

EXPRESS ECG
ET-U12

USER GUIDE



Powered by





This Guidelines describe the visual & Verbal elements that represent Express ECG Device

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Welcome

Announcement



The Contents of this Manual are subject to change without prior notice.

All information contained in this Manual is believed to be correct. **Artem HealthTech PVT LTD** shall not be responsible for errors contained herein or for identical or consequential damages in connection with the performance or use of this manual.



About the Manual

The purpose of this Manual is to provide detailed information to Users related to ECG Device, its operation and how to use the ECG Device in proper manner.

This manual gives information about all Technical Details, Android Application Use and ECG Capturing flow and precautions.

Safety Information

Instructions for Basic Safe Operations

- 1 Check periodically to make sure that there is no visible damage that affects Device's test performance.
- 2 Any necessary changes, maintenance, expansions and repairs must be performed by Artem HealthTech engineers ONLY.
- 3 NEVER USE THIS ECG DEVICE IN CRITICAL CARE SITUATION
- 4 Select a room where you perform ECG with intact Electrical infrastructure.
- 5 Medical conditions can change suddenly. If you notice any change in your medical condition, kindly consult your Doctor.

Warnings

- 1 Do not attempt self-diagnosis or self-treatment based on the measurement results and analysis. Always operated by skilled or trained clinical professionals.
- 2 Don't use with a Defibrillator.
- 3 Don't use it in the presence of flammable drugs, anaesthetics or pressurised oxygen.
- 4 Don't use accessories other than those given by Artem HealthTech PVT Ltd.
- 5 Don't try to attach it with a USB adapter.
- 6 Don't expose the Device to strong shocks or vibrations or drop or step on the Device.
- 7 Don't use the Device in X-ray room, MRI or any strong Electromagnetic forces.
- 8 Don't apply over clothing.
- 9 Keep out of reach of small children.
- 10 Please choose the accessories which are approved or recommended by the Artem HealthTech PVT Ltd, or else it may damage the Device.
- 11 Connect /Disconnect related Cables with Device gently and carefully. Don't wring or shake the data cable with force anytime.

Instructions for Basic Safe Operations

- 1 Please wipe ECG Device surface with a clean soft cloth or paper towel
- 2 Use soft cloth with medical alcohol to wipe metal electrode, when signal is too weak.
- 3 Do not drip water on ECG Device.
- 4 Never spray or pour any liquid directly on the patient Cable.
- 5 Clean the reusable electrodes after every use.
- 6 Make sure that ECG Device is free from crack.
- 7 Please check every cable and connectors are free from any damage.

Cautions

- ⚠ Don't measure when there is dust or dirt on the Electrodes. Clean them first.
- ⚠ Don't disassemble, repair or modify the Unit.
- ⚠ Keep the Device away from dust, vibrations, tinder, too high or low temperature & moisture.
- ⚠ In case of Dextrocardia (Heart is positioned on the right side of the chest instead of its normal position on the left side) don't use ECG Chest Belt Variant. In that medical condition ECG Device can be used with standard Patient Cable.
- ⚠ The conductive parts of electrodes and connectors on the ECG machine should not be in touch with other conductive parts.
- ⚠ Don't use any sharp things with Device.
- ⚠ Auto measurements cannot be used for treatment as they are only for reference.

Maintenance

- ⚠ Please wipe ECG Device surface with a clean soft cloth or paper towel
- ⚠ Use soft cloth with medical alcohol to wipe metal electrode, when signal is too weak.
- ⚠ Do not drip water on ECG Device.
- ⚠ Never spray or pour any liquid directly on the patient Cable.
- ⚠ Clean the reusable electrodes after every use.
- ⚠ Make sure that ECG Device is free from crack.
- ⚠ Please check every cable and connectors are free from any damage.

Disposal of the Device

Disposal of this product, the optional accessories should be carried out in accordance with the national regulations for the disposal of electronic products. Unlawful disposal may cause environmental pollution.

Do not use in the presence of flammable anaesthetics, drugs or pressurized oxygen.

Contradictions

- ⚠ Artem HealthTech ECG Device is not intended to be used with a Defibrillator.
- ⚠ Artem HealthTech ECG Device is not intended to be used with high frequency surgical devices.
- ⚠ Artem HealthTech ECG Device is not intended to be used for self diagnostics purposes without any trained professionals.
- ⚠ Artem HealthTech ECG Device is not intended to be used in ICU.
- ⚠ Artem HealthTech ECG Device is not intended to be used in ambulances.
- ⚠ Artem HealthTech ECG Device is not intended to be used in direct cardiac application.

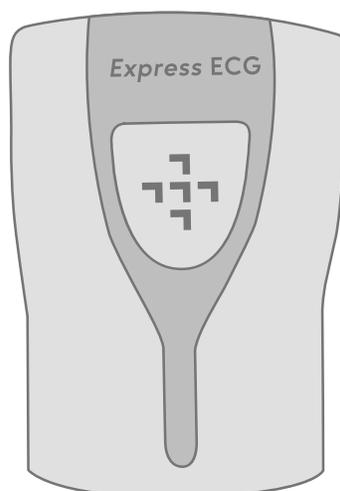
1. Intended Use

The Express ECG is a Resting Electrocardiograph designed for clinical use, aiming to record 12 Lead Electrocardiograms (ECG). It operates in conjunction with an Android app connected to an Android smartphone through a USB and OTG cable. This device is intended for use by trained medical professionals in clinical settings to identify cardiac abnormalities in adult patients. To ensure accuracy and safety, it should be utilised with approved accessories such as standard ECG cables and gel. It is crucial to emphasise that Electrocardiograms captured by the ET - U12 machine are not meant to be the sole basis for diagnosing and treating patients; they must always be reviewed by qualified physicians.

2. Device Description

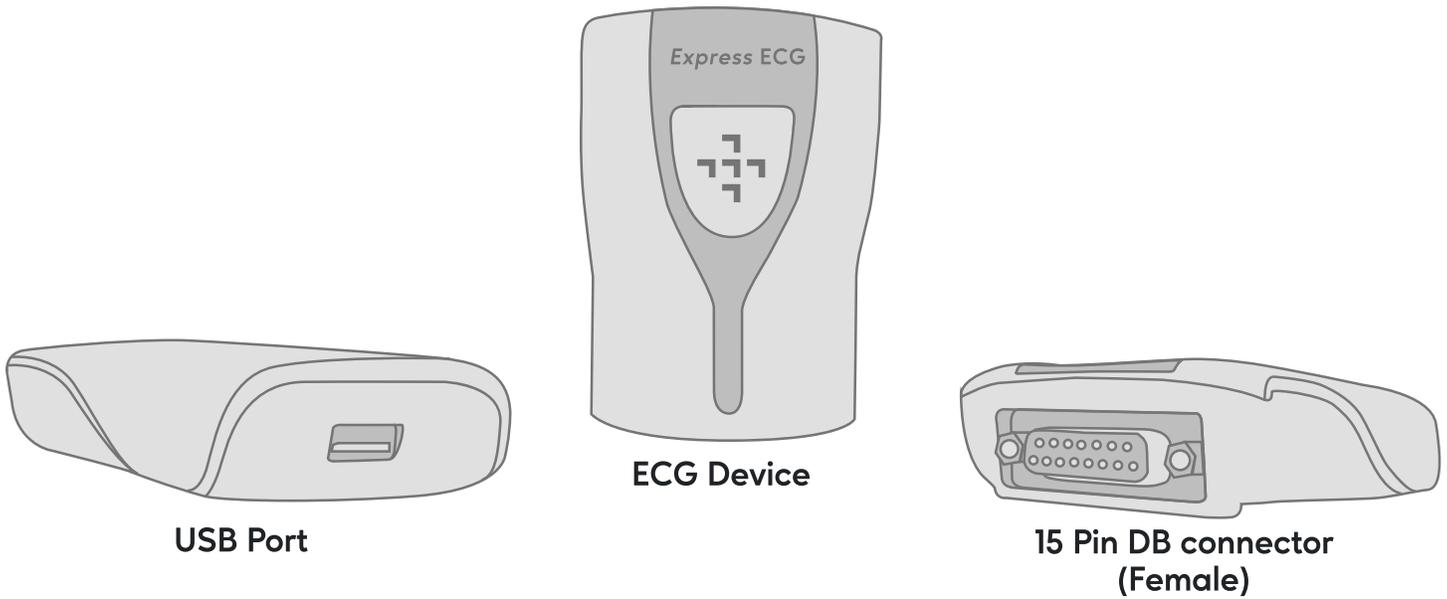
The Express ECG ET - U12 Lead Resting Electrocardiograph utilises a set of 4 limb electrodes and 6 chest electrodes to establish a connection with the patient's body. These electrodes are securely linked to the Express ECG ET - U12 unit through a cable that concludes with a DB-15 connector. A qualified medical professional prepares the patient by having them lie down on a flat surface, removing any hair if necessary from the contact points, & applying conductive gel to enhance electrode contact. Using a USB/Type C or B USB cable (OTG), the practitioner then connects an Android device to the Express ECG ET - U12 unit. Upon successful connection, the Express ECG ET - U12 unit is prepared to capture the patient's ECG. The initiation of this process is prompted by the Express ECG smartphone application, where the medical practitioner inputs patient details and proceeds to capture the resting ECG.

2.1 Main Unit



ECG Device

2.1.1 View



2.2 Parts and Accessory Devices

- ▶ Patient lead cables
- ▶ OTG USB cables (Type-C and Type-B)
- ▶ Gel
- ▶ Clamp
- ▶ Bulb electrodes
- ▶ Male To Male USB Cable

Product Specification

Environmental Specifications	Temperature (°C)	Relative Humidity (non condensing)
Operating conditions	0 to 45 °C	15-90% RH
Storage conditions	0 to 55 °C	15-90% RH

Hardware Specifications

Make & Model	ET – U12
Dimension (L * W * H)	82 mm * 57 mm * 22 mm
ECG Acquisition Type	ECG Patient Cable
Patient Cable Specification	15 pin DB Connector with 10 ECG Leads
Classification of ECG Patient Cable	Type (CF) (No Defibrillator Proof)
A/D Resolution	24 bits
Sample Rate	500 samples/second per channel
Computing & Display Device	Android Mobile
USB Connector	To connect with Android Mobile
Patient Cable Connector	Connects Patient Cable for ECG acquisition
OTG Support	Yes
Rated Voltage	5V DC through Mobile Port only (No direct supply through Power Adapter)
Rated Current	0.1 Amp
Rated Power	0.5 VA
Methods of Sterilization	NA
Degree of Mobility	Portable
USB Male to Male cable	1.5 Mtr to 3 Mtr length
Shutdown Procedure	No shutdown needed just disconnect from Mobile
Battery Available	No

Application Specifications

OS (Operating System)	Android
OS Version	Android 10 and above (Preferable)
RAM required	2 GB and above
Free Storage Space required	2 GB

Application Specifications

Measurement mode	Manual
ECG Standard	AHA,IEC
ECG Size	10 mm/mV Accuracy: $\pm 5\%$
Sweep Speed	25 mm/sec
AC Filter	50/60 Hz
Channel	12 Channel Simultaneous
Applicable Patient	Adult
Measurements	HR,PR,ST, R-R,QT,QTc,QRS,P/QRS/T Axes

3. Setting up the Equipment

3.1 Unpacking & Checking

The package contains the following components, which are dispatched with the unit:



Express ECG ET - U12 Unit	1	Patient Lead Cable	1
OTG USB cables (Type-C and Type-B)	2	Male To Male USB Cable	1
Bulb electrodes	6	Clamp	4
Gel	1	Warranty Card	1

3.2 Installation Instructions

Ensure that the Android operating system on the mobile device is at least version 11.0 and confirm that it supports USB On-The-Go (OTG) functionality.

3.3. Getting Started

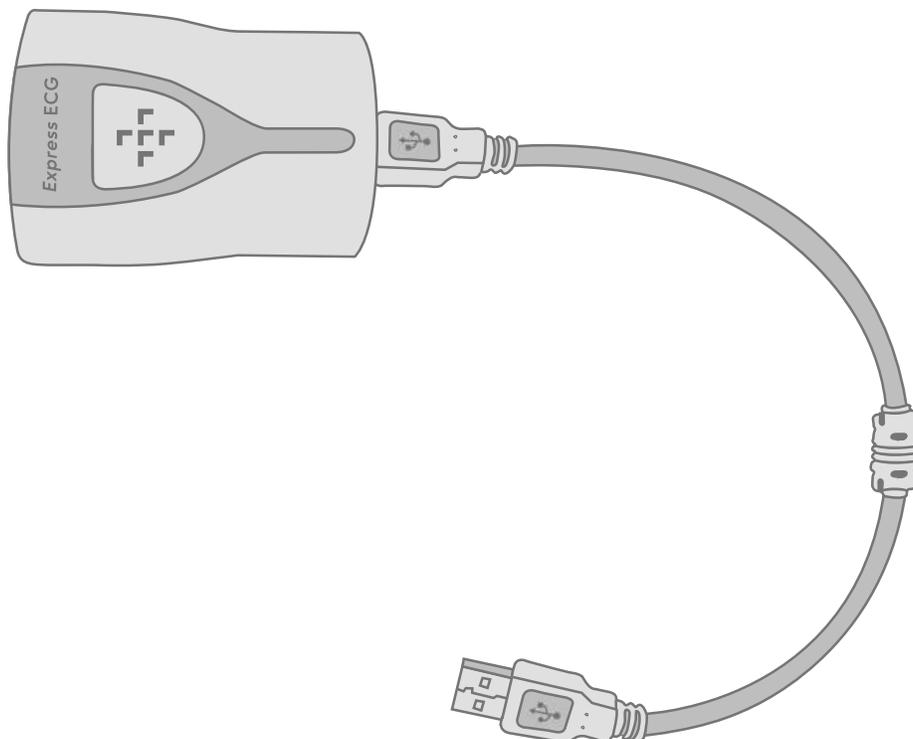
Ensure that the Android operating system on the mobile device is at least version 11.0 and confirm that it supports USB On-The-Go (OTG) functionality.

3.3.1. Connecting the device

Communication with the Express ECG ET - U12 unit is enabled through the OTG (On-The-Go) option on the mobile phone where it enables the Express ECG ET - U12 unit to transfer data to the phone.

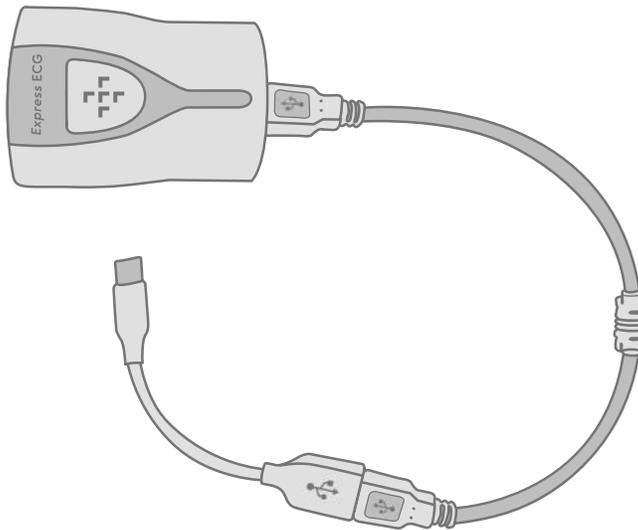
Step - 1

On the right side of the unit, you can find the USB port to connect the Male To Male USB cable.



Step - 2

There are two different types of OTG cables included depending on the USB connection required to be connected to the Male to Male USB cable.



Step - 3

Connect the smartphone with the Express ECG ET - U12 unit.

- 1 Connect a male-to-male USB cable to establish a connection with the Express ECG ET-U12 unit situated on the right side of the device.
- 2 Select the appropriate OTG cable based on the USB port indicated in the preceding step.
- 3 Connect the opposite end of the OTG cable to the USB port on the smartphone.

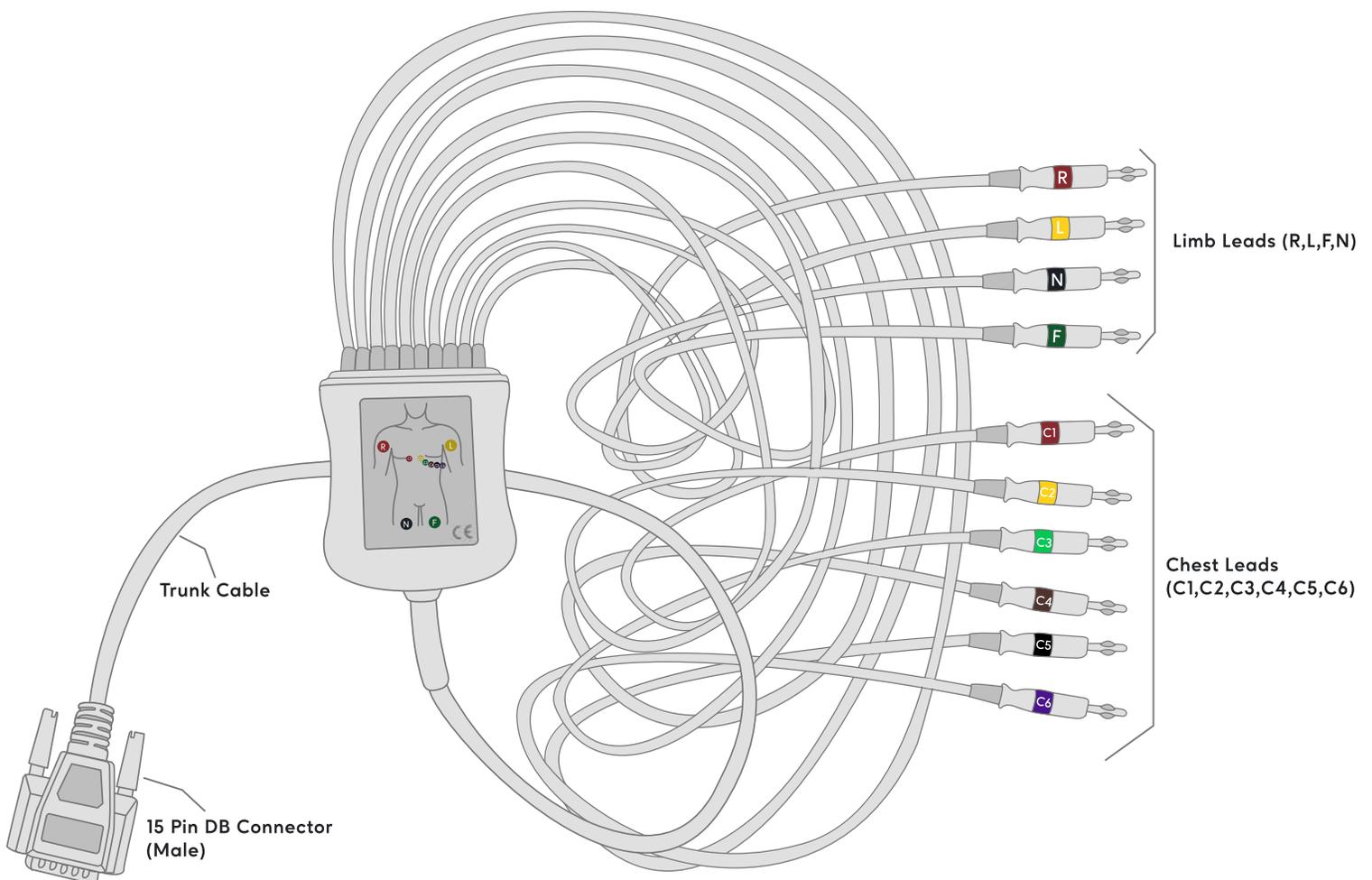


Enabling the OTG (On-The-Go) settings on your smartphone.

- Certain smartphones offer additional options to enable or disable the OTG (On-The-Go) settings..
- If necessary, activate the USB On-The-Go (OTG) setting in the Android system preferences.

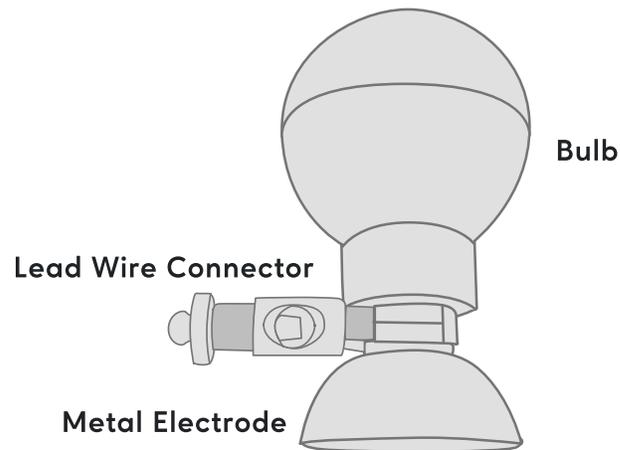
3.3.2. Connecting Lead Wires and Electrodes

Take the patient cable, bulbs, and clamps from the setup. The patient cable comprises a connector, a trunk cable, four limb lead wires, and six chest lead wires. Each lead wire is colour-coded. The connector cable connects to the ECG machine, the limb wires attach to the limb electrodes, and the chest lead wires connect to the chest electrodes.



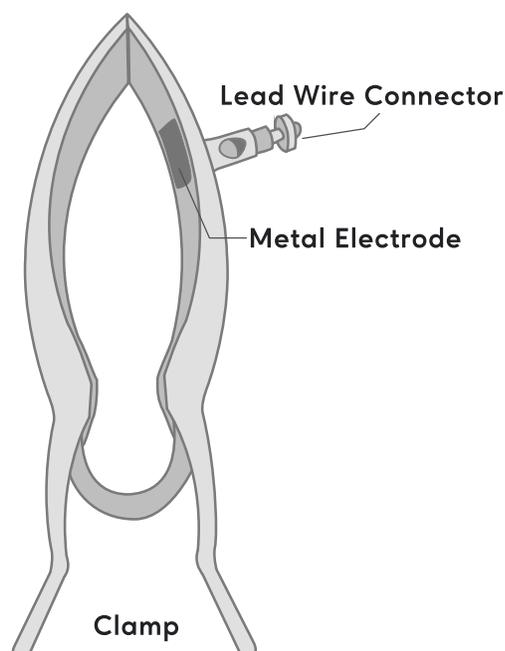
3.3.2.1 Chest Electrode

The chest electrode consists of a bulb and a metal electrode, connected by a lead wire with a 4.0 mm diameter connector.



3.3.2.2 Limb Electrode

The limb electrode comprises a plastic clamp and a metal electrode, connected by a lead wire with a connector 4.0mm in diameter.



3.3.2.3 Connecting Chest Lead Wires with Chest Electrodes

- 1 Connect the lead wires by plugging them into the corresponding lead wire connectors on the 6 chest electrodes, following the lead wire color code table provided.
- 2 Ensure that each lead wire is properly adjusted so that there is a secure and effective connection between the electrode and the lead wire.

3.3.2.4 Connecting Limb Lead Wires with Limb Electrodes

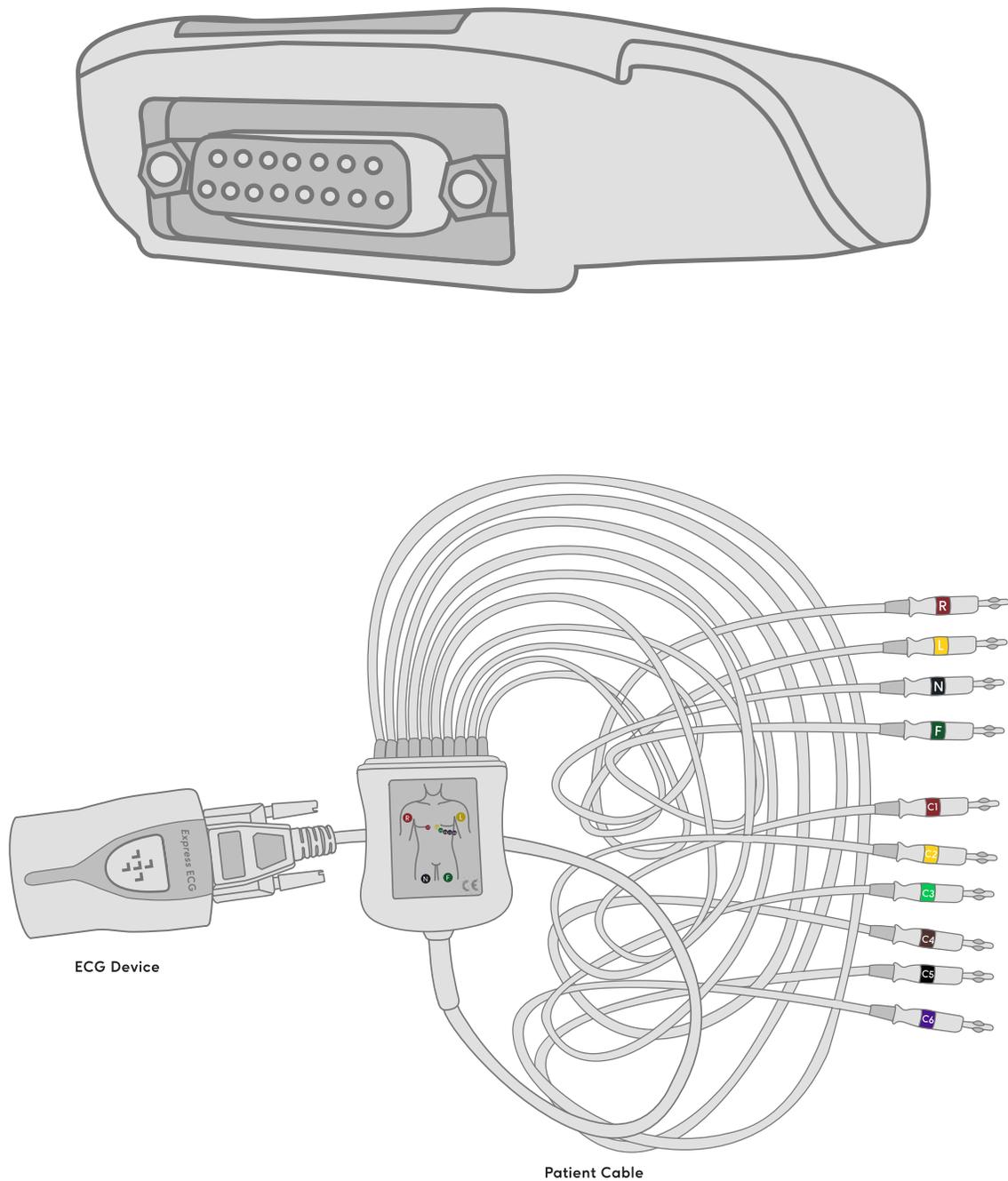
- 1 Connect the limb lead wires to the limb electrodes by following the lead wire color code table provided.
- 2 Ensure that each lead wire is appropriately adjusted to establish proper contact between the electrode and the lead wire.

Lead Wire Colour Code

LEAD	IEC		AHA	
	Label	Color	Label	Color
Right Arm	R	Red	RA	White
Left Arm	L	Yellow	LA	Black
Right Leg (Neutral)	N	Black	RL	Green
Left Leg	F	Green	LL	Red
Chest 1	C1	White/Red	V1	Brown/Red
Chest 2	C2	White/Yellow	V2	Brown/Yellow
Chest 3	C3	White/Green	V3	Brown/Green
Chest 4	C4	White/Brown	V4	Brown/Blue
Chest 5	C5	White/Black	V5	Brown/Orange
Chest 6	C6	White/Violet	V6	Brown/Violet

3.3.3. Connecting Patient Cable

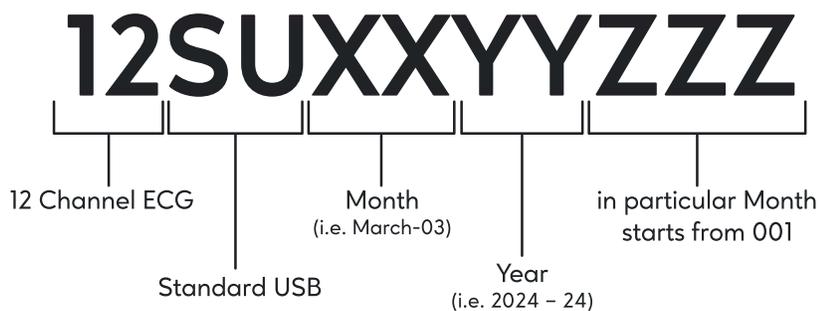
The ECG lead cable is plugged into the Express ECG ET-U12 unit, specifically into the slot located on the left side of the device.



Marking Plate



ECG Device Serial Number



4. Skin Preparation & Lead Placement

Certainly, before applying electrodes, it is crucial to communicate effectively with the patient to ensure they are informed and comfortable with the procedure. A step-by-step explanation can help alleviate anxiety and set clear expectations.

1. Assess the Patient:

- 1 Check the patient's condition.
- 1 Reassure them that the procedure is safe and comfortable.
- 1 Emphasise the importance of cooperation for accurate results.

2. Positioning:

- 1 Have the patient lie on a bed with arms at the sides and legs flat, ensuring comfort.
- 1 Apply electrodes and lead wires.

3. Instructions to the Patient:

- 1 Stay still and avoid talking.
- 1 Breathe normally.
- 1 Prevent shivering.
- 1 Avoid chewing or clenching teeth.
- 1 Stress the importance of relaxation for a clear ECG recording.

4.1. Preparing the Skin

To ensure high-quality ECG signals, it is important to follow a meticulous preparation process for the patient's skin. This involves:

- 1 Make sure the patient's chest and the areas where electrodes will be placed on limbs are visible and accessible.
- 1 If there is hair at the electrode sites, shaving may be necessary. This ensures better contact between the electrodes and the skin.
- 1 Cleanse each electrode site with alcohol to remove any oils or residues that might interfere with the electrode-skin contact.
- 1 If necessary, lightly abrade the skin at each electrode site using dry gauze. This helps remove dead skin cells, promoting better conductivity.
- 1 Ensure that the skin is thoroughly dry before attaching the electrodes. Moisture can disrupt the electrical contact between the electrodes and the skin.

4.2. Applying Electrodes

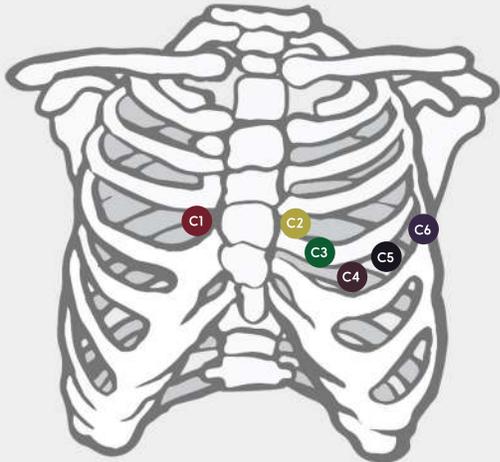
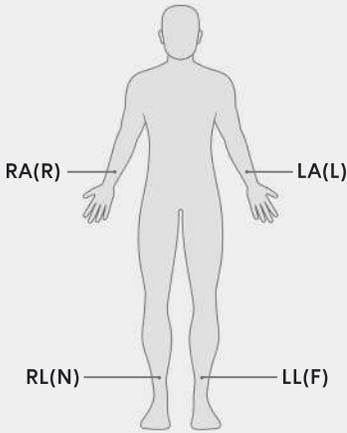
4.2.1. Electrode Placement

- 1 The table and the figure below give information about the placement/application of the electrode on the patient.

4.2.2. Applying Reusable Electrodes

4.2.2.1. Applying Limb Electrodes

when placing the limb electrodes, position them on the soft, fleshy areas above the inner wrists and ankles, avoiding direct placement on the bony parts

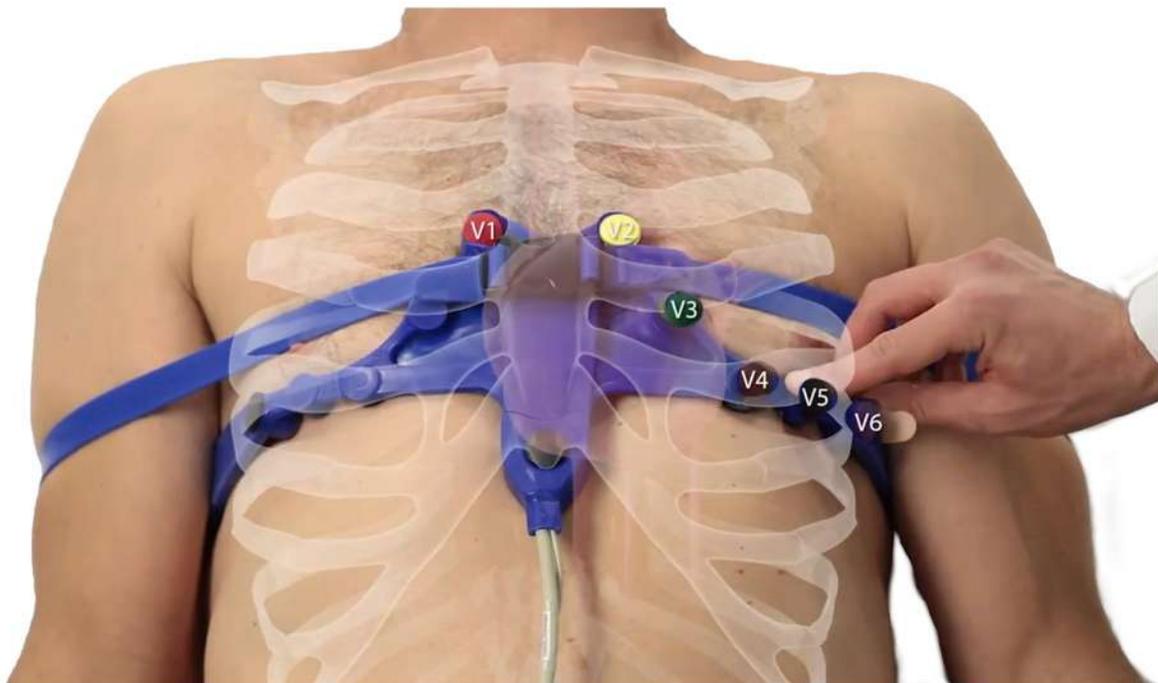
AHA	IEC	Electrode Placement	
V1	C1	Fourth intercostals space at the right sterna border	 <p>Electrode Placement (Chest Electrodes)</p>
V2	C2	Fourth intercostals space at the left sterna border	
V3	C3	Midway between V2 (C2) and V4 (C4) electrode positions	
V4	C4	Fifth intercostals space at the left midclavicular line	
V5	C5	Left anterior auxiliary line, horizontal with the V4 (C4) electrode position	
V6	C6	Left mid auxiliary line, horizontal with the V4 (C4) electrode position	
RA	R	Above right wrist	
LA	L	Above left wrist	
LA	N	Above right ankle	
LL	F	Above left ankle	

- 🔧 Ensure the electrodes are clean.
- 🔧 Connect the 4 limb electrodes to the corresponding coloured lead wires, avoiding twisting.
- 🔧 Expose the patient's arms and legs and prepare the skin as outlined in section 4.1
- 🔧 Apply a thin layer of conductive gel on each electrode site and metal electrode.
- 🔧 Place electrodes above the inside ankles and wrists on the limb sites.
- 🔧 Ensure the patient cable is securely connected to the equipment.
- 🔧 Double-check that electrodes are correctly connected to the lead wires.

4.2.2.2. Applying Chest Electrodes

- 1 Ensure the electrodes are clean and attach the 6 chest electrodes to the chest lead wires, taking care to prevent twisting in the wires.
- 1 Expose the patient's chest and prepare the skin as outlined in section 4.1.
- 1 Apply a thin layer of conductive gel to each electrode site, ensuring that the gel from one site does not mix with the gel from other sites or the metal electrodes.
- 1 Use a rubber bulb to create suction for holding the electrodes in place during application.
- 1 Securely connect the patient cable to the equipment.
- 1 Double-check that the electrodes are correctly linked to the lead wires.

ECG Belt Application



Step 1: Preparing the ECG Chest Belt

- 1 **Metal Point Cleaning:**
Begin by thoroughly cleaning all metal points on the ECG ChestBelt. This meticulous cleaning process ensures optimal signal conductivity, a crucial factor in achieving accurate diagnostic readings.
- 1 **Application of ECG Jelly Spray:**
Apply ECG Jelly Spray to the cleaned metal points on the ECG Chest Belt. This step further enhances signal transmission and patient comfort, enabling precise diagnostic data acquisition.

Step 2: Patient Comfort and Positioning

- 7 **Placing the ECG Chest Belt:**
Gently place the ECG Chest Belt on the patient's body, ensuring proper alignment with the designated contact points. This delicate placement is key to patient comfort and accurate signal capture.
- 7 **Position Verification:**
Thoroughly inspect the positioning of all contact points on the patient's body. Each point should align precisely with the corresponding anatomical landmarks to ensure optimal signal acquisition.

Step 3: Connection to ECG Device

- 7 **Connecting the 15-pin Connector:**
Securely attach the ECG Chest Belt's 15-pin connector to the designated port on the ECG Device. This connection establishes the vital link between the hardware and advanced technology.

Note:

- 7 Ensure good contact between metal electrodes and the skin for accurate ECGs.
- 7 Keep electrode placement and metal sites clean.
- 7 Prevent contact between metal electrodes during chest electrode placement.
- 7 Avoid mixing conductive gel from different sites when applying it on the chest.
- 7 Check and secure the connection of lead wires and electrodes to prevent loosening.
- 7 Clean reusable electrodes after each use.

Configuring the Express ECG ET-U12 Unit

The Express ECG ET-U12 Android application comes pre-configured, so users don't need to adjust any settings. The necessary configurations are already set up in the app.

5. ECG Capture

Step - 1

The application's user interface presents three options. To initiate patient registration, users need to select the "Registration" option. User needs to fill all details.

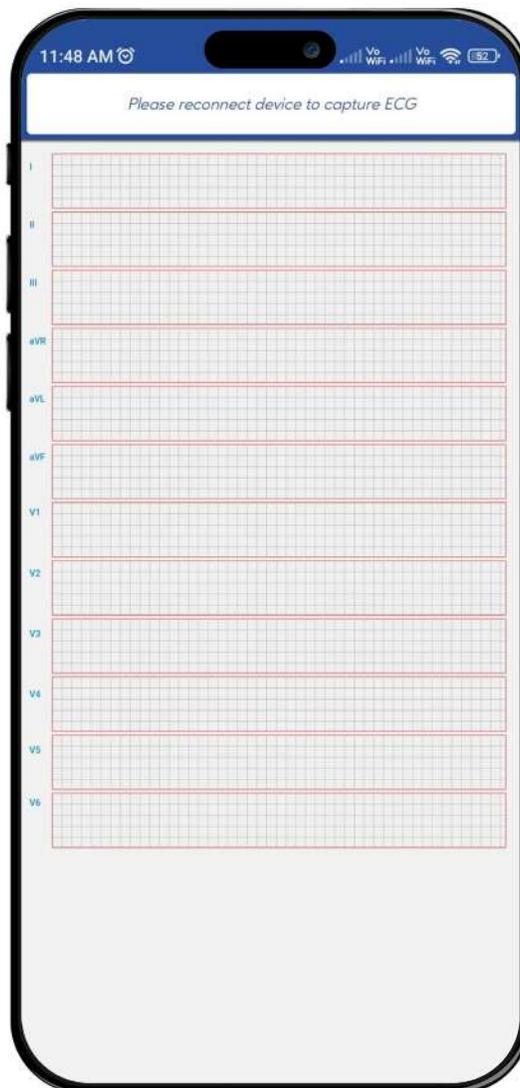


Step - 2

After completing the patient registration, you'll be directed to the application's user interface. From there, navigate to the "Capture ECG" option. In this section, you will find a list of registered patients. Choose the specific patient for whom you want to capture the ECG.

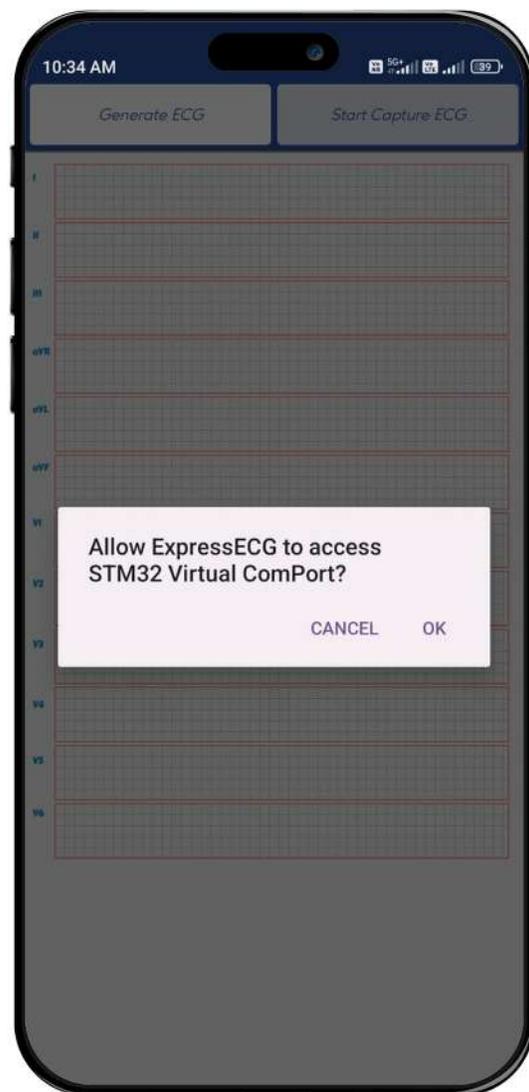
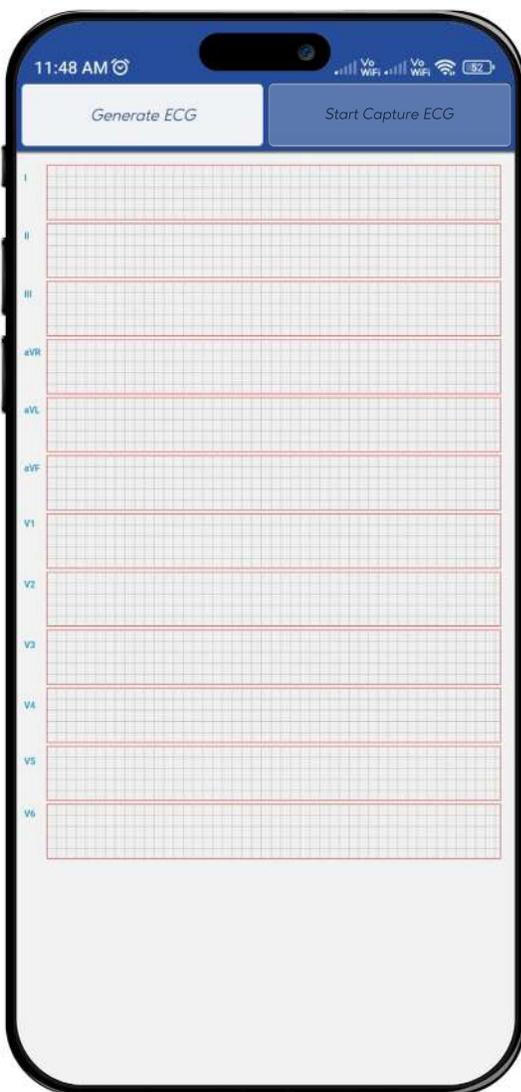
Step - 3

Navigate to the ECG graph page. On this page, you will encounter a message instructing you to connect the device for ECG capture. Proceed to connect the device to your mobile device.



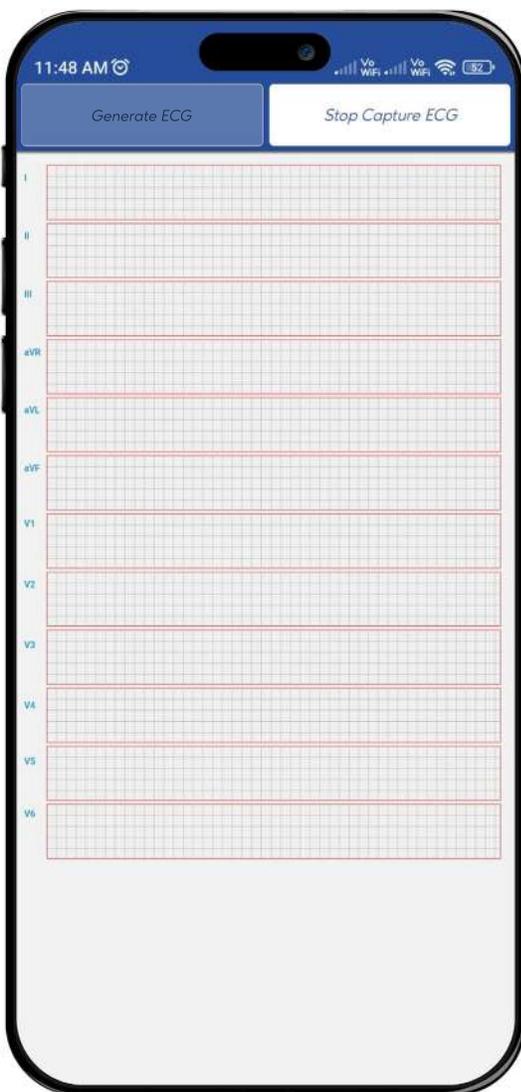
Step - 4

The blinking "Start Capture ECG" option on the right side of the page indicates that you can initiate the ECG capture process by clicking on it. A prompt will then appear requesting permission for "ExpressECG to access the STM32 virtual ComPort". Simply click on "ok" to grant the necessary access.



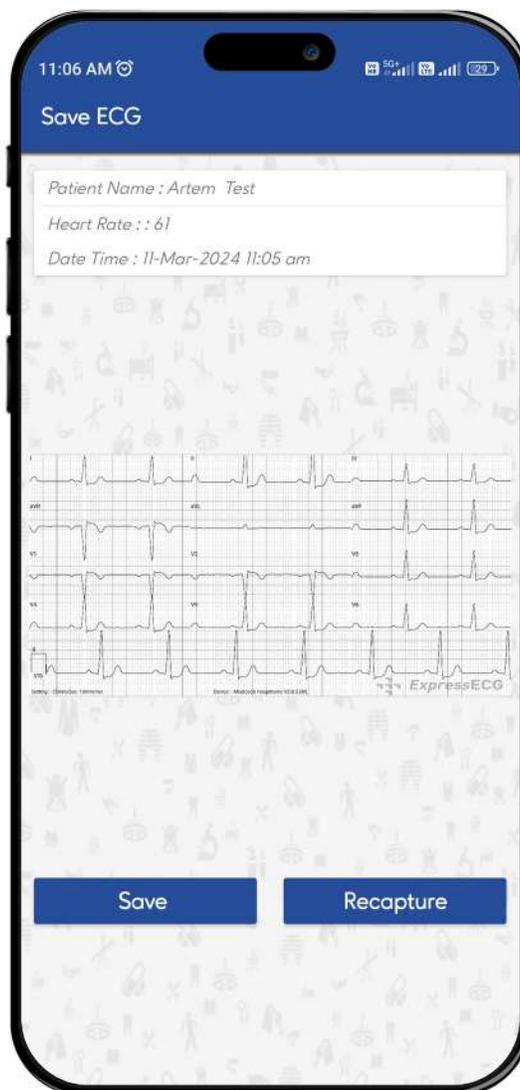
Step - 5

After ensuring that the ECG wave is satisfactory, proceed to click on the "Generate ECG" button. This will trigger a message indicating that the ECG generation process is underway, as illustrated in the accompanying figure.



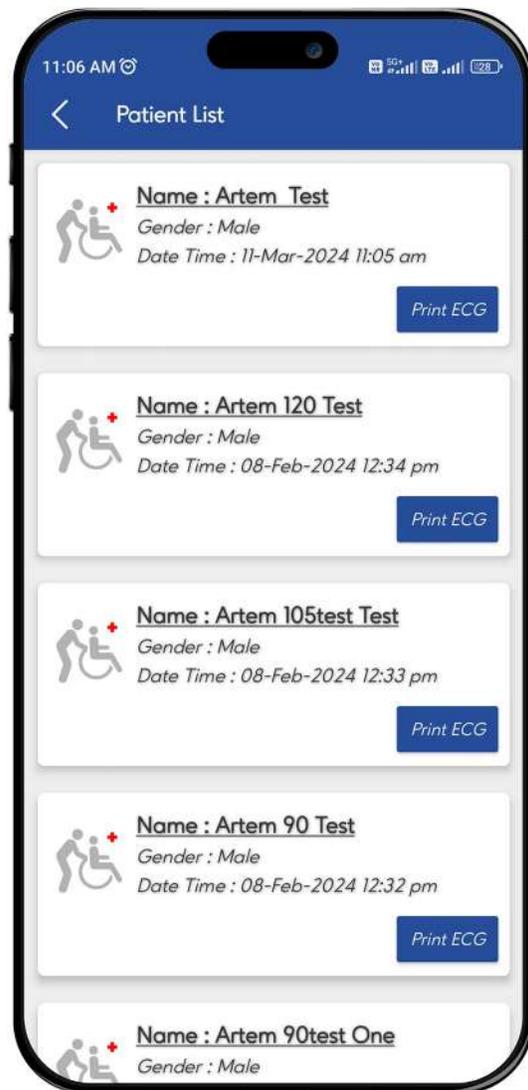
Step - 6

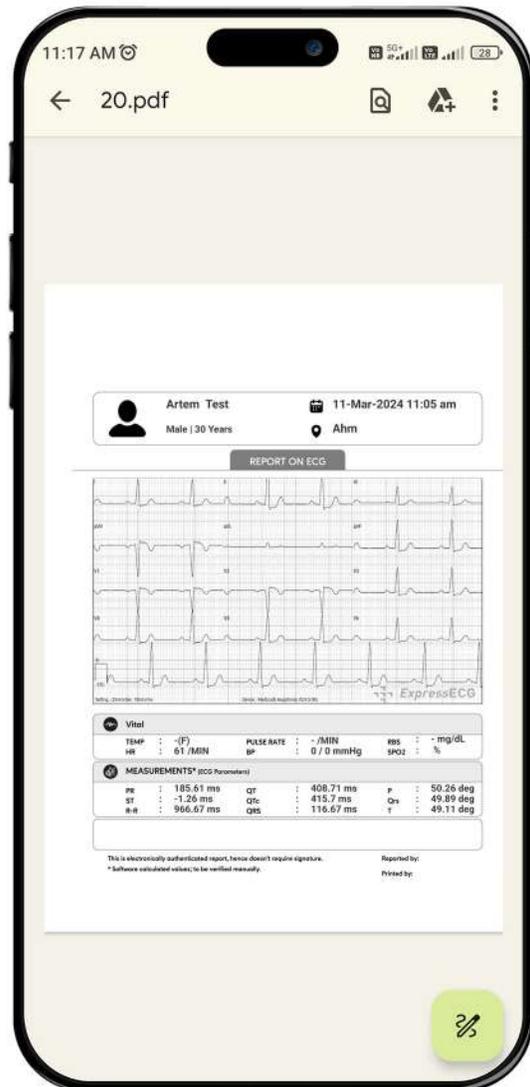
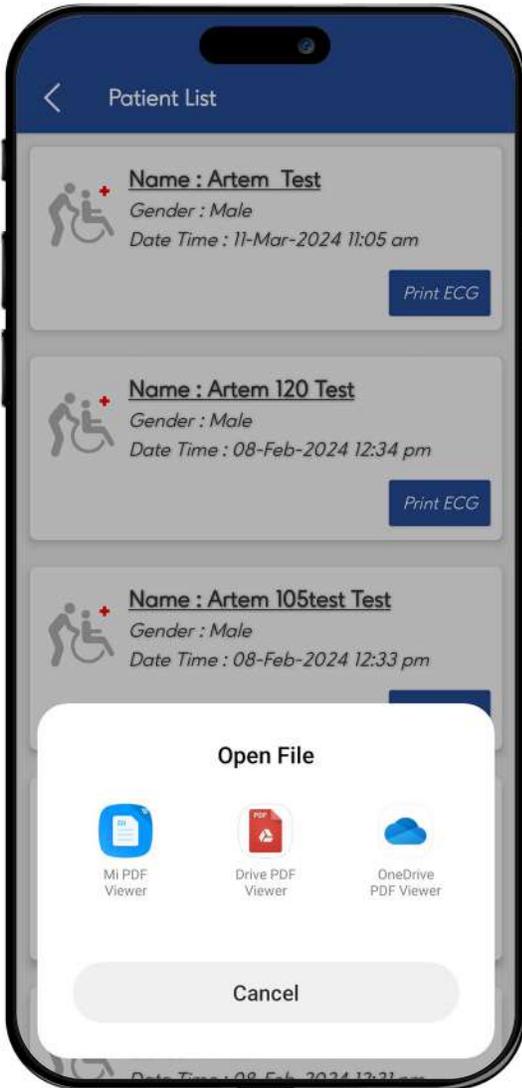
Generated ECG will display the ECG graph. If the ECG looks satisfactory, press the “**Save**” button. If not, click on “**Recapture**” and redo the capturing process .Once the ECG is successfully Saved, the capturing process is considered complete & land you on the application’s user interface.



Step - 7

After Successful ECG Save, you'll be directed to the application's user interface. You will find "Print ECG", When you click on that option your ECG which you saved will be in this patient list. Click on print ECG. Then you can find ECG Report with all parameters.





6. Shutdown Procedure

Express ECG ET-U12 device is plug and play device; there is no major shutdown process. Detach ECG Device Close Express ECG Application from Mobile.

ECG Device Emitting Radiation

The ECG machine 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. So it is under RF emissions CISPR11 Group 1.

The ECG machine 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. So it is under RF emissions CISPR11 Class A.

Instruction Messages

Messages	Explanation of Message
Allow ExpressECG to access STM32 Virtual ComPort?	While ECG Device connect with Mobile, it takes permission to connect
Please wait while generating ECG	It takes ~ 30 seconds max to generate ECG Graph

Explanation of Symbols

Symbol Graphics	Title of Symbol	Description of Symbol
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	No Trash	Indicates a medical device contain materials that can be harmful to the environment if not disposed of properly. This symbol is meant to indicate that the electronic device should be recycled or disposed of in a specific way to prevent environmental damage
	Patient Cable Connector Symbol	Indication for patient cable which is type CF compliant
	Class III	In the machine, when voltages are not exceed 25 VAC or 60 VDC, it is called as safe extra low voltage (SELV)
	DC	Works on DC Voltage
	Manufacturer	Indicates the medical device manufacturer
IP20	Ingress Protection	Protected against solid objects over 12.5mm and no protection against liquids



For any queries kindly

Contact Us

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 +91 635 969 3050

 www.artemhealthtech.com

 **ARTEM Healthtech Pvt. Ltd.**

417-418-419, 4th floor, Block D, Times Square Grand,
Sindhu Bhavan Road, Thaltej, Ahmedabad-380 059, Gujarat, India.

