dated listed and is subject to change without notice.

To obtain technical assistance or repair service, contact:

Atlanta BioMedical Corporation
305 Shawnee North Drive, Suite 250
Suwanee, GA 30024
770-904-3766

WARNING ! Do not operate the Model 4100 if it has been dropped or any physical damage is noticed.

WARNING ! Attempts to repair or service the Model 4100 by technicians without the proper qualifications or training may create a hazard which could result in serious injury to the user or patient.

WARNING ! Use only the approved parts and procedures as listed for the repair and servicing of the Model 4100. Failure to follow this service manual may create a hazard which could result in serious injury to the user or patient.

CAUTION: **Always disconnect the AC power to the Model 4100 and remove the battery when performing service or repair. Use only the line cord as supplied by Atlanta BioMedical Corporation**.

CAUTION: **When the Model 4100 is opened for service, you must work at an electrostatic controlled workstation.**

ABC 4100 Service Manual:

CLEANING CAUTIONS:

The Model 4100 may be cleaned externally with the following:

Isopropyl Alcohol
Clorox Cleaner with Bleach
Sporicidin
Cidex OPA
Soap/water

Insure that the battery pack is installed in the Model 4100 prior to cleaning. Tighten battery thumbscrew by hand. DO NOT overtighten.

Clean by pouring or spraying the cleaner onto a soft cloth, not directly onto the Model 4100, then wipe the unit clean.

Do not use strong detergents, organic solvents or solutions containing ammonium chloride to clean any portion of the Model 4100.

Do not immerse the Model 4100.

Avoid spills and inadvertent fluid entry into the Model 4100 housings.

Do not autoclave or gas sterilize the Model 4100.

Section 2: ABC Model 4100 Service Manual
Functional Testing

1. Install the battery.

2. Press the Power ON key and the unit will proceed through a power on sequence displaying the software version/date and the S/N, the LEDs should flash and then the display should indicate MAIN MENU PAGE 1 of 3.

3. The battery LED should be flashing yellow.

4. Connect the line cord and check that the unit battery LED is flashing green or steady green if battery fully charged. Disconnect the line cord and check battery LED is flashing yellow. .

5. Press the Menu key twice to get to MAIN MENU PAGE 3 of 3, select/enter <9> SYSTEM CHECK. The display should indicate reading for POS, SIZE, BATT, FORCE and PLUNGER DETECTED.

6. Completely squeeze the clutch lever and move the track all the way in, the POS reading inches should be less than .030 IN. Move the track all the way out and the reading should be between 5.570-5.630 IN.

7. With a BD 1 cc syringe loaded, the SIZE reading should be between 15.80 – 17.80 and Mono 1 should be 15.25 – 17.25. With a BD 60 cc syringe loaded the SIZE reading should be between 49.75 – 51.75, Mono 60 should be 49.80 -51.80. Gently release the syringe clamp to its resting position.

8. The BATTERY voltage will indicate the voltage charge of the battery.

9. The FORCE is a reading of the force sensor, with no syringe loaded (no force) the reading should be close to 0 LB. Apply some finger pressure to the transducer plate and the force reading should increase.

10. The PLUNGER DETECTED with no syringe loaded should be NO. Load a syringe and the PLUNGER DETECTED should be YES. Remove the syringe and it should change back to NO.

11. TEST LED/ALARM. Press the Select key and the LEDs should flash and the audio alarm should sound. Note that the System Malfunction LED and audio alarm should be activated for a very short interval at the end of the test. Check/note the battery voltage during this test, if the voltage is less than 4.8V the battery may need to be charged.

12. Press the Stop key to exit the SYSTEM CHECK and go back to MAIN MENU PAGE 3 of 3, then press the Menu key to get to MAIN MENU PAGE 1 of 3.

13. Select/Enter ML/HR mode, then Select/Enter either BD or MONO as the syringe MANUFACTURER.

14. Load a BD or Mono 60 syringe, confirm that the unit recognizes the size. Enter 0 for DELIVER LIMIT and 0 for BOLUS, enter the max rate, should be 1500 for BD 60 or 1497 for Mono 60 as default values. Then press and hold the Prime key to prime, the priming should only be approximately 5 seconds and the audio alarm should then turn on and the display should indicate RELEASE prime KEY. Then press the Deliver key to run the unit at the max rate for a full delivery. Check that the unit runs to SYRINGE EMPTY with audio alarm. The syringe should be empty .

    If any other alarms or errors occurred, refer to the alarm/error chart.

    This functional testing tested all the basic functions of the unit. The next section lists more detailed testing.

1. Power on the unit.

2. Syringe size recognition test.

Program the unit for BD syringe, then load a BD 10 mL syringe and check for syringe recognition. Press the Go Back key, remove the 10 mL syringe. Then incorrectly load a BD 5 mL syringe by loading on top of the syringe finger tab. Check that the unit does not recognize the syringe and indicated invalid size. Load the 5 mL syringe correctly and check syringe recognition. Remove the 5 mL syringe. Correctly load other syringes and check size recognition. Press the Go Back key 3 times to get to MAIN MENU PAGE 1 of 3. If there are any problems with syringe recognition, then perform SIZE calibration.

3. Plunger force test.

With force gage.
Press the Menu key twice to get to MAIN MENU PAGE 3 of 3, select/enter <9> SYSTEM CHECK. The display should indicate SYSTEM CHECK with FORCE listed.

Move the track all the way out and load the spacer onto the plunger retainer. Then load the force gage onto the unit. Turn on the force gage and zero the reading. With no force on the plunger the unit should read 0 +/- 0.12 Lbs. Slowly turn the knob on the force fixture to apply force to the plunger until 5 Lbs is indicated on the force gage, then check the reading on the unit, the reading should be 5 +/- 0.25 Lbs. Then check the

reading at 10 Lbs, unit should read 10 +/- 0.40 Lbs and then 15 Lbs, unit should read 15 +/- 0.40 Lbs. If there are any problems with the force readings, then perform FORCE calibration.

With syringe.
Reference appendix III Occlusion Force chart in the Operations Manual.

Prepare a syringe, half filled with water and load onto the unit.

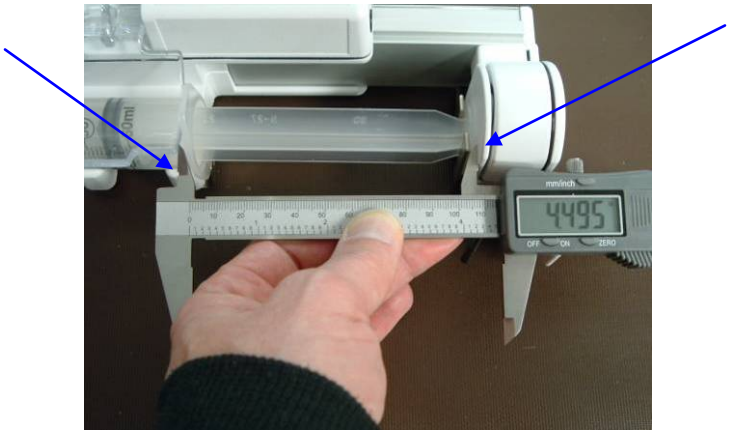
Set up program the unit for the syringe being used. Deliver/start the infusion at maximum rate and then occlude the syringe.

The unit will run to an occlusion condition. Note the reading in lbs in the lower right corner of the LCD, this is the occlusion point.

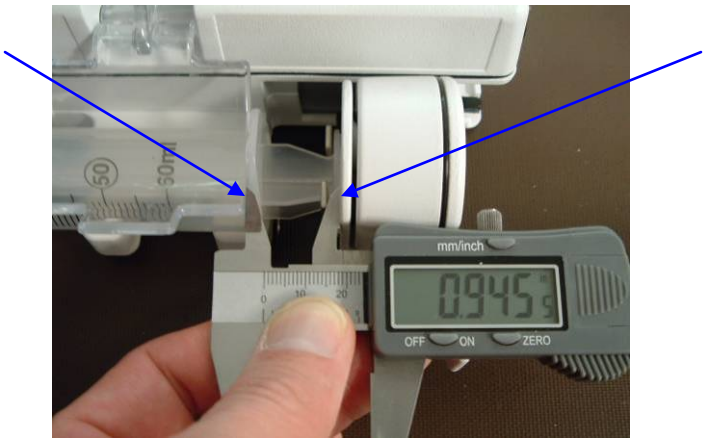
Note: the unit may be set up and tested for any of the occlusion forces listed in the table (LOW, NORM, MID or HIGH). Reference section 8.2.4 in the Operations Manual for temporary adjusting the occlusion plunger force.

4. **Plunger driver test:**

Load a BD 60 syringe, set a delivery limit of 50 mL and a rate of 1500 ml/hr. Prime the syringe to approximately the 55 mL mark on the syringe. Measure with a caliper the distance between the right edge of the clear syringe clamp and the transducer plate, record this reading.



Start the delivery and allow the unit to deliver until the DELIVERY LIMIT alarm occurs. Measure the same distance between the syringe clamp and the transducer plate. Subtract this reading from the first reading, this difference should be 3.473 to 3.615 inches.



e.g. 4.495 minus 0.945 equals 3.550

Flow rate accuracy with displacement measurement: use this chart for any of the other syringes and flow rates

B-D

Size	1	3	5	10	20	30	60	
VINC	0.44049	1.47036	2.86731	4.15229	7.23958	9.29884	14.10862	

MONO

Size	1	3	6	12	20	35	60	140
VINC	0.43574	1.56762	3.16632	4.86790	8.09352	11.08376	14.08168	28.72713

TERU

Size	1	3	5	10	20	30	60	
VINC	0.44086	1.59779	3.37154	4.97965	8.09982	10.6451	16.8932	

BDMF

Size	1	3	5	10				
VINC	0.46512	1.59575	2.73973	4.28266				

ABC

Size	140							
VINC	28.72713							

Unit for VINC is ml/inch.

VL (ml, Volume to be delivered) = Rate(ml/HR) x Time(HR)

Displacement (inch) = VL(ml) / VINC(ml/inch)

Procedure to determine expected displacement:
(1) Find VINC with given Syringe Manufacturer/Size.
(2) Determine Volume to be delivered (using Volume Limit) by multiplying Rate with Time.
(3) Find the expected Displacement by dividing VL with VINC.

Testing:
(1) Load syringe and set up rate and volume limit.
(2) Prime the syringe.

(3) Measure the initial track position.
(4) Start Stopwatch and Delivery.
(5) Check Stopwatch reading when delivery is stopped to verify the Delivery Time.
(6) Measure the track position and calculate the displacement the by the difference between the beginning and ending track position readings. Confirm that the displacement is within specification.

5. Leakage current test.

Connect the unit to the leakage current tester.

Power on the unit.

Measure the leakage current to any of the exposed metal screws of the unit, the reading should be less than 100uA in both the normal and reversed settings.

Section 3: ABC Model 4100 Service Manual
Programming

3.1 Setting the Real Time Clock

From the MAIN MENU PAGE 1 OF 3, go to MAIN MENU PAGE 3 OF 3, then <7> REAL-TIME CLOCK and Enter.

Use code 6543 and Enter

Screen will list (the current clock settings)

REAL-TIME CLOCK

YEAR (YY)=12
MONTH (MM)=06
DAY (DD)=10
0-AM, 1-PM=00
HOUR (HH)=07
MINUTE (MN)=05

ENTER: YY
12
PROGRAM # OR USE ▲▼
THEN PRESS <ENTER>

Change the appropriate settings as necessary.

3.2 Programming the Options

From the MAIN MENU PAGE 1 OF 3, go to MAIN MENU PAGE 3 OF 3, then <3> PUMP DEFAULTS and Enter.

Use code 4321 and Enter.

There are 2 programming options pages and one page of Alarm/Alert options.

The options are:

OPTIONS: Page 1 of 2

<1> SYRINGE MFGER
<2> USE B-D 1CC LL
<3> DELIVER LIMIT
<4> BOLUS ENABLED

<5> STAND-BY MODE
<6> MAX RT ML/HR
<7> PLUNGER FORCE
<8> LOCK STAND-BY
<9> LAST SETTING

Use the Menu key to go to the next options screen

OPTIONS: Page 2 of 2

<1> TOTAL UNIT
<2> RATE INPUT
<3> USE ALL MODES
<4> DISPLAY CLOCK
<5> REVERSE MOTOR

<7> ENTERAL CHECK
<8> LOCK START-UP
<9> LOCK CRTE PROG
<0> LOCK TEMP ADJ

Use the Menu key to go to the ALARM/ALERT OPTIONS screen

<1> ALARM VOLUME
<2> ALARM FREQ.
<3> ALARM DELAY
<4> STOP ALARM
<5> EMPTY ALARM
<6> LOW BATT ALARM
<7> NEAR-EMP ALARM
<8> NEAR-EMP DELAY
<9> BOLUS COMPLETE

Use the number keys to select an option, then again a number key to select an item and then the scroll keys to select and then confirm with the Enter Key. Press the Stop key to exit back to the options page.

Note: The last two lines of the LCD display operational instructions and status information.

From page 1 of 2 on the options page, press <1> to select syringe manufacturer, the choices are:

<1> B-D
<2> MONOJECT
<3> TERUMO
<4> B-D GLASS

<5> ABC

Press the Menu key to select the ENTERAL SYRINGE(s), the choices are:

<1> ETBD B-D&ETIP
<2>ETMN MONO&ETIP
<3>BAXA NeoThrive
<4>NEOM NeoMed
<5>AMP Ameritus
<6>VYGO Vygon
<7>ACAC Acacia

Then <4> key for NEOM, then the arrow keys or the Select to choose Yes or No and then confirm the entry with the Enter key. Press the Stop key to exit back to the options page. In this manner, if your facility only uses NeoMed syringes, you can choose Yes for NEOM and No for the other syringes and then the unit will only be set for NeoMed syringes.

On page 1 of 2 on the options page, press <2> to use BD 1cc luer lock syringe, the choices are YES or NO, this can be chosen using the scroll keys or the Select key. Use the Enter key to confirm your choice. If your facility uses BD 1 cc luer lock syringes then this should be set to YES. This will avoid any size recognition errors with the BD 3 cc syringe which has an outside diameter similar to the BD 1 cc luer lock syringe.

Example: From the alarm/alert options page, press the <1> key to select alarm volume, then the scroll keys to change between normal, low and high, then the Enter key to confirm the entry. A brief sound will occur after confirmation.

The factory default options can be set with the following instructions. Go to MAIN MENU PAGE 3 OF 3, then <5> BIO MED SERVICE, press the Enter key. Enter the biomed access code, 9876, and press the Enter key. Then <5> FACTORY DEFAULTS. Note that the unit will return to MAIN MENU PAGE 3 OF 3 where choice <1> is VIEW OPTIONS.

3.3 Duplicate the options configuration and saved programs.

You will use one unit that already has the options as the teacher unit and the other units that need the options will be the student units. Connect the communication cable P/N 001-5217 to the comm. port on the back of each unit.

Set up a student unit as follows:

From MAIN MENU PAGE 3 OF 3, THEN <5> BIOMED SERVICE then Enter.

Used code 9876 then Enter.

Then <3> TEACHER / STUDENT

Then <3> STUDENT, the screen will list STUDENT at the top and WAITING at the bottom.

Set up the teacher unit (unit with the options) as follows:

From MAIN MENU PAGE 3 OF 3, THEN <5> BIOMED SERVICE then Enter.

Used code 9876 then Enter.

Then <3> TEACHER / STUDENT

Then <1> TEACHER, the screen will list TEACHER at the top and SENDING DATA at the bottom.

The STUDENT unit should now list RECEIVED DATA [CONN] at the bottom.

At the TEACHER unit, press the 3 key to copy the options from the TEACHER to the STUDENT unit.

Note: at the TEACHER unit, <5> to COPY PROTOCOLS
<1> to COPY OPT. & PROT.

Press the Stop key 3 times on the STUDENT unit to exit and get back to MAIN MENU PAGE 3 OF 3.

You can verify the options are the same as follows.

From MAIN MENU PAGE 3 OF 3.

<1> VIEW OPTIONS then Enter.

The bottom of the screen will list a CRC code, this code should match between the TEACHER and STUDENT units.

You can also see and page through the options by pressing the Menu key.

Use the Stop key to exit out of VIEW OPTIONS.

3.4 Software Update

This will allow updating the software from one master Model 4100 to another Model 4100. The master 4100 must be programmed by Atlanta BioMedical.

Connect the Communication Cable between the master 4100 and the 4100 to be updated.

Master 4100: Power ON the unit and then press the Menu key twice to get to MAIN MENU PAGE 3 OF 3. Press key <5> BIOMED SERVICE, then the Enter key. Key in code 7319, then Enter key. Screen should indicate:

CLONE CODE

<1> CLONE APPLICATION

<3> CLONE BASE

USE # TO SELECT ITEM
EXIT:<Stop>

4100 to be updated: Hold down the Menu key and then Power ON. Screen should indicate:

BASE VERSION= 01.01 (or newer version)
REV. DATE= 09/01/2011 (or newer date)
CRC=EA57 S/N=8000#### (or newer CRC) #### S/N of unit

1. UPDATE/VERIFY CODE

USE # TO SELECT ITEM
REMOVE POWER TO EXIT

Press the 1 key. Screen will indicate:

UDPATE/VERIFY/CODE

EXIT:<STOP>

Master 4100: Press the 1 key to CLONE APPLICATION.

The master 4100 will indicate SENDING DATA.

The 4100 being programmed will indicate date being received.

The programming will take approximately 2-3 minutes. When programming is complete, the 4100 that was being programmed will sound the audio alarm briefly. Then the middle of the screen will indicate:

#=2 CRC;COM=B001 B001
B001 7B65 7B65 7B65

The master 4100 will now indicate:

CLONE CODE

<1> CLONE APPLICATION

<3> CLONE BASE

USE # TO SELECT ITEM
EXIT:<Stop>

Power OFF the 4100 that was just programmed. Power ON this 4100. The screen will indicate:

ABC 4100
SYRINGE
PUMP
VERSION= ##.# (version just programmed)
MM/DD/YYYY (date of this version)
S/N=8000####

SELF-TEST

Then the unit will proceed to MAIN MENU PAGE 1 OF 3. Programming is complete.

If the unit indicates: WRONG BASE VERSION!!
THEN PRESS <Enter>

Press the Enter key on the 4100. The unit will indicate:

UPDATE/VERIFY CODE B
WAITING
EXIT:<Stop>

At the master 4100: Press the <3> key to CLONE BASE. This programming will take approximately 15-20 seconds and when complete the unit will indicate:

UPDATE/VERIFY CODE B
CAF19200 E
BASE CRC=B001
WAITING
EXIT:<Stop>

Power OFF the 4100. Power ON the 4100 and then unit will proceed through the power on self test and go to MAIN MENU PAGE 1 OF 3. (as described above). Programming is complete.

Disconnect the communication cable from the 4100 that was just updated.

Section 4: ABC Model 4100 Service Manual
Spare Parts and Tool Equipment List

Spare Part List

Part Description	Part Number	Note
Battery pack	001-5104	
Line cord (120V US hospital grade)	200-0061	
Line cord (120V US)	200-0060	
Line cord (240V)	200-0062	
Overlay	001-0118	
Keypad	001-0117	
LCD	001-5117	
Lens	001-0116	
Main PCB Assembly	001-5110	to be configured to 120V or 240V
Main PCB Assembly, 120V	001-5950	
Main PCB Assembly, 240V	001-5951	
Fuse .125A	203-0104	for 120V unit
Fuse .080A	203-0105	for 240V unit
Top PCB Assembly	001-5111	
Force Sensor Assembly	001-5114	
Bottom Housing Assembly, 120V	001-5101	for 120V unit
Bottom Housing Assembly, 240V	001-5901	for 240V unit
Top Housing Assembly	001-5100	
Track /Transducer Assembly	001-5112	
Speaker Assembly	001-5211	
Potentiometer Assembly	001-5202	
Top Cable Assembly	001-5206	
Case seal	001-0050	
Transducer housing seal	001-0022	
Syringe flange retainer	001-6010	
Rubber foot	001-0431	
Retainer cluster gear	001-0040	
Cup seal	001-0044	
Ground ring	001-0432	
Seal/cover AC inlet	001-0113	
Seal/plug comm. port	111-0750	
Box (shipping)	001-9202	
Inserts (shipping)	001-9200 & 001-9201	

Contact Atlanta BioMedical Corporation at 770-904-3766 for pricing.

Tool Equipment List

Too Description	Note
Phillips #0, #1 and #2 screwdrivers	
¼ inch open end wrench and nut driver	
3/16 nut driver	
5/16 open end wrench	
9mm open end wrench	
19mm open end wrench	
5/64 hex driver	
Caliper 6 inch	
Steel rule 6 inch	
Syringes: BD 1, BD 5, BD 20, BD 60, Mono 140	
Force gage: Mecmesin Model CFG 200 p/n 860-022	
Force fixture holder and hardware : supplied by ABC (minus the gage)	

Contact Atlanta BioMedical Corporation at 770-904-3766 for pricing on force fixture.

Section 5: ABC Model 4100 Service Manual
Calibration

This section is used to calibrate the syringe pump force, size and position.

Force calibration

From the main menu screen, page 1 of 3, press the menu key twice to get to MAIN MENU PAGE 3 OF 3. Press the <5> key (BIOMED SERVICE), then the Enter key. Enter the biomed access code, 9876, and press the Enter key. Then key <1> (SENSOR CALIBRATION). Next press key <3> to enter force calibration.

Screen should be at force calibration, displaying 0 LB and hex numbers e.g. 0098. Place the spacer onto the transducer plate. Manually squeeze the gear onto the plate a few times and check that the hex numbers increase. Then with NO force applied, press the Enter key. Screen should now list 30 LB and hex numbers e.g. 007A. Place the track to the full outside position, keep the spacer in place. Turn the force gage on by pressing it's ON/ZERO key. Place the force gage onto the track and check that the force gage is reading 0 lbs. Then turn the knob on the gage clockwise to apply force to the transducer plate, turn until the gage reads 30 lbs. Then press the Enter key. Turn the knob counterclockwise and then remove the force gage and spacer from the unit. Press the Stop key to exit force calibration. Press the Stop key a second time to exit the sensor calibration mode.

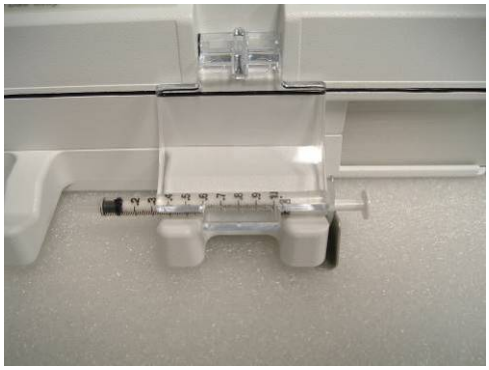
Force test:

Go to MAIN MENU PAGE 3 of 3, then <9> SYSTEM CHECK. Force readings will be displayed. Check the force sensor by setting 5 lbs on the gage and then check that the displayed reading is 5 +/- 0.25 Lbs. Repeat for 10 and 15 lbs. The displayed readings should be within 0.40 lbs. If not, repeat the force calibration above. Press the Stop key to get to MAIN MENU PAGE 3 of 3.

Size calibration

From MAIN MENU PAGE 3 of 3, Press the <5> key (BIOMED SERVICE), then the Enter key. Enter the biomed access code, 9876, and press the Enter key. Then key <1> (SENSOR CALIBRATION). Press the <1> key for SIZE calibration. Unit will be displaying B-D 1 and hex numbers e.g. 0000. Properly load the BD 1 ml syringe onto the unit. Exercise the syringe clamp a few times and then with the clamp down on the syringe. Press the Enter key.

Load the BD 5 ml syringe and repeat above, followed by the BD 20 ml, BD 60 cc and lastly the Mono 140 cc syringe. Press the Stop key to exit SIZE calibration. Press the Stop key a second time to exit the SENSOR CALIBRATION mode.

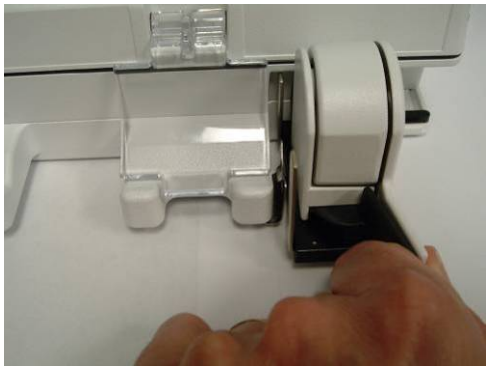


Size test:

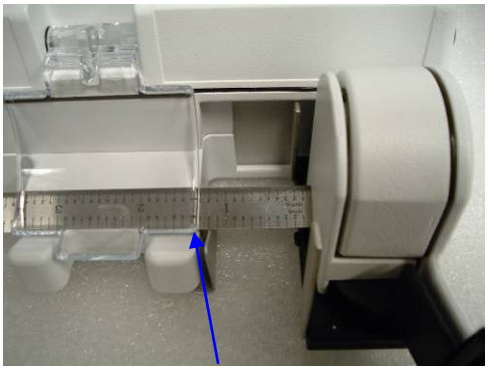
Go to MAIN MENU PAGE 1 of 3. Select any appropriate syringe manufacturer. Load each syringe size and check that the size is recognized. If not, repeat the size calibration procedure above.

Position calibration

From MAIN MENU PAGE 3 of3, Press the <5> key (BIOMED SERVICE), then the Enter key. Enter the biomed access code, 9876, and press the Enter key. Then key <1> (SENSOR CALIBRATION). Press the <2> key for POSITION calibration. Unit will be displaying POS 0 and hex numbers dependent on track position. Manually move the track all the way in to the empty position and keep the clutch lever squeezed, press the Enter key. Move the track out, place the ruler onto the saddle with the 1.3 inch line at the front edge of the saddle. Move the track until it just contacts the edge of the ruler, keep the clutch lever squeezed, press the Enter key. Then move the track farther out and place the ruler 2.3 inch line at the front edge of the saddle. Move the track in to just contact the edge of the ruler. With the clutch lever squeezed, press the Enter key. Then move the track all the way out and while keeping the clutch lever squeezed, press the Enter key. Remove the ruler from the unit. Press the Stop key to exit POSITION calibration. Press the Stop key a second time to exit the SENSOR CALIBRATION mode.



Track at empty position



1.3 inch line

Section 6: ABC Model 4100 Service Manual
Alarm and Error Codes / Troubleshooting

Problem/Condition	Troubleshooting
Low or Depleted battery	Connect the unit to ac line power to charge the battery. Refer to the Operations Manual section 9 (battery operation).
Replace battery	Check that the battery pack is installed correctly. Charge the battery pack. A completely discharged battery should charge fully in about 3 - 4 hours. Replace battery pack.
Invalid size	Check using correct MFR syringe. Check that the syringe is loaded correctly. Check if any labels or tape on the syringe are affecting the size Perform SIZE calibration. Check or replace the size potentiometer.
Syringe dislodged	Check if syringe was actually dislodged or moved. Check that the syringe is loaded correctly. Perform SIZE calibration. Check or replace the size pot.
Plunger disengaged	Check that the syringe plunger is engaged properly with retainers. Check operation of optical sensor in plunger housing, See section 2, Functional Testing.
Check track	Check that the plunger/track was not manually moved. Perform POSITION calibration. Check or replace position potentiometer.
Occlusion (plunger)	Check the configured occlusion limit. Check operation of force sensor. Perform FORCE calibration. Check or replace the force sensor assembly.
Key Stuck	Check that a key is not depressed
Error code 65 or 66	Check that the clutch is closed. Perform POSITION calibration. Check that the position encoder and position potentiometer are securely assembled to the bottom housing.
Error code 62 or 63	Contact Atlanta BioMedical Corporation
Any other error codes that are not listed here	Contact Atlanta BioMedical Corporation

Section 7: ABC Model 4100 Service Manual
Service / Repair

7.1 Final Unit Disassembly

 **The following steps must be performed at an ESD safe workstation.**

Reference pictures on next page for instructions below.

1. Disconnect the line cord/ac power from the unit and remove the battery pack from the unit.

2. Move the track in to the empty syringe position.

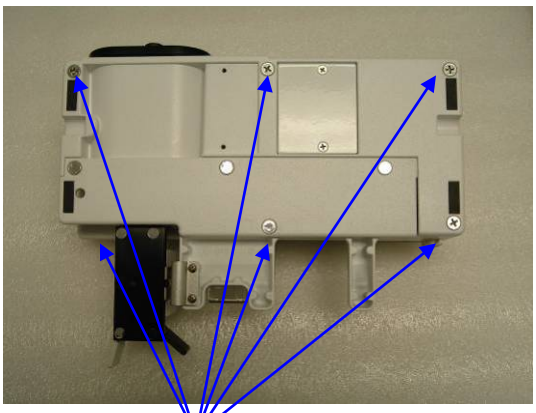
3. Remove the six screws securing the bottom housing to the top housing. Note that each screw will have a plastic cup seal, retain this on the screw. There is also a ground ring over each screw, retain these also on the screws. You do NOT need to remove the 3 saddle screws at this time.

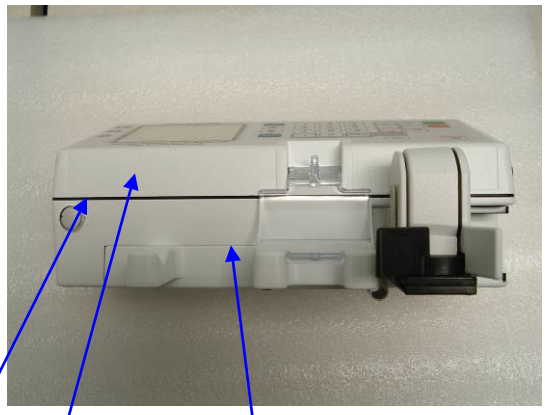
4. Carefully start to remove the top housing from the bottom housing.

5. Disconnect the flat ribbon cable from the main PCBA, disconnect the 3 pin ac cable connector from the main PCBA.

6. Remove the one screw securing the green ground wire.

7. Completely remove the top housing from the bottom housing. Carefully remove the case seal, do not stretch or pull on the seal.



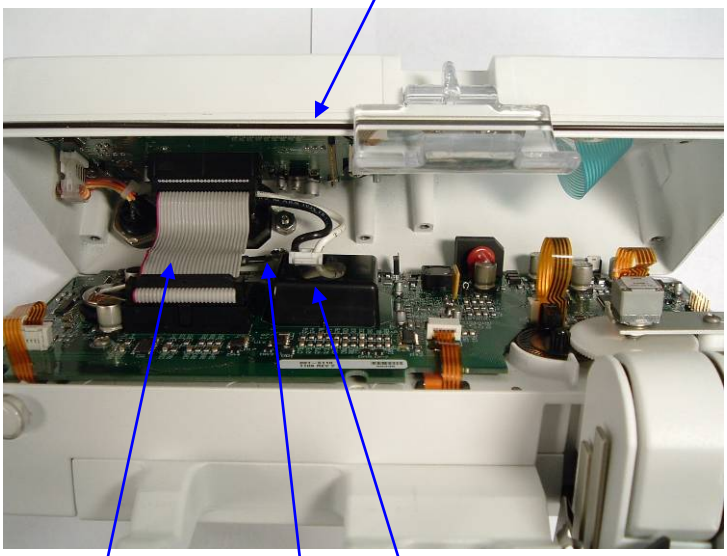


6 screws securing top to bottom

Top

Bottom

Seal



Flat ribbon cable

AC cable

Green ground wire

7.2 Final unit reassembly

1. Position the top housing over the bottom housing and secure the green ground cable to the screw stud. **CAUTION !** Ensure the green ground cable is reconnected to maintain proper ground safety.

2. Connect the flat ribbon from the top housing to J1 on the main PCBA. Connect the 3 pin ac cable to J9 on the main PCBA, ensure cable locks in place.

3. Place the top housing onto the bottom housing, carefully position the wires and take care not to pinch the flex cables along the front of the housing. Secure the housings with same 6 screws; the short one inch screw is placed in the right front corner. The remaining 5 each 2 ½ inch screws are placed three along the back and 2 along the front. Be sure that each screw has a plastic Cup Seal and Ground Ring in place. Start the screws but do not tighten. Allow a small gap between the housings. Place the Top Housing Seal in this gap, positioning the seal corners into the housing corners. Then start to tighten the 6 screws, tighten each screw a little at a time until tight. Check that the Top Housing Seal is in place. If the seal comes out, loosen the screws, re-position the seal and then re-tighten the screws.

4. Install the battery pack into the unit.

5. The unit is now ready for final testing, see section 2: Functional Testing.

7.3 Top housing disassembly

 **The following steps must be performed at an ESD safe workstation.**

1. Perform final unit disassembly as noted above.

2. Removal of the LCD/Top PCBA.

   Tools required: Phillips #1 and #0 screwdriver
   3/16 nut driver

   Note: The flex cables are connected to Zero Insertion Force (ZIF) connectors. To disconnect, pull back on the ZIF retainer and then remove the flex cable from the connector.

   Disconnect the keypad flex cable from connector J2.

   Disconnect the size flex cable from connector J3.

   Disconnect the communication cable from connector J6.

   Disconnect the flat ribbon cable from connector J1.

   Remove the 4 screws and black spacers from the top PCBA.

   Carefully remove the top PCBA/LCD from the top housing. Note that there are white plastic retaining washers at the end of the screws.

   Remove the 4 screws, spacers and hex nuts that secure the LCD to the top PCBA.

   Carefully separate remove the LCD from the top PCBA.

3. Removal of the keypad.

   Carefully remove by peeling off the overlay from the top side of the top housing.

   Carefully remove the keypad flex cables from the 2 pieces of the double sided tape in the top housing.

Carefully remove the keypad from the top side of the top housing.

Remove any adhesive from the top housing that may have been left behind using isopropyl alcohol.

4. Removal of the size potentiometer and syringe clamp.

   Tools required: 5/64 hex driver
   Phillips #1 screwdriver

   Disconnect the size flex cable from connector J3.

   Remove the 2 screws that secure the size pot bracket to the housing.

   Loosen the set screw securing the clamp plug at the left side of the housing.

   Remove one end of the spring from the clamp plug.

   Remove the other end of the spring from the clamp gear.

   Remove the gear from the housing.

   Remove the syringe clamp from the housing.

5. Removal of the ac inlet and communication cable.

   Tools required: 5/16 inch open end wrench
   Phillips #2 and #1 screwdriver
   19 mm open end wrench

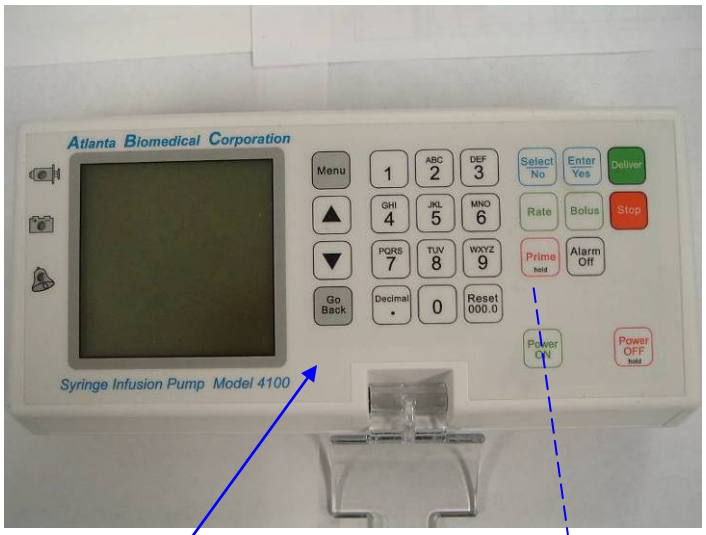
   Remove the screws and hex nuts that secure the ac inlet to the housing.

   Remove the ac inlet from the housing. Note there is a seal/cover on the AC inlet.

   Remove the large hex nut from the inside of the communication port connector. Note: There is a plastic black ring and then an O ring on the communication port connector.

   Remove the communication port cable from the housing.

   Reference the following pictures for the top housing.



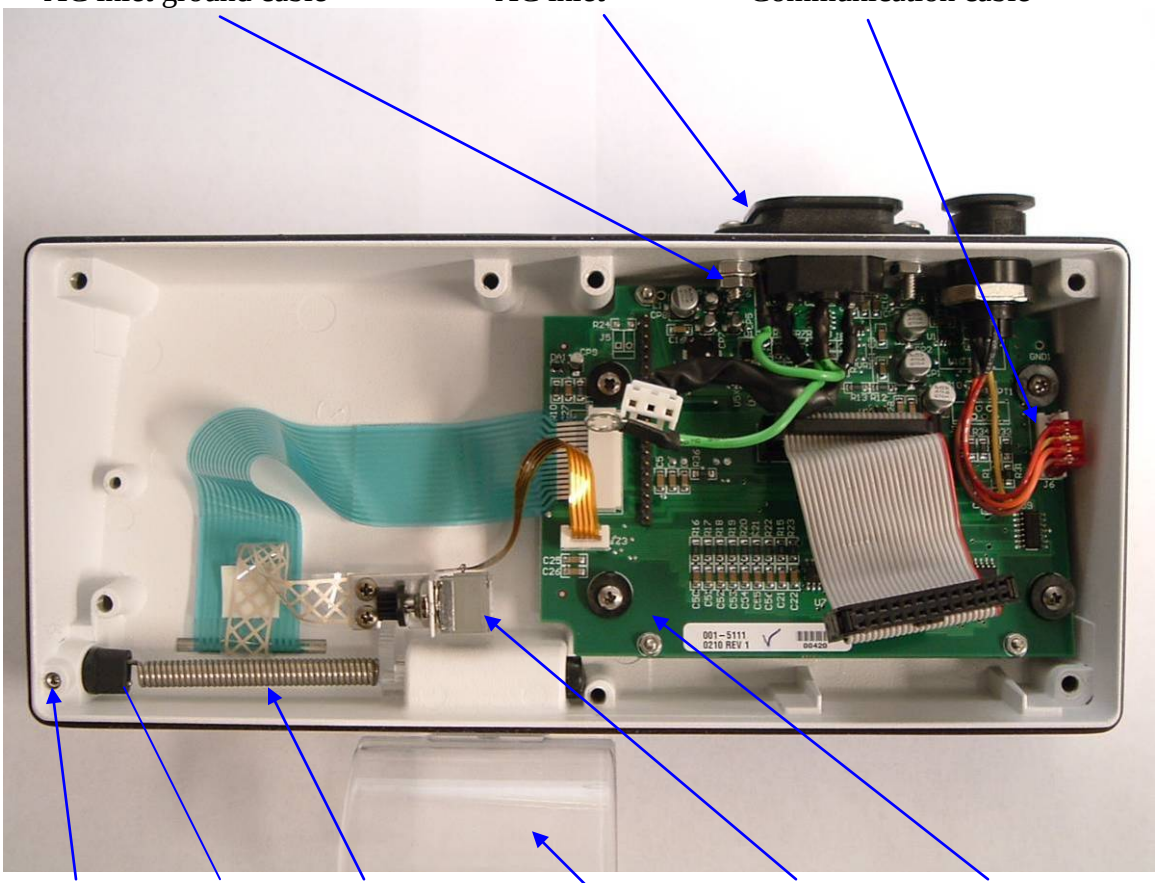
Overlay

Keypad (under overlay)

AC inlet ground cable

AC inlet

Communication cable



Set screw

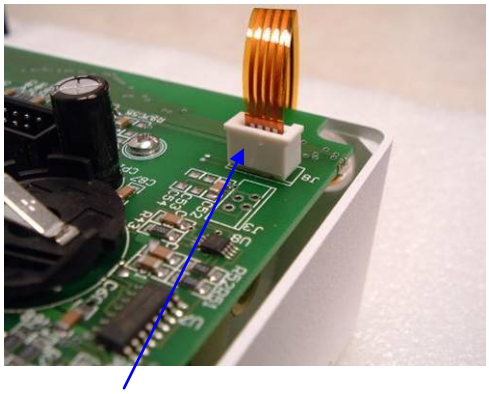
Clamp plug

Spring

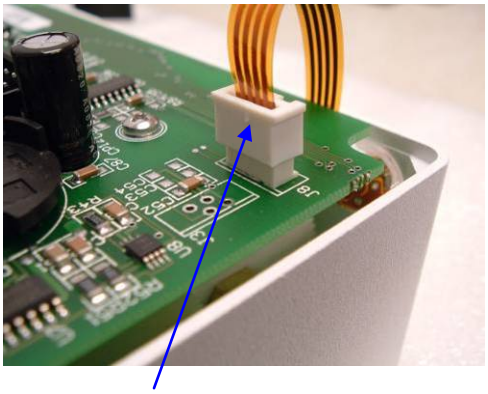
Syringe clamp

Size Pot

Top PCBA/LCD



ZIF retainer down/locked



ZIF retainer up/un-locked

7.4 Top housing reassembly

1. Reinstall the ac inlet and communication cable assemblies with the same hardware. Secure the green ground cable of the ac inlet to the top housing with the #8-32 screw.

2. Place the syringe clamp into the top housing with the concave side of the clamp facing up. Reinstall the clamp gear into the clamp. Place one end of the spring into the gear and the other end into the clamp plug. If the spring needs tightened, loosen the set screw and then turn the clamp plug CCW approximately ½ to ¾ turn and then tighten the set screw. Note: size calibration must be performed.

3. Reinstall the size pot to the top housing by first turning the size gear fully CW. Place the keypad ground cable under the size pot bracket and then install the 2 each 4-40 X 3/16 screws. The position size gear must be preset to a value of 25-50 with a BD 1 cc syringe loaded. The value can be viewed in the system check mode, main menu page 3 then system check. Note: size calibration must be performed.

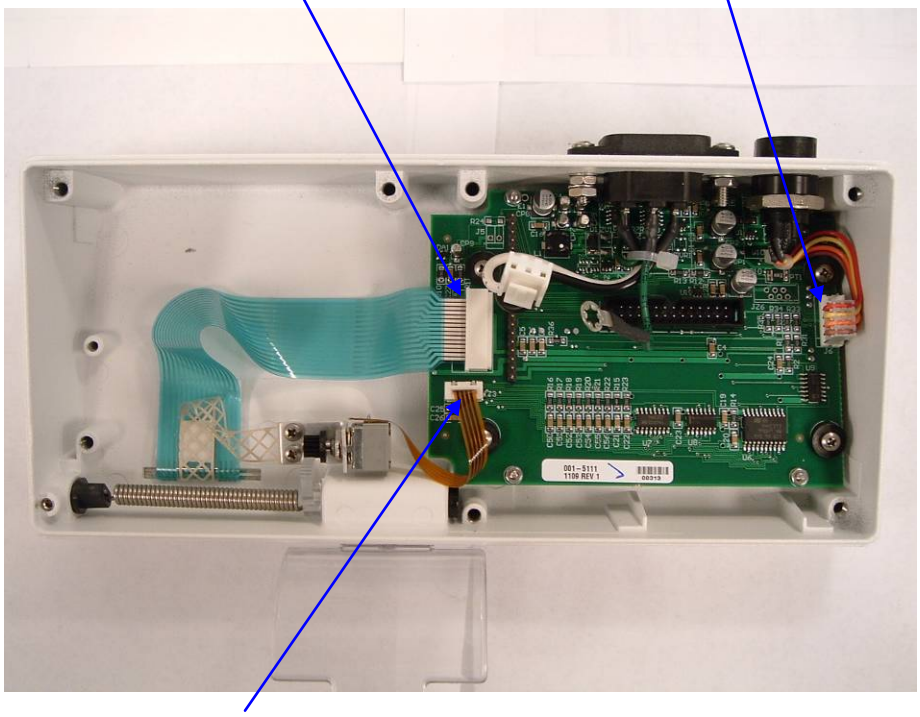
4. If replacing the keypad, remove the existing one and then completely remove any adhesive residue left on the top housing with isopropyl alcohol. Route the keypad cables through the slot in the top housing. Peel the backing from the keypad and place the keypad in the cutout area on the top housing. Route the keypad flex cable as shown and secure to the housing with double sided tape. Remove the backing from the overlay and place the overlay onto the housing and keypad in the cutout area.

5. Reinstall the top PCBA and LCD into the top housing. Check that the black spacers are set correctly on the top PCBA and then place the 4 each 4-40 X 7/16 screws through the spacers and PCBA/LCD, place a white plastic retaining washer over the end of the screws. Then place the PCBA/LCD into the housing and tighten the screws.

6. Reconnect the cables as follows:

Keypad cable to J2 and lock the ZIF retainer.

Communication cable to J6.
Note: top 2 pins unused



Size pot cable to J3 and lock the ZIF retainer.

7.5 Bottom housing disassembly

 **The following steps must be performed at an ESD safe workstation.**

1. Perform final unit disassembly as noted above.

2. The ac line fuses are located under the fuse cover. Remove the fuse cover. Remove the fuses and check if the fuse is open. Replace the fuses if needed. Reinstall the fuse cover.

3. Removal of main PCBA

   Tools required: Phillips #1 screwdriver

   Note: The flex cables are connected to Zero Insertion Force (ZIF) connectors. To disconnect, pull back on the ZIF retainer and then remove the flex cable from the connector.

   Disconnect the LED flex cable from J8.

   Disconnect the force flex cable from J2.

   Disconnect the encoder flex cable from J5.

   Disconnect the position pot flex cable from J4.

   Remove the 5 screws that secure the main PCBA to the bottom housing. Note the 1 middle screw is longer that the other 4.

   Start to remove the PCBA from the housing.

   On the bottom side of the PCBA, disconnect the speaker from J12 and the motor from J6.

   Completely remove the PCBA from the housing.

4. Removal of motor assembly

   Tools required: Phillips #1 screwdriver

   Remove the 2 screws that secure the motor to the bottom housing.

   Remove the motor from the bottom housing.

5. Removal of speaker assembly.

   Tools required: Phillips #1 screwdriver

   Remove the one screw that secures the speaker bracket to the housing.

   Remove the speaker and bracket from the bottom housing.

   Remove the speaker from the bracket by peeling off the double sided tape.

6. Removal of the position potentiometer. (pot)

   Tools required: Phillips #1 screwdriver

   Remove the 2 screws that secure the pot bracket to the bottom housing.

   Remove the pot and bracket from the bottom housing.

   Remove the hex nut that secures the pot to the bracket.

   Remove the pot from the bracket, retain the lockwasher.

7. Removal of the encoder sensor.

   Tools required: Phillips #1 screwdriver

   Remove the 2 screws that secure the encoder to the bottom housing.

   Remove the encoder from the bottom housing.

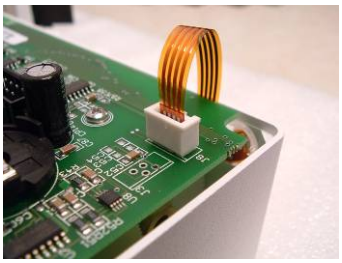
8. Removal of the syringe flange retainer.

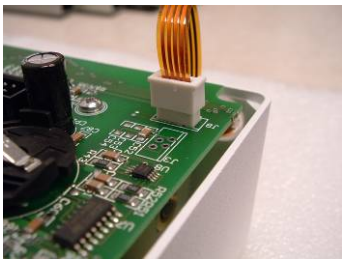
   Tools required: Phillips #1 screwdriver

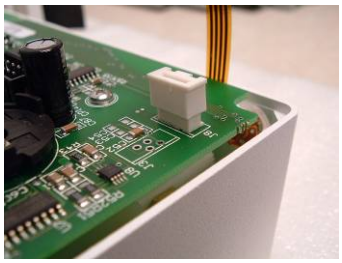
   From the underside of the retainer, remove the 2 screws securing the retainer to the saddle housing.

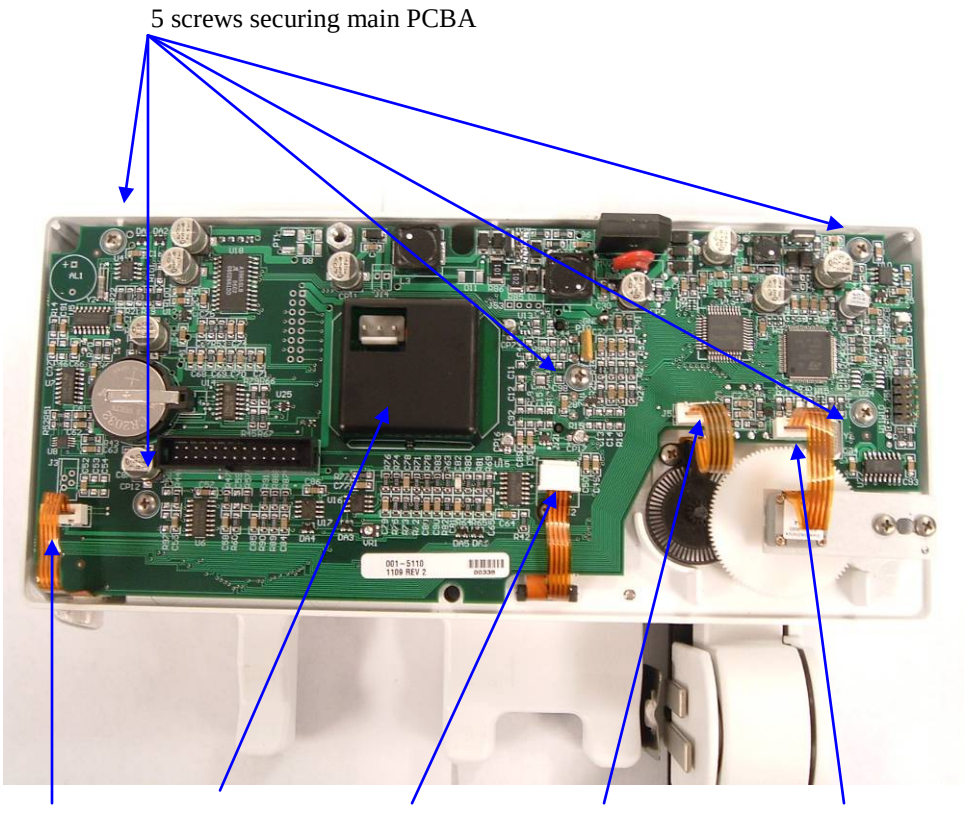
Remove the retainer. Note: Retain the plastic spacers/washers and make note of the placement between retainer and housing.

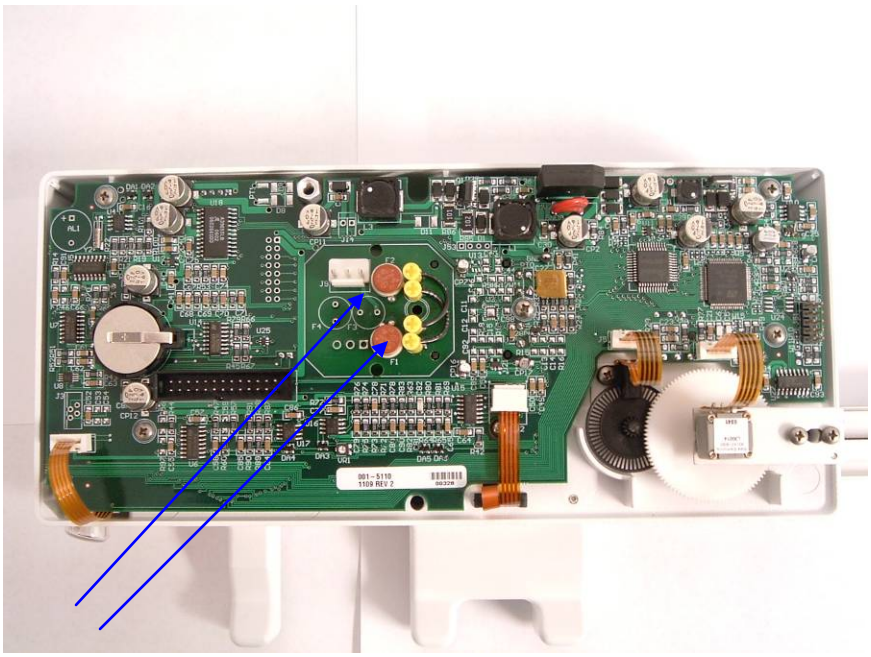
Reference the following pictures for the bottom housing.


ZIF connector down/locked

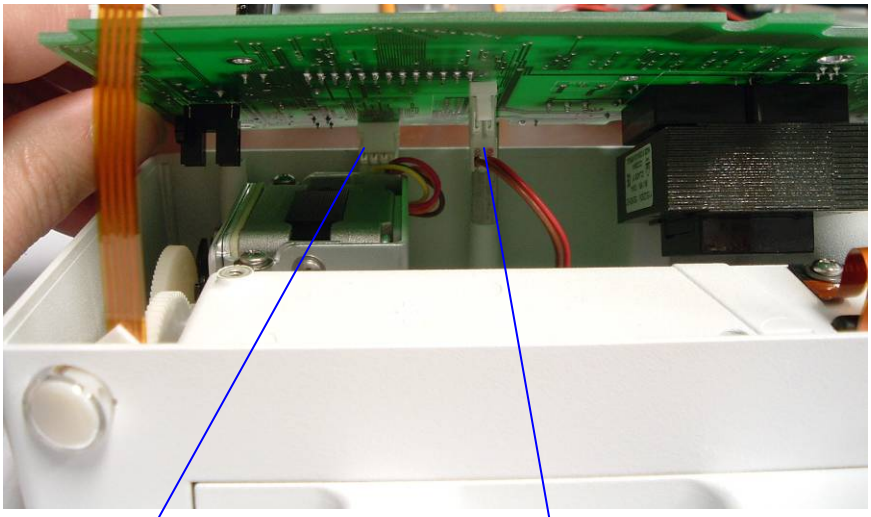

ZIF connector up


Cable removed from ZIF connector





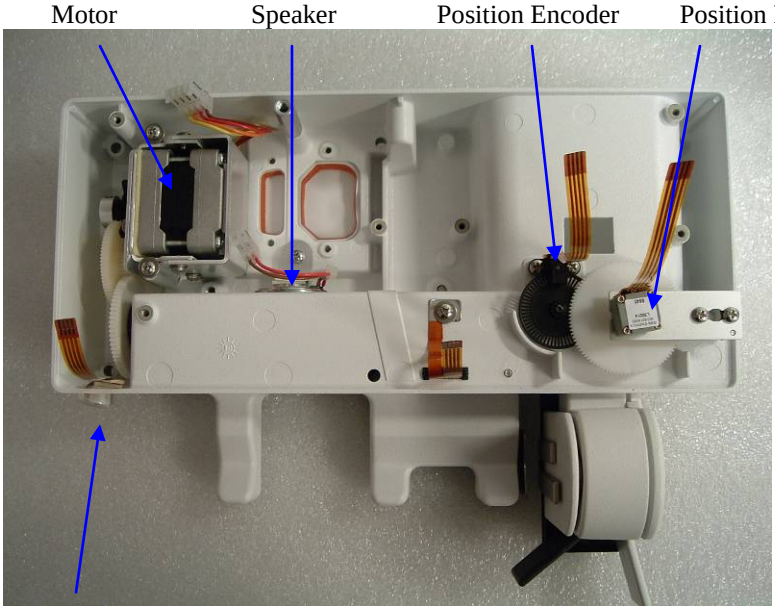
Fuses



Motor connector

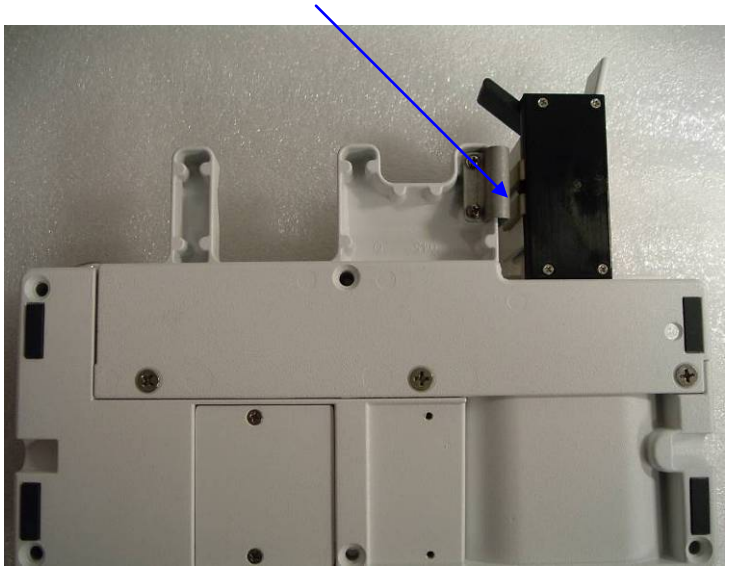
Speaker connector

Motor Speaker Position Encoder Position Pot



LEDs

Syringe flange retainer



7.6 Bottom housing reassembly

1. Reinstall the syringe flange retainer to the saddle with the two screws and washers, note that the screws go under the retainer.

2. Reinstall the encoder sensor to the bottom housing, position the sensor over/under the encoder wheel and then secure with the two screws.

3. Reinstall the position pot assembly to the bottom housing with the 2 screws. The position pot gear must be preset to the encoder gear at a value of 0A – 1A with the track at the empty position. The value can be viewed in the system check mode, main menu page 3 of 3 then system check. Note: position calibration must be performed.

4. Reinstall the speaker to the bottom housing with the one screw.

5. Reinstall the motor to the bottom housing with the two long screws and washers. The motor and its gear must be meshed with the leadscrew gear correctly to prevent excessive drag on the motor. This can be checked by using a power supply to the unit and measuring the unit current input while running max rate with a BD 60cc syringe.

6. Reinstall the main PCBA to the bottom housing. Connect the speaker to J12 and the motor to J6. Then carefully position the PCBA onto the bottom housing. Then secure the PCBA with 4 small screws and the one long screw. Then connect LED flex cable to J8, force flex cable to J2, encoder flex cable to J5, and the position pot flex cable to J4. Make sure to lock the ZIF retainers onto the connectors/cable.

7.7 Track and leadscrew removal.

 **The following steps must be performed at an ESD safe workstation.**

1. Perform final unit disassembly as noted above.

2. Track removal.

   Tools required: Phillips #1 and #2 screwdriver.
   5/32 hex allen driver

   Remove the 3 screws that secure the saddle to the bottom housing. Note: These 3 screws may have their plastic cup seals loose on the screws and not secured to the saddle housing. Retain these plastic cup seals.

Position the track at approximately midpoint of travel on the bottom housing.

Start to remove the saddle, remove the one screw that secures the green ground cable to the saddle.

Remove the saddle from the bottom housing. Note at reassembly that the saddle needs to remain aligned with the bottom housing.

Remove the 2 screws on the back of the transducer housing and remove the plate. **Caution:** Do not operate the clutch lever while the transducer back plate is removed. The seal should come off with the plate.

Remove the 1 phillips screw securing the flex ground cable to the housing.

Pull back on the ZIF retainer of the flex cable, and then remove the flex cable from the connector. Place the flex cable down into the channel of the track.

To remove the force sensor assembly: Remove the top #10-32 screw with the 5/32 hex allen driver. With this screw removed the transducer front plate and retainer housings will also be removed from the assembly. Then remove the bottom 10-32 screw. The forces sensor assembly can then be removed.

To reinstall the force sensor assembly: Install the force sensor assembly into the transducer housing. Center the force sensor assembly and secure with the bottom 10-32 screw, do not completely tighten this screw at this time. Ensure that the transducer seal is in place on the front of the housing. Rotate the plunger cam so the arm is pointing to the back, the slot on the cam should then be pointing to the front. Install the transducer plate/retainer housings onto the transducer housing. Engage the pin on the retainer housing with the slot in the plunger detector cam. Secure the plate to the housing with the top 10-32 screw. Do not fully tighten at this time. Check that the cam arm is centered in the sensor. Fully tighten both screws. Note: Force calibration must be performed.

Replace the plate and seal onto the housing and secure with the 2 screws.

Squeeze/actuate the clutch lever and slowly and carefully pull the track off of the leadscrew and the bottom housing.

Remove the screw that is securing the track green ground wire to the bottom housing.

3. Leadscrew removal

Tools required: 2 each 7/16 open end wrenches

Use one wrench and retain the hex nut at the gear end of the leadscrew.

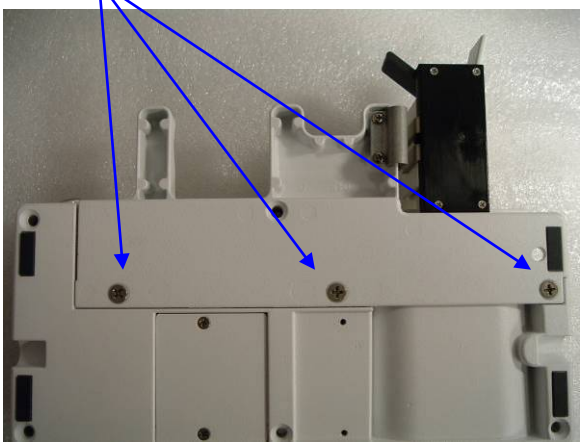
Loosen the other hex nut just inside the bottom housing at the end of the leadscrew.

Unscrew remove the leadscrew from the gear/nut. Check that the wave spring washer is retained.

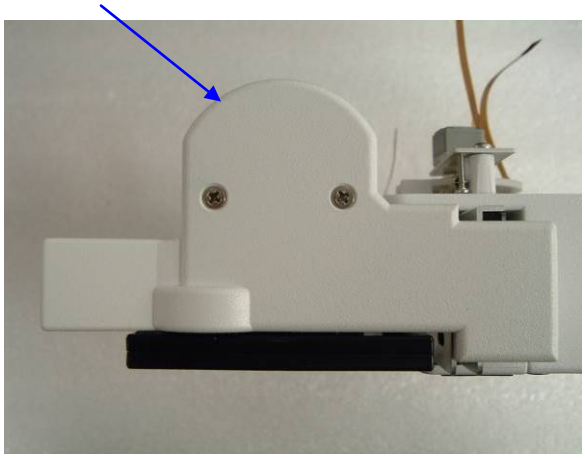
If removing the leadscrew gear, simply pull off. Note the 3 part bearing next to the gear.

Reference the following pictures for the track and leadscrew.

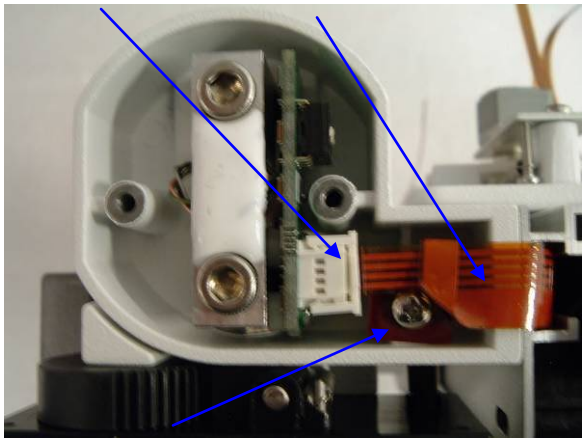
Saddle 3 screws



Transducer housing



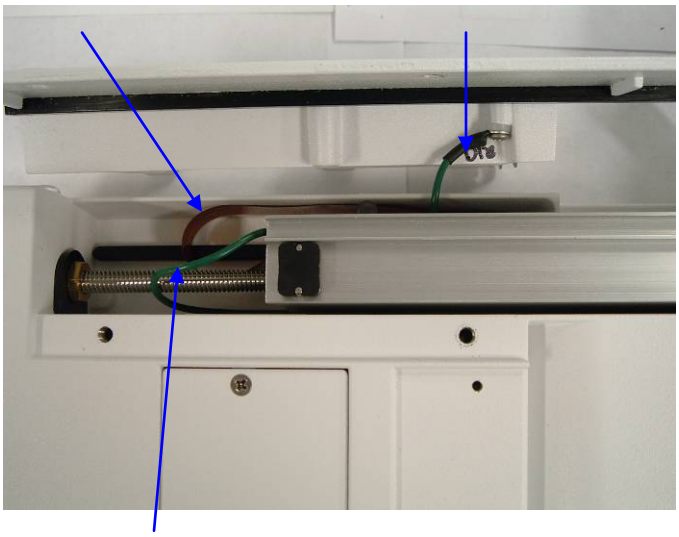
ZIF connector Flex cable



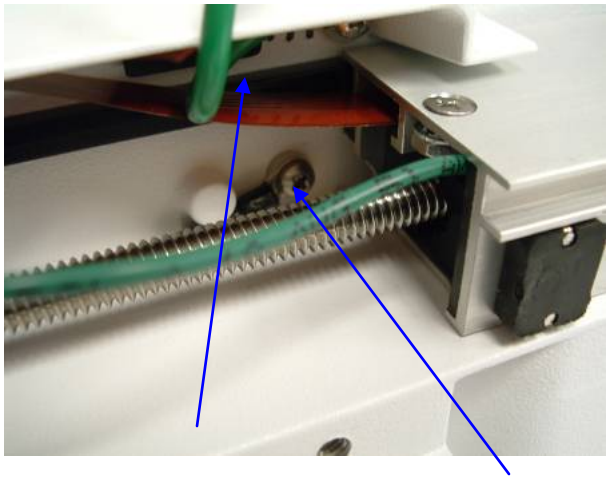
Screw securing flex ground cable

Note: saddle removed for clarity

Flex cable Saddle Ground wire

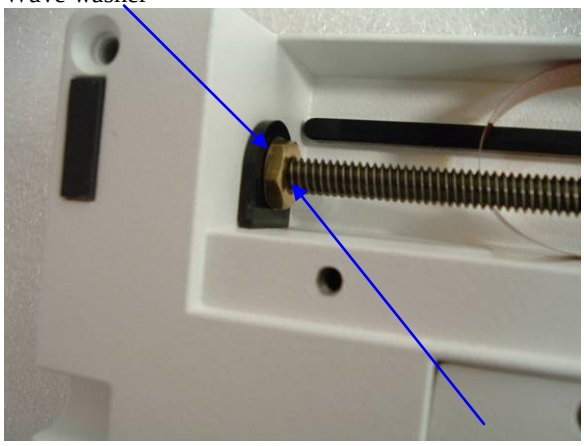


Track ground wire



Saddle ground wire Track ground wire

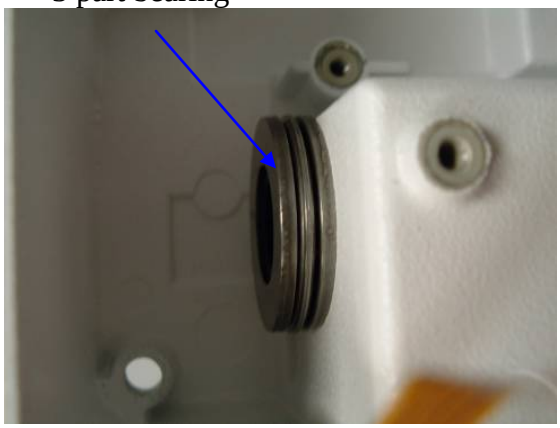
Wave washer



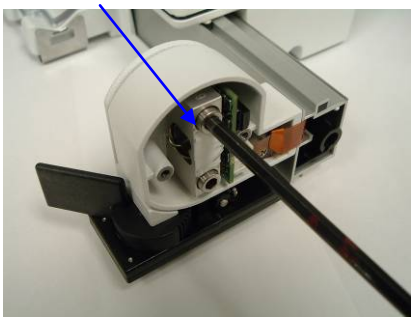
Loctite 242 threadlocker

Leadscrew hex nut and gear

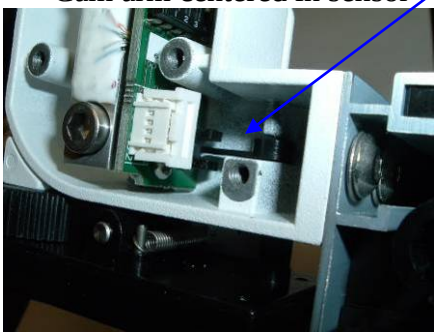
3 part bearing



Force sensor assembly



Cam arm centered in sensor



7.8 **Leadscrew and track reassembly**

1. Install the leadscrew nut onto the leadscrew and then place the wave spring washer on the leadscrew.

2. Install thread the leadscrew with wave washer and nut through the black bushing in the bottom housing and onto the gear/nut. Check that the wave washer is still centered on the leadscrew and then tighten both hex nuts. Place a drop of Loctite 242 threadlocker on the leadscrew nut.

3. Position the track onto the bottom housing and leadscrew, feed the flex cable into the channel of the track.

4. Squeeze the clutch lever to open the clutches and install the track to approximately mid point of travel.

5. Remove the 2 screws retaining the transducer plate and then remove the plate.

6. Reconnect the flex cable to the ZIF connector and secure the ground portion of the cable to the housing with the screw.

7. Check that the transducer housing seal is in place and reinstall the plate to the housing and secure with 2 screws.

8. Place the track to approximately full travel to expose the screw point for the track ground wire. Reinstall the track ground wire. Note: The plastic spacer washer goes under the ring terminal.

9. Position the saddle under the bottom housing and reconnect the green ground cable. Note: The plastic spacer washer goes under the ring terminal.

CAUTION! Ensure the green ground cables are reconnected to maintain proper ground safety.

10. Reinstall the Saddle to the Bottom housing using the 3 saddle screws, ensuring that the plastic Cup Seals are over them.

Note: Position calibration must be performed.

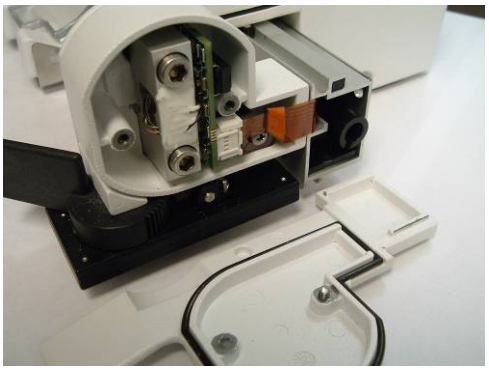
7.9 **Retainer cluster gear and shoulder bushing removal and installation**.

Tools required: Philips #0 screwdriver
5/32 hex driver
3/32 hex driver

1. Power off the unit, disconnect the line cord from the unit. Place the unit with the plunger retainer extended toward you.

2. Remove the 2 screws securing the cover to the transducer housing.

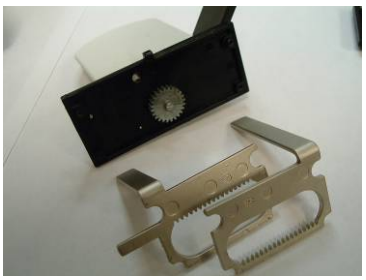
3. Remove the Phillips screw securing the transducer ground cable. Then release the latch on the ZIF connector, disconnect remove the cable from the connector.

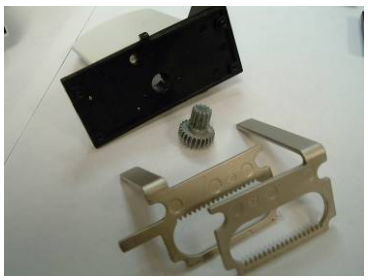


4 Remove the top hex head screw, this will allow the front plate and retainer housings to be removed from the transducer housing.

5. Turn this assembly over and (remove the tamper labels if present) then remove the 4 screws securing the retainer bottom.

6. Remove the long retainer bar, remove the short retainer bar, remove the gear. If plastic gear, this will not be reused.



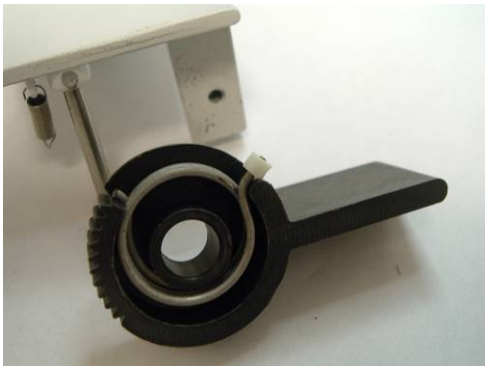


7. Place the front plate and retainer top right side up with the front plate away from you.

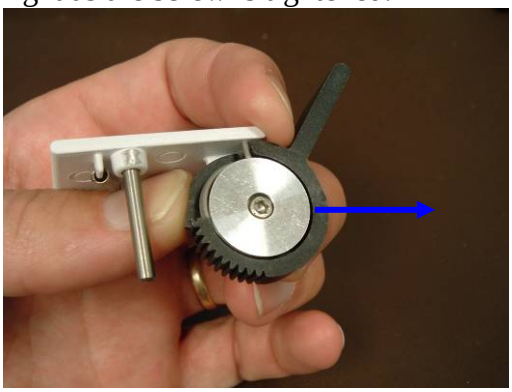
8. Remove unhook the spring from the pin in the retainer top. Then slide the front plate out of the retainer top.

9. Place the front plate upside down and remove the hex head screw securing the bushing/spring/handle. If plastic bushing, this bushing and screw will NOT be reused.

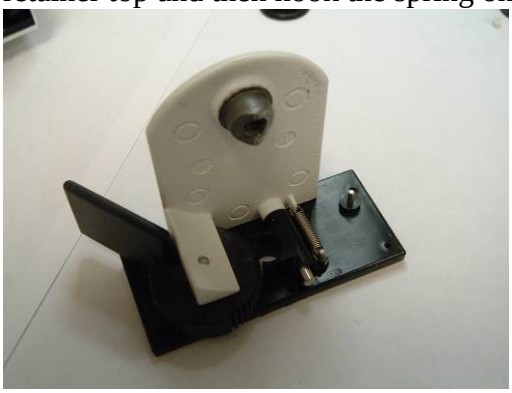
10.Remove the white spacer from the end of the spring, this space will NOT be reused.



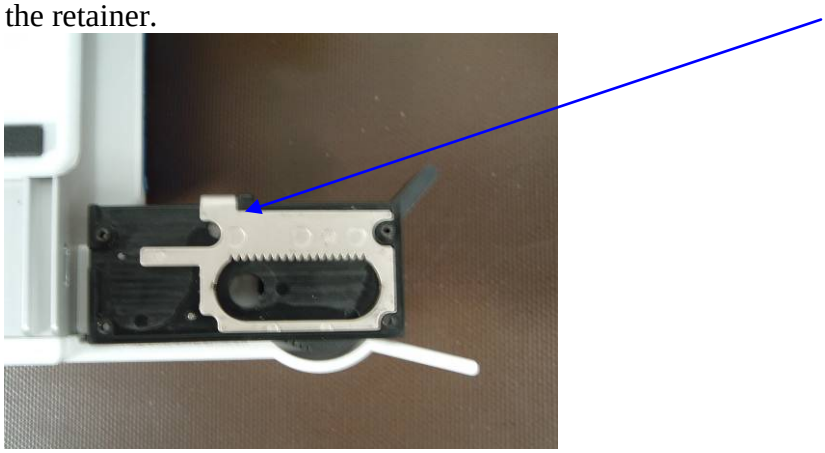
12. Install/place the end of the spring into the small hole in the front plate. Place the new metal bushing with the longer screw into the handle. Bias the handle to the right as the screw is tightened.



13. Place this assembly back into the retainer top, slide the pin into the hole in the retainer top and then hook the spring onto the pin.

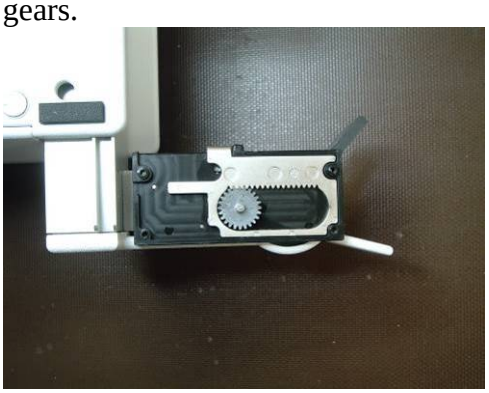


14. Install/replace the short retainer bar. Place the retainer bar completely to the right in the black retainer top. The bar should be up against the stop on the front of the retainer.

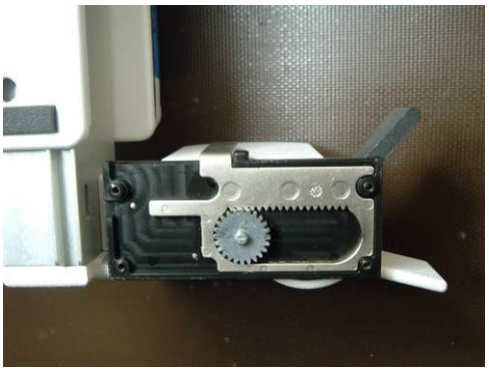


15. **IMPORTANT !** Move the black retainer top (with the retainer bar) toward the back, it will move approximately 1/8 inch, which will place the retainer bar up against the transducer front plate.

16. **IMPORTANT !** While holding the retainer in this position, install the metal cluster gear (small gear first) into the retainer, if the gear does not drop right in, recheck step #12. The larger gear teeth will engage with the gear teeth of the retainer bar. If the teeth do not line up, rotate the gear counter clock wise, to line up the gears.

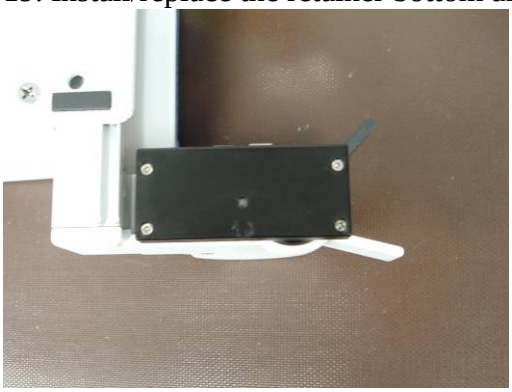


17. Check that the retainer bar is still up against the transducer front plate.



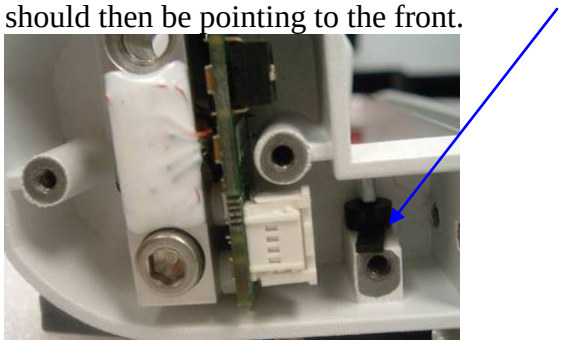
18. Install/replace the long retainer bar. Place the retainer bar completely to the left in the black retainer top. The bar should be up against the stop on the front of the retainer.

19. Install/replace the retainer bottom and secure with the 4 screws.

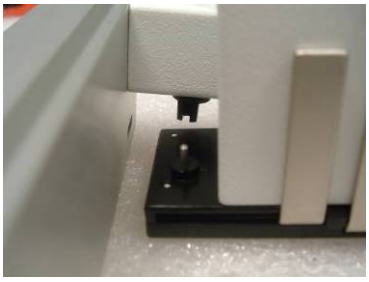


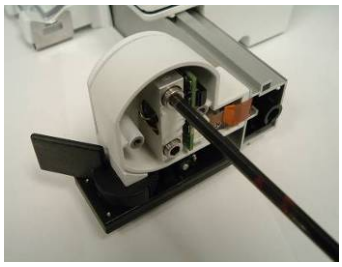
20. Loosen the bottom hex screw in the trandsducer housing. Place the centering tool through the hole in the housing and then into the top hole of the transducer. Then tighten the bottom screw. Remove the centering tool.

21. Rotate the plunger cam so the arm is pointing to the back, the slot on the cam should then be pointing to the front.

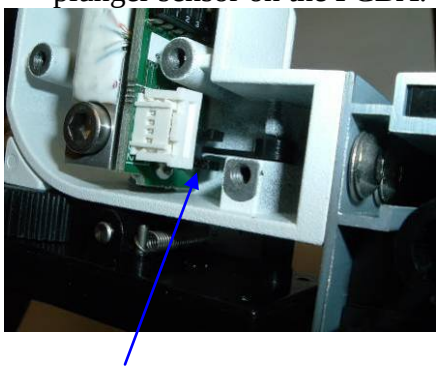


22. Place the transducer seal into the hole of the transducer housing. Then install the transducer plate / retainer housings onto the transducer housing. Engage the pin on the retainer housing with the slot in the plunger detector cam. Secure the plate to the housing with the remaining hex head screw. Reconnect the transducer cable to the connector, lock/latch the connector and secure the ground portion of the cable to the housing with the screw.

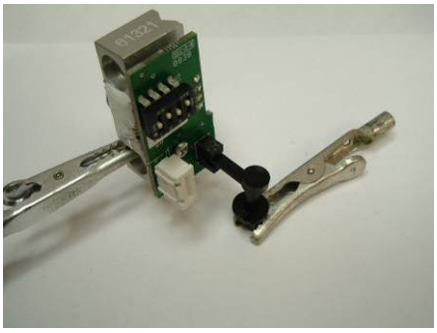




23. With the retainers back against the plate, check that the cam arm is centered in the plunger sensor on the PCBA.

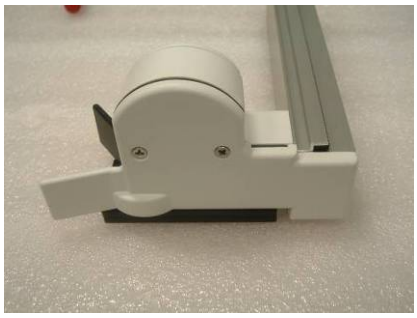


Centered in sensor



Reference only

24. Place the transducer housing seal onto the inside of the transducer housing cover. Place the cover and seal over the back side of the transducer housing and secure with 2 each screws.



25. Check the operation of the retainers as follows:

Slightly squeeze pinch the black lever toward the white extension piece of the Transducer Back Plate, the black retainer base/housing and retainer bars should first move outward away from the front plate.

Then as you continue to squeeze/pinch the lever up against the white extension piece, the retainer bars should then move in opposite directions away from each other and all the way out. At this point the clutch should be open and you can then move the retainer/track in or out. If the retainer bars do not move all the way out or if the lever does not reach the white extension piece then the timing of the gear is not correct and must be redone.

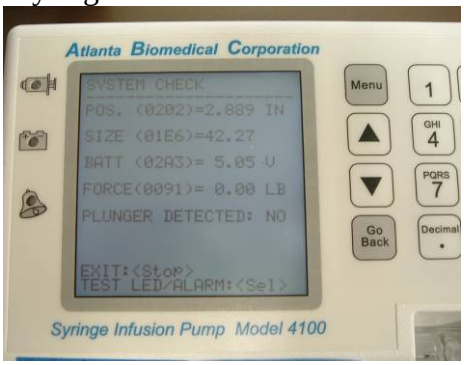
26. Test the timing and operation of the plunger detector as follows:

Power on the unit and using the menu key, go to main menu page 3 of 3.

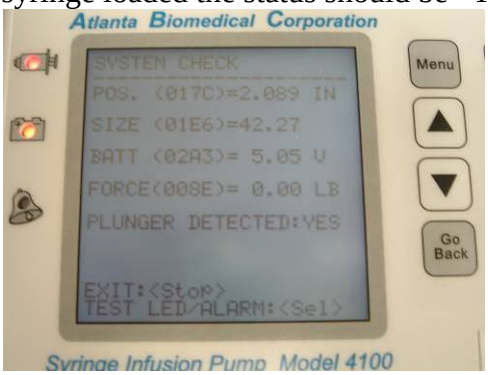
Select/Enter <9> SYSTEM CHECK

Then observe the PLUNGER DETECTED line on the screen.

With no syringe loaded the status should be “NO”



With a syringe loaded the status should be “YES”



If this is not correct, recheck the timing of the gear in step 16.

Section 8: ABC Model 4100 Service Manual
Theory of Operation

1. Introduction:

ABC Syringe Infusion Pump Model 4100 provides a continuous or bolus infusion in neonatal and pediatric intensive care, anesthesia, adult critical care or any other area where the pump use can be monitored or supervised by a trained healthcare professional. Syringe pumps are typically used when safe and precise administration of fluids contained inside a syringe is required. Infusates include drugs, antibiotics, lipids, blood, blood products, enteral solutions, or other therapeutic solutions. The pump must be friendly to the user and easy to operate. Various sensors are required to minimize user error or to detect questionable device operation to enhance patient safety.

The design of this new syringe infusion pump attempts to include the following features:

- Front syringe loading and one hand operation to actuate clutch and to secure the syringe plunger
- Wider size sensing range (1cc to 140cc) and higher motor driving torque and rate
- Battery pack can be removed externally
- Metal Housing for durability and rigidity
- Water-resistant seals
- Improved serviceability with replaceable modular units

2. Description of Hardware System

2.1 Hardware Components

The Hardware system is divided into two major sub-assemblies (S/A): Top S/A, Bottom S/A. A battery pack can be installed or removed externally without a tool. The major system components and their interconnection are shown in the **SYSTEM BLOCK DIAGRAM**. See Appendix 1.

The Hardware components are organized as below:

2.1.1 Top Housing S/A:

Top Housing, Keypad, Size Sensor S/A, AC Inlet S/A, Communication Port Cable
Top Printed Circuit Board (PCB) & LCD S/A

- Keypad is mounted on the outside surface of the Top Housing and covered with overlay.
- AC inlet S/A and Communication port are mounted on the back side of the Top Housing.
- Size sensor S/A, mounted on the inside of the Top Housing, consists of a potentiometer engaged with a gear to a syringe clamp holding down the syringe barrel to detect the size of the syringe.
- Top PCB S/A, mounted on the inside of the Top Housing, receives the connectors of the keypad, size sensor, and communication port. An LCD display module is mounted on the Top PCB S/A. A ribbon cable connects and provides communication between the Top PCB S/A and Main PCB S/A on the Bottom Housing S/A.

2.1.2 Bottom Housing S/A:

Bottom Housing, Syringe Saddle S/A
Syringe LED S/A, Speaker S/A
Main PCB S/A

Motor S/A:
Motor, Motor Mount, Motor Pinion, Cluster gear

Leadscrew Sub-system:
Leadscrew, Leadscrew Gear, Leadscrew Bushing, Leadscrew Bearing

Position Sensor Sub-system:
Position Pot S/A
Position Encoder S/A
Position Encoder Wheel/Pinion
The Position Pinion engaged with Position Gear Rack assembled onto Track to monitor the proper track movement. The Position Encoder Wheel provides signal for the Encoder and drives the Position Pot.

Track/Transducer S/A:
Track
Position Gear Rack

Clutch Sub-system:
Clutch Half Nut Pair, Clutch Cams, Clutch Tube, Clutch Pusher
The cutch halves can be opened to engage or closed to disengage with Leadscrew via a Clutch Handle in the Plunger Retaining Sub-system.

Transducer Sub-system:

Transducer Housing
Transducer Housing Cover
Transducer Plate
Force Transducer
Force Transducer PCB S/A
Force Sensor Cable

The Force Transducer is mounted on the Transducer Plate to detect the pushing force at the back of the syringe plunger. The Transducer PCB amplifies the transducer signal and also has a encoder to detect the syringe plunger detector. These two signals are sent to main PCB via Force Sensor Cable.

Plunger Retaining Sub-system:

Retainer Housing
Retainer Bars
Retainer Cluster Gear
Clutch Handle, Clutch Torsion Spring
Syringe Plunger Detector

Clutch handle engages cluster gear to move the retainer bars to secure the syringe plunger onto the Transducer Plate. One of the retainer bars is also used to actuate the Clutch halves via the Clutch actuation linkage parts. Plunger detector parts provide the status of the engagement of the retainer bars with the syringe plunger.

The Syringe LED S/A, Speaker S/A, Speaker S/A, Position Encoder S/A, Position Pot S/A, are assembled onto the Bottom Housing. Then, Motor S/A and Leadscrew Sub-system and Force cable are assembled. The Track/Transducer S/A and Saddle S/A are then assembled with the Bottom Housing. The Main PCB S/A is the last one to be mounted onto the Bottom Housing.

2.1.3 Battery Pack:

Battery Housing, Battery pack, Battery PCB S/A, Battery Thumb Screw

2.2 PCB Assemblies

2.2.1 Main PC Board S/A

This is the brain of the pump. It coordinates the AC and battery power for the system. The microprocessor drives the motor, receives signals from the sensors, communicates with LCD module and keypad on the Top S/A, and controls the audio alarm and LED indicator.
A Motor shaft rotation sensor and a Battery contact are mounted on the Main PCB. Power transformer and fuses are also on the Main PCB.

2.2.1.1 Power Supply

(1) AC power is applied to the transformer XF1 via a connector and fuses F1 & F2. The output AC voltage from the transformer is full-Wave rectified to unregulated DC voltage **+VY**.

(2) A step-down switching regulator converts +VY voltage to a regulated voltage +VX **(6.2V)**.

(3) Battery power (**BAT+**, about **5.0V** when fully charged) and +VX jointly supply the power **+VZ** for the device.
If AC power is ON, VX is higher than BAT+ and thus, VX power is used. When AC power is removed (VX=0), BAT+ will supply power to VZ.

(4) A step-down switching regulator converts VZ to a constant DC voltage **+VA (5.5V)**.
VA remains at 5.5V when battery power BAT+ is used. VA increases to 5.8V when AC power is ON (VX, 6.2V) is used. If AC line voltage drops from 115V to 90V, step-down regulator can no longer maintain VX at 6.2V. As long as VX does not drop below BAT+, power from VX will be used. If battery is not present and AC power drops to 90V, then step-up regulator steps up voltage from VX to maintain 5.5V at VA.

(5) Distributed Power:
DC voltage VA is distributed to various circuits for further conversion to other voltages (+5V and +3.3V).

(a) **+3.3M (3.3V)** is provided by a regulator to supply a stable DC power to Microprocessor and to reference diode to provide a system reference voltage **VREFX (2.5V)** to calibrate ADC readings.

(b) **+5M (5V)** is provided by a regulator to supply a stable DC power to microprocessor, PPI chip, Real-Time circuit and analog circuits: ADC chip, Size sensor, and Position Sensor.

(c) **+5M1 (5V)** is provided by a regulator to supply a stable DC power to other peripheral devices: alarm circuit, watchdog circuit, digital sensors, drivers, battery charging circuits, and motor driver logic circuit. Motor driver uses voltage VA directly.

(d) **+VSN (5V)** is generated by a regulator for the power to Force Transducer PCB.

2.2.1.2 Microprocessor System

(1) Microprocessor: ST Microelectronics uPSD 33334DV-40U6 is used. It has the following features:

(a) Fast 8-bit 8032 core microprocessor with reduced machine cycle time per instruction with relatively low power consumption.

Variety of peripherals:

(b) **Two UART ports** for serial communication

(c) Three 16-bit standard 8032 timers

(d) **256K-byte Main Flash Memory** divided into Eight 32K-byte sectors, for program code and archived history records.

(e) **32K-byte Boot Flash Memory** divided into Four 8K-byte sectors, for booting code and storage for system parameters, library, and current history records.

(f) **8K-byte Static RAM (SRAM)** for general purposed use. It can be made non-volatile with battery back-up.

(g) Very Flexible Address Decoding Circuit to allow dynamic configuration of memory during boot-up and normal operation.

(h) Built-in JTAG circuit to simplify Software Debugging without expensive Emulator.

(2) Additional I/O Ports: The microprocessor does not provide enough I/O port lines to control various circuits. A Programmable Peripheral Interface chip (PPI, Intersil 80C55A) provides additional 24 I/O port lines.

(3) System Clock: A 11.0592MHz crystal is used with microprocessor and to generate the baud rate for serial communication.

2.2.1.3 Real-Time Clock

Dallas Real-Time Clock IC (DS1337) is used to provide system real-time clock. It uses 32.768KHz watch crystal to provide signal to Counter IC (4060) to generate 32Hz and 2048Hz signals. 32Hz signal is constantly compared with system clock to assure its accuracy. 2048Hz signal is for the audio system malfunction alarm.

2.2.1.4 Motor Driver Circuit

Allegro IC (A3965SLB) is designed for battery operation with low logic supply current. It uses PWM (Pulse-Width-Modulation) method to control the power to the Stepper Motor. With this feature, the motor current consumption at low infusion rate can be greatly reduced to save battery power while providing more than ample power to drive the specified load.

2.2.1.5 Alarm / LED Circuit

(1) Watchdog Circuit:
A mono-stable logic IC (4538) serves as watchdog circuit. It will trigger system malfunction LED/alarm and shut down motor power if it does not receive pulses from microprocessor within a specified time period.

(2) Audio alarm Circuit:
Audio amplifier (TI TPA301) and a Speaker provide the audio alarm. The microprocessor generates a variable frequency signal to the amplifier to generate variable frequency alarm. Logic IC (4052) and resistors provide 3 volume settings (Low, Normal, High) for the alarm.

(3) LED Circuit:

(a) **Syringe Light**: the Bi-Color LED indicator on the Bottom Housing is driven by a driver to illuminate the syringe so that the delivery status is visible when the surrounding lighting is dim.

(b) **System Malfunction**: the Red LED on Top Housing is turned on by a driver with signal from the Watchdog circuit.

(c) **Pump/Syringe Status**: Tri-color LED on Top Housing provides the Red, Green, Yellow signals for various Pump/Syringe conditions. This LED is driven by a latch IC on TOP-PCB (74HC373).

(d) **Battery Status**: Tri-color LED on Top Housing provides the Red, Green, Yellow signals for various battery conditions. This LED is driven by a latch IC on TOP-PCB (74HC373).

2.2.1.6 Battery Charging Circuit

(1) There is a 4-pin battery contact mounted on the underside of Main PCB to connect the battery pack: **(1)BAT+, (2)TEMP, (3)RES, (4)GND**.

(2) The charging circuit on the Main PCB consists of a dedicated controller IC (TI BQ2000T), and supporting IC, FET (IRFU5505), Inductor and other resistors / capacitors. The charging circuit senses the temperature of the pack to determine the charging status of the battery. It is also used to indicate the presence of the battery pack. Microprocessor also monitors the temperature and voltage of the pack to assure proper battery charging.

A current sensing resistor allows charging controller IC to modulate FET to regulate the charging current. This resistor senses the total of battery charging current and system current. Thus, if more current is used for the motor, less current will be used to charge the battery. A variable resistor is used to calibrate the total current to a specified value, thus, limiting the maximum battery charging current.

2.2.2 Top Board S/A

Power and Control signals to the Top PCB are sent from Main PCB via 26-pin flex cable. The control signals includes Bus **EBUS(0-7)** to LCD module, Keypad scanning, and Latch. The major circuits on the Top Board S/A are the following:

2.2.2.1 Power ON/OFF circuit

The Power ON & OFF keys on the Keypad actuate the latching circuit to provide a signal **KEYON** to Main PCB to signal the Pump Power status.

2.2.2.2 TOP PCB Power Supply Circuit

The power supply circuit converts power source **VA** from Main PCB to 5V regulated voltage, LCD bias voltages.

(1) **+5MX (5V)** is provided by a regulator to supply regulated voltage to the LCD module and the most of the circuits on Top PCB.

(2) **-VEE (-12.5),** for LCD bias voltage, is generated from +5MX by voltage converter IC's.

2.2.2.3 Backlight Driver Circuit

The power to the LCD backlight is generated by a switching power supply consisting of controller IC (NCP1406) and an inductor. Microprocessor controls the light intensity of the backlight (OFF, LOW, and HIGH) via Latch (74HC373).

2.2.2.4 Keypad circuit

The keypad consists of a 4 rows and 7 columns switch matrix and two special keys for power control of the pump. The keypad is connected to the TOP-PCB. Buffer and Multiplex IC's (74HC257, 74HC05) are used for scanning the Keypad. Control signal **KEYS*** from Main PCB is used to read the keypad data to EBUS.

2.2.2.5 Latch IC

Latch IC (74HC373) is used as expansion of I/O port to drive LED indicators and various control signals to LCD backlight, RS-232 circuit. **LE** signal enables the data on EBUS to the latch.

2.2.2.6 RS-232 driver

Converter IC (MAX3311E) converts the TTL RX/TX from the Main PCB to RS232 level for communication port.

2.2.2.7 A customized graphic LCD module

The LCD module is mounted on the Top PCB. The module has 128x128 pixels and with on-board controller provides the visual display for user interaction. It can also display 16 row 21-character text lines. Microprocessor communicates with LCD controller via 8-bit parallel data bus (EBUS0-7) and other control signals.

2.2.3 Force Transducer PCB S/A

The Force Transducer PCB provides amplified signal of the Force Transducer and Plunger Detecting signal to the Main PCB.

(1) Force Sensor Amplifier (INA126) is configured as an instrumentation amplifier to amplify the differential signal from strain gauge mounted on the Transducer Plate pushing the syringe plunger. A Dip switch is used to adjust the offset voltage of the amplifier.

(2) Plunger Detecting Opto-interrupter senses the presence of the plunger detector arm to determine if the syringe plunger is properly retained by the plunger retainer bars.

(3) ZIP Connector J2 sends the amplified force signal and the plunger detecting signal to Main PCB via the Force cable.

2.2.4 Battery PCB S/A

The Battery PCB provides the gold plated contact fingers for the battery charging contact from the Main PCB. 3 wires (BAT+, GND, TEMP) from the Battery cell S/A terminals and the thermistor inside the Battery cell S/A are soldered onto this PCB to be routed to the contact fingers. There is a resettable fuse for over-current / short-circuit protection.

2.3 Electrical Interconnection:

2.3.1 Connection form Top Housing to Top PCB S/A:

(1) Keypad Cable
(2) Size sensor cable
(3) Communication Port Cable

2.3.2 Connection from Bottom Housing to Main PCB S/A

(1) Position Encoder cable
(2) Position Pot Cable
(3) Speaker Cable
(4) Motor Cable
(5) Syringe LED Cable
(6) Force Cable

2.3.3 Connection between Top Housing S/A and Bottom Housing S/A

(1) AC input Cable
(2) Top PCB S/A Cable

2.3.4 Safety Grounding

(1) Ground wire from AC input connector to Top Housing
(2) Ground wire from AC input connector to Hex Standoff on Bottom Housing
(3) Ground wire from Saddle to Bottom Housing
(4) Ground wire from Track S/A to Bottom Housing

2.4 Sensors

This section summarized various sensors implemented inside the pump:

2.4.1 Syringe Barrel Size Sensor: (Top Housing)

A potentiometer mounted with size sensing pinion engaging with the gear to the syringe clamp to translate the syringe barrel diameter to an analog signal to determine the size of the syringe.

2.4.2 Syringe Plunger Force Sensor, and Detector: (Transducer Housing S/A)

(1) Force Sensor: Force Sensor is a double-beam aluminum part with a strain gauge sensor. It is used to sense the force by Transducer plate pushing the syringe plunger.

(2) Plunger Detector: This detector senses the presence of the plunger detector arm to determine if the syringe plunger is properly retained by the plunger retainer bars.

2.4.3 Motor Shaft Rotation Sensor: (Main PCB S/A)

An opto-interrupter, mounted on the underside of Main PCB S/A, senses the vans of the disc mounted on the motor shaft to determine if motor is turning at proper speed and correct direction.

2.4.4 Track Position Sensors: (Bottom Housing)

(1) Position Opto-Encoder: A pinion/encoder wheel (with bars and gaps) engages the gear rack on the track to translate the movement of the track. The bars and gaps on the encoder is sensed by an opto-interrupter to provide a digital signal for the incremental movement of the track.

(2) Position Potentiometer: A potentiometer, mounted on the position pot gear engaging with the pinion/encoder, provides an analog signal of the absolute positional information of the track.

2.5 Handling Different AC Voltages in Foreign Countries

The current configuration of this device is for 115VAC line voltage. It can be configured for 220VAC by changing the jumper wires for the transformer XF1 and the size of the fuses (F1, F2). If the line voltage falls below 100VAC (e.g., Japan), then similar transformer with different secondary voltage should be used. The frequency of the line voltage does not affect the operation of this device.

3. Other related information

3.1 Mechanical Driving System

The rotating shaft of stepper motor translates into linear movement of the Tack via gear system and leadscrew. The syringe plunger is pushed by the Transducer Plate (mounted on the Track) when the clutch halves inside the Track are engaged with the leadscrew.

Motor shaft rotation (96 steps per revolution) to drive a motor pinion (64 pitch 20 teeth) and via a cluster gear (64 pitch 84 teeth / 48 pitch 18 teeth) to the leadscrew gear (48 pitch 72 teeth). Thus, a leadscrew gear rotation will need 1612.8 motor steps (96x (84/20) x (72/18). The leadscrew gear drives a leadscrew (20 threads/inch, double start, i.e., equivalence of 0.050" per leadscrew revolution) to move the Track S/A when the clutch halves are engaged with the Leadscrew. The Motor, Gearing system, and Leadscrew provide a combined resolution of 0.000062" per motor step (1"/16128). The Saddle housing has two stop ribs to allow a maximum traveling distance of the Track S/A of 5.6".

3.2. Factors affecting delivery accuracy of the pump

Stepping motor is used to drive the syringe. Each motor step advance is performed by the microprocessor at the motor timer interrupt. The motor timer is derived from the system clock. A separate clock is used to monitor the accuracy of the system clock.

Delivery Accuracy is determined by the following components:
(1) Accuracy of the system clock of the microprocessor
(2) Accuracy of Leadscrew
(3) Size sensor is used to determine the syringe size and the motor speed. Once the size is properly recognized, accuracy does not depend on sensors any more.
(4) All sensors are used only to confirm the system performance. No sensor feedback is used to maintain the motor speed or the delivery accuracy.

3.3 Description of Software relating to delivery accuracy

The main function of the device is to operate the stepper motor accurately and safely to drive the syringe plunger to deliver therapeutic fluids to the patient. This can be achieved by the following measures:

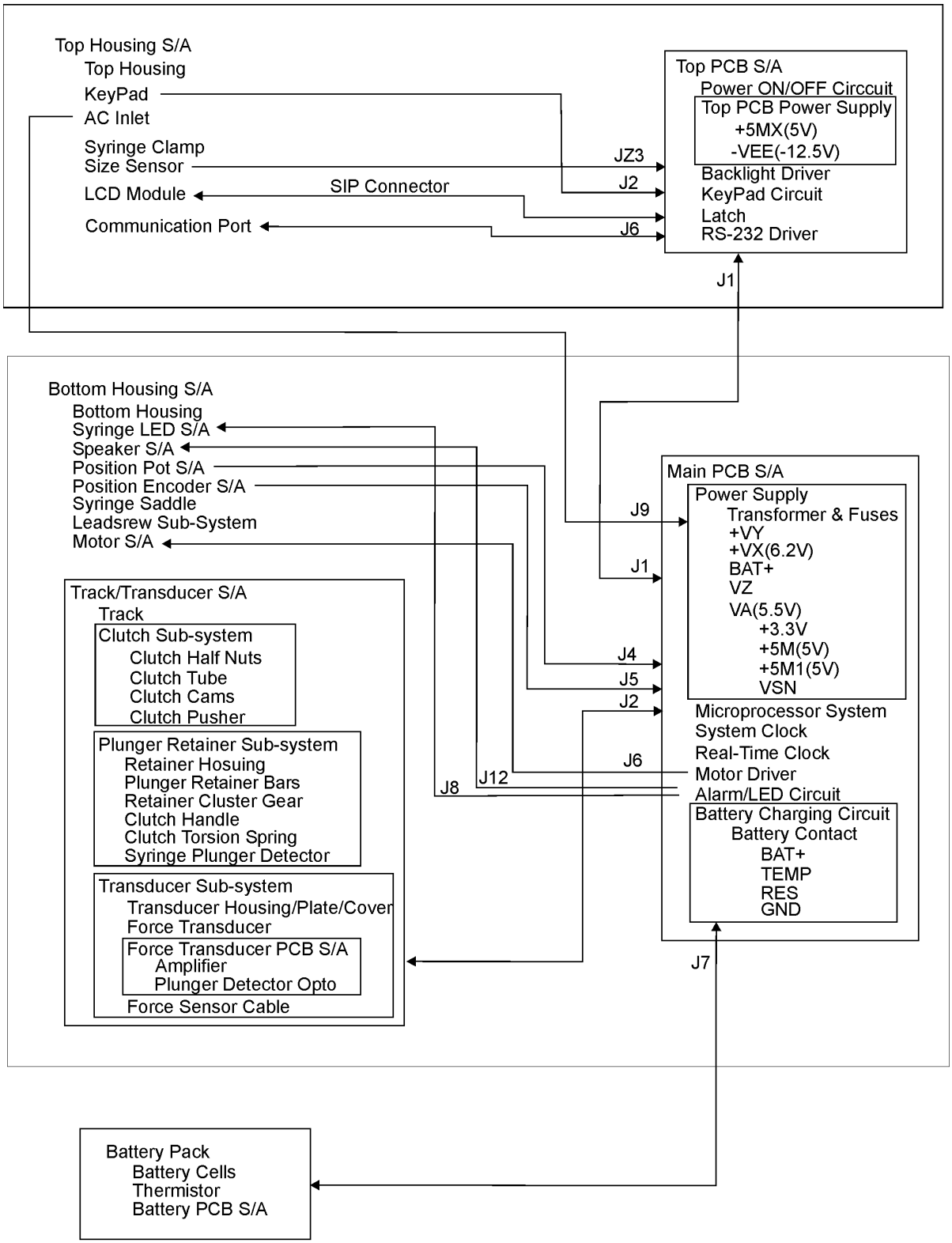
(1) Generating Accurate Data for Motor Control:
The data entered by the user together with the characteristics of the loaded syringe are used to calculate the **motor pulse rate** and to determine the **maximum pushing force** allowed at the syringe plunger.
   (a) Double calculation: The motor pulse interval conversion functions are executed twice and the identical results are verified.
   (b) Safeguard of the Motor pulse data with duplicated data and/or CRC code after the data are generated.

(2) Generating Accurate Motor Pulse from Motor Control Data
   (a) Since Motor Pulse Interval determines the motor speed, the delivery accuracy depends mainly on the correct conversion data and the accurate generation of the motor pulse interval by the Hardware/Software system.
   (b) The system uses a hardware timer and a timer interrupt function to generate the motor pulse. The timer is directly tied to system clock. Thus, the clock accuracy is directly related to the delivery accuracy.

(3) Monitoring the Progress During Delivery
Various mechanisms are used to detect possible errors during pump operation:
   (a) System clock accuracy is monitored by comparing with a 32Hz signal from an independent real-time clock.
   (b) The generated motor pulse is measured with another system timer to monitor its accuracy.
   (c) The integrity of motor pulse control variables are continuously monitored to detect any abnormal modification.
   (d) Various hardware sensors are used to monitor the actual output from the motor (i.e., motor shaft rotation and plunger movement). However, delivery accuracy does not depend on the sensors.
   (e) Additional sensors (Force, Size, Plunger detector) are monitored during delivery to detect any abnormal conditions (e.g., occlusion, syringe dislodged) to alert the user.

(4) Malfunction Detection
As a safety measure, any error above will trigger system malfunction to cut off motor power to stop pump delivery and place the pump in an alarm state.

APPENDIX 1:



SYSTEM BLOCK DIAGRAM