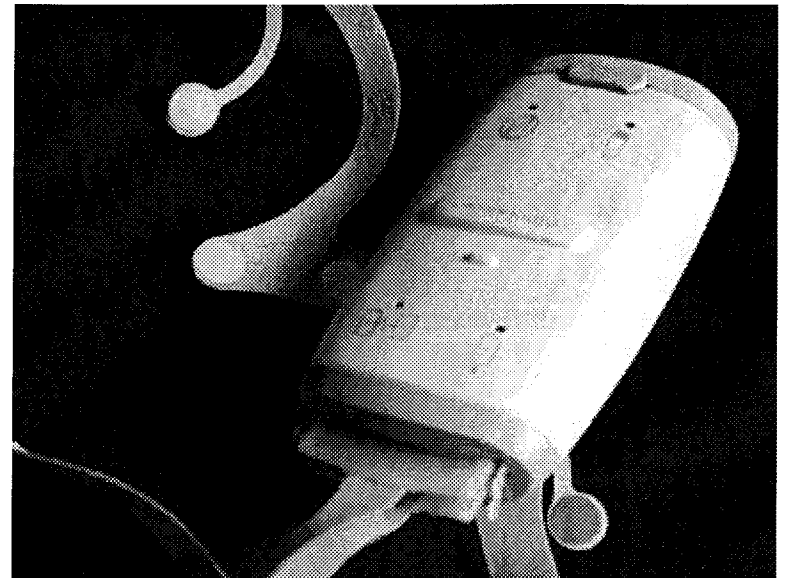




Wireless Medicine System



System User's Manual

GMP | WIRELESS MEDICINE, INC.

DRAFT: WECG SYSTEM USER'S MANUAL – FEB 1ST 2003

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INSIDE FRONT COVER



System User's Manual

Model DP 2.0
Software Version [TBD]

GMP WIRELESS MEDICINE, INC.
Fort Lauderdale, Florida

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LifeSync™ Monitor Transceivers and Patient Transceivers comply with
[UL 2601-1], [CSA C22.2 No. 601.1], EN 60601-1 and EN 60601-2-25

LifeSync™ LeadWear™ complies with ANSI/AAMI EC 53: 1995 and
EC 53/A1: 1998

The LifeSync™ system complies with Part 15 of the FCC rules. 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.

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1 – Introduction

INTENDED USE

The **LifeSync™** system is intended for use as a radiofrequency 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.

This 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.

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

Indications for Use

The GMPIWireless Medicine LifeSync 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 system will also transmit the patient respiration waveform for those ECG systems that include a respiration function.

Contraindications

The use of LifeSync is contraindicated:

- when ECG monitor output may be used to synchronize a defibrillator or other external device such as in intracardiac monitoring

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- when using internal monitoring device synchronized to external device; i.e. in electrophysiology
- during use of MRI, CAT scan or PET scan equipment

SYMBOLS

The following symbols are used throughout this manual:

- ⊗ calls attention to **WARNINGS** – conditions or practices that could result in personal injury to the patient or the clinician.
- ☑ calls attention to **CAUTIONS** – conditions or practices that could result in damage to the equipment or other property.
- 📶 calls attention to **NOTES** – information of particular importance or assistance to the user.

The following symbols may appear on LifeSync System Components:

- Direct current
- Input
- Output
- Non-ionizing electromagnetic radiation
- Attention, consult accompanying documents
- Lithium ion battery
- IPX1 Enclosure Protection Drip proof: per EN60529: 1991
- Single Patient Use
- Expiration, Use before
- Patient Connections are Type CF, protected against defibrillation

GENERAL SAFETY INFORMATION

LifeSync users should familiarize themselves with the following Warnings, Cautions and Notes.

☒ Warnings

- LifeSync should not be used as a means of synchronizing a defibrillator, due to signal latency in the radio transmission.
- Explosion Hazard - Do not use this device in the presence of flammable anesthetics.
- In order for the LifeSync system to work properly, the RL (GREEN) electrode must be connected at all times.
- The LifeSync system should only be used with LifeSync LeadWear. Substandard performance and/or damage to equipment may result from the use of incompatible components.
- Care should be taken to prevent physical contact between electrosurgical equipment and any LifeSync component.
- This device 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 system can operate in the presence of pacemaker pulses, and will detect and communicate these pulses to the ECG monitor. LifeSync may miss pacer pulses if high background noise is present. LifeSync captures signal spikes regardless of whether spikes are due to noise or pacer pulses. If LifeSync triggers frequently from background noise due to motion artifact, EMI, etc., then pacer pulses could be masked or missed by LifeSync. See further disclosure of

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pacemaker pulse rejection information in the Technical section of this manual.

☒ Cautions

- The batteries should be removed from both the Patient Transceiver and the Monitor Transceiver and stored separately when the system is not in use for extended periods of time.
- Remove the plastic film cover from the battery contacts before using.
- Do not autoclave LifeSync system components. Do not submerge LifeSync components in any liquid.
- Only use LifeSync with the following ECG monitors that have been validated for compatibility:
 - Bedside Continuous ECG Monitoring
 - Hewlett Packard Agilent V24
 - General Electric Marquette Solar 9500
 - Portable/Transportable Continuous
 - Welch Allyn Monitoring Propaq Encore
 - NonStress Test Discrete
 - HP PageWriter 100

~ NOTE: Additional ECG monitors may be added to this list of compatible monitors in updates to the User's Manual or in future technical bulletins.

Notes

- All LifeSync components that are applied to the patient are either passive (LeadWear, Armband and ComfortPatch), or internally powered (Patient Transceiver).
- The 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.
- Battery replacement is recommended after one year of use.

DEVICE DESCRIPTION

System Overview

LifeSync system components work together to eliminate cumbersome ECG leadwire set connections between ECG monitoring equipment and the patient.

Lightweight, single patient use **LifeSync™ LeadWear™** attaches directly to standard ECG electrodes in place of traditional leadwire sets. There are two types of LeadWear:

- Continuous LeadWear – for continuous five-lead or three-lead ECG monitoring
- Discrete LeadWear – for short-term collection of 12-lead diagnostic ECG signals

LeadWear is available in three sizes to fit most adult patients. A **LifeSync™ Armband** holds the Patient Transceiver in place on the patient's arm.

LifeSync LeadWear connects to the **LifeSync™ Patient Transceiver**, a lightweight, battery-powered device that communicates wirelessly with the **LifeSync™ Monitor Transceiver**. A **LifeSync™ Token** is used to “pair” the two transceivers. (“Pairing” is a process that both initiates communication and ensures that the Patient ECG signal is being displayed on the correct ECG monitor.) The Monitor Transceiver is connected to the ECG monitoring equipment with a traditional ECG leadwire set.

LifeSync Transceivers are powered by the **LifeSync™ Smart Battery**. The Monitor Transceiver can also be operated using standard AC power.

There are three simple steps to using the LifeSync System:

1. Place LeadWear on patient and connect Patient Transceiver

[photo: Patient Set Up, Distance]

2. Select appropriate Monitor Transceiver settings

[photo: Setting MT, Distance]

3. Pair the Patient Transceiver with the Monitor Transceiver

[photo: Pairing, Distance]

See the System Operation chapter of this Manual for an overview of the Basic Operation of the LifeSync system, as well as detailed instructions for the various procedures that LifeSync can support.

System Components

LifeSync™ LeadWear Kit

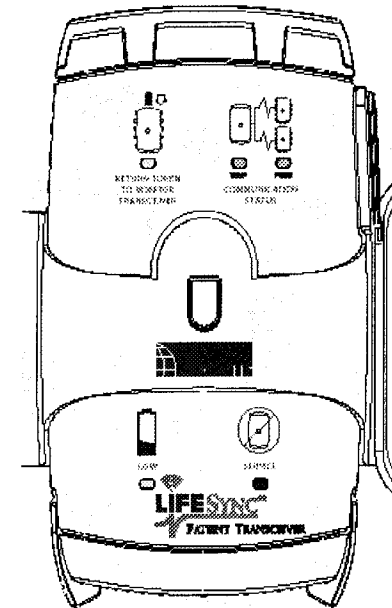
Disposable LeadWear Kits, available in three sizes, contain both Continuous and Discrete LeadWear, along with an Armband and ComfortPatch.

[photo: LeadWear Kit, Contents]

- Continuous LeadWear
Worn continuously, whenever patient's ECG signal is to be monitored
- Discrete LeadWear
Used whenever diagnostic ECG information is to be collected
- Connectors
Color-coded to ensure proper connection to the Patient Transceiver
- Armband
Worn on the patient's arm to support Patient Transceiver
- ComfortPatch
Attaches to the back of the Patient Transceiver to improve patient comfort

~ Note: LifeSync LeadWear Kit contents are non-sterile.

LifeSync™ Patient Transceiver



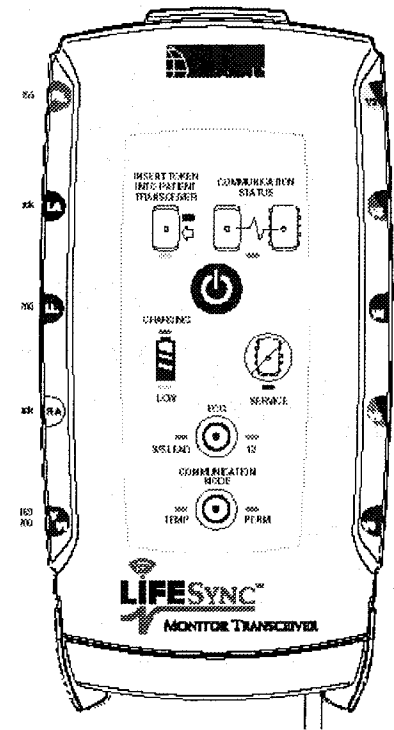
- Visual Status Indicators
Five light-emitting diode (LED) indicators provide information on what the system is doing

- LeadWear Connectors
Color-coded ports for attachment of the LeadWear connectors
Discrete Connector Port is protected by a flexible cap while not in use

- Token Port
Receptacle for the Token during pairing
Token Port is protected by a flexible cap while not in use
- LifeSync™ Smart Battery
Battery held in place by battery clips

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LifeSync™ Monitor Transceiver



- Visual Status Indicators
Nine light-emitting diode (LED) indicators provide information on what the system is doing
- Power On/Off
On/Off switch activates the system
- ECG Mode
Switches between Continuous (3/5 LEAD) and Discrete (12 LEAD) Monitoring
- Communication Mode
Switches between Temporary and Permanent Communication Mode
- Token Port
Receptacle for the pairing token

- LifeSync™ Smart Battery
Battery held in place by battery clips
- ECG Monitor Connections
Snaps for connection to ECG leadwire set
- Monitor Transceiver Charger
A built-in battery charger automatically charges the battery, whenever the Monitor Transceiver is plugged into AC power

LifeSync™ Smart Battery

LifeSync uses rechargeable 3.6 Volt lithium-ion batteries. These batteries are interchangeable between the Patient Transceiver and the Monitor Transceiver, and have a built-in “fuel” gauge. Batteries are charged in under eight hours, using the LifeSync Monitor Transceiver (or the Multi-Unit Battery Charger, available separately).

A fully charged battery will power a LifeSync Patient Transceiver for a minimum of 24 hours, and a LifeSync Monitor Transceiver for a minimum of 12 hours.

PHOTO – A: **“battery alone”**

- LifeSync™ Smart Battery Gauge
Easy-to-read gauge to indicate amount of charge left in battery
- Battery Cap
Indentations work with battery clips on transceivers to hold batteries in place

LifeSync™ Token

The LifeSync Token is used to pair the Patient Transceiver and Monitor Transceiver. It works by transferring information between the two transceivers.

PHOTO – A: **“Token”**

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LifeSync™ Monitor Transceiver Power Cord

PHOTO – A: “power cord”

The LifeSync™ Power Cord converts AC power to the 5V DC required to operate the Monitor Transceiver.

Accessories

Multi-Unit Battery Charger

The **LifeSync™ Multi-Unit Battery Charger** (available separately) charges up to eight LifeSync™ Smart Batteries at one time.

See Chapter 3 for more details on the LifeSync Battery Charger.

PHOTO – A: “battery charger”

- Battery Ports
Charging slots for up to eight LifeSync™ Smart Batteries
- Indicator Panel
Display provides information on battery charging status of each battery
- Battery Gauge Calibrator
Automatically re-calibrates battery gauge

System Indicators & Switches

The indicators and switches that appear on LifeSync system components have the following meaning and/or purpose:

Patient Transceiver



Pairing indicator:

YELLOW – SOLID: Ready to move Token back to Monitor Transceiver



Communication Status indicators:

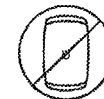
YELLOW – SOLID: No communication

GREEN – FLASHING: Communication in process



Battery Charge indicator:

YELLOW FLASHING (accompanied by periodic audible beeping): Battery charge level low, less than 60 minutes operation time left

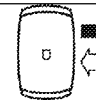


Service indicator:

RED – SOLID: Equipment malfunction

☒ Do Not Use

Monitor Transceiver



Pairing indicator:

YELLOW – SOLID: Replace Token into Monitor Transceiver Token Port



Communication Status indicators:

YELLOW – SOLID: No communication

GREEN – FLASHING: Communication in process

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Power On/Off switch:

Toggle switch. Press to turn unit ON or OFF.

Battery Charge indicators:

GREEN – SOLID: Fully charged

GREEN – FLASHING: Charging

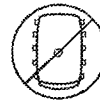
📶 NOTE: The GREEN light is only active when unit connected to AC power.

YELLOW – FLASHING

(accompanied by periodic audible beeping):

Battery charge level low, less than 60 minutes operation time left

📶 NOTE: The YELLOW light is only active when unit is NOT connected to AC power.



Service indicator:

RED – SOLID: Equipment malfunction

☒ Do Not Use

ECG Mode switch:

Press to alternate between ECG modes.

ECG Mode indicators:

GREEN – SOLID: indicates whether LifeSync is in Continuous (3/5 LEAD) or Discrete/Diagnostic (12 LEAD) mode



Communication Mode switch:

Press to alternate between communication modes.

Communication Mode indicators:

GREEN – SOLID: indicates whether LifeSync is in Temporary (TEMP) or Permanent (PERM) mode

2 – System Operation

The LifeSync system works in combination with existing ECG monitor equipment, and with standard ECG electrodes.

- NOTE: Proper function of LifeSync system with the ECG monitoring equipment should be confirmed before use with a patient. (See "System Functional Check" in Chapter 4.)

LIFESYNC SYSTEM SET UP

Install/Check Batteries in Transceivers

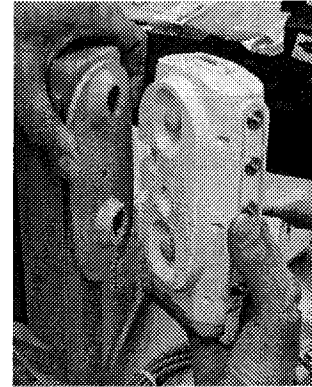
- NOTE: The Patient Transceiver requires a fully charged battery.
- NOTE: If Monitor Transceiver is to be connected to AC power, a battery must still be installed but it does not need to be charged.

[photo: Battery Installation]

[photo: Battery Indicator]

1. Release battery clips, and remove battery from each transceiver.
2. Check battery charge indicator on each battery.
If all five battery indicators are not lit, replace battery with a fully charged battery.
3. Re-install battery into each transceiver, and secure with battery clips.

Mount the Monitor Transceiver to Monitor



1. Secure the Monitor Transceiver Mounting Plate to the ECG monitor, using the supplied double-sided adhesive tape (or other method).

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

2. Insert buttons on back of Monitor Transceiver into slots on Mounting Plate, and slide transceiver unit downward.
3. Connect snaps of standard ECG leadwire set from the ECG monitoring equipment to the corresponding snap attachments on Monitor Transceiver, matching lead marking and color codes.
4. Connect Monitor Transceiver to AC power source using the Monitor Transceiver Power Cord. (Optional, if fully charged battery is present in Monitor Transceiver.)
5. Insert Token into Token Port on Monitor Transceiver.

NOTE: Monitor Transceiver will not operate without Token. Token should remain in Token Port of the Monitor Transceiver at all times, except when it is being used for pairing with a Patient Transceiver.

BASIC OPERATION

Once the batteries have been checked and the Monitor Transceiver has been installed on the ECG monitoring equipment, there are three basic steps to using the LifeSync System:

Photo: Patient
Set Up, Close Up

PATIENT SET UP

Place LeadWear on patient, and connect Patient Transceiver

Photo: Setting
MT, Close Up

TRANSCIVER SETTINGS

Select appropriate Monitor Transceiver settings

Photo: Pairing,
Close Up

PAIRING

Pair the Patient Transceiver with the Monitor Transceiver, using the Token

This Basic Operation section gives a universal description of each of these three steps.

Specific instructions for Patient Set Up, Transceiver Settings and Pairing for various LifeSync applications are discussed in the separate detailed sections that follow.

Basic Operation / Patient Set Up

Place LeadWear on patient and connect Patient Transceiver.

1. Select appropriate size LeadWear Kit for patient.

	Patient Weight (approximate)	LeadWear Size
Child	70 – 160 lb / 150 – 350 kg	S-M
Adult	90 – 160 lb / 200 – 350 kg	S-M
Adult	160 – 240 lb / 350 – 530 kg	L-XL
Adult	240 – 375 lb / 530 – 830 kg	XXL

2. Remove ComfortPatch from kit. Peel liner from adhesive, and attach ComfortPatch to back of Patient Transceiver.

PHOTO - A:
"Comfort Patch"

3. Remove Armband from kit. Slide Patient Transceiver into Armband, with tab toward the connector end of the transceiver.

PHOTO - H:
"slide pt
in arm band"

4. Secure Armband with Patient Transceiver around patient's upper arm (right arm is preferable, but not mandatory). Make sure Connector Ports are toward the patient's shoulder.

PHOTO - H:
"pt in armband 1"

The Armband is designed to be fully adjustable for any size arm. Slide end of strap through slot, from back of transceiver.

PHOTO – A:

“arm band insert”

Wrap strap back around arm away from transceiver, securing strap either with hook&loop closure of end of strap. The strap can also be wrapped tighter and secured to hook&loop closure attached to the plastic transceiver holder.

PHOTO – A:

“amr band affix”

PHOTO – A:

“arm band small arm”

5. Select LeadWear from kit as required for the desired procedure (see detailed sections).

**PHOTO–
A: “snap2”**

Connect standard silver-chloride ECG electrodes (such as _____) to non-metallic snaps on LeadWear, then place on patient.

NOTE: Diagrams for placement of LeadWear appear in detailed sections, and in LeadWear Kit.)

6. If the Armband was placed on the patient's RIGHT arm, the LeadWear connector tail(s) will run directly to the Patient Transceiver.

ILLUSTRATION – LeadWear Direct

If the Armband was placed on the patient's LEFT arm, gently loop the LeadWear connector tail(s) back across the patient's chest, so that the LeadWear connector(s) reach the Patient Transceiver.

Remove the liner from the self-adhesive patch, and gently press LeadWear together to hold loop in place.

CAUTION: Be careful not to crease the LeadWear!

ILLUSTRATION – LeadWear CrossOver

7. If connecting Discrete LeadWear, pull the flexible cap away from the Connector Port. Insert LeadWear connector(s) into Connector Port on Patient Transceiver, matching color-code and with LeadWear size label(s) facing up. Ensure that connector(s) seat securely and tabs lock into place.

PHOTO – A:
"clip close up"
cropped tight on tabs

PHOTO - A
"PT connect both"
cropped tight on
connectors

 **NOTE:** Connectors are designed to only fit in the proper Connector Port, and in the correct orientation.

Basic Operation / Transceiver Settings

Select Monitor Transceiver settings for procedure.

 **NOTE:** Make sure a Token is installed in the Token Port of the Monitor Transceiver.

1. Turn Monitor Transceiver ON using *Power On/Off* switch 
2. Use the mode switches  to select the appropriate mode (see detailed sections), and confirm selection via status indicators.

Closeup photo of
 Monitor
 Transceiver
 switches

Basic Operation / Pairing

Pair the Patient Transceiver with Monitor Transceiver.

1. Remove Token from Token Port on Monitor Transceiver.

The *Pairing* indicator  will glow SOLID YELLOW.

2. Pull the flexible cap away from the Token Port on Patient Transceiver, and insert Token into Token Port. Wait for the

Pairing indicator  on the Patient Transceiver to glow SOLID YELLOW.

PHOTO – H:

“connect pt 3”

3. Remove Token from Patient Transceiver and close flexible cap over Token Port; the *Pairing* indicator  on the Patient Transceiver will go out.

4. Replace the Token into the Token Port on the Monitor Transceiver. The *Pairing* indicator will go out, and the

Communication Status indicators   on BOTH transceivers will flash GREEN, indicating that the system is communicating. The patient's ECG Signal will appear on the ECG monitoring equipment connected to the Monitor Transceiver within a few seconds.

Basic Operation / Removal

1. Turn Monitor Transceiver OFF using *Power On/Off* switch



2. Remove connectors from Patient Transceiver, by pressing in on connector clips and pulling straight out from transceiver.

PHOTO – A:

“PT connect out”

SYSTEM OPERATION

Release Armband strap and remove transceiver from patient's arm. Remove Armband and ComfortPatch from Patient Transceiver.

3. Remove LeadWear snaps from electrodes, then gently remove electrodes from patient.
4. Discard LeadWear, Electrodes, Armband and ComfortPatch.
5. Store Patient Transceiver in a safe place.

CONTINUOUS ECG MONITORING

To continuously monitor 3-Lead or 5-Lead ECG signals

Continuous Monitoring / Patient Set Up

1. Select Continuous LeadWear (BLUE connector) from kit. Attach ECG electrodes to all snaps on the LeadWear, and place on the patient as indicated in the diagram and table below.

ILLUSTRATION(S) – LeadWear Placements

Continuous LeadWear Electrode Placement		
RL	GREEN	Left-side of chest near armpit
LA	BLACK	Left shoulder
LL	RED	Left-side of chest below navel
RA	WHITE	Right shoulder
V	BROWN	Center of chest (optional)

NOTE: The position of the RL lead on LifeSync LeadWear is different from standard ECG lead placement.

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

SYSTEM OPERATION

2. Insert BLUE Continuous LeadWear connector into BLUE slot on Patient Transceiver.

Continuous Monitoring / Transceiver Settings

1. Press *ECG Mode* switch  until the indicator over “3/5 LEAD” glows GREEN.
2. Press *Communication Mode* switch  until the indicator over “PERM” glows GREEN.

Continuous Monitoring / Pairing

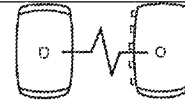
1. Pair the transceivers with the Token, ending with the Token in the Token Port of the Monitor Transceiver.

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 ECG monitor within a few seconds.

DIAGNOSTIC ECG MONITORING

To collect diagnostic 12-Lead ECG signals on a permanent basis

Diagnostic Monitoring / Patient Set Up

1. Select both Continuous and Discrete LeadWear from kit. Attach ECG electrodes to all snaps on the LeadWear, except for V (BROWN) on Continuous, and place on the patient as indicated in the diagrams and tables below.

ILLUSTRATION(S) – LeadWear Placements

Continuous LeadWear Electrode Placement		
RL	GREEN	Left-side of chest near armpit
LA	BLACK	Left shoulder
LL	RED	Left-side of chest below navel
RA	WHITE	Right shoulder
V	BROWN	Do not use for permanent 12-Lead

 NOTE: The position of the RL lead on LifeSync LeadWear is different from standard ECG lead placement.

Discrete LeadWear Electrode Placement		
V1	RED	Fourth intercostal space at right margin of sternum

SYSTEM OPERATION

V2	YELLOW	Fourth intercostal space at left margin of sternum
V3	GREEN	Midway between V2 and V4
V4	BLUE	Fifth intercostal space at junction of midclavicular line
V5	ORANGE	At horizontal level of V4 at left anterior axillary line
V6	PURPLE	At horizontal level of V4 at left midaxillary line

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

2. Pull the flexible cap away from Connector Port, and insert both LeadWear connectors into Patient Transceiver.

Diagnostic Monitoring / Transceiver Settings

1. Press *ECG Mode* switch  on the Monitor Transceiver until the *ECG* indicator over "12 LEAD" glows GREEN.
2. Press *Communication Mode* switch  on the Monitor Transceiver until the *Communication Mode* indicator over "PERM" glows GREEN.

Diagnostic Monitoring / Pairing

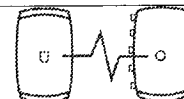
1. Pair the transceivers with the Token, ending with the Token in the Token Port of the Monitor Transceiver.

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 Diagnostic 12-Lead ECG monitor within a few seconds.

TEMPORARY SIMULTANEOUS ECG MONITORING

To collect diagnostic 12-Lead ECG signals, for a short duration, on a patient that is already on continuous ECG signal monitoring.

- NOTE: This involves a second Monitor Transceiver, set up on the Diagnostic ECG equipment.
- NOTE: This procedure uses LifeSync's TEMP mode to temporarily allow a second Monitor Transceiver to receive signals from a Patient Transceiver that is already paired with a primary Monitor Transceiver. This temporary pairing will last for up to two minutes; the Patient Transceiver then reverts to communicating only with the primary Monitor Transceiver.

Temporary Simultaneous Monitoring / Patient Set Up

SYSTEM OPERATION

1. Select Discrete LeadWear (GREEN connector) from kit, and attach ECG electrodes to the LeadWear.
Place the Discrete LeadWear on the patient (follow the diagram and table below). Remove the V (BROWN) snap of the **Continuous** LeadWear from its electrode (if used).

ILLUSTRATION(s) for LeadWear Placement

Discrete LeadWear Electrode Placement		
V1	RED	Fourth intercostal space at right margin of sternum
V2	YELLOW	Fourth intercostal space at left margin of sternum
V3	GREEN	Midway between V2 and V4
V4	BLUE	Fifth intercostal space at junction of midclavicular line
V5	ORANGE	At horizontal level of V4 at left anterior axillary line
V6	PURPLE	At horizontal level of V4 at left midaxillary line

2. Pull the flexible cap away from Connector Port, and insert GREEN Discrete LeadWear connector into GREEN slot on Patient Transceiver.

Temporary Simultaneous Monitoring / Transceiver Settings

3. Press *ECG Mode* switch  on the Diagnostic Monitor Transceiver until the *ECG* indicator over “12 LEAD” glows GREEN.
4. Press *Communication Mode* switch  on the Diagnostic Monitor Transceiver until the *Communication Mode* indicator over “TEMP” glows GREEN.

- Note: Do not change any settings on the existing Continuous ECG Monitor Transceiver.

Temporary Simultaneous Monitoring / Pairing

1. Pair the Diagnostic Monitor Transceiver with the Patient Transceiver, using the Token **from the Diagnostic Monitor Transceiver**, ending with the Token back in the Token Port of the Diagnostic Monitor Transceiver.
~ NOTE: Promptly move the Token from the Patient Transceiver back to the Diagnostic Monitor Transceiver. There may be a momentary interruption in the signal being received by the Continuous Monitor Transceiver during the secondary pairing operation.

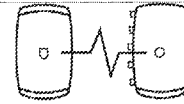
Patient Transceiver



Both PERM and TEMP *Communication Status* indicators will flash GREEN – Permanent Communication in process with one Monitor Transceiver and Temporary Communication with the other Monitor Transceiver

Continuous Monitor Transceiver

SYSTEM OPERATION



Communication Status indicator will flash GREEN –
Communication in process with Patient Transceiver

Diagnostic Monitor Transceiver



Communication Status indicator will flash GREEN –
Communication in process with Patient Transceiver

The patient's ECG signal will appear on the Diagnostic ECG monitor within a few seconds.

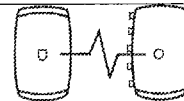
2. The Patient Transceiver will communicate with the Diagnostic Monitor Transceiver for two minutes, which should provide sufficient time to collect the 12-Lead diagnostic ECG reading.
3. After two minutes, the Patient Transceiver will stop communicating with the Diagnostic Monitor Transceiver.

Patient Transceiver



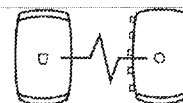
PERM *Communication Status* indicator will flash GREEN – Permanent Communication still in process with one Monitor Transceiver
TEMP *Communication Status* indicator will go out – two-minute Temporary Communication period ended

Continuous Monitor Transceiver



Communication Status indicator will flash GREEN –
Communication in process with Patient Transceiver

Diagnostic Monitor Transceiver



Communication Status indicator will flash YELLOW –
No Communication in process

4. If desired, remove the Discrete LeadWear from the patient. If used, replace the V (BROWN) lead of the Continuous LeadWear to its electrode.

TRANSFER PATIENT BETWEEN MONITORS

To permanently transfer patient from one monitor to another monitor of the same type (ie; from a stationary Continuous ECG Monitor to a Portable Continuous ECG Monitor).

- NOTE: This requires a second Monitor Transceiver, set up on the "second" ECG monitoring equipment.

Transferring Monitors / Patient Set Up

No adjustment in patient set up is required.

Transferring Monitors / Transceiver Settings

1. Press *ECG Mode* switch  on the "second" Monitor Transceiver until the indicator glows GREEN over the ECG mode for the type of monitor being used ("3/5 LEAD" for Continuous ECG, "12 LEAD" for Diagnostic ECG).
2. Press *Communication Mode* switch  until the *Communication Mode* indicator over "PERM" glows GREEN.

~ Note: Do not change any settings on the "first" Monitor Transceiver.

Transferring Monitors / Pairing

SYSTEM OPERATION

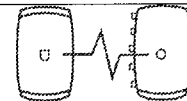
1. Pair the “second” Monitor Transceiver with the Patient Transceiver, using the Token **from the “second” Monitor Transceiver**, placing the Token back in the Token Port of the “second” Monitor Transceiver.
~ NOTE: Promptly move the Token from the Patient Transceiver back to the “second” Monitor Transceiver. There may be a momentary interruption in the signal being received by the Continuous Monitor Transceiver during the secondary pairing operation.

Patient Transceiver



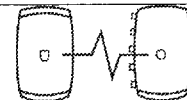
PERM *Communication Status* indicator will flash GREEN – Communication in process with Monitor Transceiver

First Monitor Transceiver



Communication Status indicator will flash YELLOW – No Communication in process

Second Monitor Transceiver



Communication Status indicator will flash GREEN – Communication in process with Patient Transceiver

The patient's ECG signal will drop from the “first” ECG monitor, and will appear on the “second” ECG monitor within a few seconds.

3 – User Maintenance

LIFESYNC™ SMART BATTERY

The LifeSync™ Smart Battery is a custom designed 3.6 Volt rechargeable Lithium-ion battery, with a built-in “fuel” gauge.

A fully charged battery will power a LifeSync Patient Transceiver for a minimum of 24 hours, and a LifeSync Monitor Transceiver for a minimum of 12 hours.

LifeSync Smart Batteries are shipped in the uncharged state, with a plastic film cover covering the contacts.

☒ **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 battery with any device other than a LifeSync Monitor Transceiver, a LifeSync Patient Transceiver or a LifeSync Battery Charger. 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 Life / Battery Disposal

It is recommended that batteries be discarded after one year of use, due to degradation of capacity. After extended use, the battery will deliver decreased operational life per charge.

Recycle or dispose of discarded batteries according to national, state and local regulations.

Battery Storage

Batteries should be removed from Transceivers and stored separately when the system is not in use for extended periods of time.

USER MAINTENANCE

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.

Removing/Replacing Batteries

Remove the battery from either transceiver by releasing the battery clips and sliding the battery out of the battery slot.

PHOTO -H
“insert batt”

PHOTO – A:
“battery install”

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

~ **NOTE:** Lift Patient Transceiver slightly away from patient's arm when changing battery while in use, to avoid pinching patient's skin or hair.

Checking Battery Charge

The LifeSync™ Smart Battery has a built-in “fuel” gauge. Press the oval on the end of the battery; each indicator represents 20% of battery capacity remaining.

PHOTO – A:
“battery full”

The LifeSync™ Smart Battery gauge is designed to be periodically “calibrated” by the LifeSync Multi-Unit Battery Charger.

- NOTE: The built-in battery charger in the LifeSync Monitor Transceiver does not perform this Battery Gauge Calibrating function.

~ NOTE: Each Transceiver has a *Battery Charge* Indicator  that flashes YELLOW when the battery is running low. A periodic audible beeping tone will also be heard. The battery must be replaced with a fully-charged battery within 60 minutes to maintain transceiver operation.

Charging in the Monitor Transceiver

The Monitor Transceiver has a built-in battery charger that operates whenever the unit is plugged into an AC power source.

The *Battery Charge* indicator  on the Monitor Transceiver will flash GREEN while the battery is charging; the light will glow SOLID GREEN when the battery is fully charged.

It takes up to eight hours for the Monitor Transceiver to fully charge a completely discharged battery.

☒ CAUTION: Use only a LifeSync Monitor Transceiver or a LifeSync Battery Charger to recharge the battery.

LIFESYNC MULTI-UNIT BATTERY CHARGER

The LifeSync Multi-Unit Battery Charger charges and conditions up to eight LifeSync Smart Batteries at a time. The charging cycle time to fully charge a completely discharged battery is up to eight hours.

The Multi-Unit Charger is designed to operate with a minimum of user intervention. The unit is turned ON by plugging the attached cord into an AC power source. Turn the unit OFF by unplugging it.

[PHOTO – A:
“Battery Charger mid”]

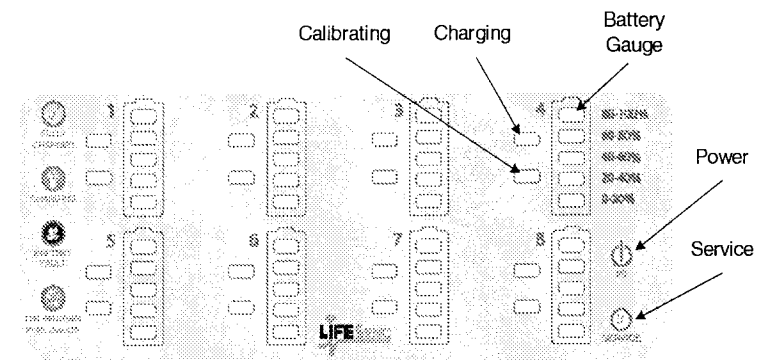
Upon power-up, the Battery Charger performs a self-test, during which all the indicators on the front panel will light up for a few seconds, then all go out except for any active indicators.

The *I/O* indicator will glow GREEN when the unit is operating properly. The *Service* indicator will glow RED if there is a fault condition.

Charging Batteries in the Multi-Unit Battery Charger

Simply place a battery into any empty charging slot, with the battery contacts **facing to the left side** of the unit. The charging cycle is automatic. Indicators on the front display panel of the charger provide information on the charging status of each battery.

☒ **CAUTION:** Use only a LifeSync Monitor Transceiver or a LifeSync Battery Charger to recharge the battery.



Multi-Unit Charger Display Panel

Charging Indicator

GREEN Fully Charged

YELLOW Charging In-process

RED Battery Fault

Calibrating Indicator

ON (BLUE) Calibrating In-process

OFF No Calibrating Needed

Battery Gauge

Column of GREEN indicators; each indicating 20% of charge

USER MAINTENANCE

CLEANING

The LifeSync Patient Transceiver, Monitor Transceiver, Battery, Battery Charger and Power Cord 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 or T.B.Q.® (Calgon Corp.). Thoroughly wipe off any excess cleaning solution.

☒ **CAUTION:** Do not use the following solvents for cleaning the Patient Transceiver, the Monitor transceiver or the Battery Charger: butyl alcohol, ethanol, Freon, bleach, acetone, hydrogen peroxide. Use of any of these solvents may lead to deterioration of plastic components. Do not autoclave any LifeSync component.

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

☒ **WARNING:** Do not allow liquid into battery slots, battery contacts, Connector Ports, Token Ports or any other openings or crevices. Do not immerse any LifeSync component in liquid.

LifeSync LeadWear is intended for single patient use only. It may be wiped with a nearly dry cloth, moistened with warm water. If LeadWear and/or the Armband becomes badly soiled, it should be replaced.

4 – Technical

OPERATIONAL DETAILS

An electrocardiograph (ECG) system monitors heart activity via the electrical impulses generated by the heart. Electrodes placed on the patient's skin produce electrical signals, which are converted by ECG monitor electronics into meaningful ECG data that can be either presented in real-time on a display, printed out for review or collected for storage. Typically, electrical signals are carried directly from the electrodes to an ECG monitor via leadwire sets and cables. The LifeSync system eliminates the wires between the ECG patient and the ECG monitor by replacing the conventional patient-to-ECG-monitor cables with a radio link.

With the LifeSync system, electrical signals from the electrodes are carried through lightweight, flexible LeadWear to the Patient Transceiver, which sends the electrical signals to the Monitor Transceiver via radio transmission. The Monitor Transceiver then passes the electrical signals directly to a conventional ECG monitor using standard leadwire sets and cables.

LeadWear

The conductive circuitry and shielding of the LifeSync LeadWear is contained between layers of insulating polyester, covered on one side with biocompatible fabric for patient comfort. Non-metallic electrode “snap” connections are color coded and marked with standard ECG lead conventions. LeadWear connectors are physically keyed and color-coded to distinguish

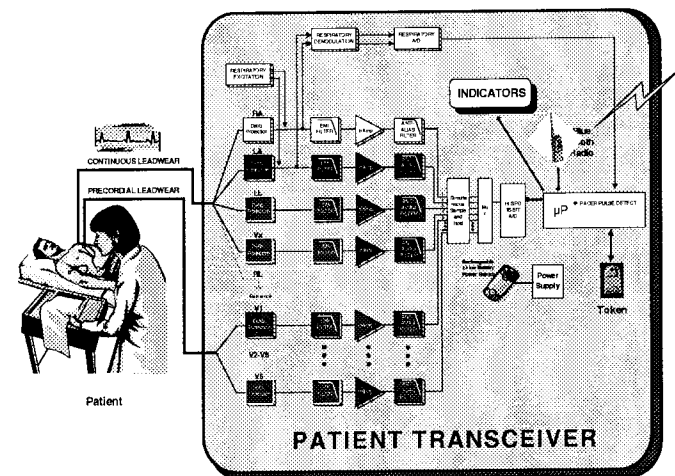
PHOTO-A:
“leadwear features”

TECHNICAL

between Continuous LeadWear – used for continuous 3-5 Lead ECG monitoring, and the Discrete LeadWear – used for short-term diagnostic 12 Lead ECG monitoring.

Patient Transceiver

The LifeSync Patient Transceiver is designed to be worn on the arm of the patient, or may be placed in a convenient location on the bed. It is powered by a proprietary rechargeable Li-ion battery with a built-in charge indicator. The unit is activated by the presence of a Continuous LeadWear connector (the connector contains a ground pin that completes a circuit within the electronics). The Patient Transceiver user interface is solely informational, using five LED indicators. There are three printed circuit board assemblies, enclosed in a plastic housing with integral gasketing and connector port shields, to provide protection from water ingress. A block diagram of the Patient Transceiver is included here, for reference only. THE PATIENT TRANSCEIVER IS NOT FIELD-SERVICEABLE.

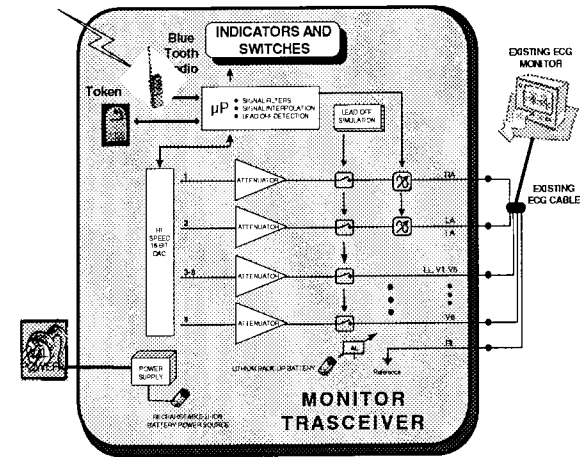


The Patient Transceiver controls the acquisition of electrical signals from the LeadWear, converts the analog signals to digital, and communicates via radio link with the Monitor Transceiver to transmit the ECG signal data. The Patient Transceiver monitors the integrity of electrode connections, reporting a "lead-off" condition in the event a lead is disconnected. A self-test function monitors the integrity of the primary Patient Transceiver functions including the microprocessor, data acquisition, internal voltage references, and radio functionality.

Monitor Transceiver

The Monitor Transceiver is designed to be physically mounted on the side of the conventional ECG monitor to which it is connected, using the provided mounting plate. It is powered by either the proprietary rechargeable Li-ion battery, or by AC power, with the provided power cord. When connected to AC power, the Monitor Transceiver also functions as a battery charger.

The Monitor Transceiver is activated by a Power On/Off switch on the front of the unit; a Token must also be in place in the Token Port for the Monitor Transceiver to function. The Monitor Transceiver user interface utilizes three dual-state switches and nine LED indicators. There are two printed circuit board assemblies, enclosed in a plastic housing with integral gasketing to protect the unit from water ingress. Ten color-coded snap terminals are provided to connect the Monitor Transceiver to the ECG monitor, using standard ECG leadwire sets. A block diagram of the Monitor Transceiver is included here, for reference only. THE MONITOR TRANSCEIVER IS NOT FIELD-SERVICEABLE.



The Monitor Transceiver communicates via radio link with the Patient Transceiver to receive the digital ECG signal, converts it back to analog, conditions and transmits the signal to the ECG monitor via the snap terminals. A self-test function monitors the integrity of the primary Monitor Transceiver functions, including the microprocessor, data acquisition, internal voltage references, and radio functionality.

Pairing Token

A process called “pairing” establishes and ensures proper communication between a Patient Transceiver and a Monitor Transceiver, using a LifeSync Token to create a radio-link between the two units. Tokens contain a non-volatile memory chip and are interchangeable. The Token is stored in the Monitor Transceiver, and records the radio identification number of the device. During “pairing”, the Token is moved to the Patient Transceiver, which receives the radio identification number of the Monitor Transceiver from the Token, and the Token now records the radio identification number of the Patient

Transceiver. The Token is then moved back to the Monitor Transceiver, which receives the radio identification number of the Patient Transceiver, and the two transceivers are radio-linked, or “paired”, and communication will begin. A Monitor Transceiver will only recognize signals from a Patient Transceiver with which it has been “paired”.

Pairing is most often done in a Permanent (PERM) mode, but there is also a Temporary (TEMP) mode. In TEMP mode, the paired transceivers will only communicate for a period of two minutes. At the conclusion of two minutes, the temporary link will be broken, and the Monitor Transceiver will stop recognizing the signal from that Patient Transceiver.

CHECKLIST FOR LIFESYNC SYSTEM KIT CONTENTS

Confirm that you received the following equipment:

Patient Transceiver Kit

- LifeSync™ Patient Transceiver
- LifeSync™ Smart Battery

[photo: Patient Transceiver Kit]

Monitor Transceiver Kit

- LifeSync™ Monitor Transceiver
- LifeSync™ Smart Battery
- LifeSync™ Token
- Monitor Transceiver Mounting Plate
- Monitor Transceiver Power Cord
- System User's Manual

[photo: Monitor Transceiver Kit]

LeadWear Kit

- LifeSync™ Continuous LeadWear
- LifeSync™ Discrete LeadWear
- LifeSync™ Armband
- LifeSync™ ComfortPatch

[photo: LeadWear Kit]

REORDER INFORMATION

LifeSync™ system components can be reordered from ____:

SYSTEM FUNCTIONAL CHECK

The LifeSync 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 Transceiver Kits
- One LifeSync Patient Transceiver Kit
- LifeSync LeadWear Kit
- ECG Patient Simulator
- Two LifeSync Compatible ECG Monitors:
one Continuous and one 12-Lead Diagnostic ECG Monitor

📶 NOTE: LifeSync system performance has been confirmed with a variety of commonly used ECG monitors. The Cautions section of Chapter 1 includes a list of LifeSync compatible ECG monitors.

Contact GMP|Wireless Medicine Customer Service or the website http://_____ for additional information on ECG monitors that are compatible with the LifeSync system.

Prepare the Batteries

📶 NOTE: LifeSync smart batteries are shipped in the uncharged state, with a plastic film cover covering the contacts.

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

indicator.

See Chapter 3 for more information on Battery Charging.

Monitor Transceiver Set Up / PowerOn 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 AC Power.
4. Press *Power On/Off* switch.
Confirm that all indicators blink in sequence (approximately one second) and an audible tone is heard.
Confirm that the GREEN *Battery Charge* indicator is flashing.
5. Press *ECG Mode* switch several times, confirming that both indicators function. Leave indicator over "PERM" mode ON.
6. Press *Communication Mode* switch several times, confirming that both indicators function. Leave indicator over "3/5 Lead" mode ON.
7. Connect leadwire cables from the Continuous ECG Monitor to the Monitor Transceiver, matching colors and lead markings.

Patient Transceiver Set Up / PowerOn Test

1. Insert the **fully charged** battery into the Patient Transceiver. Confirm that all indicators on the Patient Transceiver blink in sequence (approximately one second) and an audible tone is heard.
Confirm that the YELLOW *Battery Charge* indicator is OFF.

2. Remove Continuous LeadWear from kit and connect electrode snaps on Continuous LeadWear to Patient Simulator.
3. Insert Continuous LeadWear connector into connector port, matching colors and connector keys.

Transceiver Pairing – Single Permanent

1. Remove Token from the Monitor Transceiver.
Confirm *Pairing* indicator on Monitor Transceiver glows SOLID YELLOW.
2. Insert Token into Token Port on the side of Patient Transceiver.
Wait for *Pairing* indicator on Patient Transceiver to glow SOLID YELLOW.
3. Remove Token from Patient Transceiver.
Confirm that *Pairing* indicator goes OFF.
4. Place Token back into Token Port of the Monitor Transceiver.
Confirm that *Pairing* indicator goes OFF.
Confirm that *Communication Status* indicators on both transceivers flash GREEN (over “PERM” on the Patient Transceiver).
Confirm that the ECG signals appear on ECG monitor display, and that the ECG signals agree with the ECG Patient Simulator settings.

Monitor Transceiver Set Up – Simultaneous / Battery Check

1. Insert Token into Token Port on the top of the **second** Monitor Transceiver.
2. Place the **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 blink in sequence (approximately one second) and an audible tone is heard.

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- Confirm that the **YELLOW Battery Charge** indicator is flashing, and that an audible tone continues to beep.
4. Connect the second Monitor Transceiver to AC Power.
 5. Press *ECG Mode* switch several times, confirming that both indicators function. Leave indicator over "TEMP" mode ON.
 6. Press *Communication Mode* switch several times, confirming that both indicators function. Leave indicator over "12 LEAD" mode ON.
 7. Connect leadwire cables from the Diagnostic ECG Monitor to the second Monitor Transceiver, matching colors and lead markings.
 8. Remove the V – BROWN lead of Continuous LeadWear from the Patient Simulator.
 9. Remove Discrete LeadWear from kit and connect electrode snaps on Discrete LeadWear to Patient Simulator, including V1 – RED lead.
 10. Insert Discrete LeadWear connector into connector port, matching colors, leaving Continuous LeadWear connector in place.

Transceiver Pairing – Simultaneous

1. Remove Token from the second Monitor Transceiver. Confirm *Pairing* indicator on the second Monitor Transceiver glows SOLID YELLOW.
2. Insert Token into Token Port on the side of Patient Transceiver. Wait for *Pairing* indicator on Patient Transceiver to glow SOLID YELLOW.
3. Remove Token from Patient Transceiver. Confirm that *Pairing* indicator goes OFF.
4. Place Token back into Token Port of the second Monitor Transceiver. Confirm that *pairing* indicator goes OFF.

Confirm that *Communication Status* indicators on all three transceivers flash GREEN (over **both** “PERM” and “TEMP” on the Patient Transceiver).

Confirm that the proper ECG signals appear on both ECG monitor displays, and that the ECG signals agree with the ECG Patient Simulator settings.

5. Wait for two minutes.
After two minutes, the **second** Monitor Transceiver stops receiving signals from the Patient Transceiver.
Confirm that *Communication Status* indicator on the **second** Monitor Transceiver flashes YELLOW, the *Communication Status* indicator on the **first** Monitor Transceiver flashes GREEN, and only one *Communication Status* indicator on the Patient Transceiver flashes GREEN (over “PERM”).

Transceivers – Confirm Remaining Battery Indicators

1. Disconnect Monitor Transceivers from ECG Monitors and turn monitors OFF.
2. Remove the batteries from all Transceivers.
Disconnect the Monitor Transceivers from AC power.
3. Place the **partially charged** battery in the Patient Transceiver.
Confirm that the *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 each Monitor Transceiver.
Confirm that all *Battery Charge* indicators are OFF for each transceiver with the fully charged battery installed.
5. Place the fully charged battery back into the Patient Transceiver.
6. Place the two other batteries into the two Monitor Transceivers. Press *Power On/Off* switches.

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Confirm that the YELLOW *Battery Charge* indicators flash, and that an audible tone continues to beep.

7. Connect AC power to both Monitor Transceivers.
Confirm that the GREEN *Battery Charge* indicator is flashing. Let batteries charge for 8 hours before use.

TROUBLESHOOTING

Condition	Cause	Resolution
Either Transceiver: beeping sound is heard	Battery power is low	Remove battery and replace with a fully charged battery.
Patient Transceiver: no indicators	No power – battery too low	Remove battery and replace with a fully charged battery.
	LeadWear Connector not properly seated	Make sure LeadWear Connector is firmly seated in Connector Port.
Monitor Transceiver: no indicators	Power turned off	Press <i>Power On/Off</i> switch.
	No power – battery too low or power cord disconnected	Remove battery and replace with a fully charged battery, or check to make sure power cord is securely plugged into wall outlet.
Either Transceiver: indicators stay on	(indicators will normally flash for approx. three seconds when unit	Contact Biomedical Engineering for replacement unit.

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	is turned on)	
Either Transceiver: <i>Service Indicator</i> is lit	System Malfunction	Do Not Use. Contact Biomedical Engineering for replacement unit.
Monitor Transceiver: <i>Communication Mode</i> switch doesn't work	Communication Mode will only work when a Token is present	Make sure Token is securely seated in Monitor Transceiver.
Monitor Transceiver: <i>Communication Status</i> indicator stays YELLOW	No communication between Transceivers	Check <i>Communication Mode</i> indicator on Monitor Transceiver; if set in TEMP mode, has temporary communication period (2 minutes) expired? If so, repeat pairing procedure. Make sure distance between Transceivers is less than 25 feet. Make sure Token is properly seated in Monitor Transceiver. If <i>Pairing Status</i> indicator on Patient Transceiver is lit, repeat the pairing

		procedure
Either Transceiver: <i>Pairing Status</i> indicator does not go off	Transceiver pairing was not successful	Make sure distance between Transceivers is less than 25 feet. Repeat the pairing procedure, making sure to securely seat the Token at each step.

Troubleshooting chart (continued...)

WARRANTY INFORMATION

Appendices:

SPECIFICATIONS

Current as of 12/10/02

Parameter	Specification
# Channels - '3/5 LEAD' mode '12-LEAD' mode	4 single-ended: LA LL RA V wrt RL 9 single-ended: LA LL RA V1 V2 V3 V4 V5 V6 wrt RL
ECG Input range	±300 mV DC wrt RL minimum
ECG Frequency Response	DC-150 Hz 0.00 ± 0.25 dB; 150-500 Hz <1.0 dB
ECG Signal Gain	1.00 ± 0.01 V/V (0.0 ± 0.1 dB)
ECG Channel-Channel Gain Matching	Better than 0.995 V/V
DC Signal Error	±3 mV maximum
Pacer Pulse Response	Passes pacer pulses 2-50 mV from 0.100-2.0 ms per ANSI/AAMI EC13:2001
Signal noise – all channels WRT RL	30 µV p-p maximum
Signal Latency	Up to 500 ms
Operating Battery – Voltage Capacity Technology	3.6 VDC nominal 2200 mA-hr Rechargeable Lithium-Ion
Operating Battery Life – Patient Transceiver Monitor Transceiver	24 hrs minimum 12 hrs minimum
Size – Patient Transceiver Monitor Transceiver	8 cm (W) X 12.5 cm (H) X 3 cm (T) 8.5 cm (W) X 16 cm (H) X 4 cm (T)
Weight including Battery – Patient Transceiver Monitor Transceiver	240 g 280 g

APPENDIX

Parameter	Specification
Operating Temperature	0 to 45°C
Storage Temperature	-20 to 70°C
Atmospheric Pressure	700-1060 mbar
Housing Material	ABS
Radio Protocol	Bluetooth wireless technology
Class	Class 2
Range	10 m
Operating Frequency	2.402-2.480 GHz
Channels	79 1MHz channels
Power output level	+4 dBm maximum
Bluetooth Revision	V1.1
Water Ingress Rating	IPX1 per IEC 529 (for both PT & MT)
Patient Applied Parts	Defib proof Type CF per EN60601-1
Defibrillation Proof	Meets 400 J per EN60601-2-27
Patient Transceiver power	3.3-4.1 VDC .25A
Monitor Transceiver power	3.3-5.0 VDC 1A
Safety	EN60601-1, EN60601-2-27, UL2601-1, CSA 22.2 No 601.1
EMC	EN 60601-1-2:2001
Respiration Specifications:	
Resp. Frequency Response	0.1-2.5 Hz
Dynamic Range	8 ohm maximum
Base Impedance Range	0-1200 ohms
Excitation Frequency	39 kHz

☒ **CAUTION:** Although the LifeSync system meets all leakage current requirements for electromedical devices as defined by UL2601-1, EN 60601-1 and ANSI/AAMI ES-1 for type CF patient applied parts, leakage current requirements can be exceeded by connection of LifeSync together with other patient applied parts

to a patient. Under the circumstances where multiple patient applied parts are connected, patient leakage current from the multiple devices will sum to create a total leakage current that may exceed limits as defined by the standards referenced above.

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

[Index]

[inside back cover]

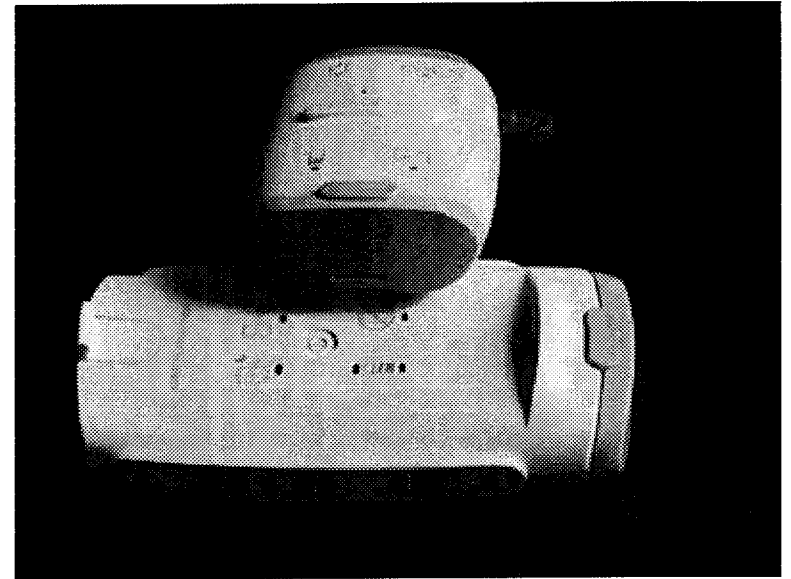
pocket for Reference materials, warranty card, etc.

GMP WIRELESS MEDICINE, INC.

Corporate Headquarters

phone

website



Content for Quick Reference Guide

- Three Step process for Using LifeSync
(from page 12 of Manual)
- Diagrams for LeadWear placement
(from page 26 & page 28)
- System Indicator & Switches chart
(from page 16 & 17)

Content for LeadWear Kit Card

- Three Step process for Using LifeSync
(from page 12 of Manual)
- Diagrams for LeadWear placement
(from page 26 & page 28)
- Diagrams for reversal of LeadWear connector
(from page 24)
- Diagram for placement & use of Armband
(not in Manual)