



FibriArt – I

User Manual



Thank you for choosing FibriArt.

We appreciate your trust in our product and are committed to ensuring your satisfaction.

Important: Retain the Original Packaging

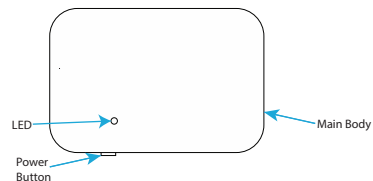
Please keep the original packaging in case the product needs to be returned.

Using the original packaging helps protect the device during transit
and ensures safe handling

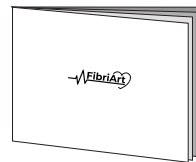
- Return the product in its original packaging
- Shipping costs for the return are the responsibility of the sender
- Send the product to your local distributor or directly to the manufacturer, as advised

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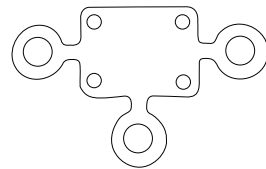
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FibriArt - I



Manual

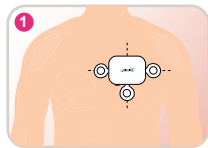


Patch



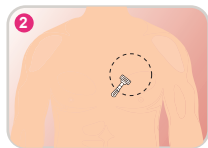
FibriArt App

How to attach device



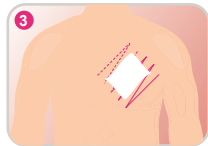
Checking the area to attach the device

Device should be attached to the upper side of left chest, check the position as shown in figure to ensure the device is attached properly



Shaving and exfoliating the device attachment area

If there is a lot of chest hair in the area where the device will be attached, use a razor to remove the chest hairs and remove foreign substances such as dead skin cells



Cleaning the area where the device will be attached with rubbing alcohol

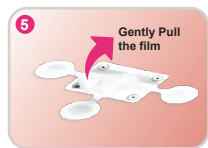
Clean the attachment area with rubbing alcohol for at least 1 minute, let it dry before attaching the device

How to attach device



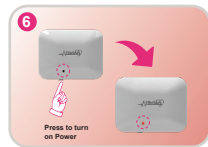
Connecting the patch with the device

Place the device over the patch aligning the snap button on patch with snap connectors on the device, press it gently so that the device will be attached with the patch (If the patch and device are connected properly you will hear snap sound)



Detaching the film and attaching the device

Detach the adhesive film from the back of the patch and attach the device with the Power On switch facing downward



Turning on the power

Press the power on switch gently you will get to know device is powered on as Red LED will start blinking

Additional Information

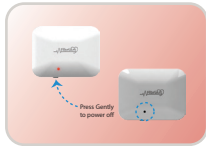


Connect to App to record ECG signal

1. Bluetooth and Location Service

Check if Bluetooth and Location service function are activated to connect the device

2. Connecting with smartphone App (FibriArt)



Turning off the power

Once you are done with your desired test, close the app, and just gently press the power button to switch off

How To Install App

For Android Users:



FibriArt
TOPIA MEDTECH

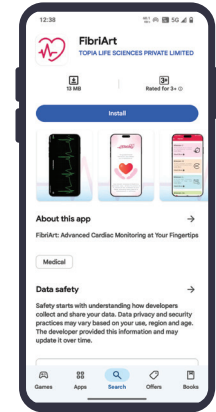
Google Play Store

Please search "FibriArt" in your Google Play Store or scan the QR code

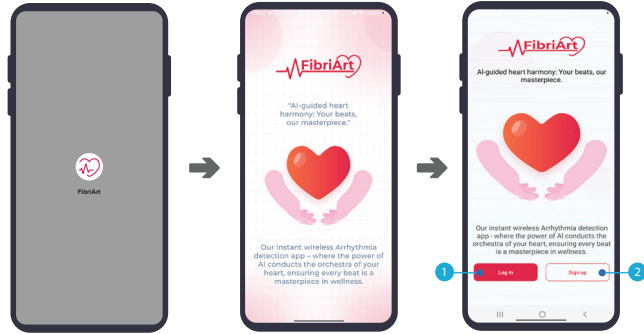
Install the App

Complete the registration steps
(If you are a doctor, register as a Doctor Account or If a Patient then register as a Patient Account)

Supports: Android 10 or later

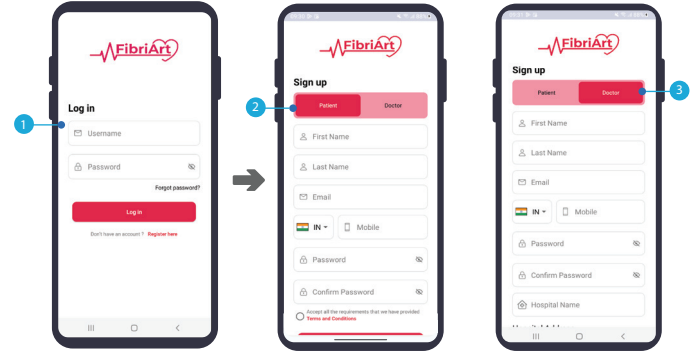


Screen with the App (FibriArt) icon and initial run screen



No	Description
1	Move to "Log In" Page
2	Move to "Sign Up" Page

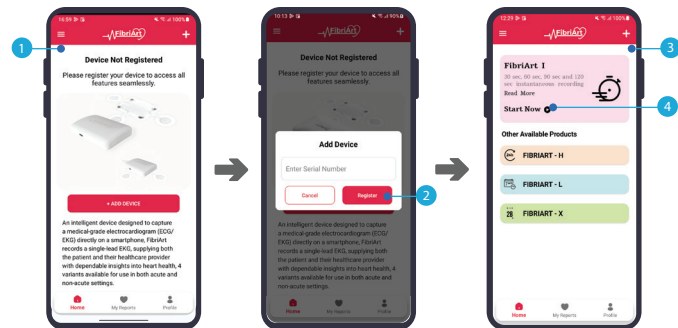
Log In/ Register Screen



No	Description
1	Login Page
2	Register Page – For creating Patient login
3	Register Page – For creating Doctor login

How to use the app

FibriArt Home Page



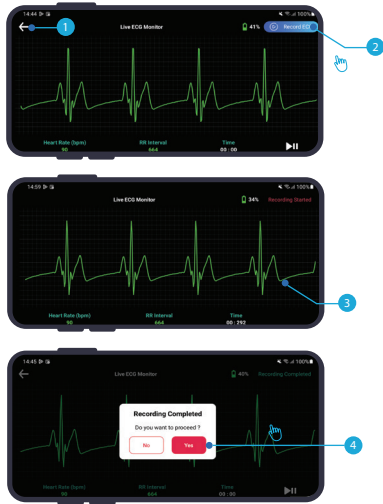
No	Description
1	Home Page – Before Device Registration
2	Serial Number Input field
3	Home Page – After Device Registration “If you have other model of FibriArt that can also be added in the same log in, once the registration is done functionality of the device will appear on the home page”
4	To move to FibriArt – I home page

How to Perform Arrhythmia Test



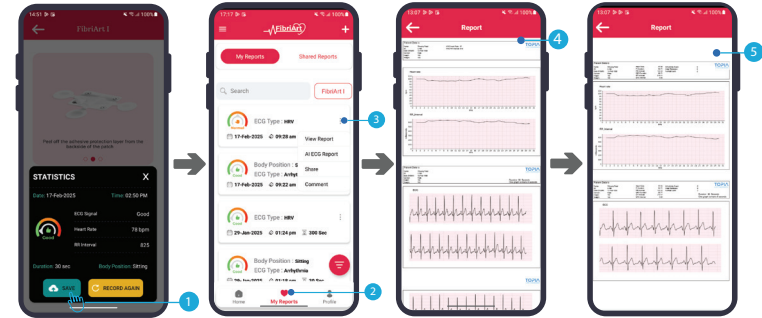
No	Description
1	Start Test
2	Select Duration for which you want to record
3	Select your body position
4	Press Connect after selecting your respective device or wait for few seconds you will be directed to recording page automatically

Live Display Screen



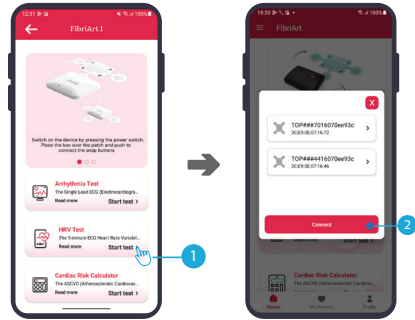
No	Description
1	Go Back
2	Press to Start Record ECG, Recording Status
3	Real Time ECG Graph
4	Click Yes if you want to proceed after recording time is complete or you can record again

How to Store ECG and view Report (Normal and Analyzed)



No	Description
1	Save your Recorded ECG or Record Again
2	Go to My Reports section to view your ECG report
3	Click on Pop Up and select which report you want to view ECG report
4	Normal Report
5	Analyzed ECG Report

How to Perform HRV Test



No	Description
1	Start Test
2	Press Connect after selecting your respective device or wait for few seconds you will be directed to recording page automatically

Live Display Screen



No	Description
1	Go Back
2	Press to Start Record ECG, Recording Status
3	Real Time ECG Graph
4	Click Yes if you want to proceed after recording time is complete or you can record again

How to Store ECG and view Report (Normal and Analyzed)



No	Description
1	Save your Recorded ECG or Record Again
2	Go to My Reports section to view your ECG report
3	Click on Pop Up and select which report you want to view or share it to your physician
4	Normal Report
5	Analyzed ECG Report

To Share Report



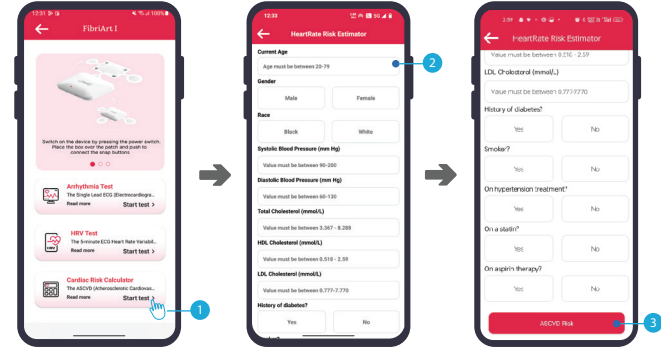
No	Description
1	On FibrArt Home Screen Click on My Reports
2	Click on Drop Down Option and Share
3	Select your doctor who is registered with FibrArt and click Send Report
4	Doctor Can view the shared report in his login and can comment on the report

To Comment on Report (Doctor Login)



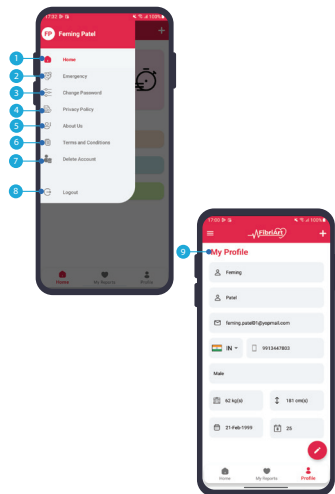
No	Description
1	On FibrilArt Home Screen Click on My Reports
2	Click on Drop Down Option and Comment
3	Commented Reports can be viewed by User by following Step 1 and 2 in his Login

For Cardiac Risk Calculator



No	Description
1	Start Test
2	Fill in the Questionnaire
3	Click on submit

Personal Details Update Process



No	Description
1	Jump to Home Screen
2	Emergency Contact Details
3	Change Password
4	Privacy Policy
5	About Us
6	Terms and Conditions
7	Account Deletion
8	Log Out
9	User Personal Details

Appendix

Caution

Contraindications

Device must not be used on:

- Childrens and Pregnant Women
- Patients with implanted pacemakers or defibrillators

The electrode must not be used in the following case:

- Patients with known allergies to adhesive materials or hydrogels
- In the presence of wounds, injury, or irritated skin on the application area

Adverse Event

Physicians should advise patients to seek medical attention if either of the following occurs

- Mild Rash
- Allergic Reaction
- Skin Irritation
- Itchiness

Warnings

- Only authorized technicians are allowed to repair or disassembl device
- Make sure to be fully aware of how to use the product
- Avoid use at locations where wireless communication interference may
- This device cannot be simultaneously used with a defibrillator
- DO NOT expose to strong electromagnetic fields, this device is MR unsafe
- The device should not be used adjacent to or stacked with other equipment's

Appendix

Precautions

- Inappropriate Application and use of the sensor may result in inaccurate measurements, please avoid the below
 - Excessive moment of the patient
 - Application outside the recommended body location
- The Following persons should consult physician before using the device
 - Patients with sensitive skin or skin allergy
 - Patients with wound on skin that contact the device
 - Patients with cardiac pacemaker, cardiac defibrillators or other implantable electrical devices
 - Pregnant women, breastfeeding mothers, infants or children
- Take caution to avoid getting liquid in the device, also avoid the following
 - Long-term exposure to water such as baths, swimming, etc.
- Avoid letting the device come into contact with organic compounds
- Beware of strong shocks and vibrations
- Once the patch is detached from the body, do not reapply it
- Portable and Mobile RF communication equipment can affect medical device
- Device is MR unsafe and should not be worn during MRI Imaging
- Measures to be taken when cybersecurity issue occurs
 - The manufacturer should be consulted if a cybersecurity issue occurs.
 - Topia Medtech
 - Email : customercare@topiamedtech.com

Clinical information

Intended Purpose

FibriArt - I record for 30 seconds up to 5 minutes, stores and transfers a single-lead electrocardiographic (ECG) trace. It can perform ECG analysis, detecting the presence of normal sinus rhythm, atrial fibrillation. It can also display the ECG when used in conjunction with a smartphone/tablet. It is intended for use by healthcare professionals, patients with known or suspected heart disease and health-conscious individuals. The device has not been tested and is not intended for pediatric use.

Target Treatment Group

- Patients who may be asymptomatic or who may suffer from transient symptoms such as palpitation, shortness of breath, dizziness, light-headedness, presyncope, syncope, fatigue, or anxiety
- Patients with heart disease such as arrhythmia

Target User

Patients and Physicians

Clinical Benefit

It measures patient's Electrocardiogram (ECG) information, analyzes and reports measured data, and helps physician or medical personnel prescribe it.

Product disposal

Disposal of Device and patch must comply with local waste disposal regulations. Non-Compliance with waste disposal regulation may result in environmental pollution

Condition for use and storage

No	Conditions for Use
1	Temperature Range: 5°C ~ 45°C
2	Relative Humidity Range: 10% ~ 95%, non-condensing

No	Conditions for Storage and Transport
1	Temperature Range: 5°C ~ 45°C
2	Relative Humidity Range: 10% ~ 95%, non-condensing
3	Keep dry and keep away from direct sunlight

Specifications

	Item	Description
ECG	Type of Applied Part	Type – BF
	Sampling Rate	300 samples / sec
	Input Offset Dynamic Range	± 650 mV
	Channel	1 Channel
	ADC Resolution	18 bits
	Input Impedance	> 500 MΩ
RF	Frequency Response	0.5 Hz – 100 Hz
	RF communication	2.4 GHz BLE 4.2
	Effective Radiated Power	< 2 mW
	RF Frequency Band of TX	2.4 GHz
Power Requirement	Bandwidth of receiver	2400 ~ 2480 MHz
	Power Supply	3.7v
Physical Characteristics	IP Classification	IP XX
	Enclosure Dimensions (L * W * H: cm)	8 cm * 6 cm * 1.5 cm
	Patch Dimensions (L * W * H: cm)	17.2 cm * 10.9 cm * 0.1 cm
	Weight (g)	

Electrical Safety and Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emission CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Class B	The device 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.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Immunity Test	IEC 60601 Test and Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESDIEC 61000-4-2)	± 8kV / Contact ± 2kV, ± 4kV, ± 8kV, ± 15kV / Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power Frequency (50 Hz) Magnetic Field IEC 61000-4-8	30 A/m 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	Test Frequency	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \cdot \sqrt{P}$ 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
	80 MHz – 2.7 GHz 80% AM at 1 kHz	
	10 V/m	
	385 MHz (Pulse Modulation 18 Hz)	
	27 V/m	
	450 MHz (FM ±5 kHz deviation 1 kHz sine)	
	28 V/m	
	710, 745, 780 MHz (Pulse Modulation 217 Hz)	
	9 V/m	
	810, 870, 930 MHz (Pulse Modulation 18 Hz)	
	28 V/m	
	1720, 1845, 1970, 2450 MHz (Pulse Modulation 217 Hz)	
	28 V/m	
	5240, 5500, 5785 MHz (Pulse Modulation 217 Hz)	
	9 V/m	
	30 W/m(CW)	
	8 V/m	
	134.2 kHz (Pulse Modulation 21.1 Hz)	
	65 V/m	
	13.56 MHz (Pulse Modulation 50 Hz)	
	7.5 V/m	

Symbols

Instructions For Use

Symbol	Description	Symbol	Description	Symbol	Description	Symbol	Description
	Manufacturer		MR Unsafe	IPXX	Ingress Protection		Caution
	Date and Country of Manufacture (Made in India)		Atmospheric Pressure Limitation		TYPE - BF Applied Part		Separate Collection for EEE
UDI	Unique Device Identifier		Humidity Limitation	MD	Medical Device	#	Model Number
RX only	Prescription Use Only		Temperature Limit		Do not Reuse (Applicable for the Patch)		Refer to IFU/Booklet
	Non-ionizing Radiation		Keep Dry		Do not use if package is damaged		