

# Tram Test Report

Test Operator Name \_\_\_\_\_

BME Control Number \_\_\_\_\_

TRAM Model \_\_\_\_\_

Date of Test \_\_\_\_\_ Start Time \_\_\_\_\_ End Time \_\_\_\_\_

## Visual Inspection

Test Step	Test Description	Result		
1	Remove module before making an inspection or cleaning the module.			
2	Check the case for cracks or other damage.	Circle One:	PASS	FAIL
3	Regularly inspect cables for fraying or other damage.	Circle One:	PASS	FAIL
4	Inspect all plugs, cables, and connectors for bent prongs or pins.	Circle One:	PASS	FAIL
5	Verify that all cables and connectors are securely seated.	Circle One:	PASS	FAIL

## General Test

Test Step	Test Description	Result		
1	Install the module in a Tram-Rac housing.			
2	Apply power to monitor by turning the rear panel power switch to the ON position.			
3	Turn the display ON by pressing the <b>DISPLAY ON/OFF</b> or <b>POWER</b> key on the front panel of the monitor.			
4	Make sure the power indicators on both the monitor and the Tram module are turned ON or illuminated green.	Circle One:	PASS	FAIL
5	Connect the patient cable to module.			
6	Attach appropriate leads to the simulator.			
7	Listen for the fan. The fan should be running whenever the Tram module is installed in a bedside monitor, but not audibly grinding.	Circle One:	PASS	FAIL

## ECG Test

Test Step	Test Description	Result		
1a	Set up the simulator:			
1b	Heart rate to 80 bpm.			
1c	ECG amplitude to 1.0 mV.			
2	Attach a patient cable and leadwires between the ECG connector on the Tram module and the leadwire connectors on the top of the simulator.			
3	Admit a patient into system.			
4a	Make sure the following conditions are true:			

4b	The monitor displays ECG lead II, and it is noise-free.	Circle One:	PASS	FAIL
4c	The monitor displays an 80 ±1 bpm heart rate.	Circle One:	PASS	FAIL
4d	If the monitor has QRS tones are turned ON, an audible tone sounds with each QRS complex.	Circle One:	PASS	FAIL
5	Make sure all seven ECG leads are available for display and are noise-free			
6	Set <b>DETECT PACE</b> to <b>PACE 1</b> .			
7	Inject an Asynchronous pacemaker rhythm with the simulator.			
8a	Observe the following with leads II, III, aVR, aVF, and V:			
8b	On the monitor, a P appears above the PVC count to denote pacemaker mode.	Circle One:	PASS	FAIL
8c	The monitor shows a 75 ±1 bpm heart rate.	Circle One:	PASS	FAIL
9a	Remove the pacemaker pulse input and return the simulator to these conditions:			
9b	Set heart rate to 80 bpm.			
9c	Set amplitude to 1.0 mV.			
10	Select lead II for display in the top trace position.			
11	Remove the RA leadwire from the patient cable.			
12a	Observe following			
12b	The monitor displays an <i>RA FAIL</i> message.	Circle One:	PASS	FAIL
12c	The monitor displays lead III in place of lead II.	Circle One:	PASS	FAIL
13	Replace the RA leadwire.			
14	Inject a 1-millivolt calibration pulse (2 Hz square wave) with the simulator and start a manual graph.			
15	Observe that the calibration pulses are properly displayed and graphed.	Circle One:	PASS	FAIL

### 12SL ECG Test

Test Step	Test Description	Result		
1	At the monitor, go to the Main Menu.			
2	Use the <b>Trim Knob</b> control to select the <i>ECG</i> parameter box.			
3	At the <i>ECG</i> menu, select <i>12 LEAD ECG ANALYSIS</i> .			
4	Observe that all 12 ECG traces are noise-free, and are displayed clearly.	Circle One:	PASS	FAIL
5	Select <i>12 LEAD ECG NOW</i>			
6	Verify Unconfirmed Analysis is performed			
7	Select <i>DELETE 12 LEAD ECG</i>			
8	Return to Main Menu			

## Respiration Test

Test Step	Test Description	Result		
1a	Set up simulator:			
1b	Set baseline impedance to 1000Ω.			
1c	Set ΔR to 0.5Ω.			
1d	Set resp lead to LL on simulator.(switch on side)			
1e	Set respiration rate to 30 breaths per minute.			
2a	Set up the monitor:			
2b	Turn the RR parameter ON.			
2c	Set the RR lead to II.			
3a	Observe these conditions:			
3b	The monitor displays a distortion-free respiration waveform.	Circle One:	PASS	FAIL
3c	The monitor displays a respiration rate reading of 30 ±2 breaths per minute.	RR Value:		
4	Set the RESP waveform to lead I at the monitor, LA at the simulator.(switch on side)			
5a	Observe these conditions:			
5b	The monitor displays a distortion-free respiration waveform.	Circle One:	PASS	FAIL
5c	The monitor displays a respiration rate reading of 30 ±2 breaths per minute.	RR Value:		

## Blood Pressure Test

Test Step	Test Description	Result		
1	Set up simulator:			
1a	Set output to 0 mmHg.			
2	Connect the BP simulator cable from the <b>BLOOD PRESSURE 1</b> connector of the simulator to the left most BP connector ( <b>BP1</b> ) of the Tram module. <i>Note: do not use any other BP connectors on simulator</i>			
3	Observe an ART1 label and graticules on the monitor.	Circle One:	PASS	FAIL
4	Zero the ART waveform.			
5	Set the simulator to BP Static, 240 mmHg.			
6a	Observe the reading on the monitor.	BP Reading:		
6b	Verify that the reading is within the specification: of 240 ± 4 mmHg	Circle One:	PASS	FAIL
7	Set the simulator to BP Dynamic.			
8	Set the BP scale on the monitor to auto.			
9a	Observe a distortion-free waveform on the monitor.	Circle One:	PASS	FAIL
9b	Observe the blood pressure reading on the monitor	BP Reading:		
9c	Verify the reading is approx. 120/80 (93)	Circle One:	PASS	FAIL

10	Remove the cable from the <b>BP1</b> connector of the <b>Tram module</b> and insert it into the <b>BP2</b> connector. <i>Leave simulator connection as it is.</i>			
11	Repeat Steps 1-2			
12	Observe a PA2 label and graticules on the monitor.	Circle One:	PASS	FAIL
12a	Change name from PA to ART.			
13	Repeat Steps 4-5			
14a	Observe the reading on the monitor.	BP Reading:		
14b	Verify that the reading is within the specification: of $240 \pm 4$ mmHg	Circle One:	PASS	FAIL
15	Repeat 7-8			
16a	Observe a distortion-free waveform on the monitor.	Circle One:	PASS	FAIL
16b	Observe the blood pressure reading on the monitor	BP Reading:		
16c	Verify the reading is approx. 120/80 (93)	Circle One:	PASS	FAIL
17	Remove the cable from the <b>BP2</b> connector of the <b>Tram module</b> and insert it into the <b>BP3</b> connector. <i>Leave simulator connection as it is.</i>			
18	Repeat Steps 1-2			
19a	Observe a CVP3 label and graticules on the monitor.	Circle One:	PASS	FAIL
19b	Change name from CVP to ART			
20	Repeat Steps 4-5			
21a	Observe the reading on the monitor.	BP Reading:		
21b	Verify that the reading is within the specification: of $240 \pm 4$ mmHg	Circle One:	PASS	FAIL
22	Repeat 7-8			
23a	Observe a distortion-free waveform on the monitor.	Circle One:	PASS	FAIL
23b	Observe the blood pressure reading on the monitor	BP Reading:		
23c	Verify the reading is approx. 120/80 (93)	Circle One:	PASS	FAIL

### Temperature Test

Test Step	Test Description	Result		
1	Attach a temperature sensor adaptor to the TEMP/CO connector of the Tram module.			
2	Set the switch on the adaptor to the 400 position.			
3	Connect a 37°C temperature test plug to the <b>T1</b> connector of the temperature sensor adaptor.			

4	Observe that a <b>T1</b> reading appears on the display with reading between 36.6 and 37.4.	T1 Reading:		
5	Move the test plug from the <b>T1</b> connector of the temperature sensor adaptor to the <b>T2</b> connector.			
6	Observe that a <b>T2</b> reading appears on the display with reading between 36.6 and 37.4.	T2 Reading:		

## Cardiac Output Test

Test with LionHeart 3C simulator

Test Step	Test Description	Result		
1	Connect the cardiac output cable adapter to the TEMP/CO connector of the Tram module.			
2	Connect the cardiac output adapter box to the cardiac output cable adapter and to the C.O. connector on the simulator (make sure connector is fully seated at simulator)			
3	At the monitor, select CO box.			
4a	Set up the monitor:			
4b	Set <i>AUTO MODE</i> : to <i>ON</i>			
4c	Set <i>INJECT TEMP</i> : to <i>BATH</i>			
4d	Set <i>SIZE</i> : to 7			
4e	Set <i>INJECT VOL</i> : to 10CC			
4f	Set <i>COMPUTATIONAL CONSTANT</i> : to 0.540			
5	Set the adapter to 0°. (approx. 576Ω on dial )			
6	Turn the simulator <b>ON</b> . Select cardiac output menu corresponding to the injectate temperature. (i.e. menu #92 for 0°, or #95 for 24°)			
7	When the monitor screen displays the message, <i>INJECT WHEN READY</i> , press <b>Enter</b> on the simulator.			
8	When computing is complete, the CO reading should be 5.0 L/m ±5% at approximately 37°C	CO Reading:		
9	Set <i>COMPUTATIONAL CONSTANT</i> : to 0.595			
10	Set the adapter to 24°. (approx 212Ω on dial)			
11	Turn the simulator <b>ON</b> . Select cardiac output menu corresponding to the injectate temperature. (i.e. menu #92 for 0°, or #95 for 24°)			
12	When the monitor screen displays the message, <i>INJECT WHEN READY</i> , press <b>Enter</b> on the simulator.			
13	When computing is complete, the CO reading should be 5.0 L/m ±5% at approximately 37°C	CO Reading:		

## SpO2 Test (Masimo)

Test Step	Test Description	Result		
1	Turn the SpO2 simulator power switch <b>ON</b> .			
2	Connect the simulator cable to the TRAM module.			
3a	Set the simulator as follows:			
3b	Set the Pulse Ox to <b>MASIMO OEM Module</b> .			
3c	Set the SpO2% to <b>97</b> .			
3d	Set the Heart Rate to <b>70</b> beats/minute.			
4a	Verify the following are displayed at the monitor:			
4b	A waveform with an SpO2 label.			
4c	An SpO2% reading between 95 - 99%.			
4d	A P-HR reading between 67 and 73 beats per minute.			

5a	Set the simulator to output the following <b>SpO2</b> values.:			
5b	97%	SpO2 Value:		
5c	Verify the displayed value is between 95-99%	Circle One:	PASS	FAIL
5d	90%	SpO2 Value:		
5e	Verify the displayed value is between 87-93%	Circle One:	PASS	FAIL
5f	80%	SpO2 Value:		
5g	Verify the displayed value is between 77 - 83%	Circle One:	PASS	FAIL
6a	Set the simulator to output the following <b>Heart Rate</b> values.:			
6b	70 bpm	P-HR Value:		
6c	Verify the displayed value is between 67 – 73	Circle One:	PASS	FAIL
6d	100 bpm	P-HR Value:		
6e	Verify the displayed value is between 97 – 103	Circle One:	PASS	FAIL
7a	Return the simulator to these conditions:			
7b	Set the SpO2% to <b>97</b> .			
7c	Set the Heart Rate to <b>70</b> bpm			
8a	Set these alarms on the monitor:			
8b	Set SpO2% LO to <b>90</b> .			
8c	Set P-HR HI to <b>90</b> .			
9	Set Heart Rate on the simulator to <b>100</b> .			
10a	Make sure the P-HR value on the monitor flashes.	Circle One:	PASS	FAIL
10b	Make sure alarm <b>does not</b> sound.	Circle One:	PASS	FAIL
11	Return Heart Rate on the simulator to <b>70</b> .			
12	Set SpO2% on the simulator to <b>80</b> .			
13a	Make sure the SpO2% value on the monitor flashes.	Circle One:	PASS	FAIL
13b	Make sure alarm sounds.	Circle One:	PASS	FAIL
14	Disconnect the simulator cable from the module.			

## NBP Tests

NOTE: When the NBP cuff is used in this procedure, it must be tightly wrapped around a tube. DO NOT place the cuff around your arm during the calibration procedures.

Test Step	Test Description	Result		
1	Connect a digital pressure meter and NBP cuff to the NBP connector on the front of the Tram module as shown			
2	Turn the DPM ON, and set its range switch to the mmHg setting			
3	From the monitor's main menu, select <i>MONITOR SETUP</i> .			
4	Select <i>SERVICE MODE</i> .			
5	Enter the password to get into the service mode. The first two digits of the password are the day of the month, and the second two digits are the month. For example, on 7 March, the password would be 0703.			
6	Select <i>SERVICE MODE</i>			
7	Select <i>CALIBRATE NBP</i>			
8	Select <i>CHECK CAL OFF</i> .			
9	Select <i>START</i> .			
10a	The text on the menu item changes from <i>CHECK CAL OFF</i> to <i>CHECK CAL IN PROGRESS</i> . Allow pressure reading to stabilize. Make sure that the pressure readings (shown as <i>CUFF</i> in the <i>NBP</i> parameter box) on the monitor display and manometer are equal ( $\pm 1$ mmHg) and the value drops not more than 10 mmHg for one full minute. If they are not equal, calibrate the NBP parameter according to procedures in "NBP Calibration" on page 4-11 of service manual.			
10b	Record manometer reading	NBP Value		
10c	Record monitor reading	NBP Value		
11	Select <i>CHECK CAL IN PROGRESS</i>			
12	Select <i>STOP</i> . The module then releases pressure in the bulb or cuff.			
13	Remove the cuff and manometer from the Tram module.			

## DEFIB SYNC Test

Test Step	Test Description	Result		
1	Connect an oscilloscope to the <b>DEFIB SYNC</b> connector on the front panel of the Tram module.			
2a	Test the ECG, Arterial BP, and Marker Out signals from the <b>DEFIB SYNC</b> connector. They should resemble the waveforms in the following figure. Note that there are two Marker Out traces shown. The top trace shows the frequency of the pulses; the bottom trace shows the pulse width.			
2b	Verify ECG	Circle One:	PASS	FAIL
2c	Verify Arterial BP	Circle One:	PASS	FAIL
2d	Verify Marker Out Frequency	Circle One:	PASS	FAIL

2e	Verify Marker Out Pulse Width	Circle One:	PASS	FAIL
3	Attach a jumper between pin 1 (Marker Out) and pin 2 (Marker In) of the <b>DEFIB SYNC</b> connector and observe negative spikes in the Rwaves of the displayed ECG waveforms.	Circle One:	PASS	FAIL
4	Remove the jumper.			

### Transport Test

Test Step	Test Description	Result		
1	Connect the Tram module to a transport display. Make sure there are batteries on the rear of the display, and that the batteries are sufficiently charged.			
2	Remove the Tram module from the Tram-rac.			
3a	Set up simulator:			
3b	Set heart rate to 80 bpm.			
3c	Set amplitude to 1.0 mV.			
4a	Observe the following:			
4b	No error messages show on the transport display	Circle One:	PASS	FAIL
4c	The transport display shows ECG lead II, and it is noise-free.	Circle One:	PASS	FAIL
4d	The transport display shows a heart rate of $80 \pm 1$ bpm.	Circle One:	PASS	FAIL
4e	If the QRS tones are turned ON, an audible tone sounds with each QRS complex.	Circle One:	PASS	FAIL
5	Make sure that you can display all of the available ECG leads.	Circle One:	PASS	FAIL

### Fan Test

Test Step	Test Description	Result		
1	Listen for the fan. The fan should be running whenever the Tram module is installed in a bedside monitor or connected to a transport display.	Circle One:	PASS	FAIL

### Completion

1. Turn all test equipment OFF.
2. Remove all test cabling from the Tram module