

Certification Exhibit

FCC ID: OF8-TM8D

FCC Rule Part: 47 CFR Part 95, Subpart H

ACS Project Number: 15-3052

Manufacturer: Life Sensing Instrument Company
Model: TM8D

Tune-Up Procedure

LIFE SENSING INSTRUMENT CO., INC.	WORK INSTRUCTION		EWI-2039 w/Attachments A, B C and D	
	LATEST REVISION DATE 2/1/13		PAGE NUMBER 1 of 8	
APPROVAL	DATE	Q. C. APPROVAL	DATE	
E. Money	11/27/12	C. Turner		

TM8D-(B)(W) ASSEMBLY AND TEST PROCEDURE

Revision A

DOCUMENT NUMBER: EWI-2039

SCOPE: The purpose of this document is to define the requirements for testing and assembling the TM8D-(B)(W) patient transmitter, part number I-1004. It is divided into three sections:

1. I-108 Programming, Alignment and Test Procedure (Attachment A)
2. M-104 Alignment and Test Procedure (Attachment B)
3. M-105 Alignment and Test Procedure (Attachment C)
4. I-1004 Final Assembly and Test Procedure (Attachment D)

APPLICABLE REFERENCE DOCUMENTS:

21 C.F.R., Part 820	Current Good Manufacturing Practices
ASTM D 3951-90	Packaging, Commercial
ANSI/ASQC Q9002	Quality Systems Model
ANSI/J-STD-001, Class 2	Requirements for Soldered Electrical and Electronic Assemblies
EIA RS-471	Symbol and Label for Electrostatic Sensitive Devices
ANSI/ASQCZ1.4	Sampling Plans for Attributes
47 C.F.R., Part 95	Personal Radio Services

Revision A changes:

First Issue

I-108 ALIGNMENT and TEST PROCEDURE

I. TEST EQUIPMENT REQUIRED

NOTICE

**ALL TEST EQUIPMENT WITH STATED ACCURACY MUST
BEAR A CURRENT CERTIFIED CALIBRATION NOTICE**

- A. Digital Multimeter, True RMS (AC volts), 4 1/2 digit minimum, 1% accuracy.
- B. DC ammeter, 5% accuracy.
- C. Oscilloscope, DC-10MHz minimum, 1% accuracy.
- D. Signal Generator, Sine Wave capable, .1-1MHz minimum range, 100ppm accuracy.
- E. Frequency Counter, DC-1MHz range, 10ppm accuracy.
- F. Power Supply, minimum 0-5 volt range at 100mA, maximum ripple, 5mV, 100ppm stability.
- G. Keil MCB900 Programmer.
- H. Flashmagic software program.
- I. Standard 9-pin male-to-female pin-to-pin serial cable.
- J. PC with Win95 or later OS.
- K. MT2051 Defibrillator test set.

II. INSPECTION

- A. Thoroughly inspect the board for possible assembly errors, such as defective or unsoldered joints, bridged pads/vias, component orientation and value or type, etc.
- B. If a modification suffix appears on the current bill of materials, determine that the mod level on the applicable subassembly is correct by referring to the applicable DCN file for details concerning the modification.
- I. Verify that the software version as listed in the TM8D console software program I-109 agrees with the version specified on the current bill of materials.

III. ALIGNMENT AND TEST

- A. Mount board onto the TM8D case header as outlined in the I-1004 TM8D final assembly procedure.
NOTE: Don't install wires that connect to the remote record switch at E8 and E9.
- B. Connect a 3.00vdc power source to the battery connections.
- C. Install current software using the TM8D console software program I-109 as outlined in document EWI-2034.
- D. Connect remote record switch wires to E8 and E9.
- E. Connect 5-lead ECG cable to a common, ground isolated signal source. Connect the Red and Brown leads to (+)signal and Green, White and Black leads to (-)signal.
NOTE: Make shortest connection possible to minimize 60Hz pickup.

The image you are viewing has been authorized as a controlled document. No unauthorized copies are allowed.

- F. Apply power. Ammeter should indicate 10 - 11mA.**
- G. Measure the dc voltages at test points listed below.**
1. TP19: 1.625 – 1.675Vdc
 2. TP14: 1.49 - 1.51Vdc
 3. TP17: 2.90 – 3.10Vdc
 4. TP18: 3.27 – 3.33Vdc
- H. Input amplitude adjustment and upper passband test.**
1. Set signal source to 10Hz, 5mV p-p sine wave.
 2. Attach RMS meter to TP5 and adjust R60 for 250mVrms.
 3. Adjust frequency until meter indicates .177mVrms. Verify signal source indication of 80 – 100Hz.
 4. Attach rms meter to TP6 and adjust R62 for 250mVrms.
 5. Adjust frequency until meter indicates .177mVrms. Verify signal source indication of 80 – 100Hz.
- J. Input overload recovery test.**
1. Attach scope to TP5 and momentarily remove either the white or red lead. Verify the immediate return of signal.
 2. Attach scope to TP6 and momentarily remove either the brown or black lead. Verify the immediate return of signal.
- K. Lead fault test.**
1. Attach DVM to TP10
 - a. With all leads connected observe 3V.
 - b. Disconnect red then white lead momentarily and observe 0 - .5V.
 2. Attach DVM to TP11
 - a. With all leads connected observe 3V.
 - b. Disconnect brown then black lead momentarily and observe 0 - .5V.
- L. Low battery test.**
1. Attach DVM to TP12 and lower supply voltage until meter indicates 0Vdc.

Power supply should indicate 1.45 – 1.50Vdc.

The image you are viewing has been authorized as a controlled document. No unauthorized copies are allowed.

M. Remote Record test.

1. Set supply voltage to 3.00Vdc.
2. Press the *Remote Record* switch. After approximately 1 second verify the presence of the remote record label on the corresponding central station channel.

N. Defibrillator test.

1. Reference document no. LSI-1004 ECG defibrillator test procedure.

O. Apply a small amount of nail polish to the potentiometers.

This concludes the I-108 board alignment and test procedure.

M-104 ALIGNMENT and TEST PROCEDURE

I. TEST EQUIPMENT REQUIRED

NOTICE

**ALL TEST EQUIPMENT WITH STATED ACCURACY MUST
BEAR A CURRENT CERTIFIED CALIBRATION NOTICE**

- A. M-104/105 test fixture.
- B. M-104/105 test cable.
- C. DC ammeter, 5% accuracy.
- D. RF signal analyzer/counter, 1GHz range, 10ppm accuracy.
- E. Power Supply, minimum 0-5 volt range at 100mA, maximum ripple, 5mV, 100ppm stability.
- F. DMM, 3 ½ digit minimum, 2% accuracy.

II. INSPECTION

- A. Thoroughly inspect the board for possible assembly errors, such as defective or unsoldered joints, bridged pads/vias, component orientation and value or type, etc.
- B. If a modification suffix appears on the current bill of materials, determine that the mod level on the applicable subassembly is correct by referring to the applicable DCN file for details concerning the modification.

III. ALIGNMENT AND TEST

- A. Verify switch positions 1 – 7 on the M-104 test fixture set for 611,00MHz.
Reference document no. EWI-2035: TM8D TRANSMIT FREQUENCY SELECTION CHART.
- B. Mount board onto the M-104 test fixture.
- C. Connect a 3.00vdc power source to the battery connections.
- D. Attach M-104 test cable to the LL (red) connector on the M-104 test fixture, and the spectrum analyzer/counter.
- E. Apply power. Ammeter should indicate 18 - 22mA.
- F. Adjust the trimmer capacitor on the M-104 for an indication of 611MHz, +/-500Hz on the counter.
- G. Verify an indication of (-)18 – (-)20dbm on the analyzer at 611MHz.
Verify that the +/-50KHz sidebands are at least 40db down from the carrier peak, and that all other sidebands to +/-1MHz are greater than 60db down from the carrier peak.

This concludes the M-102 board alignment and test procedure.

M-105 ALIGNMENT and TEST PROCEDURE

I. TEST EQUIPMENT REQUIRED

NOTICE

**ALL TEST EQUIPMENT WITH STATED ACCURACY MUST
BEAR A CURRENT CERTIFIED CALIBRATION NOTICE**

- A. Generic PC w/serial port and BG terminal software from Bluegiga.
- B. RS232-to-TTL adapter module.
- C. DC ammeter, 5% accuracy.
- D. RF signal analyzer/counter, 1GHz range, 10ppm accuracy.
- E. Power Supply, minimum 0-5 volt range at 100mA, maximum ripple, 5mV, 100ppm stability.
- F. DMM, 3 ½ digit minimum, 2% accuracy.
- G. M-105 logfile (M-105.log) located on Mfgtesting server.

II. INSPECTION

- A. Thoroughly inspect the board for possible assembly errors, such as defective or unsoldered joints, bridged pads/vias, component orientation and value or type, etc.
- B. If a modification suffix appears on the current bill of materials, determine that the mod level on the applicable subassembly is correct by referring to the applicable DCN file for details concerning the modification.

III. ALIGNMENT AND TEST

- A. Connect adapter module to serial port and power source.
- B. Initialize BG terminal program.
- C. Attach M-105 to adapter and apply power.
- D. Observe that terminal displays copyright and ready notice.
- E. Put cursor in text entry box and type [set] without brackets and press [Enter].
- F. Type [set control CD 20 0] w/o brackets. Note spaces between characters. Press [Enter].
- G. Type [set BT name WT11-{last 4 digits of MAC}] w/o brackets and press [Enter].
- H. Type [set BT SSP 3 6] w/o brackets and press [Enter].
- I. Type [set BTAUTH * {last 4 digits of MAC}] w/o brackets and press [Enter].
- J. Type [set BT baud 14400 8n1] w/o brackets and press [Enter].

NOTE: Following step III.J., terminal will no longer respond to commands until its baud rate is changed to 14400. Do this by typing 14400 in the space at upper right in the display area called "Manual Baud".

- K. Cycle power to adapter and ensure that the terminal responds with copyright and ready notice.
- L. Type [set] w/o brackets in the text entry box and press [Enter]. Ensure response reflects all changes as previously entered.
- M. Remove power from adapter and remove M-105 module.
- N. With indelible marker inscribe last 4 digits of MAC on module.
- O. Enter MAC address in M-105 logfile.
- P. Type 115200 in the space for manual baud and press [Enter].
- Q. Repeat from step III.A. for next module.

I-1004 FINAL ASSEMBLY AND TEST PROCEDURE

I. ASSEMBLY

A. Equipment required.

1. #2 phillips screwdriver
2. 1/4" nutdriver
3. General purpose, clear RTV silicone adhesive
4. General purpose "quick bond" adhesive such as "Bondini" future brush-on super glue
5. General-purpose silicon lubricant such as "Loctite" part # 51360
6. Soldering irons with small, medium and large tips
7. General purpose solder (60/40)
8. Small long nose pliers
9. Small side cutter pliers
10. Small shear cutter pliers

B. Install battery contact (item 1, part # 1004471) into battery cap (item 6, part #1004443).

C. Install threaded spacer (item 14, part #2800-300) into case housing (item 3, part #1004439).

D. Install battery sleeve (item 2, part #1004438) into end cap (item 7, part #1004453-5B).

E. Temporarily install solder tab (item 15, part #2800-953) into end cap (item 7, part #1004453-5B) with #6x1/4" (item 13, part #2800-101) screw and nut.

F. Remove the end cap (item 3, part #1004453-5B) board mounting flange with shear cutter pliers.

G. Install end cap o-ring seal (item 4, part #1004440) into the end cap (item 7, part #1004453-5B) after applying a thin film of general-purpose silicon lubricant.

H. Install battery cap o-ring seal (item 5, part #3100-074) onto the end cap neck (item 7, part #1004453-5B) and secure it with a small amount of general purpose "quick bond" adhesive.

I. Install the record switch (item 17, part #5100-289) into the end cap (item 7, part #1004453-5B), then secure it to the end cap body with a small amount of general-purpose, clear RTV silicone adhesive.

J. Attach the ECG module (item 18, part #I-108) to the end cap (item 7, part #1004453-5B).

1. Carefully solder the six board-edge solder pads on side one to the six corresponding pins from the green, red and white ECG connectors. Note: Avoid using excessive heat, but ensure proper pin-to-pad solder bonding.
2. Upon ensuring proper orientation and alignment of the board to the end cap body, use a short piece of 22-gauge bus wire to attach the solder tab from step (E) to the I-108 board at location E7 (Batt -).
3. Use the long nose pliers to carefully bend the remaining pins from the brown and black ECG connectors in such a fashion to properly mate with the corresponding board-edge solder pads on side two of the I-108 board. Proceed to solder the connections, ensuring a proper bond without using excessive heat.
4. Use a piece of 22-gauge bus wire to attach the battery sleeve (item 2, part #1004438) to E6 (Batt +) on the I-108 board in such a manner that no slack is left in the wire when completed.
5. From side two of the I-108 board, use computer wire to connect locations E8 and E9 to the record switch (item 17, part #5100-289).

The image you are viewing has been authorized as a controlled document. No unauthorized copies are allowed

- K. Attach the RF module (item 19, Part #M-104).
6. Carefully mate the six pins of J1 – J2 with the corresponding connectors J1 – J2 of the I-108 board.
 7. Solder a piece of 22-gauge bus wire between the battery solder tab (item 15, part #2800-953) and the M-104 ground pad nearest the solder tab.
 8. Secure the RF module to the ECG module by applying a small amount of general-purpose, clear RTV silicon adhesive along the J1 – J2 mating edges.
 9. Apply a 1.5” piece of adhesive backed, closed cell foam (item 16, part #3100-55) to the RF shield top.

II. TEST

- A. Install batteries and connect (all 5 leads) to an ECG simulator.
- B. Tune a central station monitor to the assigned frequency and verify the presence of an undistorted waveform for both leads.
- C. Push the remote record button for at least 1 second and verify a response from the central station chart recorder.
- D. Insert the completed end cap assembly into the case housing (item 3, part #1004439).

Note: Remember to first remove the screw and nut which temporarily held the battery solder tab (item 15, part #2800-953) in place. Use the 6-32x1/4 screw (item 13, part #2800-101) to attach the “foot” and the 6-32x1/4 screw (item 12, part #2800-004) to attach the “header” to the standoff (item 14, part #2800-300).

<p>Note: Device shall be stocked as finished goods at this time. Labels shall be added upon determination of final disposition.</p>
--

- E. Affix labels
 - a. Attach the pre-printed serial number label (item 8, part #2500-426) at the corresponding location on the case housing (item 3, part #1004439).
Serial number format: [z]TM8D-[B][W][xxxx][yyy.yy], where z=revision level, B=Bluetooth, W=WMTS, xxxx=4-digit serial number and yyy.yy=frequency from 608.00 to 614.00MHZ in 50KHz increments if WMTS, last 4 digits of MAC if Bluetooth.
 - b. Attach the FCCID label (item 10, part #2500-479) at the corresponding location on the case housing (item 3, part #1004439), which has had the manufacturing date inscribed. The format shall be “Mfg. mm/yy”.
 - c. Attach the end cap overlay (item 9, part #2500-467BS) to the end cap (item 7, part #114453-5B) at the corresponding location, using a small amount of “quick-bond” adhesive to further seal the area immediately surrounding the switch cover.
 - d. Attach the appropriate channel number label (item 11, part #2500-470) to the case housing (item 3, part #1004439) at the corresponding location.

III. INSPECTION

- A. Visually inspect the finished device for cosmetic appearance and mechanical fit.

This concludes the I-1004 final assembly and test procedure.

The image you are viewing has been authorized as a controlled document. No unauthorized copies are allowed