INSTRUCTIONS FOR USE MANUAL

ZywieZ3 ECG Monitor

Instructions for Use Manual

The precautionary instructions for user found in this section and throughout this manual are indicated by specific symbols. Understand these symbols and their definitions before operating this equipment. The definitions of these symbols are as follows:

CAUTION - Text with a "CAUTION" indicator will explain possible Safety infractions that could have the potential to cause minor to moderate injury or damage to equipment.

WARNING - Text with a "WARNING" indicator will explain possible Safety infractions that will potentially cause serious injury and equipment damage.

DANGER - Text with a "DANGER" indicator will explain possible safety infractions that are imminently hazardous situations that would result in death or serious injury.

NO SITTING - Text with a "NO SITTING" indicator will explain possible Safety infractions that will potentially cause injury and equipment damage.

NO STEPPING ON SURFACE - Text with a "NO STEPPING ON SURFACE" indicator will explain possible safety infractions that will cause equipment damage.

NOTE: Throughout this manual, "NOTE" may be found. These NOTEs are helpful information to aid in the particular area or function being described

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Table of Contents

1 Instructions for Use

ZywieZ3 Sensor is a wireless device intended for use by healthcare professionals for recording and display of physiological data in outpatient settings. The physiological electrocardiogram (ECG) data is transmitted wirelessly to a cellular device for storage, display, and transmission. The ZywieZ3 sensor can be configured by authorized persons to modify or merge or ignore any of the operational alerts, but not to set alerts related to physiological data.

1.1 Warnings

1.1.1. Do not treat patients without physician evaluation. Safety of device during pregnancy or delivery has not been established.

1.1.2. Do not treat over swollen, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).

1.1.3. Do not wear or use the sensor during magnetic resonance imaging (MRI), or electro-cautery procedures. The ZywieZ3 sensor is MR Unsafe.

1.1.4. Exposure of the wireless communications features of the device, or its accessories, may be interfered with by other devices that operate on the same frequencies.

1.1.5. Excessive body tissue, hair, or dry skin may affect the signal quality.

1.1.6. In case of skin discomfort, remove the sensor immediately.

1.1.7. For best results, the sensor must be used with the provided adhesives.

1.1.8. No servicing/maintenance is required while the device is in use.

1.1.9. Before every use, check the device. Do not use the device if it is damaged. The continuous use of a damaged unit may cause improper results.

1.1.10. The device should be used only with the components recommended for use by the manufacturer.

1.1.11. The performance of the device may be degraded if one or more of the following occur:
-operation outside the manufacturer's stated temperature and humidity range.
-storage outside the manufacturer's stated temperature and humidity range.
-mechanical shock (for example, being dropped)

1.1.12. When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight.

1.1.13. Never place any heavy objects on the storage case.

1.1.14. The device only records and transmits the ECG signal to the paired mobile app. It does not analyze the ECG recordings or detect the presence of any arrhythmias.

1.2 Contraindications

The ZywieZ3 sensor is not intended for use under the following conditions:

1.2.1 Patients who require inpatient monitoring.

1.2.2 Patients whom the attending physician thinks should be hospitalized.

1.3 Precautions for ZywieZ3 Sensor

The ZywieZ3 sensor can only record data when it is properly connected to the adhesive on your body. The ZywieZ3 sensor is water resistant, but not waterproof. You can shower with the sensor on but please adhere to the following guidelines:

1.3.1 Avoid rubbing soap around the sensor.

1.3.2 Avoid excessive water exposure to the sensor.

1.3.3 Avoid prolonged, hot showers.

1.3.4 Avoid spraying water directly onto the sensor while showering.

1.3.5 Prepare the skin before wearing the device to record a good-quality ECG.

1.3.6 No servicing or maintenance is required while the device is in use.

1.3.7 Any changes or modifications made to this equipment not approved by Zywie, Inc. may void the FCC authorization to operate this equipment.

1.3.8 The device is non-sterile. Do not use the device on wounded or irritated skin.

1.4 Precautions for ZywieZ3 Disposable Adhesive

Each ZywieZ3 sensor comes with a medical-grade disposable adhesive.

1.4.1 Avoid excessive water exposure to the adhesive.

1.4.2 After each use, discard the used adhesive.

1.4.3 When not in use, always secure the adhesive in the provided sealed pouch.

1.4.4 Before applying the adhesive to the sensor, clean both sides of the sensor with an alcohol wipe (70 % + isopropyl alcohol).

1.4.5 After the adhesive pouch is open, use it within one month. Otherwise, the hydrogel may dry out and affect performance.

1.5 Possible Adverse Effects

1.5.1 Skin irritation/hypersensitivity – Some patients may experience skin irritation or hypersensitivity due to the adhesive.

1.5.2 Allergic skin reaction – Skin irritation may also cause a possible allergic skin reaction.

1.5.3 Be careful of potential allergic reactions to acrylic and hydrogel which are the primary materials of the adhesive.

1.6 Patient Consultation and Informed Consent

Prior to using the ZywieZ3 sensor, conduct a patient consultation with informed consent. At that time, you should also discuss all potential benefits, options, risks of using the sensor, paying close attention to potential contraindications.

2 Introduction/Operation

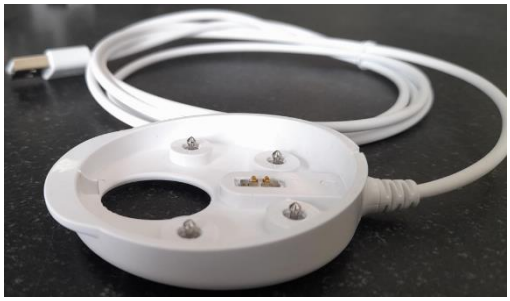
The ZywieZ3 Sensor is a wearable three-channel, rechargeable, reusable, ambulatory medical grade device intended for use in mobile cardiovascular telemetry. The ZywieZ3 sensor can collect continuous ECG data from the disposable adhesive adhered to the left chest area. The ZywieZ3 sensor uses a rechargeable lithium polymer battery to achieve 14 days continuous recording on a single charge. In case of Bluetooth disconnection, it is capable of storing patient data for up to 24 hours.

The device is intended to be used as general care for patients within healthcare settings or at home. The device is not intended to be used on critical care patients and does not replace current standards of care. The device does not provide interpretive or diagnostic statements. It is intended to provide physiological information recording for later viewing by healthcare professionals.

Instructions to charge the ZywieZ3 sensor

The ZywieZ3 sensor can be charged by placing it on the docking station as shown in the pictures below:

1. **The charging of the sensor is done using a plug-and-play charging docking station.**



2. **The user needs to place the device on the charging dock as shown in the image below, and then connect the USB port with the wall adaptor.**

3. **Charging** Indication: The ZywieZ3 sensor has red and green LEDs which indicate the charging status as following:

Is the sensor connected to a charger?	Battery status	Red LED	Green LED
No	-	Off	Off
Yes	Charging	On	Off
Yes	Fully charged	Off	On

Note:- For the charging purpose, connect the docking station with any IEC 60601 compliant charger or other electrical equipment.

3 Device Description

The ZywieZ3 Sensor is a device for acquisition, storage, and transmission of physiological data such as electrocardiogram (ECG). The physiological data is available for view in near-real time from the device (like smart phone, or watch, etc.) that is paired with the ZywieZ3 Sensor. The healthcare professionals may be able to view the data either directly on the paired device or through an application that receives the data in an encrypted form from the paired device.

The sensor uses a disposable ZywieZ3 Adhesive to maintain contact with the patient's skin. The hydrogel in the ZywieZ3 Adhesive senses the electrical signals from patient's body and conducts it to the ZywieZ3 Sensor. ZywieZ3 sensor is intended for outpatient monitoring of ECG in near real-time. All electrode inputs of the ZywieZ3 sensor do not contact conductive parts including the power supply and earth.

The ZywieZ3 Sensor provides the operational alarm information for the lead on/off status and battery status. The operational alarms are set to notify of any interruption in data collection and the overall operational status of the ZywieZ3 Sensor. The device does not have any alarms that are based on the content of physiological data recorded, stored, or transmitted.

The ZywieZ3 Sensor comes with a mobile physiological data display application built from a proprietary software library, using which authorized persons could build their own applications.

4 Intended Use

ZywieZ3 Sensor is a wireless device intended for use by healthcare professionals for recording and displaying physiological data in-home or in healthcare settings. The physiological data includes electrocardiogram (ECG). This data is transmitted wirelessly to a separate location (such as a mobile phone) for storage, display, and transmission.

The device is an ambulatory, continuous recording system with intended use as general care for patients. The device is not intended to be used on critical care patients and does not replace current standards of care. It is intended to provide physiological data recordings to be viewed by healthcare professionals at a later time.

The device is not recommended for patients who use a cardiac pacemaker, defibrillators or other implanted electronic devices.

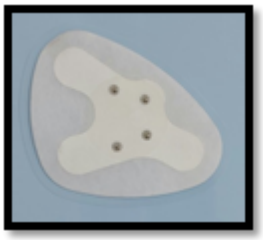
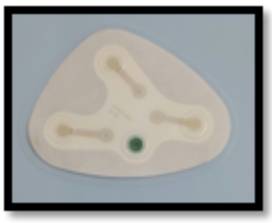
5 Cybersecurity:

1.1.1. Device pairing: Ensure the serial number (SN) shown on the paired mobile app matches with the SN printed on back of the ZywieZ3 sensor. Do not connect the mobile app to any unknow devices.

1.1.2. ZywieZ3 transfers data to the mobile app using low-power Bluetooth wireless communication 5.0 (IEEE 802.15.4-2006) which is secured with LE secure connections using ARM Trust Zone Cryptocell 310 security subsystem including, AES128 encryption and ECDH (Elliptical Curve Diffie-Hellman (ECDH) encryption algorithms. The wireless transmission frequency is in the 2.4 GHz ISM radio frequency band.

6 Accessories

The ZywieZ3 sensor kit has the following accessories.

No	Item	Qty	Specification	Patient Contacting	Remark
1.	ZywieZ3 sensor	1	Weight - 27 gm Height - 14.5 mm Dia - 51.26 mm	No contact	
2.	ZywieZ3 Adhesive	1	Length – 10.2 cm Breadth – 11.5 cm Height – 0.07 cm (without the release liner)	Left Chest Area	 
3.	Disposable adhesive pouch	1	Package Size – 15 x 20.5 cm	NA	

4.	Docking station	1	Width - 56.2 mm Length - 64 mm Height - 14.4 mm	NA	 
5.	Cellular device	1	Android phone, v8+, BLE 5, RAM 1GB+, Storage 8GB+ Android 11 Version	NA	
6.	USB charging cable	1	USB Type A, TPE coated White Length 1.5 Meter	NA	
7.	Cellular device holster	1	NA	NA	

Note

For the charging purpose, connect the docking station with any IEC 60601 compliance charger or other electrical equipment.

7 Specification

Device Specification:

Dimensions	: 51.26 x 14.5mm
Net Weight	: 27 gm
Power Input	: 5V DC, 500 mA
Battery	: Lithium Polymer 3.85V, 665 mAh
Electrical Class	: Class B
Electrotherapy Electrical Class	: Class II
Operating Temperatures	: 50° F - 113° F (10° C - 45° C)
Storage Temperatures	: 50° F - 122° F (10° C - 50° C)
Atmospheric Pressure	: 70 - 106 kPa
Humidity Range	: 10% - 95%

Technical Specification:

ECG Channels	3
Sample Rate	200 Hz
Data resolution	16 bits
Frequency Response	0.5 – 40 Hz
Duration of recording	14 days continuous recording with single charge
Device memory duration	24 hours
Input Impedance	>10MOhms
CMRR	60
Wireless Transmission	2.4GHz ISM Band (2.402 – 2.480 GHz Utilized)
Device placement position	Left upper chest area
IP rating	IP 55
Battery Specifications - Type - Life	Lithium Polymer Charging/Discharge cycle life ≥ 500 times
Wireless Transmission - Service - Bands	- Bluetooth - 2.4 GHz ISM spectrum band (2400 to 2483.5 MHz)

8 Safety & Regulatory

Device, when properly used by trained personnel, is a safe and effective instrument for the indicated clinical treatments. Keep in mind that safe operation requires a thorough understanding of the system and safety features as described in this operator manual.

Manufacturer does not make recommendations regarding the practice of medicine. Individual treatments should be based on clinical training, clinical observation, and appropriate clinical endpoints.

8.1. Operational Training

The ZywieZ3 sensor should be operated only by qualified personnel who have received appropriate training in the use of the system.

WARNING

Do not allow untrained or unqualified personnel to use the system at any time.

WARNING

Failure to follow all applicable instructions for the user may result in serious injury.

CAUTION

Do not attempt to use this system until you have been properly trained on system operation by certified personnel and have thoroughly read and comprehended this manual and the accompanying treatment guidelines.

8.2. Operational Safety

WARNING

System failure could result in an unintended increase of output power.

WARNING

Device is sensitive instruments and should not be dropped. If a device is dropped, carefully examine it for any physical damage prior to use.

WARNING

Device components should remain separated from other medical equipment to avoid inadvertent electrical coupling between devices. Inadvertent activation may cause injury to patient and/or user or equipment damage.

WARNING

No modification of the device system is allowed.

CAUTION

The use of the system can interfere with and adversely affect the operation of other electromagnetic equipment.

CAUTION

Do not operate the unit in an environment of short-wave diathermy use.

CAUTION

Prior to each use of the system, inspect the device components and cables for any damage, excessive wear, or crimping that could affect system performance or safe operation.

CAUTION

Device is designed to be operated exclusively as a unit. Only use accessories provided by Manufacturer.

CAUTION

Manufacturer cannot verify the safety of single use accessories that have been reprocessed or reused.

8.3. Additional Safety Consideration

WARNING

Do not tamper with the system. The device battery poses a fire or chemical burn hazard, if mistreated.

WARNING

Only an authorized Manufacturer Service Representative should perform service on any console or handpiece.

WARNING

Do not attempt to perform maintenance other than that which is outlined in this operator manual.

WARNING

Do not connect wet components to the device.

8.4 Regulatory

The device is a Class II medical device in the US It complies with the following:

- US FDA 21 CFR 870.2910,
- FCC part 15
- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-47

8.5. EMI-EMC, FCC Declaration Statement

FCC ID: 2BAK3Z3E

FCC Compliance Statements: This device 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. The operation is subject to the following two conditions:

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

Caution Statements:

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

INFORMATION TO THE USER

For a Class B digital device or peripheral, the instructions furnished to the user shall include the following or similar statement, placed in a prominent location in the text of the manual:

NOTE: 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.

Separation Distance

The minimum separation distance between the Antenna and the surface is 1.19mm.

ELECTROMAGNETIC COMPATIBILITY

ZywieZ3 ECG Monitor complies with the requirements of IEC 60601-1-2:2014 (EMC Collateral standard) including the radiated RF field strength 10 V/m & RF frequencies from 80 MHz to 2.7 GHz . However, even at this level of device immunity, certain transmitting devices (cellular phones, two-way radios, cordless phones, paging transmitters, RFID devices etc.) emit radio frequencies that could interrupt equipment operation if operated in a range too close to the equipment. Users should be aware of possible radio frequency interference if the handheld device is operated close to the equipment. Portable and mobile RF communications equipment may affect the normal function of the ZywieZ3 ECG Monitor.

Do not use cables or accessories other than those provided with the ZywieZ3 ECG Monitor, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.

	Handheld and mobile RF communications equipment may affect the normal function of the ZywieZ3 ECG Monitor.
	Do not use cables or accessories other than those provided with the ZywieZ3 ECG Monitor, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.

Test	Electrical Safety environment – guidance
IEC 60601-1:2005+AMD1:2012	Medical Electrical Equipment Safety standards,
IEC 60601-2-10:2012+AMD1:2016	Part 2: Particular requirements for the safety of nerve and muscle stimulators
IEC 60601-1-11:2015	Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZywieZ3® Sensor & Adhesive should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the ZywieZ3 sensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. RECOMMENDED SEPARATION DISTANCE $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 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: 

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 strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcasts 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 ZywieZ3 sensor is used exceeds the applicable RF compliance level above,

the ZywieZ3 sensor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ZywieZ3 Sensor.

B) Over the frequency range 150 kHz to 80 MHz, field strength should be less than [V1] V/m.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the ZywieZ3 ECG Monitor

The ZywieZ3 ECG Monitor device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the ZywieZ3 ECG Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ZywieZ3 ECG Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power (W) of transmitter	Separation distance (m) according to the frequency of the transmitter		
	150 kHz to 80 MHz d = 1.17 √P	80 MHz to 800 MHz d = 1.17 √P	800 MHz to 2.7 GHz d= 2.33 √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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 manufacturing's declaration – electromagnetic Immunity

The Model ZywieZ3 ECG Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the model ZywieZ3 ECG Monitor 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	± 8 kV Contact ± 15 kV air	± 8 kV Contact ± 15 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%.
Electric fast transient / burst IEC 61000-4-4	± 2.0 kV/100 kHz (AC Power port)	± 2.0 kV/100 kHz (AC Power port)	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	0.5, 1 kV (Differential mode) Line to Line 0.5, 1, 2 kV (Common mode) Line to Gnd Phase Angle: 0°,90°,270°	± 1kV differential mode ± 2kV common mode	The mains power quality should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-3	ISM band between 0.15 - 80MHz: 6V rms,	ISM band between 0.15 - 80MHz: 6V rms,	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model ZywieZ3 ECG continue operation during power mains interruptions, it is recommended that the Model ZywieZ3 ECG Monitor be powered from an uninterruptible power supply.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5 % UT (>95% dip in UT) For 0,5 cycle 40 % UT (60 % dip in UT) For 5 cycles 70 % UT (30 % dip in UT) For 25 cycles <5 % UT (>95% dip in UT) For 5 s	<5 % UT (>95% dip in UT) For 0,5 cycle 40 % UT (60 % dip in UT) For 5 cycles 70 % UT (30 % dip in UT) For 25 cycles <5 % UT (>95% dip in UT) For 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model ZywieZ3 ECG continue operation during power mains interruptions, it is recommended that the Model ZywieZ3 ECG Monitor be powered from an uninterruptible power supply.

Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	If the display is distorted, it may be necessary to position the Model ZywieZ3 ECG Monitor farther from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE: UT is the a.c mains voltage before application of the test level.			

Guidance and manufacturing's declaration – electromagnetic emissions		
The Model ZywieZ3 ECG Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model ZywieZ3 ECG Monitor should assure that it is used in such an environment		
Emission test	Compliance	Electromagnetic environment – guidance
RF emission CISPR 11	Group 1	The Model ZywieZ3 ECG Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause ant interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Model ZywieZ3 ECG Monitor is suitable for use in all establishments, including the domestic establishment and those directly connected to the public low–voltage power supply network that supplies building used for domestic purposes.
Harmonic emission IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	
Radiated RF IEC 61000-4-3	Group 1	The Model ZywieZ3 ECG Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause ant interference in nearby electronic equipment.

9 Clinical Application

The ZywieZ3 sensor is intended for use to monitor patients including, but not limited to,

a) Patients diagnosed with non-life-threatening arrhythmias.

b) Patients with symptoms that may be due to cardiac arrhythmias.

c) Patients who are at a high risk of having cardiac disease.

d) Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.

The ECG data is transmitted to the paired cellular device via Bluetooth for a later viewing by healthcare professionals. Data from this device may be used by another device to analyze or report cardiac arrhythmias.

10 Controls & Functions

The ZywieZ3 sensor records the ECG signals sensed by the adhesive on the body. ECG data is transmitted wirelessly via BLE to the Zywie SDK. The SDK posts data to the Zywie Mobile App. The App can upload the data to Cloud for further processing. The workflow is summarized in Fig. 1.

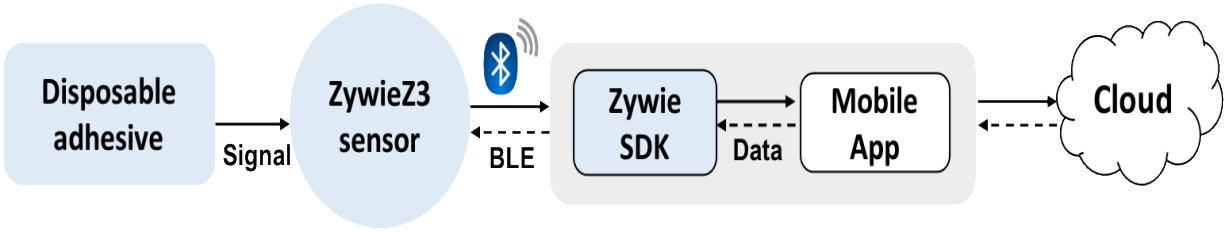


Fig. 1 Basic system workflow process

The ZywieZ3 sensor records and transmits the ECG data wirelessly to a paired device. It does not have any on-board algorithm or software to detect the heart rate or arrhythmias. The device does not provide interpretive or diagnostic statements.

The system block diagram of the ZywieZ3 sensor is shown in Fig. 2 and the description of system modules is given in the section below.

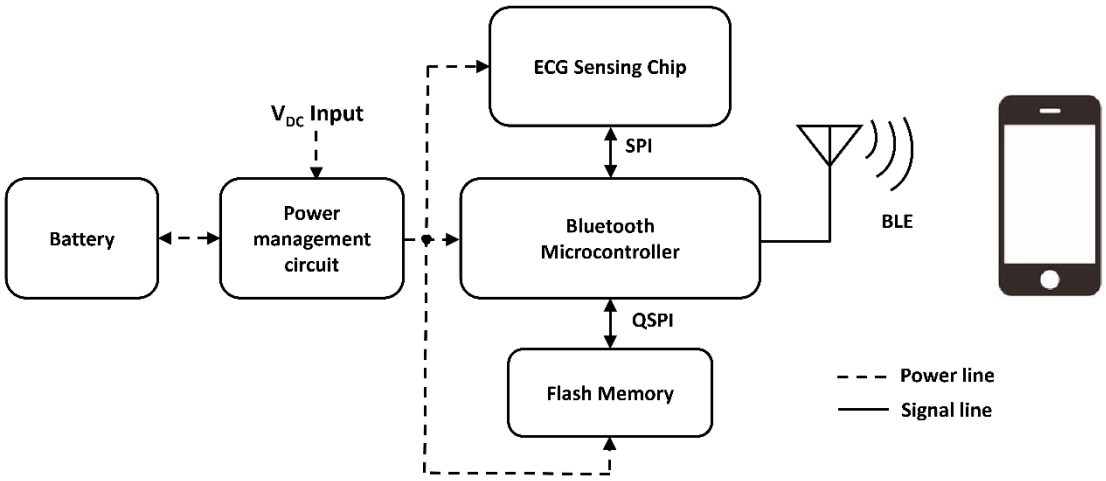


Fig. 2 Block diagram of the ZywieZ3 sensor

Power management: A rechargeable battery with a 665 mAh capacity and 3.85 V output is used to power the sensor. Power management circuits converts a 5.0 VDC input into 4.4V output to charge the battery. The minimum required current to charge the sensor is 500 mA. The power management circuit also transfers the energy from the battery to power the ECG sensor, storage chips, microcontroller, and accelerometer sensor.

Sensor: The ZywieZ3 has a 24-bit ECG sensing chip to sample the ECG data from lead I and lead II or only lead III (if lead I and II are off). The sampling frequency of ECG is 200 Hz**.**

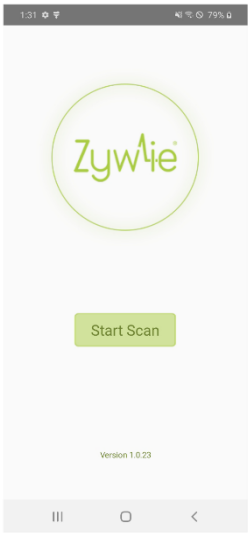
Storage: If the Bluetooth communication is disconnected, the flash memory can store the sampled ECG data up to a duration of 24 hours. The data is over-written if the disconnection is beyond 24 hours.

Communication: Device status and ECG data are processed and sent to the paired mobile via a wireless low-power Bluetooth communication with the microcontroller. The microcontroller communicates with the ECG sensor using SPI protocols. The sampled data is transferred between the microcontroller and flash memory using fast Quad-SPI (QSPI) communication.

Zywie provides ECG diagnostic services and NOT emergency medical services. If at any time during the study you think you are having a medical emergency, call your doctor, go to the emergency department, or call 911 immediately.

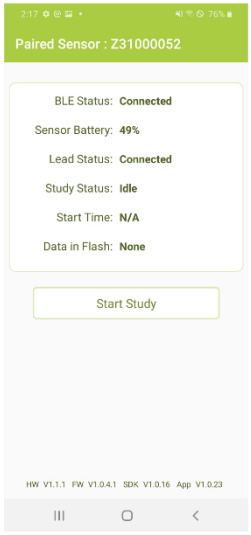
11 Application Operation

Upon successful installation of the firmware and app, proceed with pairing the app with a sensor data collection.

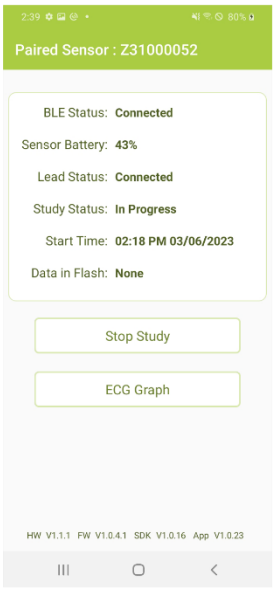


Open the ZywieZ3 app on phone and click on “Start Scan” button to look for available sensors.

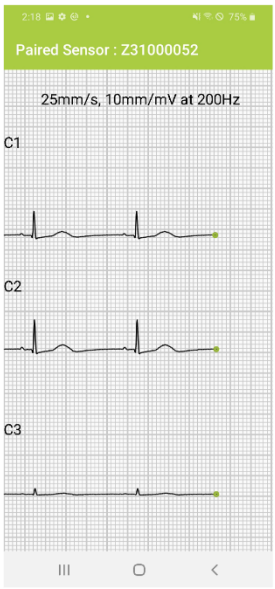
Select the sensor serial number (SN) that matches with the SN listed on the back of the sensor.



Once the sensor is successfully paired, click on “Start Study” button to start the recording.



The "In progress" study status suggests that the study has started successfully.



Near real-time three-channel ECG recordings.

Both the sensor and the phone need to be **charged and remain within 25 feet of each other** to ensure data upload is not delayed or lost.

- **Sensor:** Charge fully once every 14 days or based on the low battery warning on the app. To charge the sensor, place it in the charger provider by aligning the four snaps on the sensor with the four pins on the charger. Connect the USB adapter and plug it into the wall. The red light on the side of the sensor indicates that the sensor is still charging. When it changes to green light indicates charging is complete. The sensor cannot be charged when users are wearing it.
- **Phone:** Leave the phone on and charge overnight, every night.

12 Troubleshooting

If the device is not charging or the device is not working, please contact the authorized maintenance personnel.

Symptom	Possible Causes	Solutions
Artifact data	1. This device might be damaged. 2. This device might not be worn correctly. 3. The operation temperature is too high or too low. 4. Improper or no skin preparation. 5. Incorrect attachment of adhesive.	1. Contact your device provider. 2. Recheck device's location or contact with skin. 3. Use this device under instructed operation temperature. 4. Prepare the skin before application. 5. Follow the instructions to attach the adhesive.
No data or intermittent data received by mobile app or No BLE signal or data transmission latency	1. Bluetooth turned off in the mobile app-installed device. 2. Out of connection range. 3. Interference from other RF emitters, such as RFID metal detectors, medical equipment, etc, in the vicinity.	1. Enable Bluetooth. 2. Move the sensor close to the mobile app-installed device. 3. The sensor battery is low, charge it. 4. Restart the mobile app-installed device. 5. Move far away from any electronic equipment or change rooms or move to an open space.

Charging Indication

ZywieZ3 sensor has red and green LEDs which indicate the charging status as following:

Is the sensor connected to a charger?	Battery status	Red LED	Green LED
No	-	Off	Off
Yes	Charging	On	Off
Yes	Fully charged	Off	On

13 Maintenance

13.1 Cleaning of ZywieZ3 sensor

A patient should adhere to the following guidelines to remove the adhesive and clean the sensor:

1. Remove the sensor from chest by pulling the tab of the adhesive.
2. Clean with 70% alcohol wipes included in the kit and remove any adhesive residue on the sensor.
3. Wait for the sensor to dry completely. The sensor should be clean, dry and free of any adhesive residue before applying it to a new adhesive.

13.2 Storage of ZywieZ3 sensor

- **It is recommended to store the senso**r in a clean place.
- When passing through the airport security, if wearing the device, take it off from your body and allow TSA officers to screen the device.
- To charge the device in other countries, make sure to use the correct adapter for the standard USB (Universal Serial Bus) outlet.

13.3 Care for Disposable Adhesives:

Each ZywieZ3 sensor comes with its medical-grade disposable adhesives. Adhesives can be used for up to 14 days. However, some users may want to change the adhesives before the intended duration depending on comfortability. The adhesives are packaged in a non-sterile foil pouch. The shelf life is set at 2 years from the time they are packaged. A user should adhere to the following guidelines to use the adhesive:

- After each use, discard the used adhesive.
- Do not re-apply the adhesive once removed from the skin.
- Keep the foil pouch closed to not let the adhesives dry.
- Before applying a new adhesive, clean both sides of the sensor with an alcohol wipe.
- The adhesive should be stored in a room temperature between -40 to 80 °C.

13.4 Skin Care

The skin should be clean, dry, and free of hair. Clean the left, upper middle chest area with a 70%+ alcohol swab. Shave area if needed. Let it dry completely.

13.5 Service

Shelf life of the device is 5 Years.

The device is non-serviceable & non-repairable. Faulty units should be sent back to the Zywie team or disposed of as per the local regulations.

14 Warranty

This product warranty extends to the original consumer/ purchaser of the product.**14.1 Warranty Coverage & Disclaimers**

This product is warranted to be free from defects in materials and workmanship for one (1) year. This warranty ceases if the product has been damaged by accident, in shipment, unreasonable use, misuse, neglect, improper service, repair by unauthorized personnel or cause not arising out of defect in materials or workmanship. This warranty does not extend to any units which are used in violation of the guidelines outlined in this manual, or to units that have been altered or modified, or to damage to products or parts which have had the serial number removed, altered or defaced or rendered illegible.

14.2 Legal Remedies

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state.

14.3 Warranty Performance

During the above one-year warranty period, a product with a defect will be repaired or replaced with a reconditioned comparable unit at the distributor's option when the product is returned to the distributor. The repaired or replacement product will be in the warranty for the balance of the one-year warranty period and an additional one-month period. No charge will be made for such repair or replacement.

14.4 Customer Service

For in-warranty service for a product covered under the warranty period, no charge is made for service and return postage. Please return the product insured, packed with sufficient protection, postage insurance, prepaid to the address. The customer's duty/brokerage fee, if any, must be paid by the consumer.

14.5 Out of warranty service

There will be charges rendered for repairs made to the product after the expiration of the one (1) year warranty period after purchaser is advised appropriately. The distributor cannot assume responsibility for loss or damage during shipment. For your protection, carefully pack the product for shipment and insure it with the carrier. Ensure that you return the unit and accessories related to your problem and also that you indicate the full return address. Also, send a copy of the sales receipt or other proof of purchase to determine warranty status. C.O.D. shipments cannot be accepted.

Please send the above warranty information and in the case replacement of any accessory is needed to the following address:

Please call 877-858-7200 or email customer.service@zywie.healthcare for any questions and support.

List of Accessories: (In case of replacement or ordering)

Sr.#	Description	Part number
1	1. **ZywieZ3 sensor**	70FG68000
2	**Pouch of disposable adhesive**	Z3ADH xxxxxx
3	**Docking station to charge the sensor**	40CME01282

A statement that the MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of the EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL

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DRW# XXXXXXXX, Ver.-X.X.X

Date: DD/MM/YYYY

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