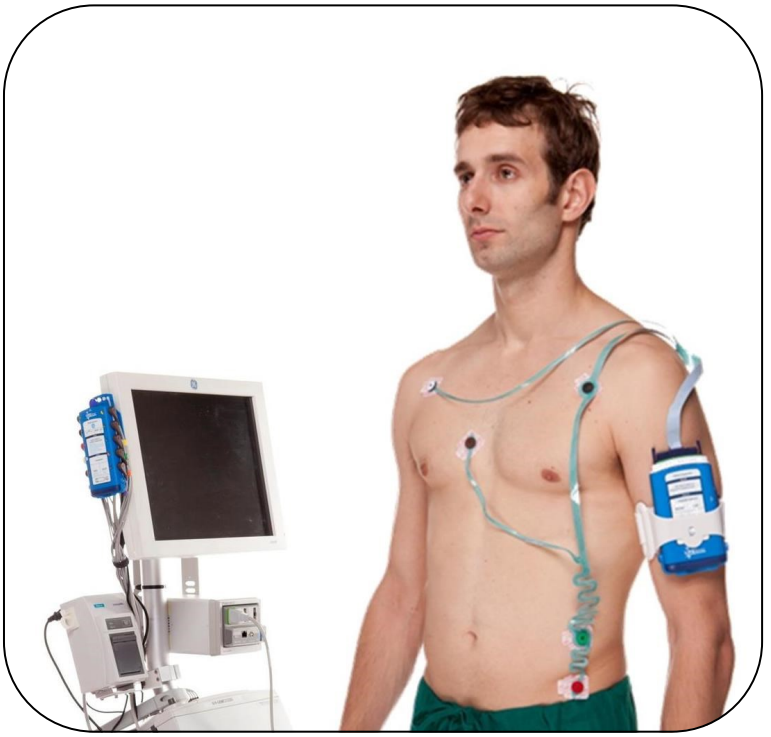
LifeSync® Bluetooth Wireless Medical Device Technology Platform Product Specifications Sheet

General Description

- The LifeSync® Bluetooth Wireless Medical Device Technology Platform is the first wireless electrocardiogram (ECG/EKG) data communication system appropriate for use in high acuity settings.
- The system consists of the LifeSync® LeadWear® Disposable and a set of wireless transceivers: a Patient Transceiver (PT) and a Monitor Transceiver (MT).
- The LeadWear® Disposable is applied to the patient's torso with standard ECG electrodes.
- The LeadWear® Disposable then plugs into the Patient Transceiver which can be placed in the patient's gown pocket or telemetry pouch.
- The Patient Transceiver transmits ECG and respiration data to the Monitor Transceiver.
- The Monitor Transceiver connects to the original reusable lead wires that are used in virtually any patient monitor currently installed in the hospital.



Summary of Features and Benefits

- Wireless ECG system ideal for bedside and transport monitoring
- Facilitates early ambulation and potentially reduces hospital length of stay (LOS)
- Untethers the patient from the monitor
- Enables unrestricted mobility within a coverage area (30' range)
- Reduces in-hospitals trips and falls caused by dangling lead wires
- Capable of 3, 5, and 12 lead continuous monitoring as well as 12 lead diagnostic tests
- Two-way error correction communication using Bluetooth wireless technology at 2.4 Ghz

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2.1 Transceivers Product Specifications Sheet

Parameter	Specification
>> ECG Specifications	
•Number of channels, single ended WRT RL	
•Continuous Monitoring 3/5 Lead Mode:	4
•Diagnostic ECG 12 Lead Mode:	9
•Channels Active	
•Continuous Monitoring 3/5 Lead Mode:	LL, LA, RA, V
•Diagnostic ECG 12 Lead Mode:	LL, LA, RA, V1, V2, V3, V4, V5, V6
•Input Dynamic Range	
•DC:	+- 300 mV DC
•AC:	10 mV p-p AC
•ECG Signal Slew Rate:	320 mV/s maximum
•Input Impedance:	>2.5 MΩ at 100Hz
•Frequency Response, Method A per EC11:1991:	DC – 40 Hz (0.0 ± 0.25 dB) and 40 – 150 Hz (0.0 ± 1 dB)
•Triangle Response, Method D per EC13:2003:	10% maximum reduction 20 ms vs 200 ms triangle wave (System test with HP Page Writer 100)
•Line Filter (60 Hz):	None
•Ch – Ch Signal noise Per EC13:2002:	30 uV p-v maximum, per EC13:2002
•Multi-channel Crosstalk:	≤ 0.5% maximum
•ECG Signal Gain WRT RL:	1.00 ± 0.01 V/V (Measured at 10 Hz)
•Ch – Ch Gain Difference:	0.1% maximum at DC – 150 Hz
•CM Rejection:	< 1 mV output with 20 Vrms input at 60 Hz. (Tested with Welch Allyn Propaq per EC13:2002)
•DC Offset, Any channel:	± 5 mV maximum
>> Leadoff Specifications	
•Leadoff sensed by Patient Transceiver, Leadoff simulated by Monitor Transceiver:	1. Leadoff sensing performed individually by PT on all 10 patient electrode connections. Respectively Leadoff simulated individually on all patient electrodes on MT. 2. Leadoff of all electrodes simulated during loss of radio link. 3. Leadoff of all electrodes simulated during loss of power to either PT or MT. Note: Power to leadoff circuit in MT is backed up by internal long-life lithium coin cell batteries.
•Leadoff sense current - LL, LA, RA, V, V1, V2, V3, V4, V5, V6:	50 nA
•Leadoff sense current - RL:	up to 500 nA
>> Pacer Pulse Specifications	
•Pacer Pulse Detection, Transmission and Reconstruction:	Signals on RA, LA, & LL channels only are acquired at ~16,000 sps and monitored for high slew rates (>10,000 mV/s). When high slew rate is detected, a high resolution 6 ms data sample is acquired and transmitted without Captures and transmits 6 ms. Detects and transmits pacemaker pulses of amplitude 2-700 mV of duration 0.2-2.0 ms and of amplitude 3-700 mV of duration 0.1-0.2 ms.
•Pacer Pulse Function Trigger Slew Rate:	When slew rate > 10,000 mV/s
>> Respiration Specifications	
•Sensing Electrodes:	RA – LA in Patient Transceiver
•Excitation Frequency:	32 KHz
•Patient Risk Current:	10 uA max with AAMI ES-1 test load
•Frequency Response:	0.25 – 2.0 Hz (± 6 dB)
•Input – Output Dynamic Range:	8 ohm p-v maximum
•Base Impedance Range:	0 – 2000 ohms
•Respiration Output:	Modulated digital potentiometer in series with RA electrode in MT.
•Minimum Respiration DC Coupled Impedance before Lead Fail	>1.2kΩ

Parameter	Specification
>> Defibrillation	
•Patient Applied Parts Type:	Defib Proof Type CF per EN 60601-1
•Defibrillation Proof:	Withstands 400 J per IEC 60601-2-27
•Recovery Time After Defibrillation Exposure:	5 s maximum
>> Radio Specifications	
•Protocol:	Bluetooth
•Revision:	V2.0
•Class:	Class 2
•Range:	10 m
•Operating Frequency:	2.402 to 2.480 GHz
•Channels:	79 1 MHz channels
•Power Output Level Patient Transceiver:	-8.3 dBm maximum (0.38 mW)
•Power Output Level Monitor Transceiver:	-2.8 dBm maximum (0.72 mW)
•Signal Latency Due To Radio:	500 ms maximum
>> Electrical Ratings	
•Operating Battery	
•Voltage:	3.6 VDC
•Capacity:	2200 mA-hr
•Technology:	Rechargeable Lithium-Ion
•Run time in Patient Transceiver:	16 hrs maximum
•Run time in Monitor Transceiver:	8 hrs maximum
•Storage Temperature:	-20 to +70 C
•Shelf Life:	2 Years
>> Environmental Conditions	
•Operating Temperature:	0 to +45 C
•Storage Temperature:	-20 to +70 C
•Atmospheric Pressure:	700 to 1060 mbar
•Water Ingress Rating:	IPX1 per IEC 60529 (both PT and MT)
>> Mechanical Specifications	
•Patient Transceiver Size:	8 x 13 x 3 cm (W x H x T)
•Patient Transceiver Weight (with battery):	220 g
•Monitor Transceiver Size:	8 x 15 x 4 cm (W x H x T)
•Monitor Transceiver Weight (with battery):	260 g
•Housing Material:	ABS
>> Agency Compliances	
•Safety:	EN 60601-1, IEC 60601-2-27, UL 60601-1, CSA 22.2 No. 601.1, CSA 22.2 No. 601.2.27
•EMC	EN 60601-1-2:2001
•RF	FCC ID: QXQ-A2005-PT01 FCC ID: QXQ-A2006-MT01
•Monitor Compatibility	ANSI/AAMI EC11:1999(R2007) ANSI/AAMI EC13:2002(R2007)

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