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

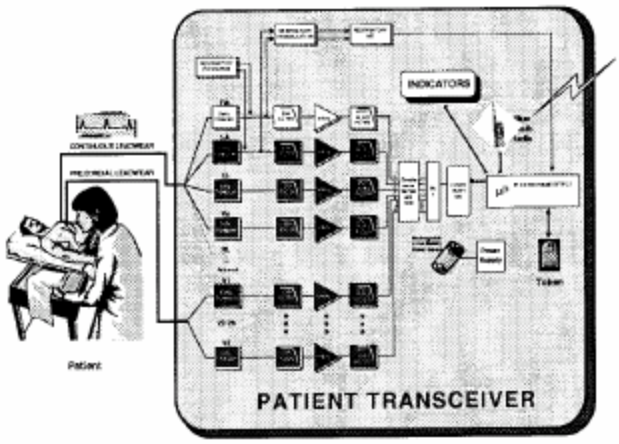
The conductive circuitry and shielding of the LifeSync LeadWear is contained between layers of insulating polyester, covered on one side with biocompatible fabric for patient comfort. Non-metallic electrode "snap" connections are color coded and marked with standard ECG lead conventions. LeadWear connectors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

PHOTO-A:
"leadwear features"

between Continuous LeadWear – used for continuous 3 or 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.

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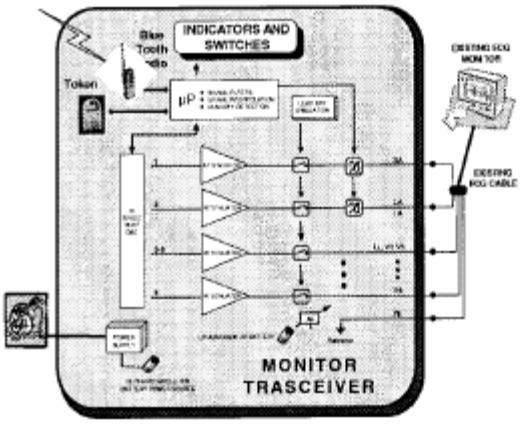

The Monitor Transceiver communicates via radio link with the Patient Transceiver to receive the digital ECG signal, converts it back to analog, conditions and transmits the signal to the ECG monitor via the snap terminals. A self-test function monitors the integrity of the primary Monitor Transceiver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