LifeSync® System

User's Manual

CE 0086

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Preface

Introduction

Indications for Use

The LifeSync® Wireless System is indicated for use when ECG monitoring is needed and a wireless cable-free connection is desired between the patient and the ECG monitor. The LifeSync® Wireless System will also transmit the patient respiration waveform for those ECG systems that include a respiration function.

Contraindications

The use of the LifeSync® Wireless System is contraindicated:

- When ECG monitor output may be used to perform a synchronized cardioversion or intracardiac monitoring
- When using an internal monitoring device synchronized to an external device; i.e. in electrophysiology
- During use of MRI or PET scan equipment
- When performing external pacing

Intended Use of LifeSync® Wireless System

The LifeSync® Wireless System is intended for use as a radio-frequency signal transmitter and receiver of patient electrocardiograph (ECG) signals which are displayed on the ECG monitors of various manufacturers' ECG systems. It can be used by clinicians to facilitate ECG monitoring of ambulatory and non-ambulatory adult patients in health care facilities by removing the conventional cable connection between the patient and the ECG monitor.

CAUTION: United States Federal law restricts this device to sale, distribution or use by, or on the order of, a licensed medical practitioner.

This User Manual is intended for use by trained clinicians, who are presumed to be familiar with the use of ECG monitoring equipment, and interpretation of vital signs collected and displayed by that equipment.

The LifeSync® Adapter is intended to be used in conjunction with various patient monitoring equipment such as ECG and EKG.

Caution/Warning Conventions

WARNING: Calls attention to WARNINGS – conditions or practices that could result in personal injury to the patient or the clinician.

CAUTION: Calls attention to CAUTIONS – conditions or practices that could result in damage to the equipment or other property.

NOTE: Calls attention to NOTES – information of particular importance or assistance to the user.

Symbols

The following symbols are used throughout this manual, and/or may appear on LifeSync® Wireless System Components:

⎓	Direct current		Patient Connections are Type CF, protected against defibrillation
	Input		Battery should not be disposed of in fire
	Non-ionizing electromagnetic radiation		ETL listed product
	Consult accompanying documents	Bluetooth	Bluetooth® Wireless Technology
Li++	Lithium ion battery	EC REP	Authorised representative in the European Community
IPX1	Enclosure Protection Drip proof: per EN60529: 1991		Temperature limitation
	Expiration, Use before		Manufacturer
		Xxxxxxxxxxxxx	(… serial no.)

Safety Information

Warnings

- Explosion Hazard – In accordance with UL 60601-1, which applies to all medical equipment, do not use this device in the presence of flammable anesthetics.
- In order for the LifeSync® LeadWear® Disposable to work properly, the RL / Right Leg / GREEN electrode must be connected to the patient at all times with appropriate electrode attached. Follow electrode manufacturer's guidelines for skin prep prior to placing electrodes on patient.
- LifeSync® LeadWear® Disposable is radiolucent. Using some digital imaging systems, it may be less apparent that LeadWear® Disposable and radiolucent electrodes are outside the body. When attached to LeadWear® Disposable snaps, electrodes with opaque posts provide a better indication that LeadWear® Disposable snaps and electrodes are outside the body.
- To ensure patient safety, only LifeSync® LeadWear® Disposable products should be used with the LifeSync® Patient Transceiver. The safety of connecting other devices, leads or cables to the Patient Transceiver has not been evaluated and may present safety hazards. Furthermore, substandard performance may result from the use of incompatible components.
- The LifeSync® Monitor Transceiver should only be connected to patient monitors as illustrated in the System Set Up section of this manual, and only to those monitors that have been validated for compatibility with the LifeSync® Wireless System. Refer to the Cautions section of this manual for a list of validated monitors, or contact LifeSync Corporation for the most current list of validated monitors.
- Only use the approved LifeSync® Power Supply (Model LS-132) in order to ensure that the Patient Monitor (to which the LifeSync® Monitor Transceiver is connected) continues to comply with risk (leakage) current, and EMI/EMC requirements.
- Normal operation of the LifeSync® Wireless System should be verified in the configuration in which it will be used before engaging in use with a patient. Inspect and test the LifeSync® Transceivers, smart batteries, and power supply frequently. Do not operate the LifeSync® Wireless System if any system component appears damaged or appears not to function properly. See System Functional Check section of this manual for procedure to verify normal operation.
- If either of the LifeSync® Transceivers detects an unrecoverable fault, the RED Service LED will illuminate continuously, indicating that service is required prior

to use of the LifeSync® Transceiver. Do not attempt to use a LifeSync® Transceiver that indicates service is required. When RED service LED is on, the LifeSync® Wireless System will stop working.

- The LifeSync® Wireless System can remain applied to a patient during defibrillation. The ECG signal will be interrupted for no more than a few seconds during defibrillation.
- The LifeSync® Wireless System should not be used to perform a synchronized cardioversion, due to signal latency in the radio transmission.
- The LifeSync® Wireless System can be used during procedures using electrosurgery machines. However, even though the LifeSync® Transceivers contain electrosurgical interference suppression filters, increased noise will likely be present while an electrosurgery device is in use. Location of the electrosurgery return pad is very important to minimize interference (be sure to follow electrosurgical manufacturer's guidelines). This effect can be reduced by selecting low impedance electrodes and ECG electrode sites that are remote from the surgical site and electrosurgical return. Avoid electrosurgical surgery burns at the ECG electrodes sites by ensuring proper connection of the electrosurgery return pad, so that the return path cannot be made through the ECG electrodes. Care should be taken to prevent physical contact between electrosurgical equipment and any LifeSync® Wireless System component. The ECG and respiration signals will be interrupted for no more than a few seconds if the electrosurgical current path is close to the ECG leads.
- To ensure patient safety, the conductive parts of ECG electrodes, any conductive parts of the LifeSync® LeadWear® Disposable or any other conductive patient applied parts should not contact any other conductive parts, including earth ground, at any time.
- LifeSync® Wireless System and LifeSync® Adapter should not be used in a Magnetic Resonance Imaging (MRI) suite. Strong magnetic fields may affect the device, causing injury to the patient and/or damage to the equipment.
- The LifeSync® Wireless System and LifeSync® Adapter can operate in the presence of pacemaker pulses, and will detect and communicate these pulses to the ECG monitor. The LifeSync® Wireless System may miss pacer pulses if high background noise is present. The LifeSync® Wireless System captures signal spikes regardless of whether spikes are due to noise or pacer pulses. If the LifeSync® Wireless System triggers frequently from background noise due to motion artifact, EMI, etc., then pacer pulses could be masked or missed by the LifeSync® Wireless System. See further disclosure of pace maker pulse detection information in the Technical section on page 54 of this manual.
- The LifeSync® Wireless System may decrease the ability of the monitor to detect marginal pacemaker pulses (e.g., pacemaker pulses having amplitudes ≤ 2.0 mV and/or widths ≤ 0.2 ms). If the monitor does not detect the pacemaker pulse, then attempt to change the monitored Lead to a Lead exhibiting a larger

amplitude pacemaker pulse. If changing the monitored Lead does not result in pacemaker pulse detection, then switch the patient to a LifeSync® Adapter.

- The LifeSync® Wireless System should not be used for external pacing.
- Impedance pneumography detects respiratory effort via changes in chest volume. Impedance pneumography can be used to detect central apnea, but apnea episodes with continued respiratory effort, such as obstructive apnea and mixed apnea, may go undetected. Artifacts due to patient motion, mattress shaking or use of electrocautery equipment may also cause apnea episodes to go undetected. Impedance pneumography is not recommended for patients with pacemakers.
- A loss of signal can occur if excess force causes damage to a LifeSync® LeadWear® Disposable that is stretched due to electrode placement on the patient. In the event of an emergency situation where excess force would be applied to the patient (resuscitation) please have a secondary method of monitor readily available to avoid a period of time where the patient is not monitored.
- When disconnecting the LifeSync® Adapter, pull on the plug itself, not on the cable.

Cautions

- The smart batteries should be removed (from both the LifeSync® Patient Transceiver and the LifeSync® Monitor Transceiver) and stored separately when the system is not in use for extended periods of time.
- Remove the plastic film cover from the smart battery contacts before using.
- Do not autoclave LifeSync® Wireless System components or LifeSync® Adapter. Do not submerge LifeSync® Wireless System components or LifeSync® Adapter in any liquid.
- LifeSync® LeadWear® Disposable is radiolucent. Areas of the circuit may show shadows on x-ray or under fluoroscopic imaging.
- The LifeSync® Patient Transceiver and LifeSync® Monitor Transceiver have been tested and shown to comply with FCC Part 15. Any changes or modifications to the LifeSync® Wireless System not expressly approved by LifeSync Corporation could cause LifeSync® Wireless System emissions to exceed those permitted under FCC rules, and would thus void the user's authority to operate the equipment.
- When using a 3 lead patient cable to connect the ECG equipment to the LifeSync® Monitor Transceiver, Welch Allyn Propaq and Philips Viridia monitors will not properly detect and display a lead fail indication if one of the three electrodes (RA, LA, LL) becomes detached from the patient. Note that the monitor will function properly if connected to the LifeSync® Monitor Transceiver with a 5 lead cable.

- If operating under conditions according to the EMC-standard 60601-1-2 (Radiated Immunity 3V/m), field strengths above 1.5 V/m may cause erroneous measurements of respiration at various frequencies when the LifeSync® Wireless System is used together with the Welch Allyn Propaq Series Monitor Systems. Therefore, if it is of critical and clinical importance to monitor respiration, it is recommended to avoid the use of electrically radiating equipment (such as electrocautery surgical pencils, and high powered portable and mobile RF communications equipment) while the LifeSync® Wireless System is being used with the Propaq Monitor. However, if respiration must be monitored in the presence of high frequency electrically radiated equipment, always monitor and set alarms for SpO2 when using the LifeSync® Wireless System together with the Propaq Monitor to monitor respiration.
- Only use the LifeSync® Wireless System and LifeSync® Adapter with ECG equipment that has been validated for compatibility. Contact LifeSync Corporation Customer Service at 866-ECG-3888 or visit the website www.LifeSyncCorp.com for information on ECG Monitors that are compatible with the LifeSync® Wireless System.

Note: Validation testing for additional ECG equipment is ongoing. Please contact LifeSync Corporation at 866-ECG-3888 for the current list of compatible equipment.

- For use within the European Community, only CE marked monitors (EN 60601-1 compliant) should be connected to the LifeSync® System. This will ensure compliance with EN 60601-1-1.

Notes

- LifeSync® Smart Battery (LS-121) replacement is recommended after one year of use.
- All LifeSync® Wireless System components that are applied to the patient are either passive (LifeSync® LeadWear® Disposables) or internally powered (LifeSync® Patient Transceiver).
- All LifeSync® Adapter components that are applied to the patient are passive (LifeSync® LeadWear® Disposables).
- The LifeSync® Monitor Transceiver can be operated as a Class II device per EN 60601-1 or internally powered.
- This device has been tested and certified to comply with emissions portion of EN 60601-1-2, Medical Electrical Equipment – Electromagnetic Compatibility – Requirements and Tests. Although this device is shielded against

Electromagnetic Interference (EMI), it is recommended that electrically radiating devices not be used in close proximity to this device.

- Portable and mobile RF communications equipment can affect the operation of the LifeSync® Wireless System.
- Operation of the LifeSync® Wireless System below a minimum amplitude of patient physiological signal may cause inaccurate results.

Introduction to the LifeSync® Wireless System

System Overview

The LifeSync® Wireless System is designed to eliminate the ECG lead wires and cables that connect patients to cardiac monitoring equipment. The system has several components which work together to carry signals from the patient to the monitor.

The lead wire function is replaced by the LifeSync® LeadWear® Disposable Cable Replacement System, which attaches directly to recommended electrode(s).

The trunk cable function is replaced by a pair of two-way radios, the LifeSync® Patient Transceiver and the LifeSync® Monitor Transceiver, which wirelessly transmit and receive ECG and respiration data.

LeadWear® Disposables connect to the LifeSync® Patient Transceiver; the LifeSync® Monitor Transceiver is connected to the ECG monitor.

A LifeSync® Token is used to synchronize the two transceivers; this ensures that the patient's ECG signal is being sent to the correct monitor.

The LifeSync® Patient Transceiver is powered by the LifeSync® Smart Battery. The LifeSync® Monitor Transceiver can also be powered by a LifeSync® Smart Battery for portable use, but is intended to be operated using LifeSync® Power Supply connected to standard AC power when available. While connected to AC power, the LifeSync® Monitor Transceiver functions as a battery charger. When the battery in the LifeSync® Patient Transceiver runs low, it can be quickly exchanged for the fully charged battery in the LifeSync® Monitor Transceiver.

The LifeSync® Patient Transceiver may be placed in a single-patient use LifeSync® Patient Transceiver Pouch to protect it from contamination by foreign debris. A LifeSync® Armband is also available to hold the LifeSync® Patient Transceiver in place on the patient's arm.

In areas where the wireless capability of the LifeSync® Wireless System is not in use, LifeSync® Adapters are available to connect the LeadWear® Disposable(s) directly to an ECG monitor.

Unpacking Checklist

Patient Transceiver

- ☐ LifeSync® Patient Transceiver
- ☐ LifeSync® Smart Battery
  (installed in the Patient Transceiver)
- ☐ User's Manual, CD*

Monitor Transceiver

- ☐ LifeSync® Monitor Transceiver
- ☐ LifeSync® Smart Battery
  (installed in the Monitor Transceiver)
- ☐ LifeSync® Token
  (installed in the Monitor Transceiver)
- ☐ LifeSync® Mounting Plate
- ☐ LifeSync® Power Supply
- ☐ User's Manual, CD*

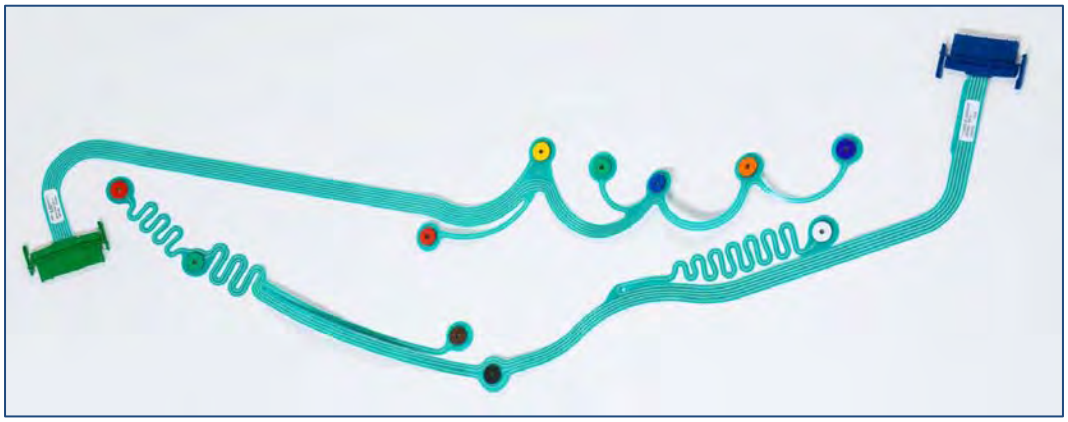
LeadWear® Disposable

- ☐ LifeSync® 3/5 Lead LeadWear® Disposable
- ☐ LifeSync® Precordial LeadWear® Disposable
- ☐ LifeSync® 12 Lead LeadWear® Disposable

** A printed LifeSync® System User's Manual is provided with each facility purchase order.*

System Components

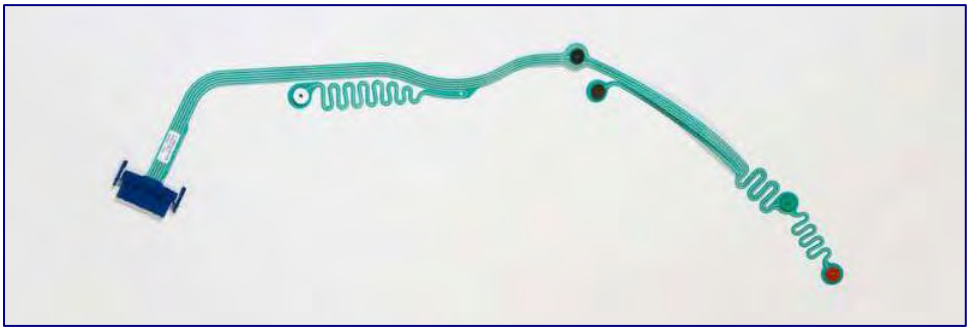
LifeSync® LeadWear® Disposable



There are two types of LifeSync® LeadWear® Disposable:

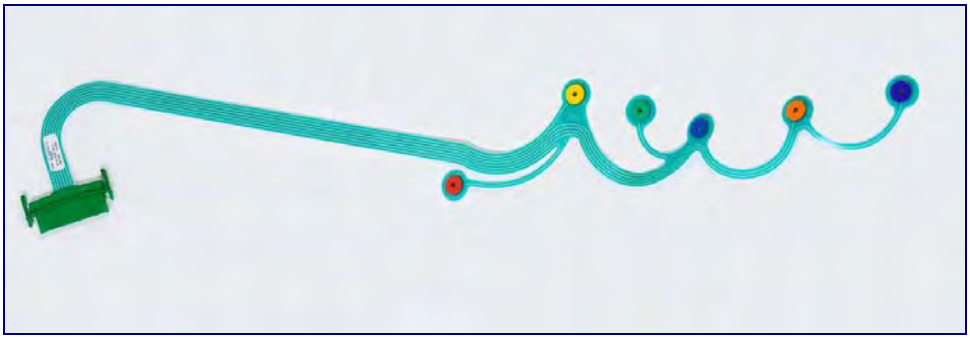
3/5 Lead LeadWear® Disposable	BLUE Connector	For continuous 3 lead or 5 lead ECG monitoring
Precordial LeadWear® Disposable	GREEN Connector	Used in combination with the 3/5 Lead LeadWear® Disposable for a 12 lead ECG monitoring

3/5 Lead LeadWear® Disposables



3/5 Lead LeadWear® Disposables				
Part #	**Size**	**Description**	**RA-LA**	**LA-LL**
LS-222	5	Large 1.0	10 – 12"	14 – 16"
LS-225	7	Large 1.1	11.5 – 17.5"	14 – 16"
LS-223	8	XXL 1.0	10 – 12"	18 – 20"
LS-226	9	XXL 1.1	13.3 – 22.5"	19 – 21"

Precordial LeadWear® Disposables



Precordial LeadWear® Disposables							
Part #	**Size**	**Description**	**V1 – V2**	**V2 – V3**	**V3 – V4**	**V4 – V5**	**V5 – V6**
LS-232 LS-235	7	Large 1.0	4.75"	2.5"	2.25"	3.0"	3.0"
LS-233 LS-236	9	XXL 1.0	4.75"	2.5"	2.25"	4.5"	4.0"

12 Lead LeadWear® Disposables

12 Lead LeadWear® Disposables			
Part #	**Size**	**3/5 Lead**	**Precordial**
LS-202	5	LS-222	LS-232
LS-205	7	LS-225	LS-232
LS-203	8	LS-223	LS-235
LS-206	9	LS-226	LS-235

LeadWear® Disposables are packaged three ways:

3/5 Lead	One 3/5 Lead LeadWear® Disposable
12 Lead	One 3/5 Lead LeadWear® Disposable and One Precordial LeadWear® Disposable
Precordial	One Precordial LeadWear® Disposable

LeadWear® connectors are color-coded to ensure proper connection to the LifeSync® Patient Transceiver: BLUE connectors on the 3/5 Lead LeadWear® Disposable and GREEN connectors on the Precordial LeadWear® Disposable.

NOTE: LifeSync® LeadWear® Disposables are non-sterile.

Patient Transceiver

LifeSync® LeadWear® Connector Ports: Color-coded ports for attachment of the LeadWear® Disposable: BLUE for the 3/5 Lead LeadWear® Disposable and GREEN for the Precordial LeadWear® Disposable. The Precordial LeadWear® connector port is protected by a flexible cap while not in use.

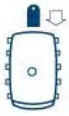
LifeSync® Token Port: Insert the Token here to synchronize the Transceivers. The Token port is protected by a flexible cap when not in use.

LifeSync® Smart Battery: Battery is removable for charging (in the Monitor Transceiver).

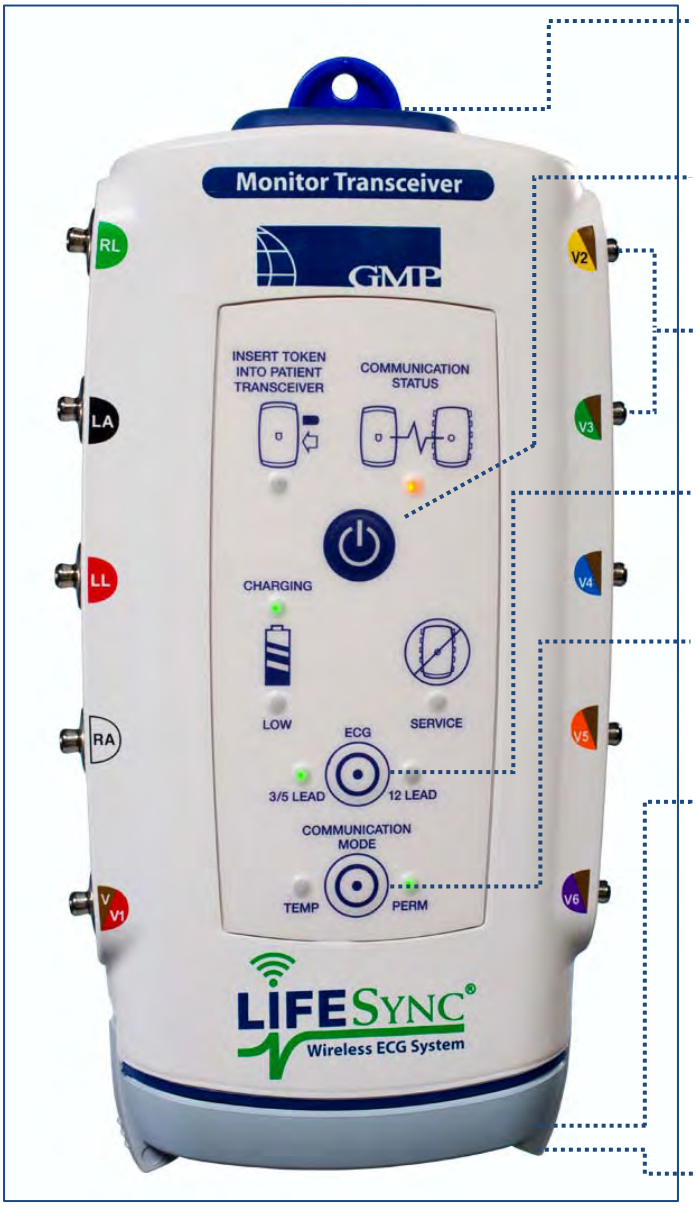
Battery Clips: Hold battery in place.

Turn Patient Transceiver ON by inserting a BLUE 3/5 Lead LeadWear® Connector into the BLUE connector port.

Visual Status Indicators:

	Return Token to Monitor Transceiver	YELLOW – FLASHING	Return Token to Monitor Transceiver (The Transceiver will BEEP once when Token is fully inserted)
	Communication Status (one for TEMP mode, one for PERM mode)	OFF	No communication
		YELLOW – SOLID	No communication
		GREEN – FLASHING	Communication in process
	Low Battery Charge	YELLOW – FLASHING (accompanied by periodic BEEPS)	Battery charge level low, less than 60 minutes operation time left.
	Service	RED – SOLID OR FLASHING	Transceiver malfunction

Monitor Transceiver



LifeSync® Token Port:
Insert the Token here to synchronize the Transceivers.

Power On/Off:
Turn Monitor Transceiver ON with On/Off switch.

ECG Monitor Connections:
Snaps for connection to ECG lead wire set.

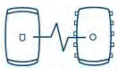
ECG Mode:
Switch between 3/5 lead and 12 lead ECG monitoring functions.

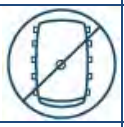
Communication Mode:
Switch between temporary and permanent communication.

LifeSync® Smart Battery:
Insert removable battery here for charging and for use with portable monitors. A built-in battery charger automatically charges the battery whenever the Monitor Transceiver is connected to the LifeSync® Power Supply plugged into AC power.

Battery Clips:
Hold battery in place.

Visual Status Indicators:

	"Insert Token Into Patient Transceiver"	YELLOW – SOLID OR FLASHING	"Insert Token Into Patient Transceiver" (The Transceiver will BEEP when Token is fully inserted)
	Communication Status	YELLOW – SOLID	No communication
		GREEN – FLASHING	Communication in process

	Power On/Off switch	ON/OFF Switch	Press to turn unit ON or OFF
	Battery Charging	GREEN – SOLID	Battery is fully charged
		GREEN – FLASHING	Battery is charging
		NOTE: The GREEN light is only active when the unit is connected to the LifeSync® Power Supply plugged into AC power.	
	Low Battery Charge	YELLOW – FLASHING (with a periodic BEEP)	Battery charge level low, less than 60 minutes operation time left.
		NOTE: The YELLOW light is only active when the unit is NOT connected to the LifeSync® Power Supply plugged into AC power.	
	Service	RED – SOLID OR FLASHING	Transceiver malfunction
	ECG Mode	Press switch to alternate between ECG modes	
		GREEN – SOLID	Indicates whether LifeSync® Wireless System is in 3/5 LEAD or 12 LEAD mode.
	Communication Mode	Press switch to alternate between communication modes	
		GREEN – SOLID	Indicates whether LifeSync® Wireless System is in Temporary (TEMP) or Permanent (PERM) mode

Smart Battery

The LifeSync® Smart Battery is a 3.6 Volt rechargeable Lithium-ion battery, with a built-in "fuel" gauge, and is interchangeable between the LifeSync® Patient Transceiver and the LifeSync® Monitor Transceiver. Batteries are shipped in the uncharged state.

The LifeSync® Smart Battery charges in less than eight hours, when installed in a LifeSync® Monitor Transceiver that is connected to the LifeSync® Power Supply plugged into 110V AC power.

NOTE: If battery is new, remember to remove the plastic tape from the battery contacts before first use. A new battery will need to be charged in a LifeSync® Monitor Transceiver for approximately eight hours before first use.

A new, fully charged battery will power a LifeSync® Patient Transceiver for a maximum of 24 hours, and a LifeSync® Monitor Transceiver for a maximum of 12 hours. At end-of-life smart battery capacity will be approximately 80% of original capacity. It is recommended that batteries be discarded after one year of normal use (400 discharge cycles).

LifeSync® Smart Battery Charge Indicator: Easy-to-read gauge on end of battery indicates amount of charge remaining. Press button to view level. Each LED represents 20% of the battery life.

Token

The LifeSync® Token is used to establish communication or synchronize the LifeSync® Patient Transceiver and LifeSync® Monitor Transceiver. The Token is not programmed for a particular transceiver; it works by transferring address and communication mode information between two transceivers during the synchronizing process.

NOTE: LifeSync® Monitor Transceiver will not operate without Token. Token should remain in Token port of the LifeSync® Monitor Transceiver at all times, except when it is being used to synchronize a LifeSync® Patient Transceiver.

Power Supply

The LifeSync® Power Supply converts AC power to the 5.5 V DC power required to operate the LifeSync® Monitor Transceiver and charge the LifeSync® Smart Battery.

NOTE: When the LifeSync® Monitor Transceiver is disconnected from the LifeSync® Power Supply or AC power, the battery will stop charging and LifeSync® Monitor Transceiver will be powered by the smart battery.

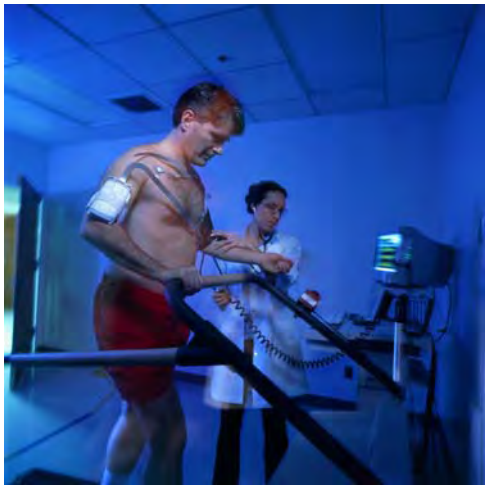
Accessories

Patient Transceiver Pouch

The LifeSync® Patient Transceiver Pouch protects the LifeSync® Patient Transceiver from fluids and other hazardous materials.

Armband

The LifeSync® Armband is for use when the LifeSync® Patient Transceiver needs to be secured to the patient's arm (i.e.: stress test, etc).



Introduction to LifeSync® Adapter

Adapters

The LifeSync® Adapter is an interface between the ECG equipment and LifeSync® LeadWear® Disposables. The LifeSync® Adapter permits the use of LeadWear® Disposables with ECG monitoring equipment via direct electrical connection.

NOTE: LifeSync® Adapters are connected directly to the trunk cable of 3/5 or 12 lead ECG monitors as well as directly connected to wireless telemetry transmitters.

NOTE: LifeSync® Adapters are non-sterile, reusable and latex free.

LifeSync® Wireless System Operation

The LifeSync® Wireless System works with existing ECG monitor equipment and with recommended electrode(s).

NOTE: Proper function of the LifeSync® Wireless System with the ECG monitoring equipment should be confirmed before use with a patient.
(See System Functional Check on page 35 of this Manual.)

Wireless System Set Up

Install/Check Smart Batteries in Transceivers

NOTE: If battery is new, remember to remove the plastic tape from the battery contacts before first use. A new battery will need to be charged in a LifeSync® Monitor Transceiver for approximately eight hours before first use.

1. Swing battery clips to the side, off the end of the battery. Remove battery from each transceiver.
2. Check battery charge indicator on each battery by pressing the oval. If all five battery indicators are not lit, replace battery with a fully charged battery. Each LED represents 20% of battery life.
3. Re-install battery into each transceiver and secure by latching battery clips back over the end of the battery.

NOTE: Use a fully charged battery. To charge the LifeSync® Smart Battery ensure the LifeSync® Monitor Transceiver is connected to the LifeSync® Power Supply and plugged to AC power and the smart battery is fully inserted and latched

Mount the LifeSync® Monitor Transceiver

1. Connect LifeSync® Monitor Transceiver to LifeSync® Power Supply and AC power source. (The Power Supply is optional if fully charged smart battery is installed in LifeSync® Monitor Transceiver.)

2. Secure the LifeSync® Mounting Plate to the desired location, using the supplied double-sided adhesive tape (or other method).

NOTE: The arrow on the LifeSync® Mounting Plate must be pointing upward.

3. Insert buttons on back of LifeSync® Monitor Transceiver into slots on LifeSync® mounting plate, and slide transceiver unit downward until it clicks into place.

4. Connect leads of the standard ECG lead wire set from the ECG equipment to the corresponding snap attachments on the LifeSync® Monitor Transceiver, matching lead marking and color codes.

5. Ensure a LifeSync® Token is seated in the Token port on Monitor Transceiver.

NOTE: LifeSync® Monitor Transceiver will not operate without LifeSync® Token. Token should remain in token port of the LifeSync® Monitor Transceiver at all times, except when it is being used to synchronize a LifeSync® Patient Transceiver.

User Instructions: Wireless Monitoring

3/5 Lead Wireless Monitoring

To continuously monitor 3 lead or 5 lead ECG signals using a cardiac monitor.

Select LifeSync® Monitor Transceiver Settings

NOTE: Make sure a LifeSync® Token is installed in the token port of the Monitor Transceiver.

1. Press Power On/Off switch to turn Monitor Transceiver ON.
2. Press ECG Mode switch until the indicator "3/5 LEAD" glows GREEN.
3. Press Communication Mode switch until the indicator "PERM" glows GREEN.

Apply LifeSync® LeadWear® Disposable

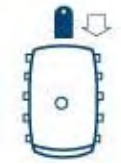
1. Select appropriate size 3/5 Lead LeadWear® Disposable (BLUE connector) for the patient (refer to size chart on page 9).

NOTE: For placement of LeadWear® Disposable on patient, refer to "User Instructions: LeadWear® Disposable for 3/5 Lead Monitoring", on page 29 of this Manual.

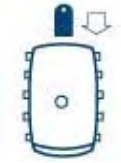
2. Insert BLUE 3/5 Lead LeadWear® Connector into BLUE slot on LifeSync® Patient Transceiver. This will turn the LifeSync® Patient Transceiver ON. Ensure that connector is seated securely and that tabs lock into place.
3. Place LifeSync® Patient Transceiver inside Patient Transceiver Pouch or Armband and seal the top of the pouch. Pouch can be placed on or near the patient.

Synchronize LifeSync® Transceivers

1. Remove token from Monitor Transceiver. The "Insert Token Into Patient Transceiver" indicator on the Monitor Transceiver will glow SOLID YELLOW.



2. Pull the flexible cap away from the token port on Patient Transceiver and fully insert token into token port. Wait for the Return Token Into Monitor Transceiver indicator on the Patient Transceiver to glow FLASHING YELLOW. The Patient Transceiver will also produce a single audible BEEP when the Token is properly seated.

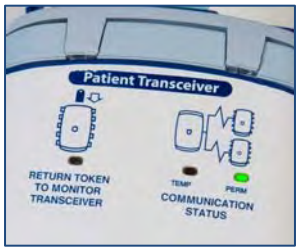


3. Remove token from Patient Transceiver and close flexible cap over token port; the Return Token Into Monitor Transceiver indicator on the Patient Transceiver will go off.

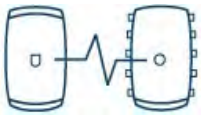
4. Fully insert the token into the token port on the Monitor Transceiver. The Monitor Transceiver will BEEP when the token is properly re-inserted and the "Insert Token Into Patient Transceiver" indicator will go off.

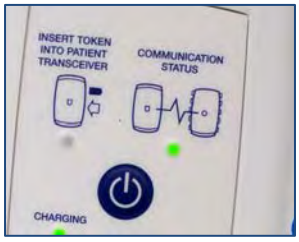
5. Within a few seconds, the Transceivers' Communication Status indicators will display FLASHING GREEN if communicating or SOLID YELLOW if communication failed. If communication fails repeat steps 1 thru 5.

Patient Transceiver
PERM Communication Status indicator will flash GREEN;
Communication in process with Monitor Transceiver



Monitor Transceiver
Communication Status indicator will flash GREEN;
Communication in process with Patient Transceiver





The patient's ECG signal will appear on the cardiac monitor within a few seconds. If ECG cardiac monitor is respiration capable the respiration signal will also appear.

12 Lead Wireless Monitoring

To continuously monitor 12 lead ECG signals using a 12 lead cardiac monitor.

Select LifeSync® Monitor Transceiver Settings

NOTE: Make sure a LifeSync® Token is installed in the token port of the Monitor Transceiver.

1. Press Power On/Off switch to turn Monitor Transceiver ON.
2. Press ECG Mode switch until the indicator "12 LEAD" glows GREEN.
3. Press Communication Mode switch until the indicator "PERM" glows GREEN.

Apply LifeSync® LeadWear® Disposable

1. Select appropriate size 3/5 Lead LeadWear® Disposable (BLUE connector) for the patient (refer to size chart on page 9) and appropriate size Precordial LeadWear® Disposable (GREEN connector).

NOTE: For placement of LeadWear® Disposable on patient, refer to "User Instructions: LeadWear® Disposable for 12 Lead Monitoring", on page 31 of this Manual.

2. Pull the flexible cap away from GREEN connector port and insert both 3/5 Lead and precordial LeadWear® Connectors into BLUE and GREEN slots on Patient Transceiver, matching colors. Inserting the Lead LeadWear® (BLUE) Connector will turn the Patient Transceiver ON. Ensure that connectors are seated securely and that tabs lock into place.
3. Place Patient Transceiver inside Pouch (or Armband) and seal the top of the pouch. Pouch can be placed on or near the patient.

Synchronize LifeSync® Transceivers

1. Remove token from Monitor Transceiver. The "Insert Token Into Patient Transceiver" indicator on the Monitor Transceiver will glow SOLID YELLOW.

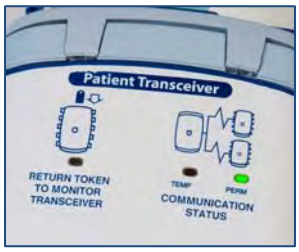
2. Pull the flexible cap away from the token port on Patient Transceiver and fully insert token into token port. Wait for the Return Token Into Monitor Transceiver indicator on the Patient Transceiver to glow FLASHING YELLOW. The Patient Transceiver will also produce a single audible BEEP when the Token is properly seated.

3. Remove token from Patient Transceiver and close flexible cap over token port; the Return Token Into Monitor Transceiver indicator on the Patient Transceiver will go off.

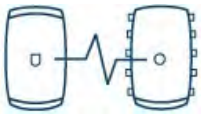
4. Fully insert the token into the token port on the Monitor Transceiver. The Monitor Transceiver will BEEP when the token is properly re-inserted and the "Insert Token Into Patient Transceiver" indicator will go off.

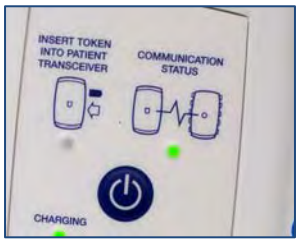
5. Within a few seconds, the Transceivers' Communication Status indicators will display FLASHING GREEN if communicating or SOLID YELLOW if communication failed. If communication fails repeat steps 1 thru 5.

Patient Transceiver
PERM Communication Status indicator will flash GREEN; Communication in process with Monitor Transceiver



Monitor Transceiver
Communication Status indicator will flash GREEN; Communication in process with Patient Transceiver





The patient's ECG signal will appear on the 12 lead ECG monitor within a few seconds. If ECG cardiac monitor is respiration capable the respiration signal will also appear.

Temporary ECG

Temp mode allows a single Patient Transceiver to communicate with two Monitor Transceivers simultaneously to monitor 3 lead, 5 lead or 12 lead ECG signal.

NOTE: This procedure requires a secondary LifeSync® Monitor Transceiver to be set up on a second ECG device.

Select LifeSync® Monitor Transceiver Settings

NOTE: • Make sure a LifeSync® Token is installed in the token port of the Monitor Transceiver.
• Do not change any settings on the primary Monitor Transceiver. The primary Monitor Transceiver is the unit that is already synchronized with the Patient Transceiver.

1. Press Power On/Off switch to turn ON the secondary Monitor Transceiver.
2. Press ECG Mode switch until the desired mode – either "3/5 LEAD" or "12 LEAD" – glows GREEN.
3. Press Communication Mode switch until the indicator over "TEMP" glows GREEN.

Temporary 12 Lead ECG Only - Apply Precordial LeadWear® Disposable

1. Select appropriate size Precordial LeadWear® Disposable (GREEN connector).

NOTE: For placement of Precordial LeadWear® Disposable on patient, refer to "User Instructions: LeadWear® Disposable for 12 Lead Monitoring", on page 31 of this Manual.

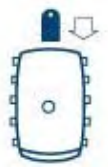
2. Remove the V (BROWN) snap of the 3/5 Lead LeadWear® Disposable (already on the patient) from its electrode (if used).

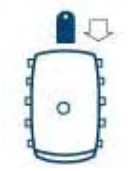
3. On the Patient Transceiver, pull the flexible cap away from connector port and insert GREEN Precordial LeadWear® Connector into slot on Patient Transceiver.

Synchronize LifeSync® Transceivers

1. Remove Token from secondary Monitor Transceiver. The "Insert Token Into Patient Transceiver" indicator on the Monitor Transceiver will glow SOLID YELLOW.

2. Pull the flexible cap away from the token port on Patient Transceiver and fully insert token into token port. Wait for the Return Token Into Monitor Transceiver indicator on the Patient Transceiver to glow FLASHING YELLOW. The Patient Transceiver will also produce a single audible BEEP when the Token is properly seated.





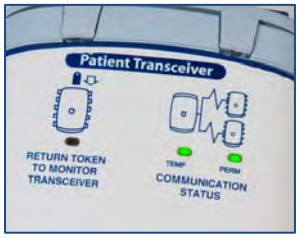
3. Remove token from Patient Transceiver and close flexible cap over token port; the Return Token Into Monitor Transceiver indicator on the Patient Transceiver will go off.

4. Fully insert the token into the token port on the secondary Monitor Transceiver. The secondary Monitor Transceiver will BEEP when the token is properly re-inserted and the "Insert Token Into Patient Transceiver" indicator will go off.

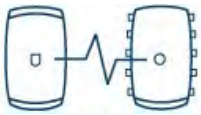
NOTE: There will be a momentary interruption in the signal being received by the primary Monitor Transceiver when the Token is placed back in the secondary Monitor Transceiver.

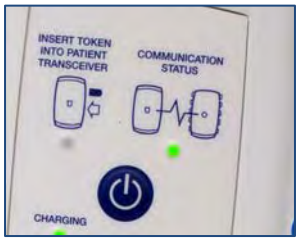
5. Within a few seconds, the Transceiver indicators will display FLASHING GREEN if communicating or SOLID YELLOW if communication failed. If communication fails repeat steps 1 thru 5.

Patient Transceiver
Both PERM and TEMP Communication Status indicators will flash GREEN; Permanent Communication in process with the primary Monitor Transceiver and Temporary Communication with the secondary Monitor Transceiver



Primary and Secondary Monitor Transceivers
Communication Status indicator will flash GREEN – Communication in process with Patient Transceiver





The patient's ECG signal will then appear on both the ECG devices.

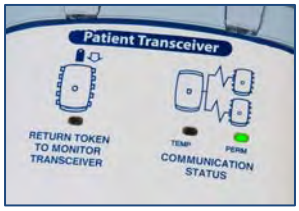
NOTE: Temporary and Permanent communication modes are independent and can be run without the other.

6. The Patient Transceiver will communicate with the secondary Monitor Transceiver for two minutes.

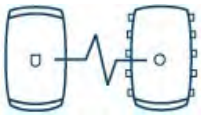
7. After two minutes, the Patient Transceiver will automatically end communication with the secondary Monitor Transceiver.

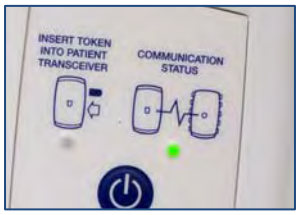
The Transceiver indicators will reflect the change in communication status:

Patient Transceiver
PERM Communication Status indicator will flash GREEN; Permanent Communication still established with the primary Monitor Transceiver. TEMP Communication Status indicator will go off.

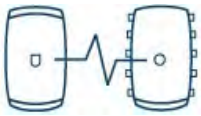


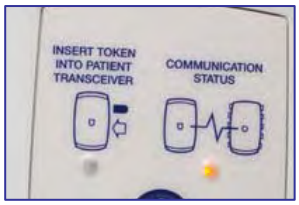
Primary Monitor Transceiver
Communication Status indicator will flash GREEN; Communication in process with Patient Transceiver





Secondary Monitor Transceiver
Communication Status indicator will flash YELLOW – No Communication





Temporary 12 Lead ECG Only – Remove Precordial LeadWear® Disposable

1. Disconnect the GREEN Connector from the Patient Transceiver. The Precordial LeadWear® Disposable may now be removed from the patient, or may be left in place for a future use. If necessary, replace the V (BROWN) lead of the 3/5 Lead LeadWear® Disposable.

NOTE: Place ECG lead electrode on V (BROWN) lead before placing on patient.

Patient Transfer: Wireless to Wireless

To permanently transfer a patient from one monitor to another monitor.

NOTE: This requires an extra LifeSync® Monitor Transceiver - ECG device set up.

Select Transceiver Settings

NOTE: Make sure a LifeSync® Token is installed in the token port of the LifeSync® Monitor Transceiver.

1. Press Power On/Off switch to turn the extra LifeSync® Monitor Transceiver ON. This is the transceiver attached to the monitor that the patient is being transferred to and will become the primary Monitor Transceiver.
2. Press ECG Mode switch on this transceiver until the indicator glows GREEN for the appropriate ECG mode ("3/5 LEAD" or "12 LEAD").
3. Press Communication Mode switch until the indicator over "PERM" glows GREEN.

Synchronize LifeSync® Transceivers

1. Remove Token from extra Monitor Transceiver and place in token port on the Patient Transceiver; wait for the BEEP. Remove token, replace flap, place token back in extra Monitor Transceiver; wait for BEEP.

NOTE: Step by step instructions for 3/5 LEAD wireless monitoring are found on page 18. Step by step instructions for 12 LEAD wireless monitoring are found on page 20.

System Removal

1. Leave the Monitor Transceiver attached to the side of the patient monitor until its next use. The Monitor Transceiver can be left on unless it will not be used for an extended period of time.
   To turn the Monitor Transceiver OFF, Press Power On/Off switch.
2. Remove Patient Transceiver from Patient Transceiver Pouch or Armband. To remove LeadWear® connectors from Transceiver, squeeze clips on LeadWear® connector and pull straight out from Transceiver.
3. Gently remove LeadWear® Disposable and electrodes from patient.
4. Discard LeadWear® Disposable, electrodes and Patient Transceiver Pouch/Armband.
5. Store Patient Transceiver in a designated storage location.

NOTE: If system is not to be used for an extended period, the batteries should be removed from the Patient Transceiver and the Monitor Transceiver, and stored separately.

Smart Batteries

The Monitor Transceiver should be connected to the Power Supply and plugged to AC power at all times, in order to ensure the battery is fully charged. When the smart battery in the Patient Transceiver runs low, it can quickly be exchanged for a fully charged smart battery in the Monitor Transceiver.

NOTE: Each Transceiver has a Battery Charge Indicator that flashes YELLOW when its battery is running low, accompanied by a periodic BEEP. Replace the low battery with a fully-charged battery within 60 minutes to maintain Transceiver operation.

Charge Level Indicator

Each Smart Battery has a built-in charging gauge. Press the oval on the end of the gauge to view the charge indicator. Each LED represents 20% of battery capacity.

WARNING: Battery capacity will change over the life of the battery. A fully charged unit does not mean that the battery is capable of running the Patient Transceiver. If battery capacity is more than one year old, it is recommended that the battery be replaced.

Exchanging Smart Batteries

Remove the smart battery from the Transceivers by releasing the battery clips and sliding the smart battery out of the battery slot.

Insert the replacement smart battery with contacts and wide part of battery cap toward front of Transceiver. Secure the battery clips.

NOTE: Exchanging smart batteries does not require re-synchronization of the Transceivers.

Charging Smart Batteries

When the Monitor Transceiver is connected to the Power Supply and plugged to AC power, it functions as a charger for the battery. The smart battery reaches full charge in less than eight hours.

NOTE: At end-of-life smart battery capacity will be approximately 80% of original capacity. It is recommended that batteries be discarded after one year of normal use (400 discharge cycles)

CAUTION: Use only a LifeSync® Monitor Transceiver to recharge the battery.

Monitor Transceiver Battery Charging Indicator

The Battery Charging indicator on the front of the Monitor Transceiver displays a GREEN light when the battery charger function is active.

When the Monitor Transceiver is not connected to the Power Supply and plugged to AC power and is being powered by a smart battery, the battery charger function is inactive and the Battery Charging indicator will not be lit.

When the Monitor Transceiver is connected to the Power Supply and plugged to AC power and has a less-than-fully-charged smart battery installed, the Battery Charging indicator will flash GREEN, to indicate that the smart battery is charging. It will take up to eight hours for the Monitor Transceiver to finish charging a discharged smart battery. The Battery Charging indicator will glow SOLID GREEN when charging is complete.

Smart Battery Storage

The smart battery should be removed from the Patient Transceiver and stored separately when not in use for more than a few days. (See more information about battery storage in the Maintenance and Troubleshooting section, on page 39 of this Manual.)

CAUTION:

- Store smart batteries between -40°C and 70°C/ -40°F and 160°F.
- Store smart batteries away from direct sunlight in a low humidity location with little temperature variation.
- Discard smart batteries according to national, state and local regulations.

Respiration

If the Monitor Transceiver is being used with a patient monitor that is equipped to display patient respiration via thoracic impedance pneumography, the patient monitor will continue to display patient respiration as long as the patient monitor is configured to derive respiration from lead I or lead II. Consult ECG equipment manual for more information about proper settings and operation of the respiration function. Also, refer to the Specifications section of this manual for details on LifeSync® Wireless System respiration function.

User Instructions: LeadWear® Disposable

3/5 Lead Monitoring

1. Remove LeadWear® Disposable from package.

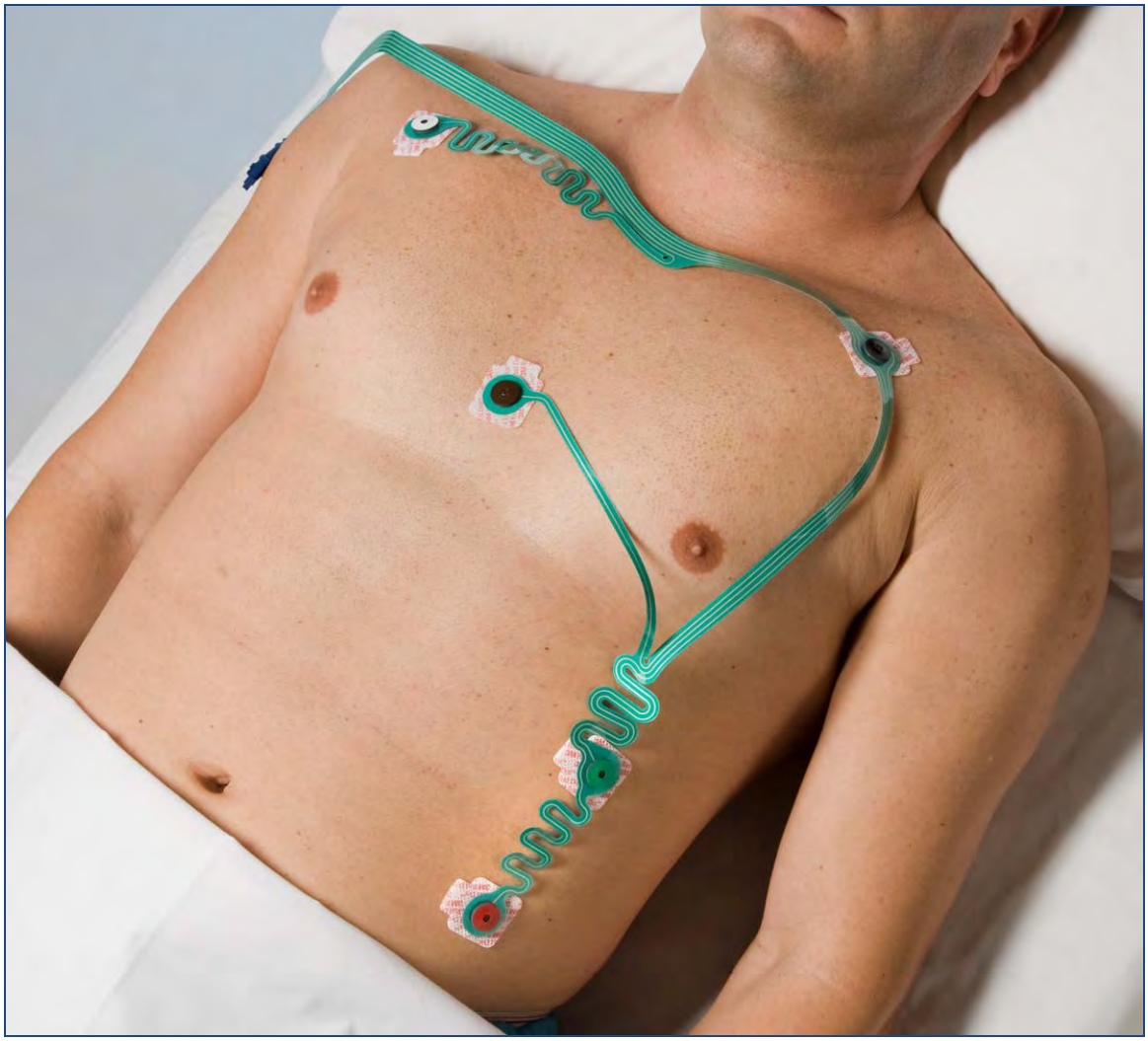
NOTE: Release LeadWear® Disposable from the package insert card with care, by pressing on the colored side of each snap. DO NOT pull snaps out of holes by tugging on the LeadWear® Disposable itself.

2. Attach recommended electrode(s) to all snaps on the LeadWear® Disposable, and place on the patient as indicated in the diagram and table below.

NOTE: Follow electrode manufacturer's guidelines for skin prep prior to placing electrodes on patient.

NOTE: Place electrode LA on the left shoulder first. See chart for remaining electrode placements.

3/5 Lead LeadWear® Disposable Electrode Placement		
LA	Black	Left shoulder
RA	White	Right shoulder
LL	Red	Left-side of chest below navel
RL	Green	Left-side of chest just above LL
V	Brown	Center of chest (optional)



NOTE: The position of the RL (Right Leg) electrode with the LifeSync® LeadWear® Disposable is different from standard ECG lead placement.

NOTE: Confirm the fit of LeadWear® Disposable on patient. If lead placements don't reach or there is too much slack, select a different size.

12 Lead Monitoring

1. Remove LeadWear® Disposable from package(s).

NOTE: Release LeadWear® Disposable from the package insert card with care, by pressing on the colored side of each snap. DO NOT pull snaps out of holes by tugging on the LeadWear® Disposable itself.

2. Attach recommended electrode(s) to all snaps except for V (BROWN) on 3/5 Lead LeadWear® Disposable, and place on the patient as indicated in the diagrams and tables below.

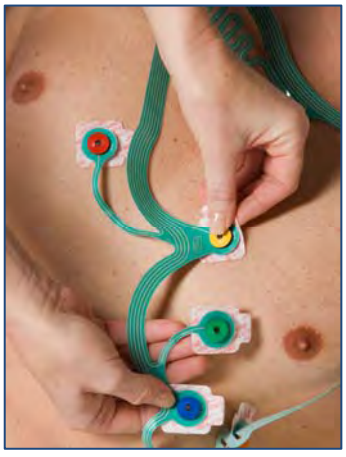
NOTE: Follow electrode manufacturer's guidelines for skin prep prior to placing electrodes on patient.

NOTE: Place electrode LA on the left shoulder first. See chart for remaining electrode placements.

3/5 Lead LeadWear® Disposable Electrode Placement		
LA	Black	Left shoulder
RA	White	Right shoulder
LL	Red	Left-side of chest below navel
RL	Green	Left-side of chest just above LL
V	Brown	Not used for 12 Lead ECG

NOTE: Place electrode V2 first. See chart for remaining electrode placements.

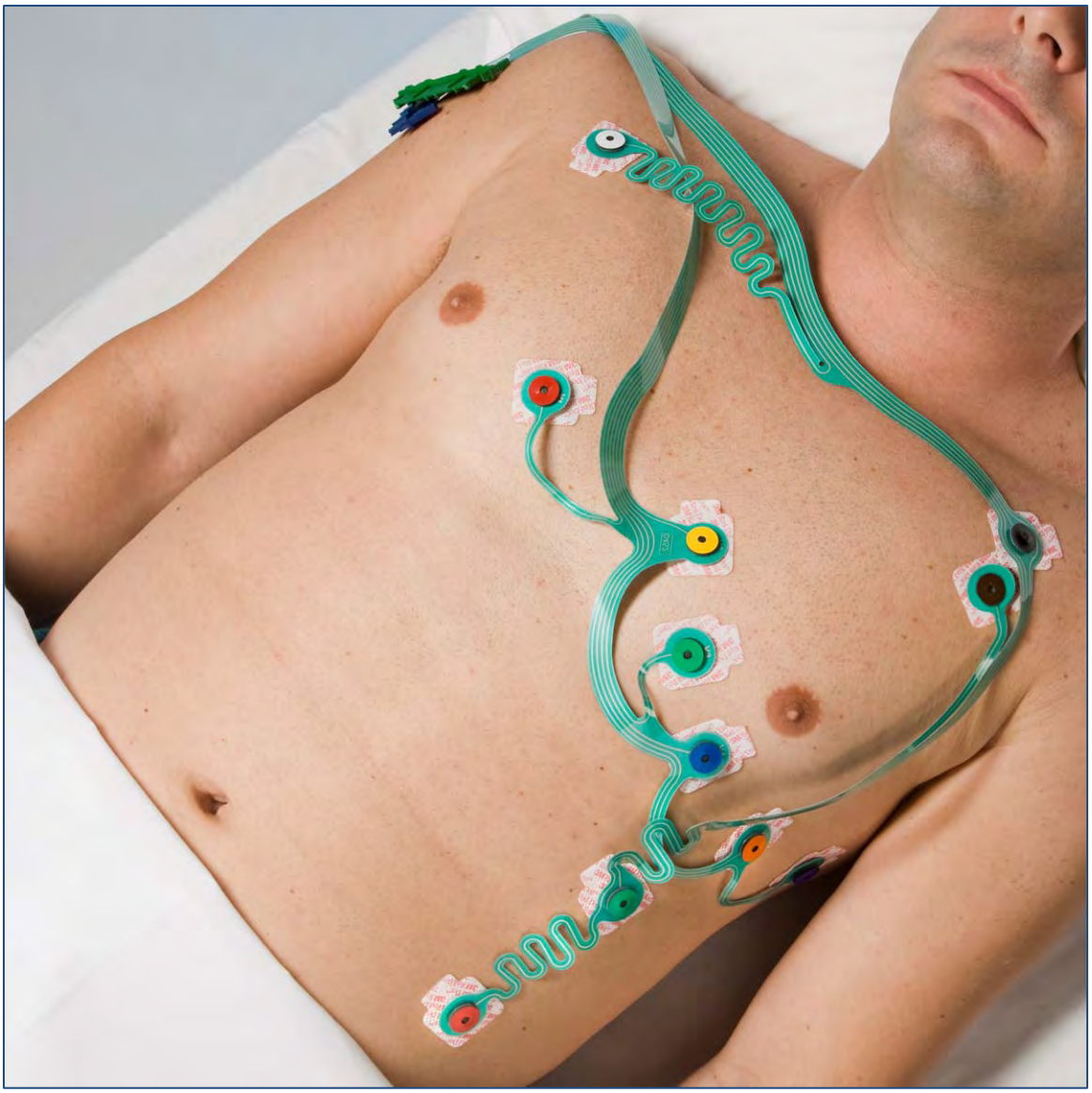
Precordial LeadWear® Disposable Electrode Placement		
V1	Red	Fourth intercostal space at right sternal border
V2	Yellow	Fourth intercostal space at left sternal border
V3	Green	Midway between V2 and V4
V4	Blue	Fifth intercostal space midclavicular line
V5	Orange	At horizontal level of V4 left anterior axillary line
V6	Violet	At horizontal level of V4 left midaxillary line



NOTE: Although the V lead on the 3/5 LeadWear® Disposable is not used for 12 lead operation, it should be fastened to the patient's chest in order to avoid accidental pulling of the LeadWear® Disposable.

NOTE: The position of the RL (Right Leg) electrode with the LeadWear® Disposable is different from standard ECG lead placement.

NOTE: Confirm the fit of LeadWear® Disposable on patient. If lead placements don't reach or there is too much slack, select a different size.



LifeSync® Adapter Operation

User Instructions: Adapters

12 Lead Adapter

To use LeadWear® Disposable directly with 12 Lead ECG monitoring equipment.

1. Select appropriate size 3/5 Lead LeadWear® Disposable (BLUE connector) and appropriate size precordial LeadWear® Disposable for the patient (refer to size chart on page 9).

NOTE: For placement of LeadWear® Disposable on patient, refer to "User Instructions: LeadWear® Disposable for 12 Lead Monitoring", on page 31 of this Manual. Ensure the monitor is set for 12 Lead monitoring.

2. Connect Adapter to the trunk cable or monitoring equipment.
3. Connect the LeadWear® Disposables (BLUE and GREEN connector) to the Adapter.

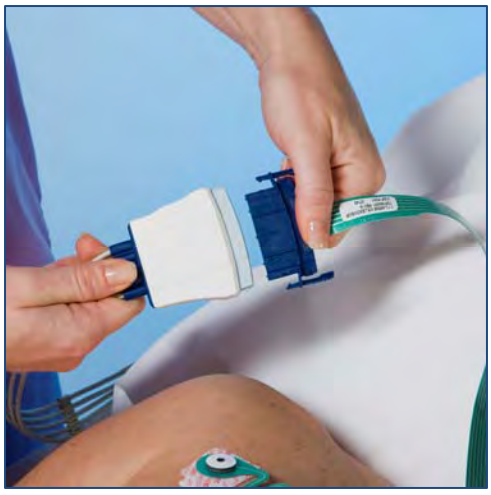
3/5 Lead Adapter

To use LeadWear® Disposable directly with ECG monitoring equipment.

1. Select appropriate size 3/5 Lead LeadWear® Disposable (BLUE connector) for the patient (refer to size chart on page 9).

NOTE: For placement of LeadWear® Disposable on patient, refer to "User Instructions: LeadWear® Disposable for 3/5 Lead Monitoring", on page 29 of this Manual.

2. Connect Adapter to the trunk cable or monitoring equipment.
3. Connect the LeadWear® Disposable (BLUE connector) to the Adapter.



Patient Transfer: Wireless to Adapter

To permanently transfer a patient from wireless monitoring to a wired connection.

1. Connect Adapter to the trunk cable or monitoring equipment.
2. Remove LeadWear® Disposable from the LifeSync® Patient Transceiver, by squeezing clips on LeadWear® Connector(s) and pulling straight out from transceiver.
3. Connect LeadWear® Disposable (BLUE connector 3/5 Lead or GREEN connector 12 Lead) to the Adapter.

Maintenance & Troubleshooting

System Functional Check

The LifeSync® Wireless System requires neither technical maintenance nor calibration.

It is recommended that the following procedure be used to confirm the proper function of system components before initial use, and at regularly scheduled intervals, as dictated by the institution's plan for equipment performance confirmation.

Required Equipment

Two LifeSync® Monitor Transceivers
One LifeSync® Patient Transceiver
LifeSync® LeadWear® Disposable
ECG/RESP 12 Lead Patient Simulator
Two LifeSync® System Compatible ECG Monitors:
- One 3/5 lead Cardiac Monitor (including trunk cable and lead wires)
- One 12 lead ECG Machine (including trunk cable and lead wires)

NOTE: The LifeSync® System performance has been confirmed with a variety of commonly used ECG equipment. Contact LifeSync Corporation Customer Service at 866-ECG-3888 or visit the website www.LifeSyncCorp.com for information on ECG monitors that are compatible with the LifeSync® System.

A. Smart Batteries Preparation

NOTE: Smart batteries are shipped in a partially charged state, with a plastic film cover covering the contacts. This film should be removed prior to use.

1. Remove the plastic film cover from the smart battery contacts.
2. Leave one smart battery uncharged. Charge a second smart battery to the fully charged state. Partially charge a third smart battery, to the point that only one LED is lit on the battery charge indicator.

B. Monitor Transceiver Set Up/Power on Test/Battery Charger

1. Insert Token into Token port on the top of the first Monitor Transceiver.
2. Place the uncharged battery in this Monitor Transceiver, confirming that the plastic film contact cover has been removed.
3. Connect Monitor Transceiver to the Power Supply and plug to AC Power.
4. Press Power On/Off switch. Confirm that all indicators light for approximately one second and an audible BEEP is heard, this is a user interface test. Confirm that the GREEN Battery Charging indicator is flashing.
5. Press ECG Mode switch several times confirming that both indicators function. Select ECG 3/5 Lead mode.
6. Press Communication Mode switch several times, confirming that both indicators function. Select PERM Communication Mode.
7. Connect lead wires from the cardiac monitor to the Monitor Transceiver, matching colors and lead markings.

C. Patient Transceiver Set Up /Power on Test

1. Insert the fully charged battery into the Patient Transceiver.
2. Remove 3/5 Lead LeadWear® Disposable from package. Insert 3/5 Lead LeadWear® Connector into connector port, matching connector colors and connector keys.
3. Confirm that all indicators light for approximately one second and an audible BEEP is heard, this is a user interface test. Confirm that the Low Battery Charge indicator is OFF.
4. Connect electrode snaps on 3/5 LeadWear® Disposable to Patient Simulator.

D. Transceiver Synchronizing – Single Permanent

1. Remove Token from the cardiac Monitor Transceiver. Confirm "Insert Token Into Patient Transceiver" Status indicator on Monitor Transceiver glows SOLID YELLOW.
2. Insert Token into Token port on the side of Patient Transceiver. Wait for Return Token To Monitor Transceiver Status indicator on Patient Transceiver to FLASH YELLOW. Confirm that Patient Transceiver produces a single BEEP when Token is fully seated.
3. Remove Token from Patient Transceiver. Confirm that Return Token To Monitor Transceiver Status indicator goes OFF.
4. Place Token back into Token port of the cardiac Monitor Transceiver. Confirm that the Monitor Transceiver produces a single BEEP, and that the "Insert Token Into Patient Transceiver" Status indicator goes OFF. Confirm that Communication Status indicators on both Transceivers flash GREEN (over "PERM" on the Patient Transceiver). Confirm that the ECG/Respiration signals appear on the cardiac monitor display, and that the ECG/Respiration signals agree with the ECG Patient Simulator settings.

E. Monitor Transceiver Set Up – Temporary 12 Lead

1. Insert Token into Token port on the top of the second Monitor Transceiver.
2. Place the third partially charged battery in the second Monitor Transceiver, confirming that the plastic film contact cover has been removed.
3. Press Power On/Off switch. Confirm that all indicators light for approximately one second and an audible BEEP is heard, this is a user interface test. Confirm that the YELLOW Low Battery Charge indicator is flashing and that an audible tone continues to beep.
4. Connect the second Monitor Transceiver to the Power Supply and plug to AC Power.
5. Press ECG Mode switch several times confirming that both indicators function. Select ECG 12 Lead mode.
6. Press Communication Mode switch several times, confirming that both indicators function. Select TEMP Communication Mode.
7. Connect lead wires from the 12 lead ECG machine to the second Monitor Transceiver, matching colors and lead markings.
8. Remove the V – BROWN lead of 3/5 LeadWear® Disposable from the Patient Simulator.
9. Remove Precordial LeadWear® Disposable from package and connect electrode snaps on Precordial LeadWear® Disposable to Patient Simulator, including V1 – RED lead.
10. Insert Precordial LeadWear® connector into GREEN connector port. Leave 3/5 Lead LeadWear® Connector in place.

F. Transceiver Synchronizing – Temporary 12 Lead

1. Remove Token from the ECG machine Monitor Transceiver. Confirm "Insert Token Into Patient Transceiver" Status indicator on this Monitor Transceiver glows SOLID YELLOW.
2. Insert Token into Token port on the side of Patient Transceiver. Wait for Return Token To Monitor Transceiver Status indicator on Patient Transceiver to FLASH YELLOW. Confirm that Patient Transceiver produces a single BEEP when the Token is fully seated.
3. Remove Token from Patient Transceiver. Confirm that Return Token To Monitor Transceiver Status indicator goes OFF.
4. Place Token back into Token port of the ECG machine Monitor Transceiver. Confirm that the Monitor Transceiver produces a single BEEP, and that the "Insert Token Into Patient Transceiver" Status indicator goes OFF. Confirm that Communication Status indicators on all three transceivers flash GREEN (both "PERM" and "TEMP" on the Patient Transceiver). Confirm that the proper ECG signals appear on both ECG equipment displays, and that the ECG signals agree with the ECG Patient Simulator settings.
5. Wait for two minutes. After two minutes, the ECG machine Monitor Transceiver stops receiving signals from the Patient Transceiver. Confirm that the Communication Status indicator on the ECG machine Monitor Transceiver SOLID

YELLOW, the Communication Status indicator on the cardiac Monitor Transceiver flashes GREEN, and only the "PERM" Communication Status indicator on the Patient Transceiver flashes GREEN.

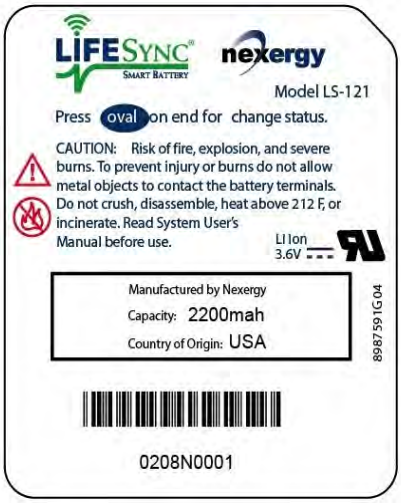
G. Transceivers – Confirm Low Battery Charge Indicators on Patient Transceiver

1. Disconnect Monitor Transceivers from ECG equipment and turn equipment OFF.
2. Remove the batteries from all Transceivers. Disconnect the Monitor Transceivers from the Power Supply and plug to AC power.
3. Place the partially charged battery in the Patient Transceiver. Confirm that the Low Battery Charge indicator flashes YELLOW and an audible tone continues to beep. Remove the LeadWear® connector to turn Patient Transceiver OFF.
4. Place the fully charged battery in one Monitor Transceiver. Turn the Transceiver ON and confirm that all Low Battery Charge and Battery Charging indicators are OFF. Repeat with the other Monitor Transceiver.
5. Place the fully charged battery back into the Patient Transceiver.
6. Connect both Monitor Transceivers to the Power Supplies and plug to AC power. Confirm that the GREEN Battery Charge indicator is flashing. Let batteries charge for 8 hours before use.

Smart Battery

Battery Life

It is recommended that batteries be discarded after one year of normal use (400 discharge cycles). Recycle or dispose of discarded batteries according to national, state and local regulations.



CAUTION: • Remove the plastic film cover from the battery contacts before using.
• Do not short the battery terminals.
• Do not try to connect a LifeSync® Smart Battery with any device other than a LifeSync® Monitor Transceiver or a LifeSync® Patient Transceiver.
• Do not expose to high temperature (above 60°C / 140°F).

WARNING: • Do not incinerate, submerge, crush, disassemble or autoclave the battery.
• Do not recharge or reuse battery that has been submerged; discard or recycle it immediately.

Battery Storage

Batteries should be removed from Patient Transceivers and stored separately when not in use for more than a few days.

NOTE: The Patient Transceiver will continue to draw a small amount of power from the battery even when LeadWear® Disposables are not connected and all indicators are off. If batteries are stored for more than a month they will need charging.

NOTE: Storing the battery for a long period of time without use may degrade the battery capacity.

CAUTION: • Store batteries between -40°C and 70°C/ -40°F and 160°F.
• Keep batteries in low humidity location with little temperature variation.
• Keep batteries away from direct sunlight.

Adapter Maintenance

Before use, check that the product is intact and clean.

WARNING: Do not use if you see signs of deterioration or damage. Make sure there are no cracks, cuts, tears, or breaks in the insulation and that the connectors are in good condition.

Use only recommended cleaning substances and disinfectants listed in the cleaning section of this Manual. Others may cause damage not covered by warranty, reduce the useful life of the product, or cause safety hazards.

CAUTION: Never immerse or soak the adapter.

CAUTION: Do not sterilize adapters by autoclave, radiation or steam.

Always follow and retain the instructions accompanying the cleaning and disinfecting substances you are using. Dilute according to the Manufacturer's instructions.

Keep adapter free of dust and dirt; clean and disinfect the adapter after each use. Protect the adapter from strong UV radiation.

NOTE: LifeSync® Adapters are non-sterile, reusable and latex free.

Cleaning LifeSync® System Components

Cleaning the Transceivers, Battery and Power Supply

The LifeSync® Patient Transceiver, Monitor Transceiver, Smart Battery and Power Supply may be cleaned as needed by wiping with a nearly-dry cloth, moistened with one of the following cleaning solutions: warm water and soap, Fantastik®, Cidex®, 70% isopropyl alcohol, T.B.Q.® (Calgon Corp.) Thoroughly wipe off any excess cleaning solution with a dry cloth.

CAUTION:
- Do not use the following solvents for cleaning the transceivers: butyl alcohol, ethanol, Freon, bleach, acetone, hydrogen peroxide.
- Use of any of these solvents may lead to deterioration of plastic components.
- Do not sterilize by autoclave, radiation or steam any LifeSync® System Components.

CAUTION:
- Transceivers should have batteries installed whenever they are cleaned.
- Batteries may be cleaned separately but care must be taken to avoid wetting the metal battery contacts.

WARNING:
- Do not allow liquid into battery slots, battery contacts, connector ports, and Token ports or any other openings or crevices.
- Do not immerse any LifeSync® System Component in any liquid.

Cleaning and Disinfecting Adapters

Clean the adapters by wiping with a lint free cloth, moistened with warm water and mild detergent or soap solution.

CAUTION: Never use oils or strong solvents.

Allow adapters to dry completely after cleaning.

Disinfect the adapters by using a chemical disinfectant such as ethanol, propanol, or glutaraldehyde.

CAUTION: Use only recommended cleaning substances and disinfectants. Others may cause damage not covered by warranty, reduce the useful life of the product, or cause safety hazards.

Cleaning the LeadWear® Disposables

LifeSync® LeadWear® Disposables are intended for single patient use only. They may be wiped with a nearly-dry cloth, moistened with warm water. If a LeadWear® Disposable becomes badly soiled, it should be replaced.

NOTE: These recommendations are provided for guidance only. The actual cleanliness of devices depends upon techniques and actual cleaning practices employed by the user.

Troubleshooting

In each section, start at the top of each solution set and work down.

Symptom	Cause	Solution
Patient Transceiver won't turn On	• 3/5 Lead LeadWear® blue connector not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• Battery is discharged or defective	• Charge battery or replace with fully charged battery and ensure it is properly latched. • Replace defective battery
	• Battery contacts covered	• Uncover and charge battery
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver failure	• Replace Patient Transceiver *
Monitor Transceiver won't turn On	• Power supply not connected to Monitor Transceiver or AC outlet	• Connect power supply to Monitor Transceiver and AC outlet, verify green light on Charging indicator
	• Monitor Transceiver is not On	• Turn Monitor Transceiver On with power on/off switch
	• Faulty AC outlet	• User another AC outlet
	• Battery contacts covered (if running on battery)	• Uncover and charge battery
	• Faulty power supply	• Replace power supply
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
Patient Transceiver Intermittent On/Off	• 3/5 Lead LeadWear® blue connector not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• Battery not fully inserted	• Ensure battery is fully inserted and latched
	• Faulty battery	• Replace battery
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver failure	• Replace Patient Transceiver *

Symptom	Cause	Solution
Monitor Transceiver Intermittent On/Off	• Power supply not properly connected to Monitor Transceiver or AC outlet	• Ensure power supply properly connected to Monitor Transceiver and AC outlet, verify green light on Charging indicator
	• Battery not fully inserted (if running on battery)	• Ensure battery is fully inserted and latched
	• Faulty battery	• Replace battery
	• Faulty power supply	• Replace power supply
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
Transceivers Red Service light On	• Unit needs servicing	• Replace Patient Transceiver or Monitor Transceiver *
All LEDs On	• Unit needs servicing	• Replace Patient Transceiver or Monitor Transceiver *
No or Intermittent Communication "synch" between Transceivers	• Monitor Transceiver Communication Mode TEMP/PERM mode was pressed	• Select correct TEMP/PERM Communication Mode and Synchronize transceivers
	• Token not fully inserted on Monitor Transceiver	• Fully insert token on Monitor Transceiver and synchronize if needed
	• Patient Transceiver or Monitor Transceiver not turned On	• Ensure both units are turned On and synchronize if needed
	• Out of range or at edge of range	• System range exceeded – move patient back within 30 feet of Monitor Transceiver
	• Permanent communication will drop briefly (3 to 4 seconds) while initiating Temporary 12 lead Monitoring	• Intermittent condition may last up to 20 seconds if temporary communication cannot be established
	• 3/5 Lead LeadWear® blue connector not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver failure	• Replace Patient Transceiver *
	• Monitor Transceiver failure	• Replace Monitor Transceiver *

Symptom	Cause	Solution
Patient Transceiver beeping	• Low or faulty battery	• Re-charge battery, or replace with fully charged battery
	• Battery not fully inserted	• Ensure battery is fully inserted and latched
	• Turns on and off intermittently	• Check 3/5 Lead LeadWear® connector for damage, replace if needed. • Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver failure	• Replace Patient Transceiver *
Monitor Transceiver beeping	• Power supply not connected to Monitor Transceiver or AC outlet, resulting in low battery	• Connect power supply to Monitor Transceiver and AC outlet, verify green light on Charging indicator
	• Battery not fully inserted (if running on battery)	• Ensure battery is fully inserted and latched
	• Faulty battery	• Replace battery
	• Faulty power supply	• Replace power supply
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
Patient Transceiver All LEDs Intermittent On/Off	• 3/5 Lead LeadWear® blue connector not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• Battery not fully inserted	• Ensure battery is fully inserted and latched
	• Faulty battery	• Replace battery
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
Monitor Transceiver All LEDs Intermittent On/Off	• Power supply not properly connected to Monitor Transceiver or AC outlet	• Ensure power supply properly connected to Monitor Transceiver and AC outlet, verify green light on Charging indicator
	• Battery not fully inserted (if running on battery)	• Ensure battery is fully inserted and latched
	• Faulty battery	• Replace battery
	• Faulty power supply	• Replace power supply
	• Monitor Transceiver failure	• Replace Monitor Transceiver *

Symptom	Cause	Solution
Battery does not last 24 hours on Patient Transceiver or 12 hours on Monitor Transceiver	• Battery not fully charged at start when replaced	• Ensure battery is fully charged at installation
	• Battery at end of life, or faulty	• Replace battery
Monitor Transceiver not charging battery, or Monitor Transceiver battery charge indicator not lit	• Power supply not connected to Monitor Transceiver or AC outlet	• Connect power supply to Monitor Transceiver and AC outlet, verify green light on Charging indicator
	• Battery not fully inserted	• Ensure battery is fully inserted and latched
	• Battery contacts covered	• Uncover and charge battery
	• Faulty battery	• Replace battery
	• Faulty power supply	• Replace power supply
	• Faulty AC outlet	• User another AC outlet
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
V Lead Off (for 3/5 Lead only)	• Monitor Transceiver in 12 LEAD ECG mode	• Switch to 3/5 LEAD ECG mode
	See No ECG or Leads Off section	
No ECG or Leads Off	• Electrode(s) faulty, not properly placed or skin not properly prepped	• Replace electrode(s) and ensure proper skin prep and placement
	• Poor LeadWear® Disposable connection to electrode(s)	• Ensure that LeadWear® Disposable is firmly attached to electrode snaps
	• LeadWear® connectors not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• LeadWear® damaged	• Inspect for damage and replace if needed
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Patient Transceiver battery is discharged or defective	• Charge battery or replace with fully charged battery and ensure it is properly latched. • Replace defective battery

Symptom	Cause	Solution
No ECG or Leads Off Continued	• Power supply not connected to Monitor Transceiver or AC outlet	• Connect power supply to Monitor Transceiver and AC outlet, verify green light on Charging indicator
	• Monitor Transceiver is Off	• Turn Monitor Transceiver On with power on/off switch
	• Incorrect 3/5 Lead or 12 Lead ECG mode selected	• Ensure proper 3/5 Lead or 12 Lead ECG mode selected
	• Lead wire(s) damaged or poor connections to Monitor Transceiver	• Check lead wire(s) are free of damage and firmly connected to Monitor Transceiver. Replace if damaged
	• Trunk cable damaged or disconnected from lead wires or ECG monitor	• Check trunk cable for damage or disconnection. Replace if damaged
	• Out of range or at edge of range	• System range exceeded – move patient back within 30 feet of Monitor Transceiver
	• Transceivers not synchronized	• Re-synchronize
	• ECG monitor not operating properly	• Check ECG monitor
	• Patient Transceiver failure	• Replace Patient Transceiver *
	•Monitor Transceiver failure	• Replace Monitor Transceiver *
Inverted signal on ECG equipment	• Incorrect lead wire connections to Monitor Transceiver	• Check lead wire(s) are in the correct lead and properly placed on the Monitor Transceiver
	• LeadWear® leads incorrectly placed	• Check LeadWear® leads are properly placed
Intermittent ECG, Artifact and Noise	• Electrode(s) faulty, not properly placed or skin not properly prepped	• Replace electrode(s) and ensure proper skin prep and placement
	• Poor LeadWear® Disposable connection to electrode(s)	• Ensure that LeadWear® Disposable is firmly attached to electrode snaps
	• LeadWear® connectors not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• LeadWear® damaged	• Inspect for damage and replace If needed
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *

Symptom	Cause	Solution
Intermittent ECG, Artifact and Noise Continued	• Battery not fully inserted	• Ensure battery is fully inserted and latched
	• Patient Transceiver battery is discharged or defective	• Charge battery or replace with fully charged battery and ensure it is properly latched. • Replace defective battery
	• Power supply not connected to Monitor Transceiver or AC outlet	• Connect power supply to Monitor Transceiver and AC outlet, verify green light on Charging indicator
	• Monitor Transceiver is Off	• Turn Monitor Transceiver On with power on/off switch
	• Incorrect 3/5 Lead or 12 Lead ECG mode selected	• Ensure proper 3/5 Lead or 12 Lead ECG mode selected
	• Lead wire(s) damaged or poor connections to Monitor Transceiver	• Check lead wire(s) are free of damage and firmly connected to Monitor Transceiver. Replace if damaged
	• Lead wire(s) too close to AC power source	• Separate lead wires from AC power source
	• Trunk cable damaged or not properly connected to lead wires or ECG monitor	• Check trunk cable for damage and proper connection. Replace if damaged
	• Out of range or at edge of range	• System range exceeded – move patient back within 30 feet of Monitor Transceiver
	• Token not fully inserted on Monitor Transceiver	• Fully insert token on Monitor Transceiver and synchronize if needed
	• Transceivers not synchronized	• Re-synchronize
	• Motion artifact	• Advise patient to be still
	• ECG monitor not operating properly	• Check ECG monitor
	• Patient Transceiver failure	• Replace Patient Transceiver *
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
No, Intermittent or Noisy Respiration	• Electrode(s) faulty, not properly placed or skin not properly prepped	• Replace electrode(s) and ensure proper skin prep and placement
	• LeadWear® leads incorrectly placed	• Check LeadWear® leads are properly placed, alternative placement may interfere with respiration

Symptom	Cause	Solution
No, Intermittent or Noisy Respiration Continued	• Poor LeadWear® Disposable connection to electrode(s)	• Ensure that LeadWear® Disposable is firmly attached to electrode snaps
	• LeadWear® Blue connector not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® blue connector correctly; replaced if damaged
	• LeadWear® damaged	• Inspect for damage and replace if needed
	• End cap damaged	• Check end cap, replace Patient Transceiver if damaged *
	• Lead wire(s) damaged or poor connections to Monitor Transceiver	• Check lead wire(s) are free of damage and firmly connected to Monitor Transceiver. Replace if damaged
	• Lead wire(s) too close to AC power source	• Separate lead wires from AC power source
	• Trunk cable damaged or disconnected from lead wires or ECG monitor	• Check trunk cable for damage or disconnection. Replace if damaged
	• Respiration function not selected on ECG equipment	• Select proper respiration function settings
	• Patient Transceiver failure	• Replace Patient Transceiver *
	• Monitor Transceiver failure	• Replace Monitor Transceiver *
Adapter No ECG or Respiration	• Electrode(s) faulty, not properly placed or skin not properly prepped	• Replace electrode(s) and ensure proper skin prep and placement
	• LeadWear® leads incorrectly placed	• Check LeadWear® leads are properly placed, alternative placement may interfere with respiration
	• Poor LeadWear® Disposable connection to electrode(s)	• Ensure that LeadWear® Disposable is firmly attached to electrode snaps
	• LeadWear® connectors not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• LeadWear® damaged	• Inspect for damage and replace if damaged

Symptom	Cause	Solution
Adapter No ECG or Respiration Continued	• Trunk cable damaged or disconnected from Adapter or ECG monitor/telemetry box	• Check trunk cable for damage or disconnection. Replace if damaged
	• Respiration function not selected on ECG equipment	• Select proper respiration function settings
	• ECG monitor or telemetry box not operating properly	• Check ECG monitor or telemetry box
	• Adapter Failure (housing damage, broken wire(s), socket damage, plug damage etc.)	• Replace Adapter *
Adapter Intermittent, Noisy ECG or Respiration	• Electrode(s) faulty, not properly placed or skin not properly prepped	• Replace electrode(s) and ensure proper skin prep and placement
	• LeadWear® leads incorrectly placed	• Check LeadWear® leads are properly placed, alternative placement may interfere with respiration
	• Poor LeadWear® Disposable connection to electrode(s)	• Ensure that LeadWear® Disposable is firmly attached to electrode snaps
	• LeadWear® connectors not fully inserted or defective (curling, scratches, etc.)	• Remove, inspect for damage and replace or reinsert LeadWear® Connector correctly; replaced if damaged
	• LeadWear® damaged	• Inspect for damage and replace if damaged
	• Trunk cable damaged or not properly connected to Adapter or ECG monitor/telemetry box	• Check trunk cable for damage and proper connection. Replace if damaged
	• Lead wire(s) too close to AC power source	• Separate lead wires from AC power source
	• ECG monitor or telemetry box not operating properly	• Check ECG monitor or telemetry box
	• Adapter Failure (housing damage, broken wire(s), socket damage, plug damage etc.)	• Replace Adapter *

*If problem cannot be resolved contact LifeSync Corporation Customer Service toll-free at 866-ECG-3888 (866-324-3888) or email us at CustomerService@LifeSyncCorp.com

Technical / Specifications

Specifications

The LifeSync® System meets all applicable requirements for Cardiac Monitors, Heart Rate Meters and Alarms as well as applicable requirements for Diagnostic Electrocardiographs per ANSI/AAMI EC13:2002 and ANSI/AAMI EC11:1991 respectively.

Parameter	Specification	
	3/5 LEAD MODE (continuous monitoring)	**12 LEAD MODE (diagnostic ECG)**
Number of Channels, single-ended, wrt RL	4	9
Channels Active	LL, LA, RA, V	LL, LA, RA, V1-V6
Input Dynamic Range	± 300 mV DC; 10 mV p-p AC	
ECG Signal Slew Rate	320 mV/s maximum	
Input Impedance	>2.5 MΩ at 100 Hz	
Leadoff Sense Current	50 nA for LL, LA, RA, V, V1-V6 up to 500 nA for RL	
Frequency Response Method A per EC11:1991 Triangle Response Method D per EC13:2002	 DC-40 Hz 0.0 ± 0.25 dB 40-150 Hz 0.0 ± 1 dB 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	30 µV 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 @ DC-150 Hz	
CM Rejection	<1 mV output with 20 Vrms input at 60 Hz (tested with Welch Allyn Propaq per EC13:2002)	
Leadoff: • 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 electrodes in 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.	
DC Offset – any channel	± 5 mV maximum	

Parameter	Specification	
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	Pacer Pulse functions triggers when ECG signal slew rate exceeds 10,000 mV/s	
Signal Latency due to radio	500 ms maximum	
Operating Battery	Voltage	3.6 VDC
	Capacity	2200 mA-hr
	Technology	Rechargeable Lithium-Ion
Operating Battery Life	Patient Transceiver	Monitor Transceiver
	24 hrs maximum	12 hrs maximum
Size	8 x 12.5 x 3 cm (W x H x T)	8.5 x 16 x 4 cm (W x H x T)
Weight (includes battery)	240 g	280 g
Rated Voltage/Current	3.6 VDC, 0.25 A	5.5 VDC .75 A
Operating Temperature	0 to 45 °C	
Storage Temperature	-20 to 70 °C	
Atmospheric Pressure	700-1060 mbar	
Housing Material	ABS	
Radio Protocol Class Range Operating Frequency Channels Power output level PT MT Bluetooth® Revision	Bluetooth® wireless technology Class 2 10 m 2.402-2.480 GHz 79 1MHz channels -8.3 dBm maximum (.38 mW) -2.8 dBm maximum (.72 mW) V1.1	
Water Ingress Rating	IPX1 per IEC 60529 (for both PT & MT)	
Patient Applied Parts type	Defib proof Type CF per EN60601-1	
Defibrillation Proof	Withstands 400 J per IEC 60601-2-27	
Recovery time after defibrillation exposure	5 seconds, maximum	
Safety	EN60601-1, IEC60601-2-27, UL 60601-1 CSA 22.2 No 601.1 CSA 22.2 No 601.2.27	
EMC	EN 60601-1-2:2001	
Respiration Specifications: Sensing Electrodes Excitation Frequency Patient Risk Current Frequency Response Input-Output Dynamic Range Base Impedance Range Respiration Output	 RA-LA (in Patient Transceiver) 32 kHz 10 µA max with AAMI ES-1 test load - 0.25-2.0 Hz (±6 dB) 8 ohm p-v maximum 0-2000 ohms Modulated digital potentiometer in series with RA electrode (in MT)	

LifeSync® System Performance with Welch Allyn Propaq Model 206

Pacer Detection and Display (per EC13:2002 section 4.2.9.12) - pacemaker pulses of amplitudes and durations as follows will be indicated on the display as a pacemaker pulse with a vertical dashed line:

- 100-200 µs pulse width amplitude 3-750 mV
- 200-2000 µs pulse width amplitude 2-750 mV

Pacemaker Pulse Rejection without Overshoot (per EC13:2002 section 4.1.4.1):

Pacemaker Pulse rejection without Overshoot	
Description:	HR Accuracy:
Pacemaker Pulses (ventricular or A-V sequential) with no QRS	Propaq indicates '---' for HR – all combinations
Normal Pacing – (ventricular or A-V sequential)	Rejects approximately >95% of pacemaker pulses
Ineffective Pacing – (ventricular or A-V sequential)	Rejects approximately > 95% of pacemaker pulses

Pacemaker Pulse Rejection with Overshoot (per EC13:2002 section 4.1.4.2):

Pacemaker Pulse Rejection with Overshoot		
Description:	HR Accuracy:	
	Pulses 2-100 mV 100-500 µs	Pulses 100-700 mV 0.5-2.0 ms
Pacemaker Pulses (ventricular or A-V sequential) with no QRS	Rejects approx. >95% of pacemaker pulses	Rejects approx. >75% of pacemaker pulses
Normal Pacing (ventricular or A-V sequential)	Rejects approx. >95% of pacemaker pulses	Rejects approx. >75% of pacemaker pulses
Ineffective Pacing (ventricular or A-V sequential)	Rejects approx. >95% of pacemaker pulses	Rejects approx. >75% of pacemaker pulses

Caution: The LifeSync® System may miss pacer pulses if high background noise is present. The LifeSync® System captures signal spikes regardless of whether spikes are due to noise or pacer pulses. If the LifeSync® System triggers frequently from background noise due to motion artifact, EMI, etc., then pacer pulses could be masked or missed by the LifeSync® System.

Recommended separation distances between portable and mobile RF communications equipment and the LifeSync® System

The LifeSync® System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LifeSync® System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LifeSync® System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter Watts:	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=[3,5/V_1]\sqrt{P}$:	80 MHz to 800 MHz $d=[3,5/E_1]\sqrt{P}$:	800 MHz to 2,5 MHz $d=[7/E_1]\sqrt{P}$:
0.01	0.12m	0.12m	0.23m
0.1	0.37m	0.37m	0.74m
1	1.2m	1.2m	2.4m
10	3.7m	3.7m	7.4m
100	12m	12m	24m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity			
The LifeSync® System is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeSync® System should assure that it is used in such an environment.			
Immunity test:	IEC 60601 test level:	Compliance:	Electromagnetic environment – guidance:
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LifeSync® System requires continued operation during power mains interruptions, it is recommended that the LifeSync® System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC main voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The LifeSync® System is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeSync® System should assure that it is used in such an environment.			
Immunity test:	IEC 60601 test level:	Compliance level:	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the LifeSync® System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{P}$ m $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ***(a)***, should be less than the compliance level in each frequency range ***(b)***. Interference may occur in the vicinity of equipment marked with the following symbol: (RADIO ICON)
Radiated RF IEC 61000-4-3	3 V/m 80 kHz to 2,5 GHz	3 V/m** ** See note on respiration function at levels >1.5 V/m in respiration section	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LifeSync® System is used exceeds the applicable RF compliance level above, the LifeSync® System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the LifeSync® System.
(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration – electromagnetic emissions		
The LifeSync® System is intended for use in the electromagnetic environment specified below. The customer or the user of the LifeSync® System should assure that it is used in such an environment.		
Emissions test:	Compliance:	Electromagnetic environment – guidance:
RF emissions CISPR 11	Group 1	The LifeSync® System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The LifeSync® System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Note: The LifeSync® Transceivers each contain a Class 2 Bluetooth® technology radio that transmits at 2.40-2.48 GHz. Although no interference is likely, during installation, equipment in the vicinity of the LifeSync® System should be monitored for continued proper operation in the presence of the Bluetooth® transmitters.		

Manufacturer's Information

The LifeSync® System is covered by one or more of the following Patents: 5,862,803; 5,957,854; 6,289,238; 6,441,747; 6,496,705; 6,577,893; 6,611,705. Additional patents are pending.

LIFESYNC CORPORATION EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

The LifeSync® System complies with UL 60601-1, CSA C22.2 No. 601.1, EN 60601-1 and EN 60601-2-27. LifeSync® LeadWear® Disposables comply with ANSI/AAMI EC 53: 1995 and EC 53/A1: 1998. The LifeSync® System complies with 1999/5/EC, 93/42/EEC.

The LifeSync® System complies with Part 15 of the FCC rules.

Patient Transceiver FCC ID: QXQ-A2005-PT01
Monitor Transceiver FCC ID: QXQ-A2006-MT01

Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

EC REP

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The information contained in this document is subject to change without notice. LifeSync Corporation makes no Warranty of any kind with respect to this information.

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Toll Free: 866-ECG-3888 (866-324-3888)
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Reorder Information

Printed copies of this User Manual are available directly from LifeSync Corporation. Reorder # LS-164

LifeSync® System components can be reordered from LifeSync Corporation, by calling toll free 866-ECG-3888 (866-324-3888).

For convenience, LifeSync® Reorder codes and/or Model Numbers appear on all LifeSync® System components.

