ALIVECOR®

Instructions for Use (IFU)
for
Impala System (AC-027)

27LB07.X03

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℞ only

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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Table of Contents

Introduction

1. Impala is a portable electrocardiograph that records four leads, derives four leads, and synthesizes four leads to create a 12-lead ECG recording for diagnostic purposes.
    a. The device consists of the following components:
    - Impala hardware, which connects to standard gel-based ECG electrodes (off the shelf) to measure and record ECG leads.
    - Impala app, which provides the user interface and ECG display functions. The Impala app functions on a smart device such as a smartphone or a tablet.

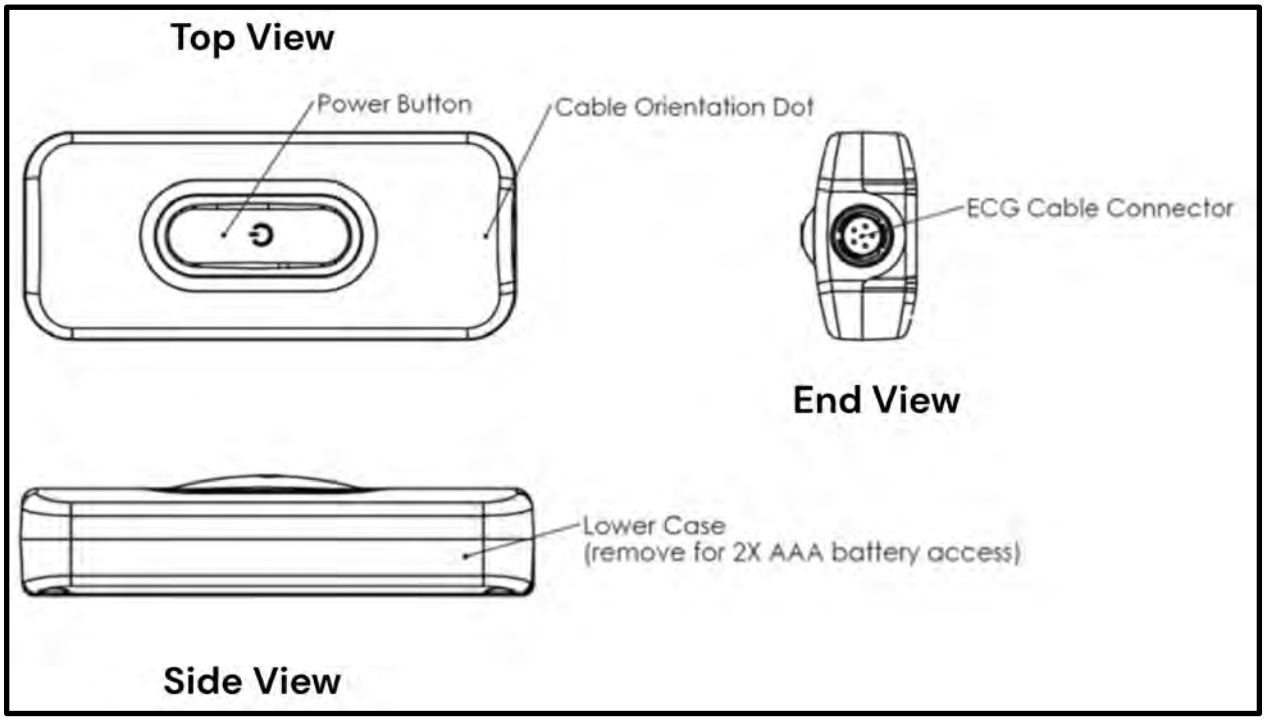
2. The Impala hardware measures and records 4 leads ('Recorded Leads').
    a. The device can record the following sets:
        i. Leads I, II, V2 and V4 (Default)
        ii. Leads I, II, V1 and V4 (Alternate)
    b. The Impala app uses the Recorded Leads to derive the remaining limb leads (i.e. Leads III, aVR, aVL, aVF) using the standard relationships.
    c. The remaining precordial leads (i.e. Leads V1, V3, V5, V6, or Leads V2, V3, V5, V6) are synthesized using a machine learning model ("Synthesized Leads").

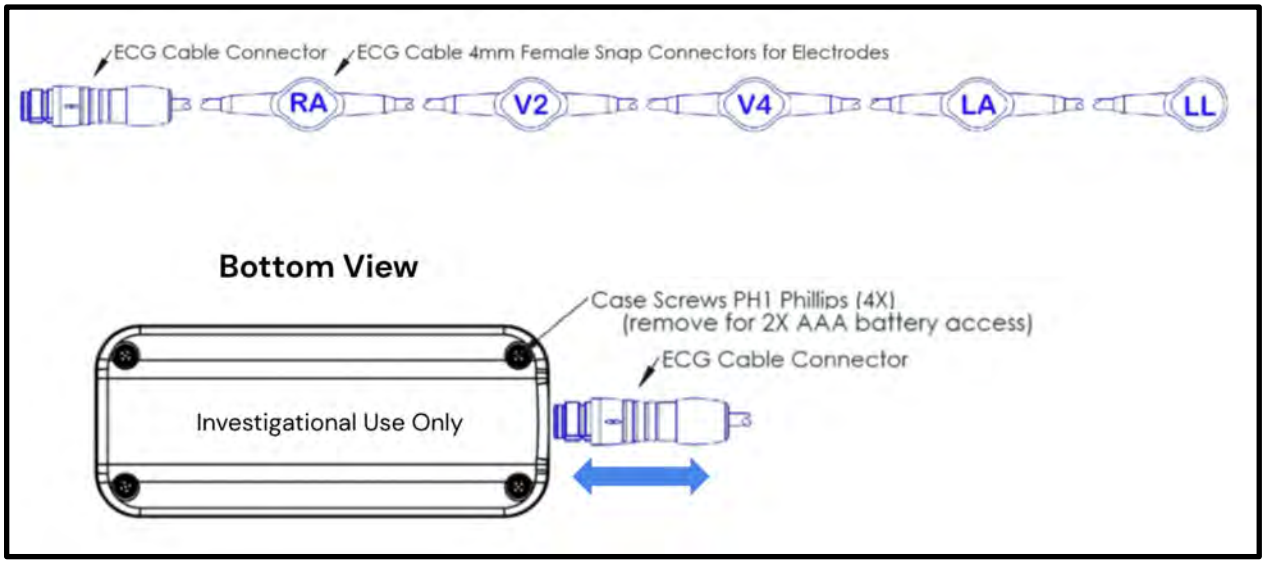
3. Impala requires a compatible smartphone or tablet and the Impala app.
    a. The list of compatible devices can be viewed at www.alivecor.com/compatibility
    b. The Impala app can be downloaded from the Apple App store

Indications For Use

Impala is intended to record, store, and transfer a 12-lead diagnostic resting electrocardiogram (ECG). Impala acquires four leads (Leads I, II, V2, V4, or Leads I, II, V1, V4). The device derives Lead-III and unipolar limb leads aVR, aVF and aVL, and synthesizes Leads V1 or V2, V3, V5, V6. Impala is intended for use with patients aged 18 years and older. Impala is intended for use by healthcare professionals, or trained personnel in healthcare facilities (e.g. the doctor's office or hospital) and in acute settings.

Guide to Parts





Accessories

- **Tab Electrodes** “Resting Electrodes”

Tab electrodes are small, adhesive patches that are applied directly to the skin. These electrodes have the following specifications:

Adhesion: Low to medium (typically for resting applications)
Size: Typically rectangular around 1.2" x 0.8" with 10 electrodes/card and 10 cards/pkg
Material: Silver/Silver Chloride (Ag/AgCl) usually with plastic backing
Sterilization: Alcohol wipe skin and let dry before electrode attachment

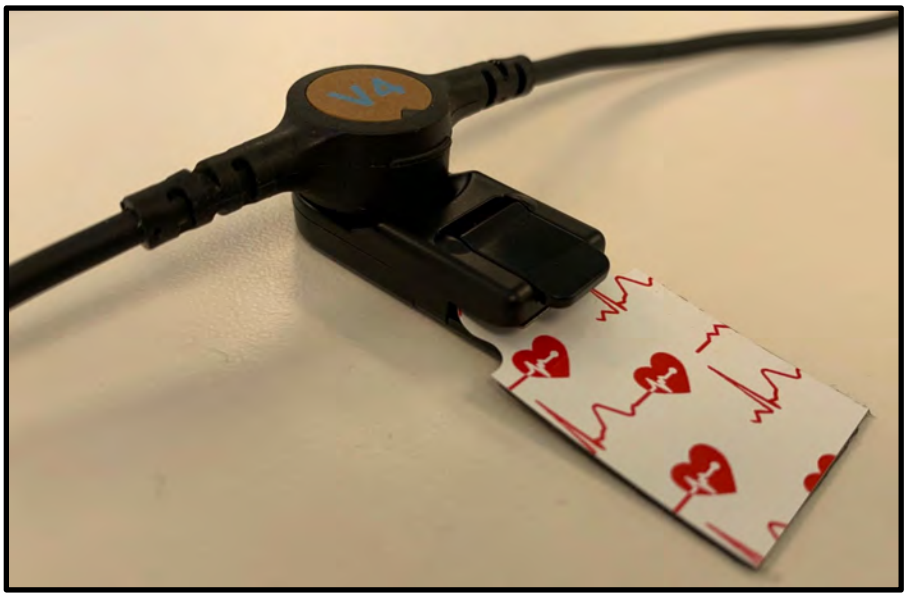
- **Snap Electrodes** “Monitoring Electrodes”

Snap electrodes are small, adhesive patches that are applied directly to the skin. These electrodes have the following specifications:

Adhesion: Medium to High (typically for active monitoring applications)
Size: Typically around 1.25” square, rectangle, or circular shaped with 3 or 5 electrodes/pkg
Material: Silver/Silver Chloride (Ag/AgCl) usually with cloth/foam backing
Sterilization: Alcohol wipe skin and let dry before electrode attachment

- **Snap to Tab Adaptors**

Snap to tab adaptors have a male snap connector that mates with a female snap connection on the Patient Lead Wire. They are inserted between the ECG electrode and the ECG machine's lead wire, allowing the Tab Electrodes to be used with Impala.



Warnings

1. AliveCor does not guarantee that the patient is not experiencing an arrhythmia or other health conditions with any ECG result, including normal.
2. DO NOT use this device to record heart rate and heart rhythm only.
3. AliveCor makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the products as instructed.
4. The device has not been tested for and is not intended currently for pediatric use.
5. Keep device away from young children. Contents may be harmful if swallowed. Device contains two AAA alkaline batteries that are not accessible during normal use but, if exposed, can be a choking hazard and may cause severe tissue injury if ingested.
6. DO NOT replace the batteries when the device is in use.
7. DO NOT take a recording while driving or during physical activity.
8. DO NOT store in extremely hot, cold, humid, wet, or bright conditions.
9. DO NOT immerse the device or expose the device to excessive liquid.
10. DO NOT use while charging your smartphone or tablet
11. DO NOT drop or bump with excessive force.
12. DO NOT expose the device to strong electromagnetic fields.
13. MR-Unsafe. Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core
14. DO NOT place electrodes in contact with other conductive parts including earth.
15. DO NOT use un-approved accessories. Use of non-AliveCor approved accessories or transducers and cables could result in electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
16. DO NOT use adjacent to or stacked with other equipment because it could result in improper operation
17. DO NOT use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of the Impala System. Otherwise, degradation of system performance could result.
18. DO NOT use the Impala App with a damaged smartphone, as this can cause malfunctions or errors in the device. If your smartphone is damaged, please have it repaired or replaced before using the Impala App again.
19. The ECG displayed in the Impala app or the PDF generated by the App should be reviewed by a qualified medical professional. Users with limited medical knowledge should not attempt to diagnose or treat any medical condition based solely on the ECG results displayed in the app. Always consult with a qualified medical professional if you have any concerns or questions about the patient's ECG results.
20. DO NOT use the system in an environment devoid of limited user vision/ limited visibility environment.
21. During use, ensure that the Patient Lead Wire is detangled and carefully routed to reduce the risk of patient strangulation or asphyxiation.

22. After use, ensure that the Impala hardware is properly stored in its designated case.
23. Despite the defibrillator-proof nature of the Impala device, it is crucial to avoid touching the defibrillation pads or paddles directly against the metal cable snap connectors during defibrillation procedures. Direct exposure to the electrical discharge may interfere with the device's performance.
24. Do not use the device without following the proper cleaning/intermediate level disinfection as mentioned in this IFU
25. DO NOT use the Impala device before carefully following the recommended operating procedures as guidelined in this Instructions for use
26. The synthesized lead's output may be affected by external factors such as noise, interference, poor electrode contact, incorrect lead placement, etc. and may cause inaccuracies in the ECG output. Qualified medical professionals must consider these limitations before making any diagnoses of potential cardiac conditions or any clinical decisions when using synthesized leads.
27. The Impala device is NOT intended for use in environments where electrosurgery procedures are performed. The device may not be immune to the high levels of electromagnetic disturbances typically present in such environments.

Cautions ⚠

Disposal instructions: To protect the environment and human health, it is important to dispose of medical devices in a responsible manner. Please do not dispose of AliveCor's products with municipal waste, as there may be hazardous substances in the electrical or electronic components.

Impala Device is intended for use by a physician or by trained professionals. Read all instructions for use and specifications provided prior to use.

Features & Functionality

Impala is a 12 lead diagnostic resting ECG device that measures four leads, derives four leads and synthesizes additional four leads to create a 12-lead ECG recording for diagnostic purposes.

Impala uses Bluetooth to wirelessly transmit ECG data from the device to your smartphone or tablet.

What is an ECG?
Also known as an electrocardiogram, an ECG is a test that detects and records the strength and timing of the electrical activity in the heart. Each heartbeat is triggered by an electrical impulse. The ECG represents the timing and strength of these impulses as they travel through the patient’s heart.

Getting Started

1. Remove the Impala hardware from the packaging.

2. Download the Impala App (Application) to your smartphone/tablet device. Impala hardware can only be used with the Impala app.

Setting up your Impala for the first time

1. Download the desired application from the Apple App Store by searching for its app name from the table above. .
    a. Be sure to use a compatible iOS device (check the compatible device list at www.alivecor.com/compatibility).
    b. Do not use the Impala device with unsupported software. Verify that you have Impala App installed on your device.

2. Make sure **Bluetooth is turned on** in your smartphone or tablet settings.

3. Launch the app and follow the instructions on-screen.

4. You will then be taken to the recording screen.

Recording an ECG

Follow the instructions below to record an ECG.

1. Remove the Impala ECG module and the patient lead wire from the case
    - Connect the ECG module to the patient lead wire if not already connected.

2. Open the app on your smartphone/tablet
    - Ensure the Bluetooth is turned ON in your smartphone/tablet settings

3. Follow on-screen instructions on the Impala app for connecting the Impala device to your smartphone/tablet and entering the patient information within the application.
    - Press the button on the ECG module to initiate Bluetooth connection. The LEDs should be ON

4. During ECG assessment, the patient should be supine
    - Their skin at the ankles, chest and arms below the elbows should be exposed.

5. Clean the areas where you will place electrodes with alcohol prep pads to remove dirt and oil and allow the areas to dry.

6. Place the gel electrodes in the locations of one of the following lead sets (5 total electrodes). See Figure 1 below.
    - Default Lead set 1: V2, V4, RA, LA and LL
    - Alternate Lead set 2: V1, V4, RA, LA and LL

Note: Electrodes with Snap connections OR tab connections can be used. Tab electrodes require Snap-to-Tab adaptors for connecting them to the wire leads.

For accurate measurements, proper electrode placement is crucial.

- V1 placement: Fourth intercostal space to the right of the sternum
- V2 placement - Fourth intercostal space to the left of the sternum
- V4 placement - Fifth intercostal space at the midclavicular line
- RA placement - Anywhere between the right elbow and right wrist
- LA placement - Anywhere between the left elbow and the left wrist
- LL placement - Anywhere below the left knee and above the left foot

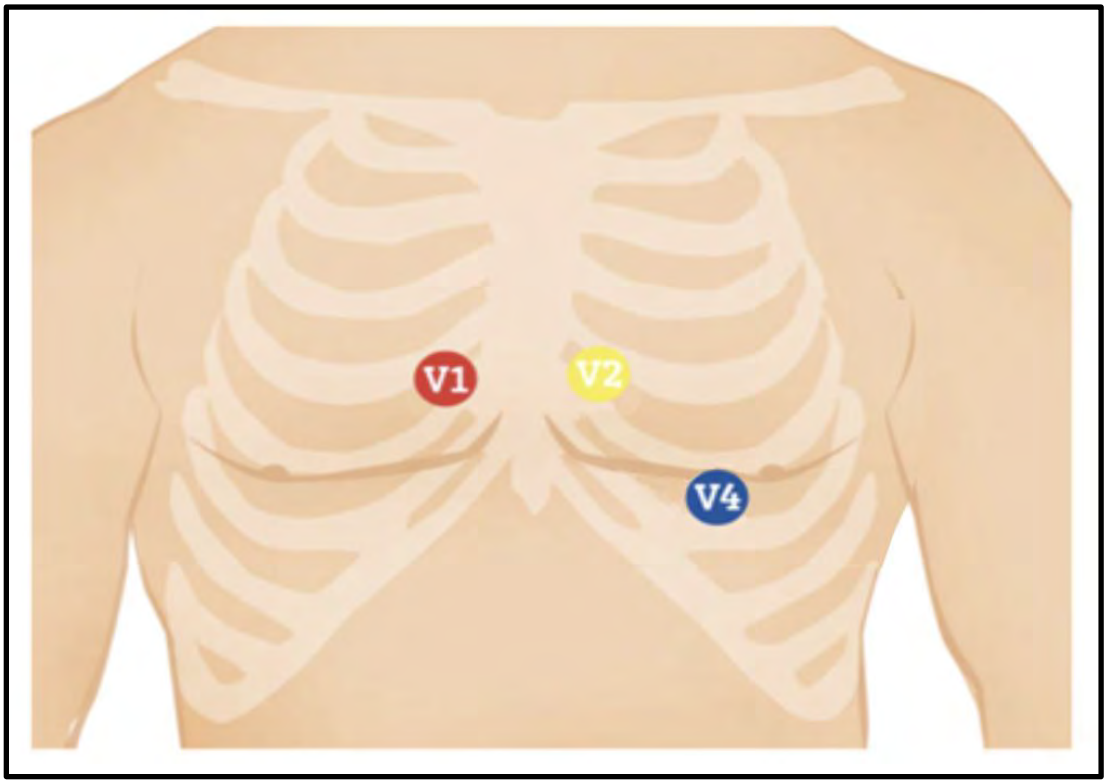


Figure 1: V1, V2 and V4 Electrode Placements

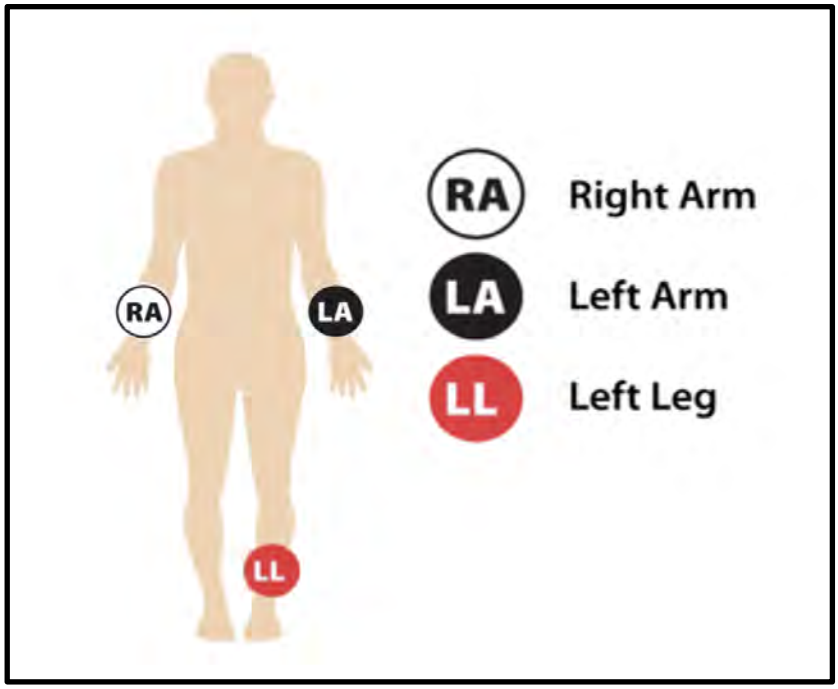


Figure 2: RA, LA, and LL Electrode Placements

7. When using snap electrodes, connect the patient lead wire snap connectors to the electrodes adhered at LL, LA, RA, V2 (or V1) and V4 locations using the snap connections.
    - When using tab electrodes, connect the patient lead wire snap connectors to the snap connections on the provided Snap-to-Tab adapters then connect the adapters to the tab electrodes using the lever connectors on the adapters. Lift the lever tab, place the jaws of the adapter over the electrode's protruding tab, then press down on the lever to lock it in place.

Note: When using the Alternate Leadset setting (V1, V4, RA, LA, and LL), you should connect the patient lead wire snap connector labeled as V1/V2 to the V1 location on the patient.

8. After connecting the electrodes, activate the Impala ECG module by pressing its button, ensuring that the LED light illuminates. Proceed by selecting the "**Record**" button on the Impala app on your synced smartphone or tablet to start capturing the ECG data.
    - Maintain stillness while the on-screen timer progresses from 0 to 10 seconds. Once a minimum of 10 seconds of data has been recorded, select the 'Save' button on the Impala App to finalize and end the recording process.

9. Once the recording completes as indicated on the Impala app, remove all connectors and electrodes.

10. The device will turn off automatically after use.

Environmental Specifications

Operational Temperature:	-10°C to +40°C
Transient Operational Temperature:	-18°C to +50°C Up to 20 mins usage
Operational Humidity:	0% to 95% (non-condensing)
Storage Temperature:	-18°C to +55°C
Storage Humidity:	0% to 95% (non-condensing)
Operational Pressure:	54 kPA to 101kPa Operational from sea level up to 16,404 ft / 5,000 m altitude, or any altitude above this in an aircraft with a pressurized cabin. Device has been qualified for use in both fixed wing and rotary wing aircraft.

Expected Service Life

The expected service life for Impala is 5 years.

Impala is designed to allow a minimum 3 years of battery shelf life from the date the device was manufactured and minimum 600 30-second recordings on one set of batteries. The batteries can then easily be replaced. For details regarding the battery replacement process, please refer to the 'Battery Replacement Instructions' section in this guide below.

Maintenance

No service or repair should be performed on the Impala hardware other than the maintenance listed in this section.

Cleaning Impala Device

Regular maintenance of the Impala hardware is necessary to ensure accurate and reliable performance. It is recommended to thoroughly clean and disinfect the device before and after each use using one of the approved cleaning and disinfection agents as outlined in this section below:

a. Alcohol-based disinfecting wipes (Sani Wipes)
b. Benzethonium Chloride-based disinfecting wipes (Cavi Wipes)

To clean and disinfect the device, follow these instructions:

- Ensure the device is turned off and disconnected from any power source before cleaning and disinfecting.
- Put on a pair of disposable gloves before handling the cleaning and disinfecting agents.
- Select either a Sani Wipe or Cavi Wipe for thorough cleaning and disinfection.
- Remove a wipe from the container.
- For the ECG Module, gently wipe all surfaces, ensuring thorough coverage. Use a consistent wiping motion, such as a horizontal or vertical stroke, and apply the wipe at least 3-5 times on each surface to ensure effective disinfection.
- For the Patient lead wire, gently wipe along the entire length of the cable, including the connector and snap junctions. Pay particular attention to areas where contamination or debris might accumulate.
- For the Snap-to-Tab Adaptors, carefully and thoroughly clean and disinfect the adaptor body.
- Allow all components to air dry for at least 3-5 minutes before reassembling and using the device, as per the disinfectant wipes' instructions for contact time to ensure effective disinfection.
- After cleaning, perform a visual inspection of the device. Check for any surface damage, corrosion or other forms of damage.

Store the cleaning agents according to their respective manufacturer's instructions and ensure they are within their expiration dates.

WARNING

- Always follow the manufacturer's instructions for the cleaning and disinfecting agents and ensure that the device is turned off before cleaning.
- Additionally, avoid using abrasive materials or excessive force when cleaning the device to prevent damage.

- Do not immerse the device in liquid or allow excessive moisture to enter the device during cleaning and disinfecting.
- Exterior Visual Inspection: Inspect the Device for any surface damage, or corrosion or any other form of damage. This cleaning process has been validated to ensure effective cleaning of the device.

Battery Replacement Instructions

Battery Type: AAA Alkaline

1. Gather the provided screwdriver and two AAA **Alkaline** batteries.
2. Ensure the Impala device is turned OFF.
3. Locate the battery compartment on the back side of the ECG module and note four screws located in the corners.

4. Use the screwdriver to remove the four screws that hold the battery compartment in place.
5. Remove the battery compartment cover and take out the old batteries.
6. Insert the new AAA batteries into the compartment, following the correct polarity (+/-).
7. Replace the battery compartment cover and use the screwdriver to reattach the four screws, being careful not to over-tighten.
8. Turn on the Impala device by pressing the power button to ensure that it is working properly.
9. If the device does not turn on, check the battery compartment and ensure that the batteries are inserted correctly.
10. Dispose of the old batteries in accordance with local regulations.

Electromagnetic & Other Interferences

- Impala has been tested and deemed in conformance with the relevant requirements in IEC 60601-1-2:2014 Class B for Electromagnetic Compatibility (EMC).

FCC Compliance

FCC ID: 2ASFFAC027

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.

CAUTION: Changes or modifications not expressly approved by AliveCor could void your authority to use this equipment.

To view FCC information on the Impala app:

1. On the home screen, tap  on the top right of the screen to access the information screen.
2. Scroll to view the FCC ID and other applicable regulatory information.

Ingress Protection Marking

Impala is IP54 rated. Impala is protected against dust and is not affected by splashing water from any direction. Impala has been tested with relevant requirement standard 60529:1989/AMD2:2013/COR1:2019.

Essential Performance

Impala has been tested to the relevant requirements of standard IEC 60601-2-25:2011 for the basic safety and essential performance of electrocardiographs.

The essential performance of Impala ECG device is to accurately record the electrical signals from the patient's heart and provide a clear and detailed 12 Lead ECG waveform for diagnostic purposes. Our device records 4 leads and derives 4 leads, and then synthesizes an additional 4 leads to obtain a diagnostic level ECG of 12 leads that can be displayed for diagnostic purposes.

In accordance with IEC 60601-2-25, the electrocardiograph equipment meets the following requirements in terms of Essential Performance:

- Protection against defibrillation (subclause 201.8.5.5.1)
- Essential performance and accuracy of ME equipment (Subclause 201.12.1.101)
- Electrostatic Discharge (Subclause 202.6.2.2.1)
- Filters (201.12.4.105.3)

In the event that noise or interference affects the quality of the recording, the device may not provide accurate results. Ensure that the environment is free from potential sources of interference, such as other electronic devices or strong electromagnetic fields, to minimize the risk of inaccurate results.

The operator should take appropriate measures to minimize the impact of the noise or interference, such as repositioning the patient or the device, before continuing with the recording.

The Impala device is powered by internal batteries and does not have a power supply cord. Therefore, subclauses 2.6.2.4.1 and 202.6.2.6.1 from IEC 60601-2-25 do not apply. Additionally, the Impala device is not intended to be used in an electrosurgery environment, and therefore, subclause 202.6.2.101 from IEC 60601-2-25 does not apply.

Applied Parts

The 5 electrodes (Right Arm Electrode, V2/V1 Electrode, V4 Electrode, Left Arm Electrode, and Left Leg Electrode) are Type CF Defibrillation Protected Applied Parts.

Operational temperature conditions for the device are -10°C to 40°C.
Transient operational temperature conditions for the device are: -18°C to 50°C for up to 20 minutes contact duration.
If ambient temperature exceeds +41°C, Applied Parts can exceed +41°C.

Troubleshooting

If you experience difficulties using your Impala, refer to the troubleshooting guide below or contact technical support at support@alivecor.com.

I'm having trouble getting a clear recording.

- Use new non-expired gel electrodes of the proper tab or snap variety.
- Ensure that the skin is cleaned with an alcohol swab and allowed to dry completely before electrode application.
- Disconnect any cables connected to phones (charging, headphones, etc.)
- Ensure the patient is in Supine and relaxed position during the recording
- Avoid close proximity to items that may cause electrical interference (electronic equipment, computers, chargers, routers, etc.).
- Make sure that the environment is free from potential sources of interference, such as other electronic devices or strong electromagnetic fields.
- Take appropriate measures to minimize the impact of the noise or interference, such as repositioning the patient or the device, before continuing with the recording.

My Impala hardware is not working.

- Make sure your device is compatible with the Impala ECG hardware and meets the minimum requirements listed in the IFU.
- Make sure Bluetooth is turned on in your smartphone or tablet settings and follow the steps in "Record an ECG".
- If Bluetooth is on, try to unpair and pair again to your Impala ECG .
- Ensure that the Impala device is securely attached to the electrodes and that the electrodes are properly placed on the skin.
- Check the Impala device for any physical damage or defects and contact customer support if necessary.
- Try using the Impala device with a different smartphone or tablet to see if the issue is with the hardware or the device being used.
- Check that the batteries in your Impala ECG hardware are properly inserted, oriented according to their polarity, and not expired. Replace them with fresh batteries if necessary, following the instructions in the IFU.
- If Bluetooth is on and your device is not connecting or pairing it’s possible that your battery needs to be replaced. Follow the “Maintenance” instructions to replace the battery.
- If the device still does not power on or function correctly after replacing the batteries, contact customer support for further assistance.

Electrical Safety

Guidance and manufacturer's declaration - electromagnetic emissions		
Impala is intended for use in the electromagnetic environment specified below. The customer or the user of Impala should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Impala ECG hardware uses RF energy only for its internal function. RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is intended for use by healthcare professionals, or trained personnel in healthcare facilities and in acute settings.
Harmonic emissions IEC 61000-3-2	N/A	Impala ECG hardware is powered from two AAA batteries and does not require AC mains power.
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration—electromagnetic immunity			
Impala is intended for use in the electromagnetic environment specified below. The customer or the user of Impala 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	±2 kV contact ±4 kV contact ±6 kV contact ±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	±2 kV contact ±4 kV contact ±6 kV contact ±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±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%.
Electrical fast transient/burst IEC 61000-4-4	N/A	N/A	Impala is powered from 2 Alkaline AAA batteries and does not require AC mains power.

Surge IEC 61000-4-5	N/A	N/A	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration—electromagnetic immunity			
Impala is intended for use in the electromagnetic environment specified below. The customer or the user of Impala 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 2.7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Impala ECG hardware, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V_1}]\sqrt{P}$ < 80MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 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 broadcast, and TV broadcast 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 Impala is used exceeds the applicable RF compliance level above, Impala should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Impala.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and Impala

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3

10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined 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.

Privacy and Security

Cybersecurity is crucial to the safe and effective operation of your Impala device. It's integral to the protection of patient privacy and the integrity of the system and associated information. The security of your smart device, which serves as a primary interface with your device, must be maintained diligently. The Impala App, which is essential for the operation of the device, is distributed with a digital signature. This signature serves as a guarantee that it originates from a trusted source and hasn't been tampered with.

The Impala device operates within a secured environment, designed with features that limit access to only approved users. The device is configured to be accessible only through secure pathways, ensuring the confidentiality, integrity, and availability of your information.

It is assumed that the Impala device and the corresponding Impala App are being used within a secured environment. It's essential that this environment is well-protected, using a firewall or router protections, to ensure that only authorized external hosts have secure network access.

Security Responsibility

Regular upgrades and security patching are part of the ongoing cybersecurity protocols for the Impala device and the Impala App. These updates are integral to maintain the device and the app's security and to ensure the latest and most secure software is applied.

Malicious Software Protection

The computing environment is increasingly hostile, with threats arising from malicious software, including viruses, worms, Trojan horses, denial of service attacks, and other malware. A vigilant defense on multiple levels is required to keep the Impala device and the Impala App free from compromise.
To protect against these threats please adhere to the following instructions:

- Protect your Apple ID account with a unique and strong password. Follow the instructions at Apple ID Security.
- Set a passcode for your device. Follow the instructions at Set a Passcode.
- Enable automatic updates for your Impala device OS. By default, these updates are turned on. Follow the instructions at Update OS.
- Enable automatic updates for the Impala device's apps. These updates are also enabled by default. Follow the instructions at Enable Automatic App Updates.
- Ensure that your Impala device has WiFi or cellular connectivity so that updates can be downloaded and installed. Follow the instructions at WiFi Connectivity and Cellular Connectivity.
- Enable automatic backups for your Impala device. Follow the instructions at Automatic Backups.

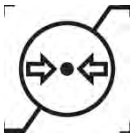
- Please also refer to resources provided to protect a device from cybersecurity threats: FDA Cybersecurity

Once the above steps are completed, launch your Impala App and enter the unique username and strong password provided to you.

Please remember that cybersecurity is an ongoing process, not a one-time setup. Continuous maintenance of your smart device's security and the Impala App is paramount to protecting against unauthorized access, ensuring the functionality of the device, and safeguarding your personal and patient data.

Equipment Symbols

These symbols will be used in the packaging and other labeling of the Impala hardware.

Symbol	Interpretation	Symbol	Interpretation
	Manufacturer		Refer to instruction manual/booklet
	Read instructions before use		Do not dispose with household waste
	Temperature range		Do not cut, shred or attempt to destroy device
	Humidity range	REF	Model number
	Atmospheric pressure range	SN	Serial number
	Type CF Applied Part (Defibrillation-Proof)	IP54	Protected from water spray from any direction
			MR unsafe

Impala Specifications

ECG Module Weight	81.5 g
ECG Module Size (Dimensions)	Length: 102.0 mm Width: 43.0 mm Height: 23.85 mm with Silicone Button
ECG Module Materials	Top and Bottom Case: ABS Button: Silicone Light Guide: Polycarbonate
Patient Lead Wire Length	2736.0 mm
Patient Lead Wire Leads	Impala system ECG cable with 5 electrode (RA, V1/V2, V4, LA, LL)
Patient Lead Wire Materials	Jacket and Strain Reliefs: Thermoplastic Polyurethane Snaps: Brass RoHS3 with Nickel Plating Electrode Labels: Polyethylene Terephthalate with reverse screen printing
Snap to Tab Adaptors	5x adaptors are included, enabling the Patient Lead Wire to connect with tab electrodes.
Carrying Case Material	Polypropylene
Electrode Labeling	Abbreviations and colors to comply with either IEC or AAMI standards
Electrode Compatibility	Compatible with a wide range of tab and snap electrodes, including but not limited to the following: - 3M™ Red Dot™ Resting EKG Electrode 2360 Radiolucent - 3M™ Red Dot™ ECG Monitoring Electrodes, 2570-5, Radiolucent, Foam, Diaphoretic, with Abrader - 3M™ Red Dot™ Monitoring Electrode, 2560-5 - Kendall™ 5400 Diagnostic Tab Electrodes - Kendall™ 530 Series Foam Electrodes
Operating Conditions	Temp: -10°C to +40°C Humidity: 0% to 95% (non-condensing) Pressure: 54 kPA to 101kPa

Storage Conditions	-18°C to +55°C 0% to 95% (non-condensing)
Power Requirements	2x AAA Alkaline Batteries (1.5V) - Replaceable
Device Lifetime	5 Years
Connectivity	Bluetooth 5.1
Wireless Range	10m
Input Channels	Simultaneous acquisition of 4 ECG channels (8 standard leads)
Input Dynamic range	+/- 400mV
ADC	24bit, 192kHz/channel
Data Resolution	22bits, 1uV LSB
Measured Leads	8 standard leads I, II, III, aVR, aVL, aVF, V1, V4 or I, II, III, aVR, aVL, aVF, V2, V4
Performance Specifications	
Acquisition Sampling Rate	750Hz/channel for recording and analysis
Frequency Response	DC to 150Hz
Defibrillator Protection	ECG Module and Patient Lead Wire are isolated from system and operator
Leads Off Indicator	The status of the connection is displayed on the recording screen of the Impala App. When a connection is established, the leads will turn green. Conversely, if there is no contact, the leads will appear gray.
Permanent Filters	Digital 3 stage 5th order SINC filter
Common Mode Rejection	100dB
Battery Life	3 years shelf life
Algorithmic Determinations	Corvair - Determinations Algorithm

Physician's Guide

Introduction

Impala is a portable 12-Lead resting electrocardiograph (ECG) device that acquires 4 ECG leads from a patient, and using software generates the remaining leads to create a 12-lead ECG recording. The device can be used by healthcare professionals (HCPs) to record a diagnostic resting ECG, where traditional 10 electrode 12 lead ECG recorders are not practical due to cost, size, time, or need for specialized clinicians to administer. Examples may include physician offices, "minute clinics", and remote and field locations, including use by first responders.

Figure 3: Impala hardware

The Impala hardware consists of the Impala ECG Module that connects to the Patient Lead Wire. The Patient Lead Wire is a single cable that includes five snap-on electrodes. These hardware elements are further discussed below. Impala also consists of a mobile software application, the Impala App that executes on a mobile computing platform (MCP), such as an Apple® iPhone® smartphone. To use Impala, a compatible smartphone or tablet is required along with the Impala app. You can view the list of compatible devices at www.alivecor.com/compatibility. To record an ECG, the user positions standard off-the-shelf (OTS) ECG gel electrodes on the patient and snaps the connectors in the Patient Lead Wire onto the electrodes.

Impala allows for two options for which set of reduced leads are acquired:

1. Lead Set 1: Leads {I, II, V2, and V4}, with electrodes on RA, LA, LL, V2, V4; and
2. Lead Set 2: Leads {I, II, V1, and V4} with electrodes on RA, LA, LL, V1, and V4.

All leads are acquired using standard diagnostic ECG electrode positions, i.e., with RA on the right arm, LA on the left arm, LL on the left leg, V1 precordial lead on the 4th intercostal space (ICS), right margin of the sternum, V2 precordial lead on the 4th ICS left margin of the sternum, V4 precordial lead on the 5th ICS at the midclavicular line.

The Lead Set option is selected by the HCP in the Impala App. During a recording, the Electronics Module simultaneously acquires a 10-second ECG for the Lead Set selected by the user and transmits the recorded ECG to the Impala App. Using Leads I and II provided in the input, Impala computes Leads III, aVL, aVR, and aVF using standard math for such lead computation. The remaining precordial leads are synthesized using an AliveCor proprietary lead synthesis algorithm. The complete 12-lead ECG is then displayed to the user.

The Impala App also integrates a 12-lead ECG analysis software called Corvair to provide rhythm and morphology determinations, and interval measurements. Corvair is intended for use by HCPs to analyze a diagnostic-bandwidth ECG and only requires 4 ECG leads for analysis, specifically, either Leads {I, II, V2, and V4}, or Leads {I, II, V1, and V4}.

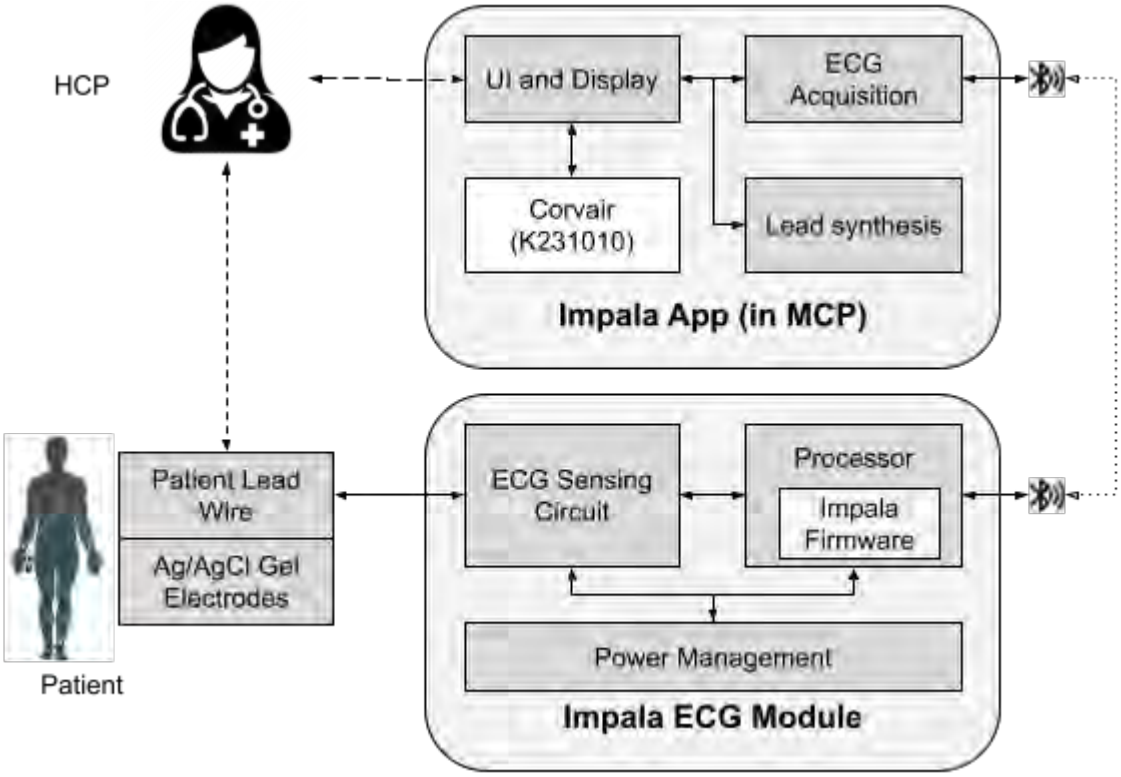


Figure 4: Impala functional block diagram

Impala is intended to record, store, and transfer a reduced 12-lead diagnostic resting electrocardiogram (ECG). The device acquires four leads (Leads I, II, V2, V4, or Leads I, II, V1, V4), derives Lead-III and Augmented Limb leads aVR, aVF and aVL, and synthesizes Leads V1,V3, V5, V6 or V2, V3, V5, V6. It is suitable for use with patients aged 18 years and older.

This device is intended for use by healthcare professionals, or trained personnel in various clinical settings, including hospitals, clinics, and emergency medical services, particularly in scenarios

where traditional 12 Lead ECG machines may not be accessible or practical. Impala is a prescription use device that must be used under the guidance of a physician. Be sure to ensure that the ECG and any analysis results are reviewed by a cardiologist or other expert ECG clinician.

Using the Impala ECG Device

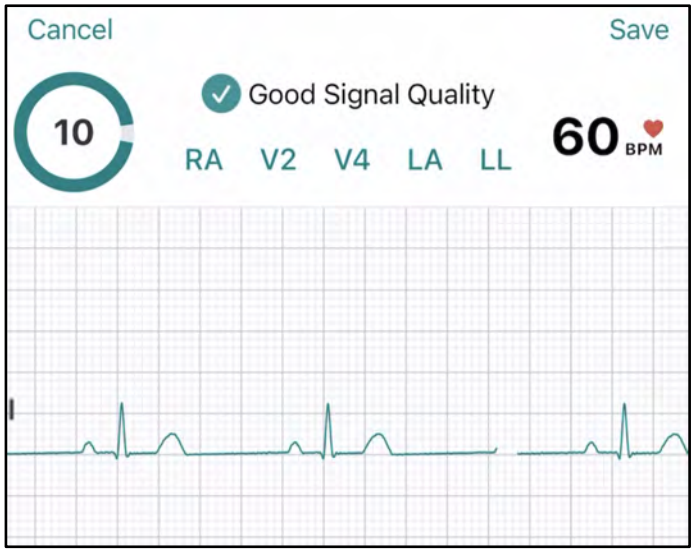
To start using your Impala ECG device, unpack the hardware and download the associated Impala App on your compatible iOS device. Once installed, enable Bluetooth to connect your device to the Impala hardware and launch the application.

When ready to record an ECG, connect the ECG module to the patient lead wire and ensure the patient is suitably prepared with exposed skin at the ankles, chest, and arms below the elbows. After cleansing these areas, place the gel electrodes at specific locations depending on whether you are using default Lead set 1 (V2, V4, RA, LA, and LL) or alternate Lead set 2 (V1, V4, RA, LA, and LL).

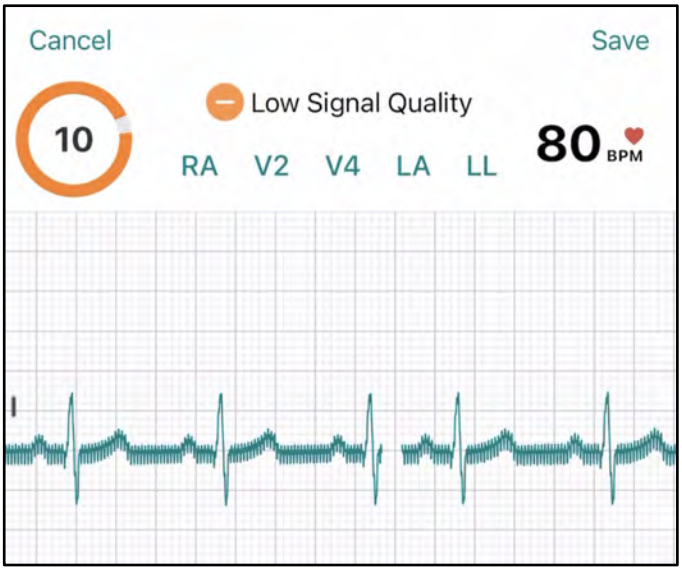
Once the electrodes are placed and connected, activate the Impala ECG module and begin recording by selecting the "Record" button on the Impala App. A minimum of 10 seconds of data is required for a complete recording,

During the live recording, pay attention to the ECG signal quality ring. This ring is your guide to understanding the quality of the ECG signal being captured. A low-quality signal typically results from noise interference, which could impact the accuracy of the ECG recording.

- **Green** Ring signifies a good quality signal. This indicates that all 10 seconds of the current ECG recording are of high-quality.



- **Yellow** Ring signifies a low-quality signal. If even one second of the last 10 seconds of ECG recording had a low-quality signal due to noise interference, the ring would stay yellow.



Once you have a recording of at least 10 seconds, you can select the 'Save' button on the app to conclude the process. While it is recommended that you save when the entire 10 seconds have good signal quality, the software does not restrict you from saving a 10 second ECG even if the signal quality is low.

Remove the connectors and electrodes from the patient once the recording is completed. The device will automatically switch off after use. Please be sure to clean and disinfect the device after every use.

For a more detailed step-by-step guide on using the Impala ECG device, please refer to the instructions provided in the Sections above within this document.

Configuration of Standard and Reduced ECG Lead Sets

The standard 12-lead ECG employs 10 electrodes, with four limb leads and six chest or precordial leads. Eight leads acquire signals directly (I, II, and V1-V6), and four are computed from leads I and II in the following manner:

III = II – I
aVR = -(I + II) / 2
aVL = I – II/2
aVF = II – I/2

An artificial reference signal, called the Wilson Central Terminal (WCT), is created to produce the reference unipolar signals for all six chest leads. These chest leads are initially measured directly

as a vector using their corresponding chest electrode and the reference electrode of RA. Subsequently, WCT is subtracted to yield the final chest leads V1 through V6.

For many years, researchers have investigated reduced ECG lead sets as an alternative to standard 12-lead ECGs. These studies aim to simplify the 12-lead ECG acquisition process while maintaining diagnostic performance equivalent to the original 12-lead ECG. These reduced lead sets can generally be classified into two types:

- The first uses a subset of the 12-lead ECG, such as the set comprising leads (I, II, V1, V5), as studied by Drew et al. (2002), or the set composed of leads (I, II, V2, V5) as examined by Nelwan et al. (2004).
- The second employs non-standard electrode positions, which typically results in a total of four chest leads and one reference lead, as proposed by Dower et al. (1988).

Impala ECG Device's approach to Reduced Lead Set

Inspired by these previous studies, our team chose to employ a subset of the standard 12-lead ECG in the Impala ECG device. More specifically, we retained the same limb leads I, II, and added two additional precordial leads (V leads). To determine the best precordial leads to use, we sought answers to the following question:

Which two precordial leads produce the least error between synthesized leads (the remaining four V leads) and measured leads?
In response to the question, AliveCor's internal research team performed an analysis of various combinations of acquired precordial leads to synthesize the remaining precordial leads (Table 1). This research showed the combination of recorded V1/V4 and V2/V4 leads show the best correlation of synthesis of the remaining precordial leads to their respective recorded leads. .

Table 1: Research analyzing the impact of using different lead combinations to synthesize precordial leads

Acquired leads used for synthesis	**Cross-correlation of the synthesized leads to the same acquired lead**						
	V1	**V2**	**V3**	**V4**	**V5**	**V6**	**Mean**
I, II, V2	0.93	1	0.89	0.82	0.84	0.87	0.89
I, II, V3	0.87	0.89	1	0.90	0.86	0.87	0.90
I, II, V4	0.76	0.65	0.82	1	0.93	0.87	0.84
I, II, V5	0.66	0.36	0.47	0.87	1	0.94	0.72
I, II, V1, V5	1	0.90	0.82	0.92	1	0.95	0.93
I, II, V2, V5	0.93	1	0.91	0.93	1	0.95	0.95
I, II, V2, V4	0.94	1	0.95	1	0.94	0.89	0.95

I, II, V1, V4	1	0.91	0.91	1	0.94	0.88	0.94

The analysis revealed that the combinations of V2, V5, and V2, V4 showed the highest mean correlation, scoring 0.95, indicating a very good match between synthesized and measured leads. The combination of V1, V4 also demonstrated a high correlation, with a mean score of 0.94. Notably, the combination of I, II, V2, V4 was found to be particularly effective in detecting abnormal ECG morphology, especially in the anterior location, one of the most clinically significant sites. The lead V1 is also the best lead for detecting P waves.

Taking these results into account, the Impala system offers the option to use two lead sets. Lead Set 1 consists of I, II, V1, and V4, while Lead Set 2 comprises I, II, V2, and V4. The precordial leads V1, V2, and V4 have clear landmarks that are relatively easier to identify than leads V3, V5, and V6. Thus, the use of these specific lead sets not only provides a reliable measure of ECG signals in the reduced lead set approach, but also makes the Impala ECG device highly efficient and adept at capturing a broad range of heart signal information.

Using Synthesized Leads on the ECG Report

Synthesized leads serve an essential function in terms of aiding physicians in viewing ECGs in the familiar standard resting ECG format (Figure 5). This conventional format is an integral part of most clinical professional's toolset, encapsulating vital patient demographics, ECG measurements, ECG interpretations, and the standard 12-lead ECG signal plots.

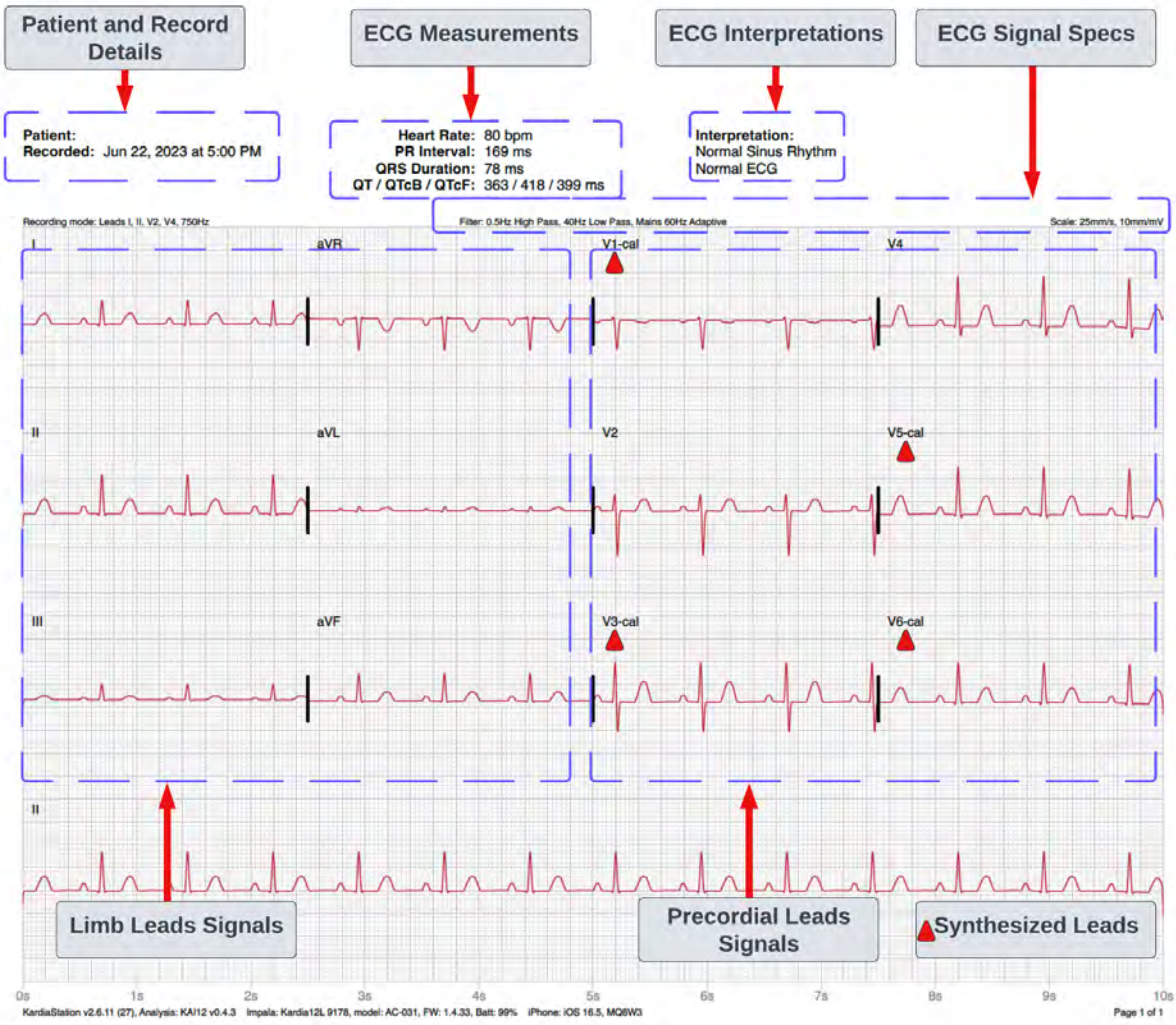


Figure 5. A reduced 12-lead Resting ECG report from Impala. For ease of identification in the figure above, red triangles mark the leads that are synthesized.

In Figure 5, which illustrates a reduced 12-lead resting ECG report, the precordial leads marked by red triangles are synthesized from other measured leads. The actual measured leads include all limb leads and two precordial leads, namely V2 and V4.

The process of synthesizing leads can be generally represented by the following formula:

V_lead_synthesized = Function (Weight, Leads_measured) (1)

Here, 'V_lead_synthesized' signifies the synthesized lead signals, 'Leads_measured' are the measured leads, 'Weights' are the coefficients, and 'Function()' represents the mathematical relationship that derives the synthesized leads from the Weights and Measured leads.

Although this function can be non-linear, a linear function is preferred for its simplicity and usability. During the linear model's training, an effort is made to minimize any form of error between the measured and synthesized leads.

While synthesized leads may differ slightly from the actual measured leads, they still prove to be invaluable for physicians when checking the ECG. This is particularly so given that synthesized leads exhibit a correlation of over 85% with the corresponding measured leads.

Choosing Between Leadset 1 [I, II, V1, V4] and Leadset 2 [I, II, V2, V4]

In the context of reduced lead ECG interpretation, we focus on two primary leadsets: Leadset 1 and Leadset 2.

Leadset 1 includes limb leads I, II, and precordial leads V1 and V4. Lead V1, positioned in the fourth intercostal space to the right of the sternum, delivers detailed insights into the right atrium and right ventricle. This lead is particularly valuable for its capacity to detect P waves, making it excellent for diagnosing possible arrhythmias (J. Lee et al., 2018). Lead V4, situated in the fifth intercostal space in line with the middle of the clavicle, provides pivotal data about the anterior wall of the left ventricle, often considered the best lead for detecting anterior ischemia and infarction.

In contrast, Leadset 2 consists of limb leads I, II, and precordial leads V2 and V4. Lead V2, located in the fourth intercostal space to the left of the sternum, provides valuable information about the septal region of the heart. This lead is particularly useful for diagnosing possible infarctions and ischemias, as it's often considered the best lead for detecting both septal and anterior ischemia and infarction (L. Wang et al., 2017). The inclusion of lead V4 in this set, similar to Leadset 1, ensures comprehensive coverage of the anterior wall of the heart, and some information for laterval location due to its closeness to v5, the lateral lead.

Both leadsets, through Impala's patient lead wires and electrode combination, utilize a minimum lead set to provide maximum information on the heart's inferior (lead II, III, aVF), anterior (V2, V4), and frontal plane’s lateral wall (lead I, aVL) activities. The selection of the precordial lead set combination V1/V4 or V2/V4 is facilitated by the same patient lead wire, with the electrode placement on the patient's chest being the only variable. This feature provides the clinician with an easy option to perform both a Lead Set 1 and a Lead Set 2 recording relatively quickly to get an enhanced evaluation of the patient’s heart activity in the anterior and septal regions.

Thus, the decision between Leadset 1 and Leadset 2 should be guided by specific diagnostic needs, the patient's specific conditions, and the healthcare setting. In summary, lead set [I, II, v1, v4] is optimized for certain arrhythmia determinations, like atrial flutter, while lead set [I, II, v2, v4]

is optimized for morphology determinations. By offering these two leadsets, Impala empowers healthcare professionals to make more informed diagnostic decisions.

References:
J. Lee, G. McManus, et al. (2018). "The Right Ventricular Leads: Importance in Electrocardiography". Journal of Electrocardiology.
L. Wang, H. Zhang, et al. (2017). "Septal and Anterior Wall Ischemia on Electrocardiography". Cardiology Journal.

Integration of Corvair within Impala and Reference Guide

Corvair, a Software as a Medical Device (SaMD), is designed to be used by healthcare professionals for the analysis of diagnostic-bandwidth Electrocardiograms (ECGs). Corvair has been seamlessly integrated into Impala to enhance our ability to provide high-quality, reliable ECG analysis.

The Corvair software interfaces with Impala, contributing its comprehensive analysis capabilities to our existing technology. With this integration, Impala is capable of capturing and analyzing a 10-second ECG, offering robust rhythm, morphological analysis, and ECG interval estimation.

Corvair requires only four ECG leads for analysis - either leads {I, II, V2, V4} or leads {I, II, V1, V4}, i.e. the same leads directly acquired by Impala. Despite this, it provides a full suite of rhythm, morphological, and interval determinations, tailored to meet varying clinical requirements. With Corvair's two operational modes, High Sensitivity and High Specificity, Impala can optimize for either sensitivity or positive predictive value (PPV), according to the needs of the specific clinical situation.

For more comprehensive information on how Corvair works within Impala, and to understand the full potential of this integration, we will be providing a detailed Corvair Physician's Guide. This guide will be available on a dedicated URL, which will be updated once Corvair receives regulatory clearance. The guide, serving as an annex to this document, will offer an in-depth look at Corvair's features and instructions for use including warnings, making it an invaluable resource for healthcare professionals seeking to make the most out of the Impala system.

[Placeholder for Corvair Physician's Guide URL]