



SunTech Medical

Tango M2[®]

Tango M2 NIBP Stress Test Blood Pressure Monitor

Service Manual



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1.0 Introduction

1.1 Before beginning any operation or service on the Tango M2, read and understand the user manual (SunTech part number 80-0055-00), which is available for download from SunTechMed.com.



WARNING: ADDITIONAL WARNINGS AND CAUTIONS MAY BE FOUND IN THE TANGO M2 USER MANUAL.

1.2 The SunTech Medical Tango M2 Non-Invasive Blood Pressure Monitor (NIBP) is used to obtain blood pressure (BP) and heart rate (HR) readings during exercise testing. It can be used in conjunction with most common Stress Test systems or as a standalone monitor when using a Tango M2 equipped with internal ECG. The essential set-up consists of the monitor, pneumatic/K-sound patient cable, and Orbit-K blood pressure cuff with K-sound microphone.

1.3 The Tango M2 is typically interfaced to a host stress test system and receives its analog or digital ECG trigger via a coaxial cable with a BNC connection. Communication between the stress system and the monitor is via an RS-232 null modem cable or USB-A (Stress System) to USB-B (Tango M2) cable. An optional internal ECG board is available for standalone operation.

2.0 Scope

2.1 This manual is a SunTech Medical controlled document. It contains the instructions necessary to maintain accurate blood pressure measurements obtained through the use of the Tango M2 NIBP Monitor. This manual should be used to maintain the monitor safely in accordance with its function and intended use. This manual was created with the audience of Biomedical engineering professionals in mind. Biomedical professionals are expected to have a working knowledge of medical procedures, practices, and terminology as required for completing these testing parameters.




















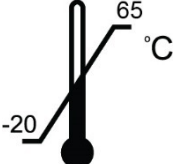

2.2 The Tango M2 monitor should only be serviced by a SunTech Medical trained and certified technician. The monitor does not contain any user serviceable parts and should only be opened by an authorized service representative. To perform the routine calibration check, only a trained biomedical technician should check calibration of the Tango M2.

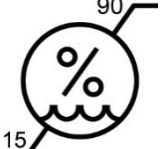


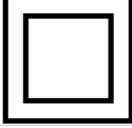


3.0 Regulatory Information

All icons and symbols listed below are items that can be found on the Tango M2 monitor itself, the power supply for the Tango M2, or within the literature provided within the Tango M2 monitor's shipping box.

3.1 Icons and Symbols

	DKA™ MODE for auscultatory measurement of blood pressure (during exercise).		OSC MODE for oscillometric measurement of blood pressure (non-exercise).
	Patient Cable connection for BP cuff (pneumatic).		Patient Cable connection for K-sound microphone.
	Warning message		Caution message
	SpO2 Sensor. Type BF Applied Part		ECG Input.

RS-232	RS-232 Serial communication port		9V DC input. Power connection configuration - positive voltage; negative shield.
	BNC external ECG trigger		Headphone
	USB-A or USB-B		Defibrillator protected
	ETL Classified		Device may contain materials which may be hazardous to human health.
	Power On/Off		Refer to User Guide
	No SpO ₂ alarm		Attention, consult accompanying documents
	Manufactured By		Manufacture Date
	PSE Mark: Japanese Medical Device Approval		For indoor use only
	No serviceable parts inside		Product complies with the requirements of the RoHS directive, 2011/65/EU
	Meets ELSA 2007, CEC efficiency level V EU (EC) No 278/2009 Phase II		Fragile
	Shipping Temperature should be kept between -20° C and 65°C		CE Mark: product meets the Medical Device Directive and is CE marked to indicate conformance

	Shipping Humidity should be kept between 15% and 90%		Item and shipping container should be kept dry
	Warranty Seal		Class II isolation equipment
	Recognized component certified by UL to both Canada and U.S. requirements		European Authorized Representative

4.0 Tango M2 Inputs & Outputs

4.1 Tango M2 Inputs

- 4.1.1 Power Switch, located on rear of enclosure. This is a latching, push button on/off switch that removes or provides power to the monitor circuitry.
- 4.1.2 External (Analog or Digital) ECG Trigger Input. This is a BNC connection which provides the ECG signal from the host stress system to the Tango M2.
- 4.1.3 Optional ECG Patient Cable (3 lead to 6-pin DIN). Provides the ECG signal to the Tango M2. Used only if the Tango M2 is not using an external ECG source. e.g. a stress system.
- 4.1.4 Front Panel Keypad. Six-key membrane pad used to control the Tango M2 operations.
- 4.1.5 9VDC medical grade power supply, SunTech PN 19-0012-01.

4.2 Tango M2 Outputs

- 4.2.1 7" color LCD with LED backlighting.
- 4.2.2 Beeper (for audible feedback).

4.3 Tango M2 Combined Inputs & Outputs

- 4.3.1 Pneumatic / K-Sound Patient Cable. Connects the Tango M2 pneumatic pump to the arm cuff, and the Tango M2 K-Sound circuitry to the K-Sound microphone.
- 4.3.2 9-Pin bi-directional RS-232 serial port. Used for communicating with the host system.
- 4.3.3 USB-B port used for communicating with the host stress system (alternative to the RS-232 serial port).
- 4.3.4 USB-A port used for downloading measurement history from the Tango M2 or uploading software/firmware updates.

5.0 Operational Modes & Menu System Description

5.1 Normal Operation - The Tango M2 utilizes a menu-driven system. All settings are controlled by using the front panel keypad. Operation is via the keypad or through communication with a host stress system. Refer to the Tango M2 User's Manual for detailed instructions on using the system under normal operational conditions.

5.2 Diagnostics Menu - Certain maintenance operations may be accessed by a hidden key sequence that is not normally available to the user. The Maintenance Menu is accessed by the following keypad input sequence:



WARNING: ANY CHANGES MADE WITHIN THE DIAGNOSTIC MENU CAN ALTER BP ACCURACY. IT IS STRONGLY RECOMMENDED THAT NO CHANGES ARE MADE TO THE TANGO M2 DIAGNOSTIC MENU.

1. Press and hold the MENU key.
2. Press and release the UP arrow key.
3. Press and release the Down arrow key.
4. Press and release the Down arrow key.
5. Press and release the UP arrow key.
6. Release the Menu key.

The available options are shown on-screen and are more fully discussed in the following sections.

In addition to the options used by the standard maintenance procedures (described later in this manual), the Diagnostics Menu also provides access to the Configuration Options settings and Direct Hardware Control.

5.2.1 Verify Calibration – Selecting this option will display the current pressure within the Tango M2 system. This option should be used with a T-Tube kit (SunTech part number 98-0030-00). Overpressure and safety timeout (pressure above 15mmHg in system for greater than 180 seconds) are disabled. Also, the system will display values up to 320mmHg. Exiting the diagnostic menu will enable overpressure, the safety timeout and the display will no longer display pressures above specified ranges as provided in the User Manual.

5.2.2 Calibrate

5.2.2.1 Verify Calibration – Selecting this option will display the current pressure within the Tango M2 system. This option should be used with a T-Tube kit (SunTech part number 98-0030-00). Overpressure and safety timeout are enabled.

5.2.2.2 Calibrate –



WARNING: CALIBRATION SHOULD ONLY BE PERFORMED BY QUALIFIED PERSONNEL USING A CALIBRATED REFERENCE PRESSURE GAUGE! THIS SET-UP IS CRITICAL TO THE ACCURACY OF THE TANGO M2 MONITOR!

The person calibrating the monitor must allow the pressure to stabilize at each pressure point setting before pressing ENTER. Two pressure points will be set during the calibration, 0mmHg and 250mmHg. When complete, Verify Calibration must be performed. See Section 4.3 for more details on setting the calibration.

5.2.3 Test Input Channels – SunTech use only.

5.2.4 Test Hardware

5.2.4.1 Pump – Pumps run at full power when set to On and shut off fully when set to OFF.

5.2.4.2 Valve – Dump valve closes when set to Closed and opens when set to Open.

5.2.4.3 Bleed Valve – Step valve closes when set to Closed and opens when set to Open.

5.2.4.4 Control Valve – Linear control valve closes completely when set to Closed and opens completely when set to Open.

5.2.4.5 Beeper – sounds Beeper when set to On and turns off beeper when set to OFF



WARNING: ANY CHANGES MADE WITHIN THE CONFIGURATION SET-UP CAN ALTER BP ACCURACY. Settings other than the factory settings have been untested and are not validated settings. It is strongly recommended that no changes are made to the Tango M2 configurations listed below.

5.2.4.6 Bin Skip – This setting is used to help determine the K-sound window for analysis. This value is normally set to 3 when the ECG trigger is set to Digital. The value is set to 0 when the ECG trigger is set to Analog. Options are Auto (0 or 3, depending on ECG trigger setting) and 1 – 15 in increments of 1 and will override the aforementioned values associated with the ECG trigger setting.



WARNING: Any change in this value can cause incorrect detection of K-sounds.

5.2.4.7 ECG Delay – This delays the window of K-sound detection and should normally be set to 0ms. This setting is used to compensate for any time delay the host stress test system might induce in the ECG trigger. Delays range from Default (no delay) to 600ms in increments of 5ms.



WARNING: Any change in this value can cause incorrect detection of K-sounds.

5.2.5 Transparent Mode – SunTech use only.

5.2.6 Special – SunTech use only.

6.0 Tango M2 Routine Preventative Maintenance Procedures

The Tango M2 monitor is designed to perform within the description contained in the user manual and inserts. The monitor should be operated, maintained and repaired in accordance with the instructions provided within this documentation. After use, it is important to perform preventative maintenance to ensure the efficient operation of the monitor. It is the responsibility of the SunTech Medical trained and certified technician to review the following:

1. Check calibration of the device every two years.
2. Never knowingly use a defective device.
3. Contact the nearest authorized SunTech Medical Service Center should repair or replacement become necessary.
4. Further, the user of the device bears sole responsibility for any malfunction resulting from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than SunTech Medical or authorized service personnel.

SunTech offers the following checks, tests, and calibrations to properly maintain your Tango M2 monitor.

6.1 Verification Of Pressure Calibration

Equipment Required:

- Calibrated reference sphygmomanometer.
- 500ml volume.
- Hand Inflation Bulb with bleed valve.
- Tubing, T-connector, and miscellaneous connectors.

6.1.1 T-connector the sphygmomanometer, the 500ml volume and the inflation bulb together and connect to the patient cable hose connection.

6.1.2 Access the Diagnostics Menu (see section 5.2).



WARNING: Any changes made within the diagnostic menu can alter BP accuracy. It is strongly recommended that no changes are made to the Tango M2 Diagnostic Menu.

- 6.1.3 Within the Diagnostics Menu, select Verify Calibration. The Tango M2 will now have its valves closed and will display the pressure applied to the patient hose connector.
- 6.1.4 Verify the Tango M2 calibration by inflating manually and checking the sphygmomanometer against the pressure reading on the Tango M2 display. Verify the readings as shown in Table 1 below.

Calibrated Reference Pressure (mm Hg)	Tango M2 Displayed Pressure (mm Hg)
0	0 - 1
50	48 - 52
100	98 - 102
150	148 - 152
200	198 - 202

250	248 - 252
280 (note)	278 - 282

Table 1: Pressure Verification Table

NOTE: If using Verify Calibration under Calibration Menu, increase pressure to 280mmHg slowly, to avoid overshooting 280 mmHg and tripping the overpressure limit.

6.1.5 If any pressure reported by the Tango M2 is outside limits, the monitor must be calibrated (see section 6.2).

6.1.6 Press ENTER to open the valves and release the pressure from the system.

6.1.7 Selecting EXIT or pressing the Start/Stop button will leave the Diagnostic Menu.

6.2 Set Calibration

Equipment required:

- Calibrated reference sphygmomanometer.
- 500ml volume.
- Hand Inflation Bulb with bleed valve
- Tubing, T-connector, and miscellaneous connectors

6.2.1 T-connector the sphygmomanometer, the 500ml volume and the inflation bulb together and connect to the patient cable hose connection.

6.2.2 Access the Diagnostics Menu (see section 5.2).



WARNING: Any changes made within the diagnostic menu can alter BP accuracy. It is strongly recommended that no changes are made to the Tango M2 Diagnostic Menu.

6.2.3 Select Calibrate from Diagnostics Menu and select Calibrate again.

6.2.4 Open the bleed valve on the pneumatic bulb to obtain 0mmHg pressure. Ensure the reference sphygmomanometer displays 0mmHg and then press ENTER to set the zero point in the Tango M2.

6.2.5 Close the bleed valve on the bulb and inflate to 250mmHg. Allow the pressure to stabilize, adjusting as necessary to maintain the pressure at exactly 250mmHg on the reference sphygmomanometer. Press ENTER to set the 250mmHg point into the Tango M2. Note: A failure will be displayed if the monitor recognizes a pressure is outside reasonable expected limits of a calibration pressure. The qualified user will be prompted to cancel (that calibration point will not be set) or retry.

6.2.6 Calibration is now complete.

6.2.7 Select Verify Calibration and follow steps in 6.1. If verify calibration continues to fail, do not use the Tango M2 monitor and contact SunTech Medical, Inc.

6.3 Leak Rate Test

Equipment Required:

- Stop Watch.
- 500ml volume.
- Hand Inflation Bulb with bleed valve.
- Tubing, T-connector, and miscellaneous connectors.

6.3.1 T-connector the 500ml volume and the inflation bulb together and connect to the patient cable hose connection.

6.3.2 Access the Diagnostics Menu (see section 5.2).



WARNING: Any changes made within the diagnostic menu can alter BP accuracy. It is strongly recommended that no changes are made to the Tango M2 Diagnostic Menu.

- 6.3.3 Select Verify Calibration in the Diagnostics Menu. The Tango M2 will now have its valves closed and will display the pressure applied to the patient hose connector.
- 6.3.4 Inflate the pressure to 250mm Hg. Allow the system to stabilize for 1 minute, re-adjusting to 250mm if required. Note the exact pressure, and simultaneously start the stop-watch. After 60 seconds have elapsed, the pressure should not have dropped by more than 6mmHg.
- 6.3.5 Press ENTER to open the valves and release pressure from the system.

6.4 Safety Timeout Check

Equipment Required:

- Stop Watch.
- 500ml volume.
- Hand Inflation Bulb with bleed valve.
- Tubing, T-connector, and miscellaneous connectors.

6.4.1 T-connector the 500ml volume and the inflation bulb together and connect to the patient cable hose connection.

6.4.2 Access the Diagnostics Menu (see section 5.2).



WARNING: Any changes made within the diagnostic menu can alter BP accuracy. It is strongly recommended that no changes are made to the Tango M2 Diagnostic Menu.

6.4.3 Select Calibrate from the Diagnostics Menu and then select Verify Calibration.

Note: It is important to use the Verify Calibration from the Calibrate menu as this has all safety mechanisms enabled.

6.4.4 Using the inflation bulb, set the pressure in the system to approximately 200mmHg per the monitor's displayed value. Start the stopwatch as soon as pressure exceeds 15mmHg. The monitor will release the pressure from the system after 160 to 180 seconds. Stop the stopwatch as soon as pressure falls below 15mmHg. This time must be 180 seconds or less.

6.5 Overpressure Check

Equipment Required:

- Stop Watch.
- 500ml volume.
- Hand Inflation Bulb with bleed valve.
- Tubing, T-connector, and miscellaneous connectors.

6.5.1 Using a T-connector the 500ml volume and the inflation bulb together and connect to the patient cable hose connection.

6.5.2 Access the Diagnostics Menu (see section 5.2).



WARNING: Any changes made within the diagnostic menu can alter BP accuracy. It is strongly recommended that no changes are made to the Tango M2 Diagnostic Menu.

6.5.3 Select Calibrate from the Diagnostics Menu and then select Verify Calibration.

Note: It is important to use the Verify Calibration from the Calibrate menu as this has all safety mechanisms enabled.

6.5.4 Using the inflation bulb, set pressure to approximately 280mmHg pressure per the monitor's displayed value. Slowly continue to inflate the system until the UUT opens the valves and releases the pressure. This must occur between 290mmHg and 320mmHg.

7.0 Tango M2 Non-Routine Maintenance Procedures

The monitor should only be serviced by a SunTech Medical trained and certified technician. The monitor does not contain any user serviceable parts and should only be opened by an authorized service representative. Contact SunTech Medical if service is required during the 2 year warranty period.

For monitors that are outside the warranty period the enclosure may be removed and the circuit boards separated if it is required to inspect the unit for mechanical damage (e.g. for liquid ingress after spillage or if the unit has been dropped).

7.1 General Internal Inspection

Note: THE WARRANTY FOR THE TANGO M2 MONITOR WILL BE VOIDED IF THE WARRANTY SEAL IS BROKEN. The Tango M2 monitor should only be serviced by a SunTech Medical trained and certified technician.



WARNING – Prior to servicing any internal components, disconnect device from power. Failure to remove power may result in a shock hazard and/or severe injury.

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

- 7.1.1 Open the enclosure by removing the four Philips head screws located on the four corners of the rear enclosure (one covered by warranty seal).
- 7.1.2 See section 6 for disassembly instructions.
- 7.1.3 Inspect assembly for damage or contamination. Should any damage or liquid contamination be evident, the Tango M2 should be re-assembled and returned to SunTech for board replacement and full re-test. Any dry contamination (e.g. dust or small objects that may have fallen through the grill) may be removed, using a brush or gentle compressed air.
- 7.1.4 See section 6 for reassembly instructions.
- 7.1.5 Perform a Leak Rate test and a Timeout Test (as described in Section 4) to verify that the pneumatic system is functioning correctly. If either fails, open the monitor back up and check for damage and kinks in the pneumatic tubing.

8.0 Disassembly and Reassembly

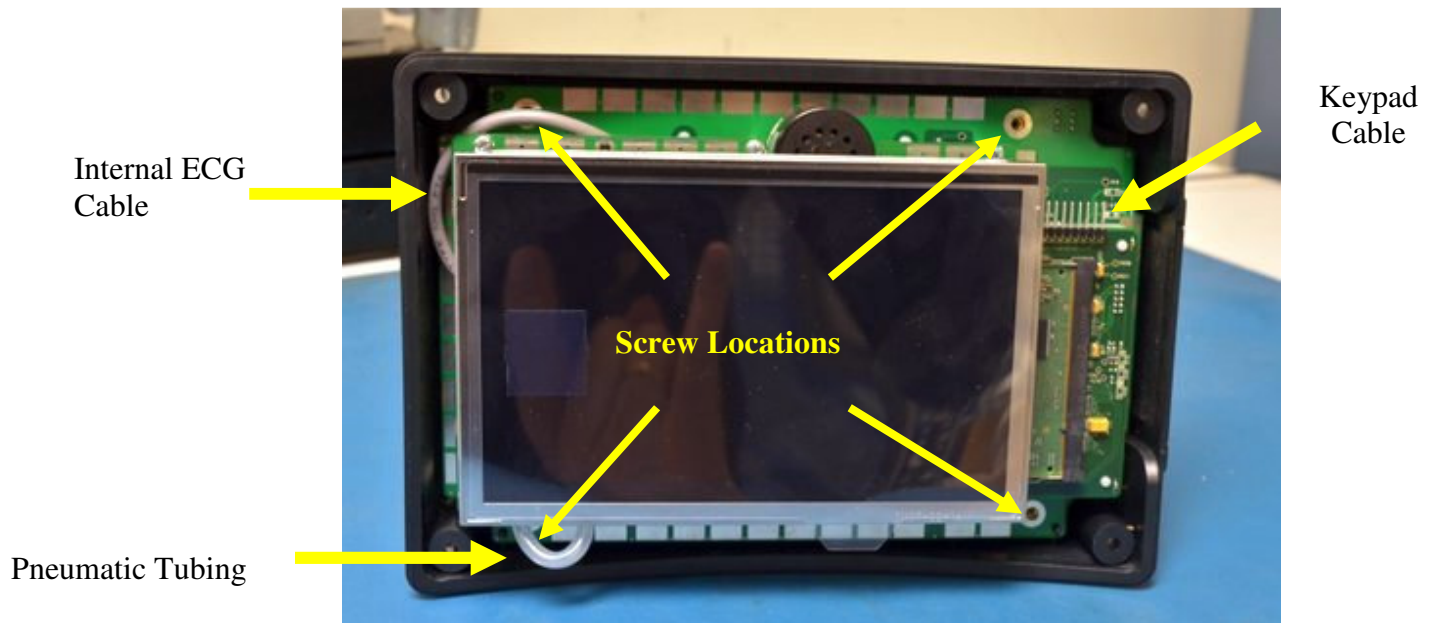
Note: There are three variants of monitors used for the 99 level: The variant with the original LCD is part number 97-0144-00. Variant 97-0191-00 has a different LCD within the monitor. A different LCD is contained within variant 97-0227-00. The LCDs are not interchangeable between monitors. Disassembly is virtually the same, however the variants 97-0191-00 and 97-0227-00's LCD are mounted differently in that they also have a mounting tray and do not have the same connections. They are connected solely by a ribbon cable and no other connectors. The difference between variants 97-0191-00 and 97-0227-00 is that the newest variant has an LCD overlay attached to the LCD itself around the border of the LCD. Pictures of all three variants are provided in this document. If the LCD requires replacement in the 97-0227-00 variant, see 97-0227-XX-PP, as there are additional instructions for mounting this LCD to the UI board.

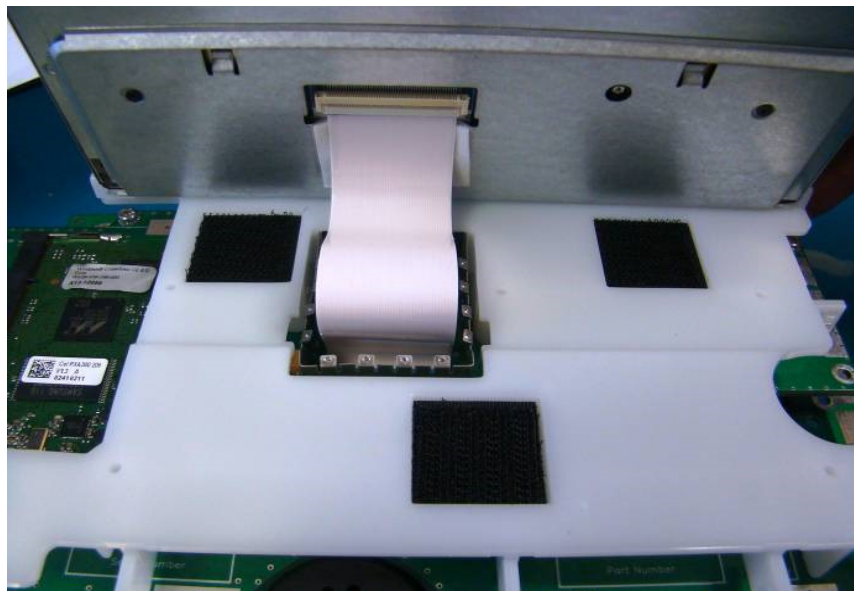
8.1 Disassembly

97-0227-00 (Latest LCD)



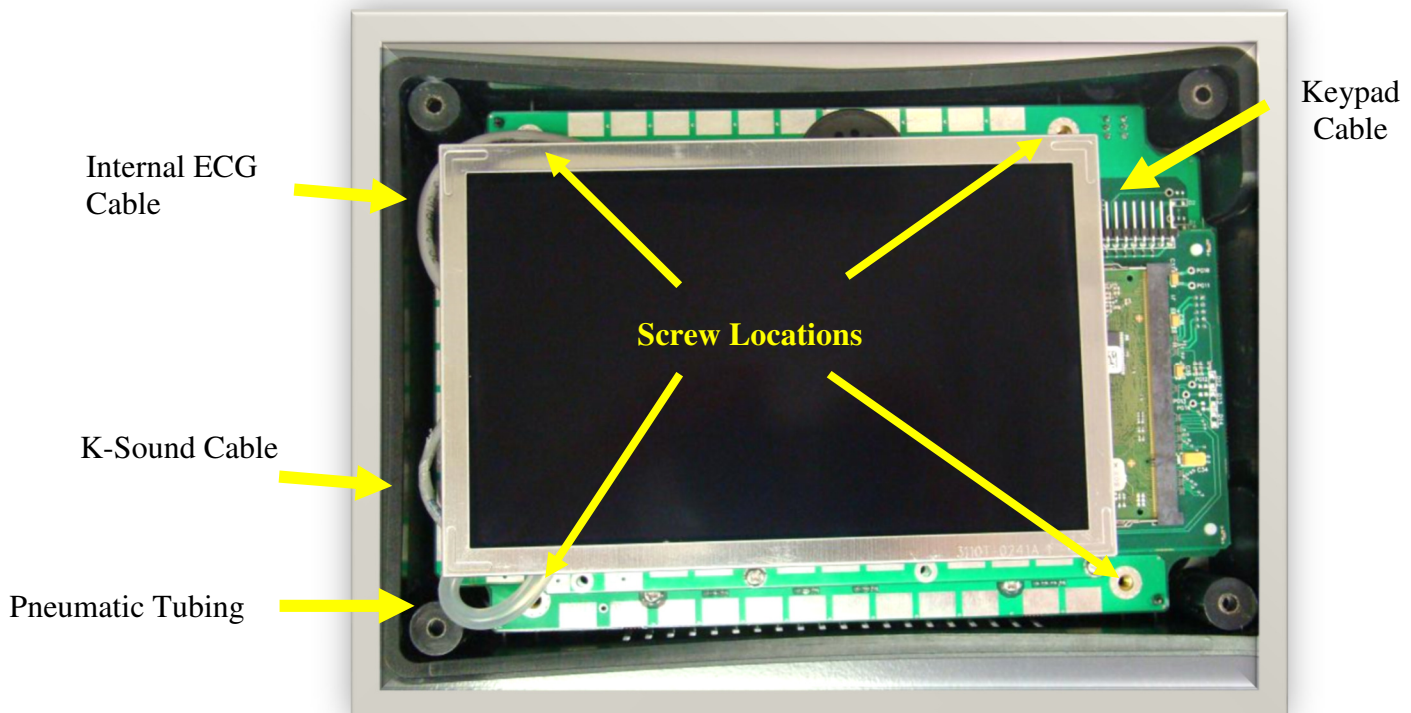
97-0191-00 (next generation LCD)





97-0191-00 when LCD lifted

97-0144-00 (original LCD)



8.1.1 Place the Tango M2 display downwards on a soft surface. Remove the four screws located in the wells on the rear enclosure. The warranty seal must be broken to access all of the screws.

Note: THE WARRANTY FOR THE TANGO M2 MONITOR WILL BE VOIDED IF THE WARRANTY SEAL IS BROKEN.

- 8.1.1.1 Place the Tango M2 unit on the rubber feet and pull the front enclosure away from the rear enclosure.
- 8.1.1.2 Remove the front enclosure keypad cable from the UI board.
- 8.1.2 Place the Tango M2 unit on the back side with the display facing up. Remove the four screws and tooth washers that hold the Tango M2 assembly to the rear enclosure.
- 8.1.3 Place the Tango M2 on the rubber feet and pull the side of the Tango M2 board assembly with the power button.
 - 8.1.3.1 Slide the blue power button off of the power switch.
- 8.1.4 Place the Tango M2 unit on the back side. The pneumatic manifold and K-sound cable must be disconnected before the unit can be completely removed from the rear enclosure.
 - 8.1.4.1 Pneumatic manifold: Pull the tubing from the barbed connection on the rear enclosure. Thread the tubing back through the I/O board so that the tubing exits straight out of the K-DKA module.
 - 8.1.4.2 K-sound cable: Disconnect the K-sound cable from J1 on the K-DKA board located underneath the pump tray. J1 is the three-pin connector on the edge of the K-DKA board. Thread the cable back through the I/O board. The connector and cable should remain attached to the rear enclosure.

8.2 Reassembly

- 8.2.1 Place the rear enclosure on the back side to reinsert the unit. The pneumatic manifold, K-sound cable, and power button must be reconnected first before the unit can be fully inserted back into the rear enclosure.
 - 8.2.1.1 K-sound cable: Thread the cable up through the smaller hole and back out the larger hole in the I/O board. Reattach the K-Sound cable to J1 on the K-DKA board.
 - 8.2.1.2 Pneumatic manifold: push the tubing up through the rectangular cutouts on the I/O and UI boards and slide the tubing onto the barbed connector.
 - 8.2.1.3 Power button: slide the power button onto the power switch.
 - 8.2.1.4 Place the rear enclosure on the rubber feet and insert the unit onto the four guide pins. Ensure that the pneumatic tubing is not crimped by the K-sound cable or by the unit itself. The pneumatic tubing should form a loop. (See picture at the beginning of section 8.)
- 8.2.2 Secure the module to the rear enclosure.
 - 8.2.2.1 Insert a screw and tooth washer into each screw location. Tighten securely.
- 8.2.3 Place the Tango M2 unit on the rubber feet and reattach the front enclosure keypad cable to the UI module.
- 8.2.4 Place the Tango M2 display downwards on a soft surface. Insert the four screws located in the wells on the rear enclosure. Tighten securely, ensuring that the keypad cable is not crimped.
- 8.2.5 Perform a Leak Rate test and a Timeout Test (as described in Section 6) to verify that the pneumatic system is functioning correctly. If either fails, open the monitor back up and check for damage and kinks in the pneumatic tubing.

Appendix 1

Tango M2 Spare Parts List

PART NUMBER	DESCRIPTION
99-0027-39	Tango M2 Preventative Maintenance Kit (Contains 1 Adult Plus cuff with microphone, 1 Adult Large cuff with Microphone, and 1 Tango M2 Patient Cable).
92-0140-00	Tango M2 K-DKA Board, Tested
98-0030-00	T-tube kit (For calibration – English Only)
58-0029-01	Keypad overlay w/lens
55-0119-00	Pump
55-0093-00	Valve (linear)
55-0043-05	Valve (dump)
55-0143-00	Valve (step)
39-0112-00	Enclosure, Tango M2, Front
39-0101-00	Light pipe (for LED on front enclosure)
39-0102-00	Power button (attaches to power switch)
39-0106-00	Enclosure, Tango M2, Rear
42-0002-00	Hole plug (non-ECG units only)

Appendix 2

Key to Exploded Views

Drawing Reference (97-0144-XX-AD)	Quantity	Part Description	SunTech Part Number
FH1	1	Front Cover Subassembly	39-0112-00
LP1	1	LED Light Pipe	39-0101-00
LENS1	1	Lens w/Lens Overlay	58-0029-01
DISP1	1	LCD	26-0012-00
PWA2	1	Tango M2 UI Board	92-0139-00
PWA1	1	Tango M2 I/O Board	92-0138-00
PB1	1	Power Button	39-0102-00
M1	4	Pump	55-0119-00
MT1	1	Pump Mounting Tray	39-0094-00
LBL1	1	Device Label	71-0369-00
FT1	4	Rubber foot	42-0001-00
RH1	1	Rear Housing	39-0106-00

Appendix 3
Tango M2 Monitor Assembly 97-0144-XX-AD Rev B

