Signalife

Clear Data. Trusted Results.

User Manual

Version 1.0
March 28, 2006

For Systems Containing:
Patient Monitor Software Part VS00023 Rev. 1.0
Display/Print Utilities Software Part VS001 Rev. 1.0

Manufactured for:
Signalife, Inc.
531 South Main St,. Suite 301
Greenville, SC 29601
(864) 233-2300

Table of Contents

Section 1

Device Description

The Signalife Fidelity 100 ECG Monitor is a true 12- lead, 10-electrode, ambulatory, wireless, digital ECG recorder that transmits patient ECG data. This system is intended to transmit, display and print ECG data from patient electrodes connected to the Fidelity 100 patient monitoring device worn in a belted pouch. The monitoring device communicates wirelessly via a Bluetooth™ connection to a touch screen computer where ECG data is then displayed for review and print for analysis by a physician. The Signalife Fidelity 100 ECG Monitoring System utilizes the company's proprietary signal processing circuitry to capture real time ECG data and is not intended to alarm.

The system includes a patient monitoring device, a battery charger to recharge the non-serviceable, 7.2V Li-Ion battery, a touch screen PC, an uninterrupted power supply (UPS), printer, carrying pouch (for the patient monitoring device) and a cart. Software for the system is factory installed. A start up accessory equipment set with electrodes and a patient cable are also included.

Please note the following UL 60601-1 Classification criteria for the Fidelity 100 patient monitoring device:

- Internally powered equipment
- "Defibrillation-proof" Type CF Applied Part
- IPX0 Ordinary Protection
- Continuous Operation
- **WARNING - Equipment is not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.**

Patient Monitoring Device Features:

- Acquisition of a true 12-lead ECG utilizing 10 patient attached electrodes.
- Operates on a rechargeable Lithium-Ion battery.
- Small, lightweight, comfortable to wear and made of a durable design.
- No moving parts.
- The device requires no service and contains a single factory replaceable part, a rechargeable 7.2 V Li-Ion Battery.
- The device is protected against the effects of exposure to a defibrillator.
- Patient may be monitored in the conventional resting mode or while ambulatory in the physician's office.

Section 2

Required System Accessories

The following is a description of accessory equipment approved by the manufacturer required to operate the system. A start up set is included with the initial delivery.

The Signalife Fidelity 100 should only be used with the lead wires provided. To order additional sets call Signalife, Inc. at 864-233-2300 for assistance.

Accessories listed below have been tested and approved, and are recommended for use:

Patient Cable
Model LW-07001/10A
Advantage Medical Cables
10630 Wiles Rd.
Coral Springs, FL 33076
Tel: 800 358-2468

Electrodes
3M™ Red Dot Button Snap Monitoring Electrodes
Model #2237,
3M OEM Healthcare Products
St. Paul, MN 55144-1000
Minneapolis, MN
Tel: 1-800-228-3957

ConMed® Cleartrace ECG Electrodes
Ref 1700-001
ConMed Corporation
310 Broad St.
Utica, NY 13501

The Signalife System components and manufacturers:

Touch Screen PC
Model L05-17P4
A.T. Software Solutions, Inc.
12444 Bougainvillea Way
Riverside, CA 92503
Tel: 951-785-1619
West Windsor, NJ 08550, USA
Tel: 1-609-799-5366

Patient Monitoring Device
Fidelity 100
Manufactured by Signalife, Inc,
531 S. Main St.
Greenville, SC 29601
Tel: 864-233-2300

Display and Print Utility Software
Part VS00023 Rev. 1.0
Manufactured by Signalife, Inc.
531 S. Main St.
Greenville, SC 29601
Tel: (864) 233-2300

System Components continued:

Printer
Model HL-2040
Brother
100 Somerset Corporate Blvd.
Bridgewater, NJ 08807
Tel: 908-704-1700

Uninterrupted Power Supply
Model XS 1200
APC
132 Fairgrounds Rd
W. Kingston, RI 02892
Tel: 877-800-4272

Patient Pouch
Nathan Quest Model #4817N
Penguin Brands, Inc.
P.O. Box 1036
Sharon Hill, PA 19079
Tel: 610-534-8700

System Cart
Micro Workstation
Model BLTDBLWS2
Balt, Inc.
2885 Lorraine Ave
Temple, TX 76501
Tel: 800-749-2258

Section 3

Intended Use and Indications for Use

The Signalife Fidelity 100 ECG Monitoring System is a true 12-lead system capable of monitoring ECG data by a medical professional where ECG monitoring is prescribed by a physician. The system records, displays and prints ECG data from each of the 12 leads and transmits the data via Bluetooth to a PC. The system can be used in a traditional patient resting mode or while the patient is ambulatory in the physician's office.

The Signalife Fidelity 100 ECG Monitoring System is not intended to sound any physiological alarms.

The Fidelity 100 is not intended for infants weighing less than 10 kg. It does not calculate a heart rate or determine a pulse.

Section 4

Instructions for Use

1. Getting Started:

- Turn on computer.
- Turn on monitoring device by depressing the “ON” switch
- After a brief series of flashes the green power indicator will remain illuminated. The device is now ready for data collection.

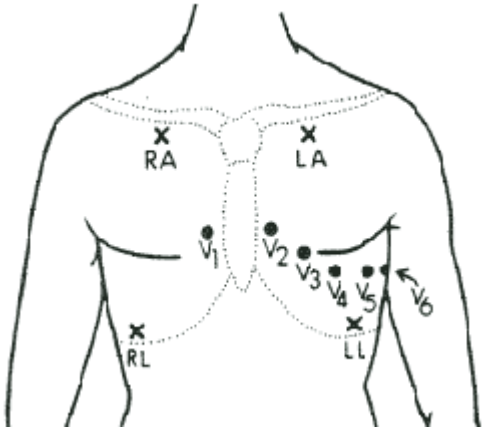
NOTE: *If the yellow indictor flashes slowly and the green indicator is lit, the device is signaling a Low Battery condition and the battery must be fully recharged before starting any data collection by turning the unit off and plugging in the charger.*

NOTE: *If the red indicator remains illuminated and the green indicator is lit, the device is signaling a Hardware Error condition (see Troubleshooting Tips for instructions on how to call for technical assistance).*

- Insert the monitoring device into the patient pouch and confirm lead set connection.

2. Patient Hook-Up:

- Position the patient.
- Prepare the skin by cleaning site of each electrode placement with alcohol, if patient has hair on chest, shave for best results.
- Abrade skin at each electrode site.
- Attach electrodes to snaps on lead set.
- Adhere electrodes to skin in preferred lead placement.
- Lead placement should always be recorded above the ECG tracing by the healthcare professional and considered during the healthcare professional’s evaluation.



NOTE: *For best results in ambulatory use, attach the waist pouch containing the monitor to the patient then spin pouch on belt around to the patient’s lower back.*

3. ECG Report:

- Touch “Start ECG” located on PC screen.
- The system will require up to 40 seconds for cold start-up.
- View ECG on the PC screen.
- Touch “Print” located on the PC screen to print.
- Touch “Stop” located on the PC screed to stop data capture.

NOTE: *There will be approximately 10 seconds of delay between ECG display and print as the print function is activated after 10 seconds of data capture.*

NOTE: *A minimum distance of 3 feet and a maximum distance of 30 feet should be maintained between the patient and the PC while the system is in use.*

4. Patient Disconnect:

- Disconnect the patient when test completed by gently removing electrodes from skin.
- The system is ready for new use.
- Clean as directed.
- Turn monitoring device off prior to recharging.

At the end of its useful life, the Fidelity 100 patient monitor and battery charger should be returned to the manufacturer for disposal.

Please see the contact information at the end of this manual to make arrangement for a return.

Section 5

Frequency or Duration of Use

The frequency or duration of use is determined by the physician.

Hazards

The patient monitor device complies with Voluntary Consensus standards for Ambulatory ECGs and general medical devices that provide for the safe use of this device.

Please refer to the Device Specification Section of this Operator's Manual for a complete list of these standards.

Warnings

WARNING - Equipment is not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.

WARNING - This device is not for infant usage of 10 kg or less

WARNING – A minimum distance of 3 feet between the PC and the patient worn monitor must be maintained during the ECG monitoring session.

WARNING - Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Only approved accessories should be used to operate this equipment.

Patient Monitor LED Indicators and Operating Symbols

Patient Monitoring Device LED Symbols Description

Symbol	Description
5010 	**"ON"/"OFF" (push-push)** To indicate connection to or disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved. Each position, "ON" or "OFF", is a stable position.
5039 	**Aerial (USA: Antenna)** On radio receiving and transmitting equipment. To identify the aerial (antenna) terminals. This symbol should be used unless it is essential to specify the type of aerial (antenna).
5639 	**Rechargeable battery** To identify equipment which shall only be used with rechargeable (secondary) cells or batteries, or to identify rechargeable cells or batteries. When shown on a battery holder, the symbol also indicates the positioning of the cells.
5034 	**Input** To identify an input terminal when it is necessary to distinguish between inputs and outputs.
0434 	**To signify caution – see Section 5 for warning types.**
5336 	**Defibrillation-proof type CF applied part** On medical equipment. To identify a defibrillation-proof type CF applied part complying with IEC 60601-1. *Note 1 - C = Cardial.* *Note 2 - F = Floating applied part.*
5031 	**Direct current** To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.

Touchscreen PC Icon Descriptions

Press to start ECG signal capture

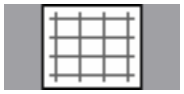
Press to shutdown the system

Press to Zoom In on the ECG signal

Press to Zoom Out on the ECG signal

Press to return to default view

Press to print captured ECG signal



Press to turn on/off grids for printing on plain paper
Default position is ON

Press to exit current ECG session

Contraindications

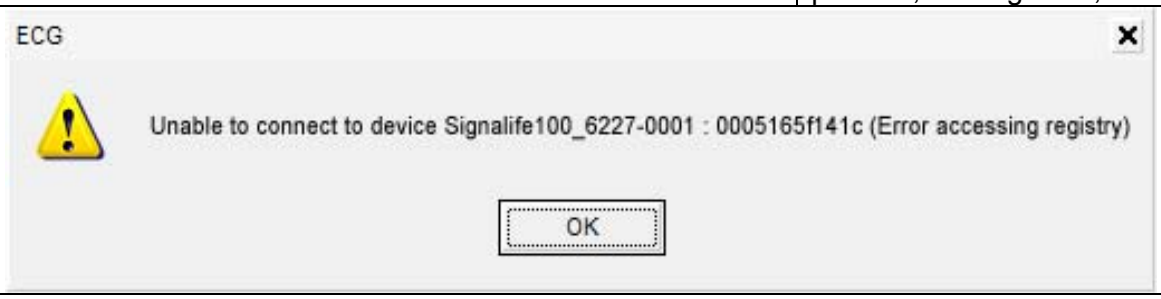
There are no known contraindications to the prescribed use of this device.

Side Effects and Precautions

There are no known side effects from either resting or ambulatory ECG monitoring.

Section 6

Troubleshooting Guide

Problem	Action
PC ok, and Fidelity 100 malfunctioning with a fault error reported – Red & Green LED On or Red, Yellow & Green.  or 	Battery depleted, recharge or replace. Battery not serviceable by user
PC ok unit functioning with low battery LED warning – Yellow & Green LED On 	Battery Low, Recharge
PC ok, Fidelity 100 ok, fault error reported – Red & Green LED On 	Unit out of range, move monitor to within 30 ft. of the PC. Shutdown PC, turn off unit, restart PC and unit.
PC Message “Unable to Connect to Signalife 100_6227-0001 : 0005165f141c (Error accessing registry)”	Touch “OK” and press Start ECG again. If problem persists, call Signalife, Inc.
	
PC Message “Unable to Connect to Signalife 100_6227-0001 : 0005165f141c (Device not found)”	Touch “OK” and press Start ECG again. If problem persists, call Signalife, Inc.
	
Fidelity 100 not functioning – Red & Green LED ON 	Internal device error – Restart to clear. If red light persists, contact Signalife, Inc.

Section 7

Device Specifications

• Electrode	10
• Leads	12
• Input Impedance	1 GΩ (typical)
• Frequency Response	0.05 – 100 Hz
• Digital Sampling Rate	500 samples/sec
• A/D Conversion bits	12
• Battery	Lithium-Ion 7.2 V rechargeable
• Dimensions	6.1 x 3.5 x 1.3 inches
• Operating Time (max.)	24 hours

Transport and Storage

• Operating Position	Any
▪ Weight (without battery)	5.5 oz.
▪ Case Material	ABS, Color-PMS Cool Gray
• Device Range	30 ft.
• FCC ID	TW7100
• Defibrillation recovery time	60 sec.

This device 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.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The Fidelity 100 shall operate to the specifications herein when operated in normal use under the least favorable combination of the following environmental conditions:

a.) Ambient Temperature Range of 0° C to +45° C
b.) Relative Humidity Range of 10 to 90%.
c.) Atmospheric Pressure Range of 700 to 1060 hPa

The Signalife Fidelity 100 patient monitoring device complies with the applicable sections of the following voluntary consensus standards:
ANSI/AAMI EC-38,
IEC 60601-1
IEC 60601-2-47
IEC 60601-1-2
UL 60601-1
EN 60601-1
EN 60601-1-2

In addition, the Signalife Fidelity 100 patient monitoring device meets the following RF standards for radiofrequency devices:
FCC Part 15.249
FCC Part 15, Class B Digital Device
IC RSS-210
EU R&TTE
FCC OET 56, OET 65C RF Exposure to Humans

Section 8

Cleaning and Service

This patient monitoring device contains no user serviceable parts. Service should therefore, not be attempted. The single factory replaceable part is the 7.2 V Li-Ion battery. This replacement can only be completed by a trained factory representative upon return of the unit to the manufacturer.

Cleaning should be completed after usage using a cloth dampened with warm water and a mild household detergent to clean exterior surfaces. The device should not be submerged in any liquid.

PC cleaning should be completed following the manufacturer's instructions.

Wire set should be cleaned following the manufacturer's instructions.

Disinfection or sterilization is not required.

Section 9

Technical Assistance and Service

If you have any questions regarding the proper operation of this device or experience any difficulty with its operation please call the number below for technical assistance or service.

Signalife, Inc.
531 South Main St.
Greenville, SC
1-866-365-1114 Phone Toll Free

Hours of Operation - 9 AM and 5 PM (Eastern Time)
Monday – Friday
Closed on major holidays

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The Signalife Fidelity 100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Signalife Fidelity 100 should assure that it is used in such an environment.		
Emissions test	Compliance	Guidance
RF emissions FCC Part 15 RSS-210 EN 300 220-3	Subpart C	The Signalife Fidelity 100 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions FCC Part 15 RSS-210 CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	The Signalife Fidelity 100 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.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 1 Guidance and manufacturer's declaration – EMI			
The Signalife Fidelity 100 is intended for use in the electromagnetic environment specified below. The customer or the user of the Signalife Fidelity 100 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	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	Not applicable	Not applicable	
Surge IEC 61000-4-5	Not applicable	Not applicable	
Voltage dips, short Interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.