HeartBeam AIMIGo Clinician Portal

User Manual

Document Revision 8

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Warnings/Cautions/Definitions

The terms **WARNING, CAUTION**, and **NOTE** are used throughout this manual to point out hazards, and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance.

⚠ **WARNING:** *indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.*

CAUTION: *indicates a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.*

NOTE: *provides application tips or other useful information to assure that you get the most from your equipment.*

Additional safety messages that provide appropriate safe operation information may be found throughout this manual.

Warnings

- ⚠ **WARNING:** The synthesized 12-L ECG output is contraindicated for the assessment of any urgent, serious, or life-threatening conditions or arrhythmias. The synthesized 12-L ECG output is solely intended for manual assessment of normal sinus rhythm and the following non-life-threatening arrhythmias: sinus arrhythmia, sinus tachycardia, sinus bradycardia, atrial premature complexes, atrial fibrillation, and ventricular premature complex.
- ⚠ **WARNING:** The safety and effectiveness of the synthesized 12-L ECG output signal has been evaluated for assessment of non-life-threatening arrhythmias only. Other cardiac conditions have not been investigated.
- ⚠ **WARNING:** If deemed clinically necessary, a standard 12-L ECG should be obtained for confirmation and final clinical assessment.
- ⚠ **WARNING:** Patients should not complete Patient Onboarding if they are feeling unwell or are experiencing any cardiac related symptoms (such as heart palpitations, dizziness, light headedness, etc.).

Cautions

- The AIMIGo device is not intended for patients with tremors and/or those unable to place and maintain the device in the correct position for the duration of the recording
- Filters applied to ECG signals may impact the ECG signal morphology, including significant attenuation of low-level atrial activity (P-waves / Flutter-waves), which may result in inability to discriminate certain types of arrhythmias (e.g., Atrial Fibrillation/Atrial Flutter). The ECG report produced by HeartBeam AIMIGo is not intended for analysis of the T-wave or other morphological ECG evaluation.
- While the portal will time-out and close your session automatically after a period of inactivity, it is recommended to always remember to log out from AIMIGo portal after finishing your session, especially when using public or shared computers.
- If you suspect that your computer is compromised or encounter any suspicious activity while accessing the portal, promptly sign-out and notify your IT team.

Additional safety messages that provide appropriate safe operation information may be found throughout this manual.

Introduction

This User Manual describes the system requirements and instructions for using the cloud-based HeartBeam Clinician Online Portal and ECG Viewer (the “portal”). For information specific to the HeartBeam AIMIGo ECG device for patient use, please refer to the HeartBeam AIMIGo Patient User Manual (D-10001).

The HeartBeam AIMIGo Clinician Portal and ECG Viewer are intended for clinicians that prescribe the AIMIGo device for the purpose of recording and collecting ECGs on patients diagnosed with, or at-risk for, cardiac diseases.

Collectively, the HeartBeam AIMIGo Device, HeartBeam Application, and HeartBeam Clinician Portal comprise the HeartBeam AIMIGo System ("System").

HeartBeam AIMIGo System Indications for Use

The HeartBeam AIMIGo™ System is a portable, non-invasive recorder intended to record, store, and transfer a patient's 3-Lead (in three-directions) electrocardiogram (ECG) acquired from 5 electrodes. The device is intended to be used by adult patients in either a clinical setting or at home. The device does not conduct cardiac analysis and can be used with an ECG Viewer software system for manual interpretation of non-life-threatening arrhythmias by a physician or healthcare professional.

HeartBeam 12-Lead ECG Synthesis Software Indications for Use

The HeartBeam 12-L ECG Synthesis Software synthesizes a 12-L ECG from the HeartBeam 3-Leads (in three-directions) recording device, producing a visual 12-L ECG representation that is similar, but not identical, to the same leads of a standard diagnostic 12-L ECG.

The synthesized 12-L ECG output is solely intended for manual assessment of normal sinus rhythm and the following non-life-threatening arrhythmias: sinus arrhythmia, sinus tachycardia, sinus bradycardia, atrial premature complexes, atrial fibrillation, and ventricular premature complex. The synthesized 12-L ECG output is not intended for the assessment of any other arrhythmia or conditions (including but not limited to: other atrial arrhythmias, ventricular arrhythmias, hypertrophy, conduction disorders, myocardial infarction or ischemia, pacemaker functions, localization of arrhythmia foci, ECG wave abnormalities, and/or any other disorder). The software does not conduct cardiac analysis and is not intended to replace a standard 12-L ECG. The 12-L ECG Synthesis Software is intended for adult use only.

Abbreviations & Definitions

ECG	Electrocardiogram
HCP	Healthcare Provider/Professional
MFA	Multi-factor Authentication
URL	Uniform Resource Locator (“Link” used withing web browser)
AF, AFib	Atrial Fibrillation
IFU	Instructions For Use

AIMIGo ECG Recording Device	Portable, non-invasive recorder intended to record, store, and transfer a patient’s 3-Lead electrocardiogram (3-L ECG). The ECG Recorder communicates with the Patient Application to transfer the 3-Lead ECG recorded signal to the cloud-based AIMIGo 12-L ECG Synthesis Software. **See Patient User Manual for more detail.**
Standard 12-Lead ECG Machine	**EDAN SE-1515 DX-12** machine used to record a patient 12-Lead ECG using 10 electrodes applied to the body (“Traditional 12-Lead Machine”, “Standard ECG Machine”).
Patient Registration	The process of enrolling a patient into the HeartBeam AIMIGo System through the clinician portal. It includes adding patient information, assigning the AIMIGo Device, uploading their standard 12-Lead ECG, and completing AIMIGo Onboarding recordings.
Patient Re-Registration	The process of updating a patient enrollment on the clinician portal in response to an event that warrants a new PTM to be generated. It includes updating the patient weight, uploading a new standard 12-Lead ECG, and completing AIMIGo Onboarding recordings.
Patient Onboarding	Within Patient Registration, the Patient task of completing three AIMIGo recordings using their assigned AIMIGo Device.
AIMIGo 12-L ECG Synthesis Software	The cloud-based software algorithm designed to synthesize 12-Lead ECGs from the 3-L ECG signals collected from the AIMIGo ECG Recorder device. The algorithm is used to establish three types of outputs: (1) Personalized Transformation Matrix, (2) the Baseline Synthesized 12-Lead ECGs during an Onboarding ECG Recording Session, as well as (3) subsequent User Initiated Synthesized 12-Lead ECGs used for both (a) asymptomatic, routine monitoring recordings and (b) symptomatic recordings purposes.
Onboarding ECG Recording Session	The Onboarding ECG Recording Session consists of (A) capturing Reference AIMIGo 3-L ECG recordings using the AIMIGo ECG Recording device and (B) a Reference Standard 12-L ECG recording. The purpose of these recordings (A and B) is to collect the input signals required by the AIMIGo 12-L ECG Synthesis Software to generate the Personalized Transformation Matrix and establish a Baseline Synthesized 12-L ECG for each patient during onboarding.
Reference Standard 12-Lead ECG (“Standard 12-Lead ECG”)	This is the 12-Lead ECG (12-L ECG) output recorded from a Standard 12-Lead ECG machine. This standard 12-L ECG signal serves as an input to the AIMIGo 12-L ECG Synthesis Software.
Reference AIMIGo 3-Lead ECG	This is the 3-Lead ECG signal obtained with the AIMIGo ECG Recording device during the Patient Onboarding. This Reference 3-L ECG signal serves as an input to the AIMIGo 12-L ECG Synthesis Software. The recorded 3-L ECG is used by the AIMIGo 12-L ECG Synthesis Software, in conjunction with the Reference Standard 12-Lead ECG input, to generate the Personalized Transformation Matrix that is then used to establish a Baseline Synthesized 12-ECG during onboarding for each patient. **See Patient User Manual for more detail.**
Personalized Transformation Matrix (“PTM”)	This is an output of the AIMIGo 12-Lead ECG Synthesis Software. To create the PTM, the AIMIGo 12-Lead ECG Synthesis Software algorithm uses both a Reference Standard 12-Lead ECG signal and Reference AIMIGo 3-Lead ECG signal captured during Patient Onboarding. Once the matrix is generated during the Onboarding Session, the AIMIGo 12-Lead ECG Synthesis Software uses the

	Personalized Transformation Matrix to create a Baseline Synthesized 12-Lead ECG, and subsequent User Initiated Synthesized 12-Lead ECGs.
Baseline Synthesized 12-Lead ECG	This is an output of the AIMIGo 12-L ECG Synthesis Software created from the Reference Standard 12-Lead ECG input signal, Reference AIMIGo 3-Lead ECG input signal, and Personalized Transformation Matrix. The Baseline Synthesized 12-Lead ECG can be used as a comparator for future User Initiated Synthesized 12-Lead ECGs generated by the AIMIGo 12-L ECG Synthesis Software. **The Baseline 12-Lead ECGs are viewable in the ECG Viewer by selecting the '12 Leads' toggle.**
Assessment AIMIGo 3-Lead ECGs	This is the 3-L ECG signal obtained with the AIMIGo ECG Recording device during regular use (i.e., for either asymptomatic, routine monitoring recordings and symptomatic recordings). This 3-L ECG signal serves as an input to the AIMIGo 12-L ECG Synthesis Software. The AIMIGo 12-L ECG Synthesis Software applies the previously generated Personalized Transformation Matrix to the newly recorded Assessment 3-L ECG recording to create an Assessment synthesized 12-Lead ECG rendering. **The Assessment 3-Lead ECGs are viewable in the ECG Viewer by selecting the '3 Leads' toggle.**
Assessment Synthesized 12-Lead ECGs	This is an output of the AIMIGo 12-L ECG Synthesis Software that is generated for assessment (both for asymptomatic, routine monitoring recordings and symptomatic recordings purposes). The AIMIGo 12-L ECG Synthesis Software algorithm generates the Assessment synthesized 12-Lead ECGs by applying the Personalized Transformation Matrix that was established during onboarding, to a newly recorded Assessment AIMIGo 3-L ECG signal obtained from the AIMIGo ECG Recording device. The Assessment synthesized 12-Lead ECGs reflect a patient's current ECG status and can be compared to the Baseline Synthesized 12-Lead ECG for assessment of clinically relevant changes. **The Assessment 12-Lead ECGs are viewable in the ECG Viewer by selecting the '12 Leads' toggle.**
EMG Noise	Electromyographic (EMG) noise refers to unwanted interference generated by muscle activity that contaminates the ECG signal. This noise can obscure the underlying cardiac activity, making it challenging to accurately interpret the ECG recording. EMG noise typically manifests as high-frequency spikes or fluctuations in the ECG signal, often occurring during movements or muscle contractions. To mitigate the effects of EMG noise, HeartBeam has developed an enhanced filter referred to as the Iterative Regeneration Method (IRM), a novel method for efficient EMG-noise suppression. The main hypothesis behind the method is that the temporary removal of the dominant ECG components (QRS complexes and T waves) which enables the extraction of the noise with the minimum alteration to the signal. Essential characteristics of the IRM are the preservation of heartbeat morphology by retaining the low-frequency content and the preservation of inter-beat variation. The morphology preservation is particularly important in segments with small amplitude, such as the P wave crucial for diagnosis of atrio-ventricular blocks.
Baseline Wander	Baseline wander is a low-frequency noise that can distort the true signal, often caused by patient movement, respiration, or poor electrode contact. Cubic spline filtering is a mathematical technique used to correct baseline wander in electrocardiogram (ECG) signals and other physiological recordings. This approach is the foundation of the HeartBeam approach to baseline wander removal.
60Hz Filter	The 60Hz notch filter is designed to specifically target and attenuate the 60Hz frequency component from a signal. Lighting and power lines can introduce 60Hz noise into the AIMIGo device and subsequently the recordings. By applying a 60Hz notch filter, this interference can be reduced, improving the quality and clarity of the recorded signal.

System Requirements

Use a PC or Mac with a reliable internet connection (recommend stable 5Mb download and 5Mb upload speed) and an operating system that supports one of the following JavaScript enabled browsers:

- Google Chrome, Version 108+
- Microsoft Edge, Version 117 +
- Firefox, Version 108+

NOTE: The HeartBeam Clinician Online Portal ensures that the browser from which it is accessed uses TLS 1.3 or higher and will reject connecting with an unsupported protocol version or a browser which is untrusted.

Cybersecurity Guidance, Recommendations, and Information

Ensuring the utmost security and integrity of patient data is our highest concern. To contribute to the safeguarding of both patient information and the overall integrity of AIMIGo portal, we recommend that all clinicians and users adhere to robust cybersecurity practices on their computer.

Password Best Practices

Protecting your account starts with a robust password. The integrity and confidentiality of patient data are of utmost importance, and a strong password is the first line of defense against unauthorized access. Always follow your organizations recommendations and consider the below best practices when selecting and managing your password:

- Never reveal your passwords to others, don't write your password down
- Use different passwords for different accounts
- Longer passwords are better, use 16 characters when possible
- Make passwords complex, include upper-case and lower-case letters, numbers, and special characters
- Utilize multi-factor authentication (MFA) when offered by your organization

Essential Anti-Virus Requirements

- Use Reputable Anti-Virus Software: Ensure that your computer is equipped with anti-virus software from a trustworthy provider. Keep the software enabled and ensure that it is set to automatically update to defend against the latest threats.
- Conduct Regular Scans: Execute comprehensive scans of your computer periodically to identify and neutralize any potential threats.
- Keep Your System Updated: Always ensure that your operating system, browsers, and software are up to date to benefit from the latest security patches and updates.
- Enable Firewall: Ensure that your computer's firewall is enabled to safeguard against unauthorized access.

Enable Firewall

- Ensure that your computer's firewall is enabled to safeguard against unauthorized access.

Keep Your System Updated

- Always ensure that your operating system, browsers, and software are up to date to benefit from the latest security patches and updates.

General Best Practices

- Be Wary of Emails: Be cautious with emails that appear suspicious, especially those that ask for personal information, or provide links and attachments. Even if they appear to come from known contacts or organizations, verify their authenticity.
- Avoid Public Wi-Fi for Accessing Patient Data: Refrain from accessing patient data when connected to public Wi-Fi networks. If it is imperative, use a Virtual Private Network (VPN) to secure your connection.

CAUTION: Log Out: While the portal will time-out and close your session automatically after a period of inactivity, it is recommended to always remember to log out from AIMIGo portal after finishing your session, especially when using public or shared computers.

- User Education: Ensure that everyone accessing the platform is educated on cybersecurity principles and the importance of safeguarding digital information.

Patient Data from the AIMIGo Device and Mobile Application

- Clinicians do not need to interact with the patient's mobile device.
- For any concerns or questions regarding the security of the patient's device, healthcare professionals can contact our technical support team for detailed information and assistance.

In Case of a Security Incident on your Computer

CAUTION: If you suspect that your computer is compromised or encounter any suspicious activity while accessing the portal, promptly:

- Follow your organization's protocol for cybersecurity incidents
- Change your password
- Inform the HeartBeam support team

NOTE: Remember that safeguarding against viruses and cyber threats is a collective effort. By adhering to these practices and requirements, we contribute to a more secure and reliable digital environment for all users of AIMIGo portal.

HeartBeam Detection Capabilities for Cybersecurity Events

The HeartBeam Infrastructure includes multiple detection mechanisms to identify potential cybersecurity threats. These mechanisms are designed to monitor for unauthorized access attempts, unusual data transmission patterns, and other indicators of possible security breaches. Specific detectable cybersecurity events include:

- Unauthorized login attempts to the HeartBeam Server Infrastructure
- Malware or virus detection within the HeartBeam Server Infrastructure
- Unusual data transfer activity within the HeartBeam Server Infrastructure
- System integrity breaches within the HeartBeam Server Infrastructure

NOTE: In the event of a detected cybersecurity threat within the HeartBeam Server Infrastructure users will be informed by e-mail or phone call. HeartBeam will provide details about the detected threat, steps taken to mitigate the threat, and additional actions required from the user (if applicable). Detailed remedial instructions will be provided in the event of a cybersecurity incident.

Troubleshooting Guide if the Clinician Online Portal is Unavailable

- Check the status of the internet connection being used to access the Clinician Portal and ensure it is connected to a stable, operational network.
- Ensuring the URL for the Clinician Online Portal is entered correctly (see Log-in to the Clinician Portal section for URL).
- If the above two steps do not result in successful access to the Clinician Online Portal, contact HeartBeam customer support.

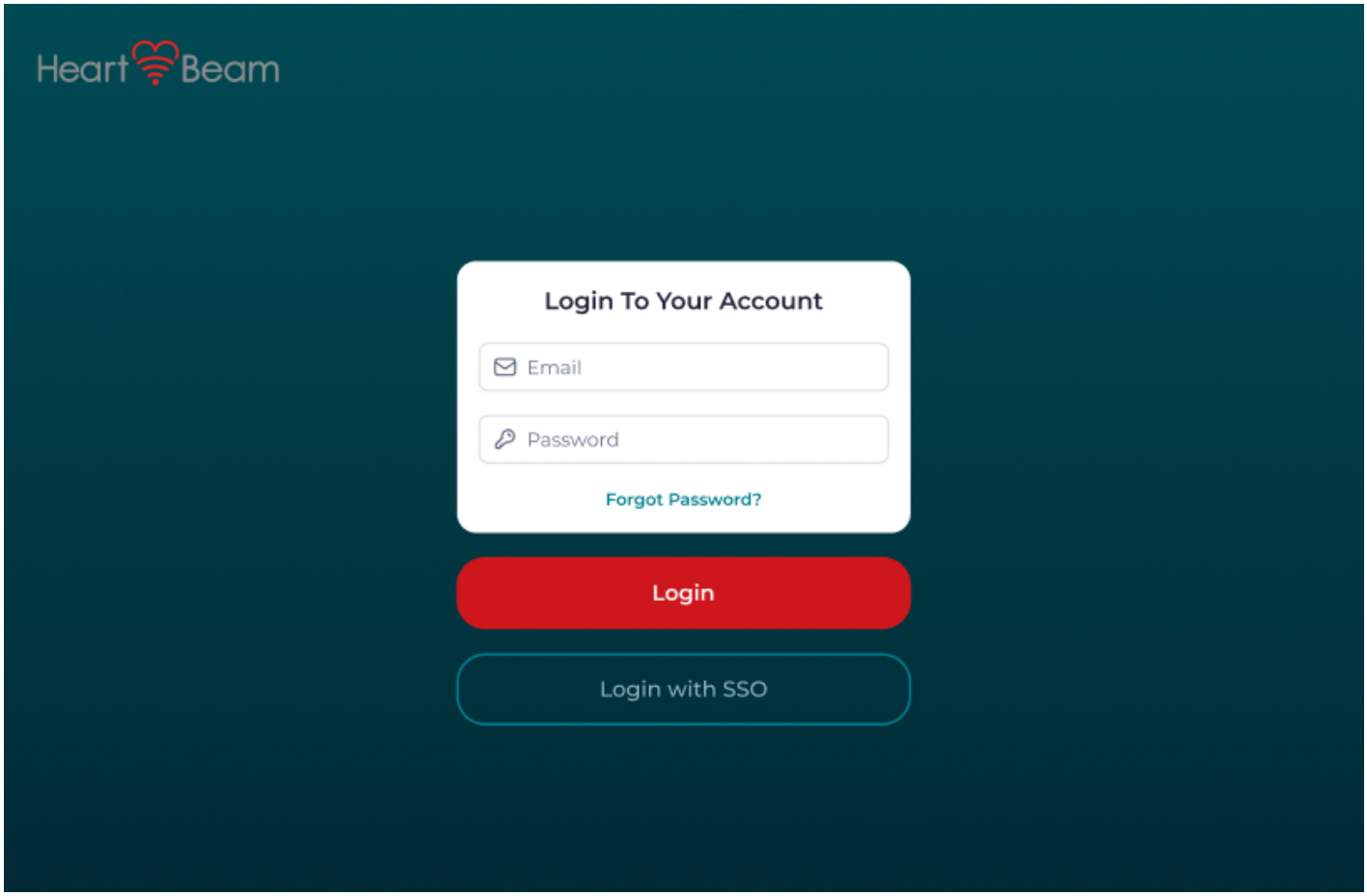
Accessing the AIMIGo Clinician Online Portal

Log-in to the Clinician Portal

From your web browser, navigate to the portal login page found here:

https://care.heartbeam.com

Enter your Username and Password then click **Login** to access the portal.

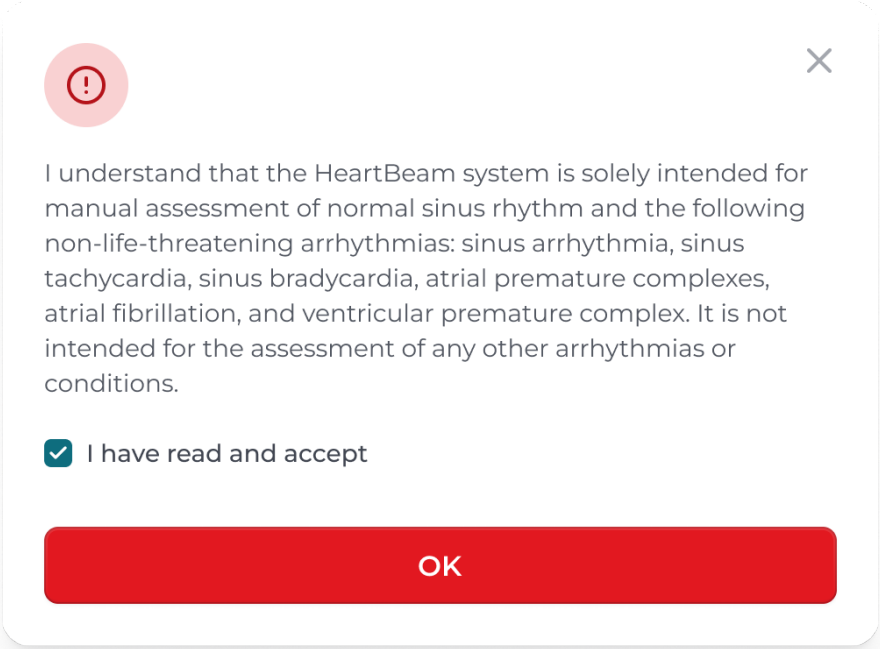


NOTE: You may login using Single-Sign On (SSO) if offered by your organization.

System Acknowledgement

CAUTION: Upon logging in to the portal as a first-time user you will be required to acknowledge you understand the below caution terms. Please check “I have read and accept” and click ‘OK’ to continue.

I understand that the synthesized 12-L ECG output is solely intended for manual assessment of normal sinus rhythm and the following non-life-threatening arrhythmias: sinus arrhythmia, sinus tachycardia, sinus bradycardia, atrial premature complexes, atrial fibrillation, and ventricular premature complex. It is not intended for the assessment of any other arrhythmias or conditions.



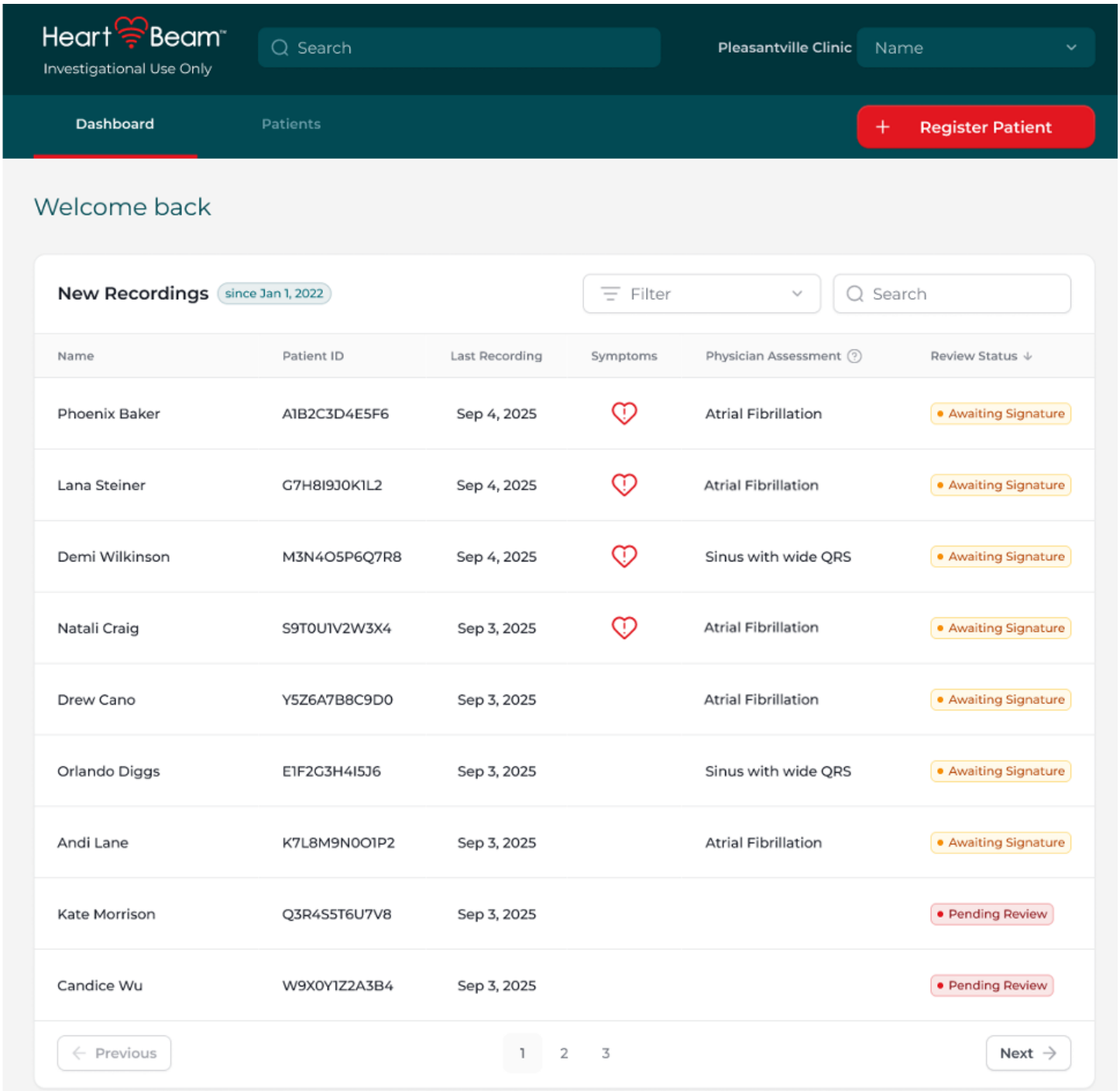
Recordings Dashboard – Review Patient Recordings

After successful login you will be directed to the Recordings Dashboard. The dashboard will show the list of your patients with recent recordings that are ready for review. You may scroll through your patients, filter columns, or search. Clicking on a patient row will open the Patient Record view of all available recordings.

Filter & Search Functions

- Filters: A clinician may use the Filter function to sort through recordings by Symptoms, Recording Date, and Review Status
- Search: A clinician may use Search to look for patient recordings by symptoms, name, and patient ID.

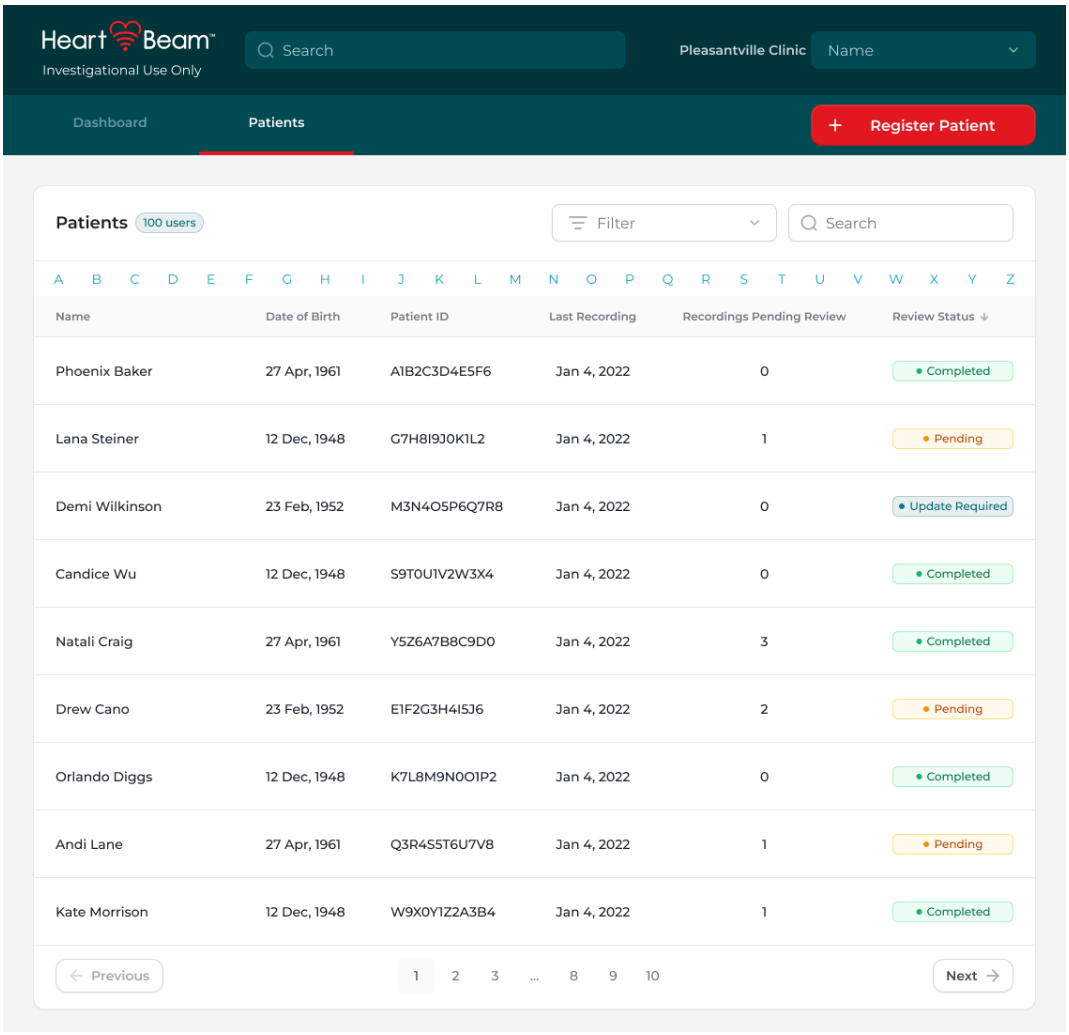
Recordings Dashboard - Columns	
Name	First Name Last Name
Patient ID	Registered Patient ID
Last Recording	Mon DD, YYYY of Most Recent Recording
Symptoms	A heart icon indicates that a user noted they experienced symptoms. Hover over the icon to view their symptoms.
Physician Assessment	Initial ECG review completed by the clinician
Review Status	Pending Review, Awaiting Signature, or Reviewed and Signed


HeartBeam
Investigational Use Only
Search
Pleasantville Clinic
Name
Dashboard
Patients
Register Patient
Welcome back
New Recordings
since Jan 1, 2022
Filter
Search
Name
Patient ID
Last Recording
Symptoms
Physician Assessment
Review Status
Phoenix Baker
A1B2C3D4E5F6
Sep 4, 2025
Atrial Fibrillation
Awaiting Signature
Lana Steiner
G7H8I9J0K1L2
Sep 4, 2025
Atrial Fibrillation
Awaiting Signature
Demi Wilkinson
M3N4O5P6Q7R8
Sep 4, 2025
Sinus with wide QRS
Awaiting Signature
Natali Craig
S9T0U1V2W3X4
Sep 3, 2025
Atrial Fibrillation
Awaiting Signature
Drew Cano
Y5Z6A7B8C9D0
Sep 3, 2025
Atrial Fibrillation
Awaiting Signature
Orlando Diggs
E1F2G3H4I5J6
Sep 3, 2025
Sinus with wide QRS
Awaiting Signature
Andi Lane
K7L8M9N0O1P2
Sep 3, 2025
Atrial Fibrillation
Awaiting Signature
Kate Morrison
Q3R4S5T6U7V8
Sep 3, 2025
Pending Review
Candice Wu
W9X0Y1Z2A3B4
Sep 3, 2025
Pending Review
Previous
1
2
3
Next

The Patients Dashboard – Listing of Your Patients

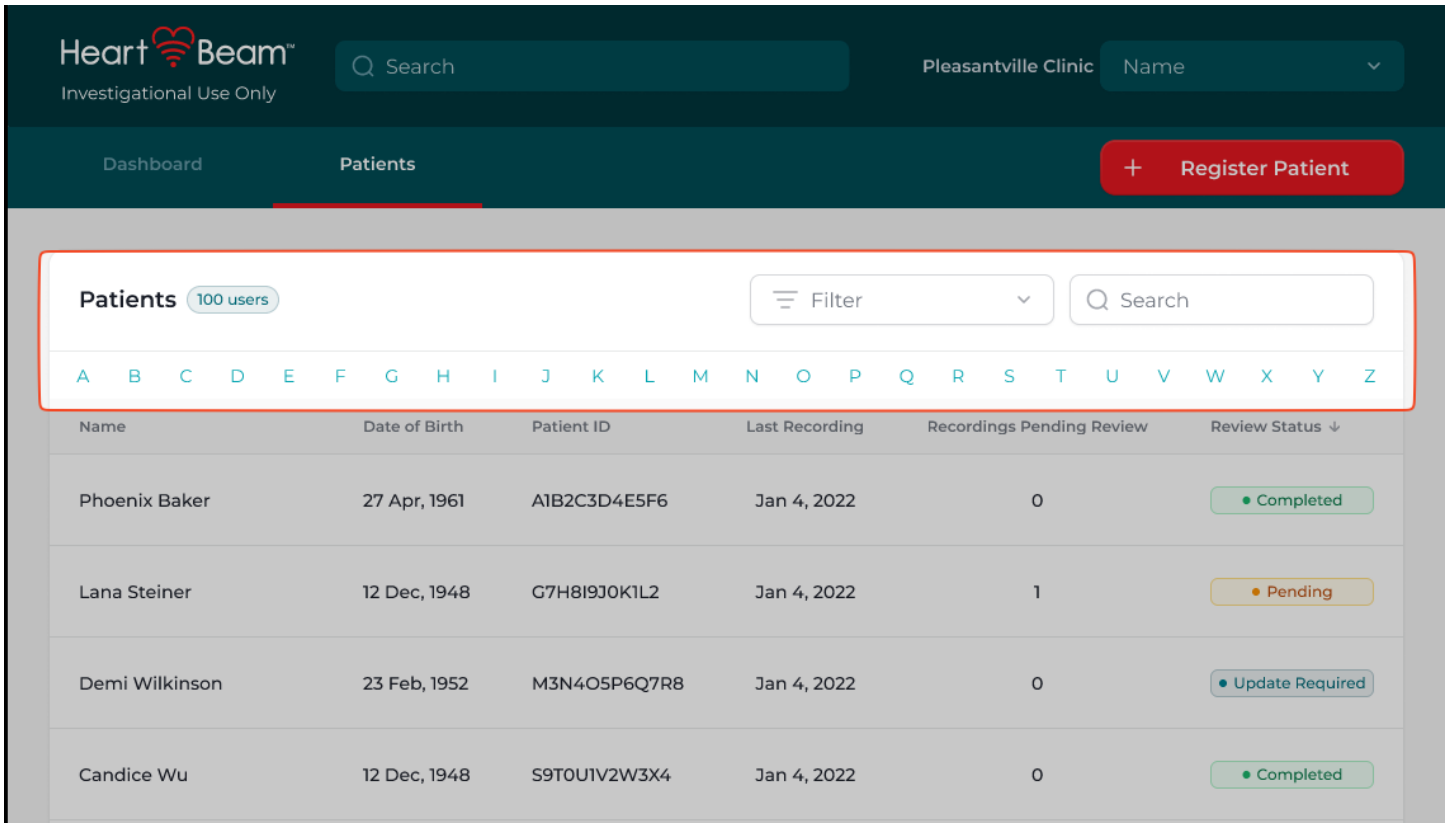
After successful login you will be directed to the Patient Dashboard. The dashboard will show the list of your patients. You may scroll through your patients, filter columns, or search. Clicking on a patient row will open the Patient Record view of all available recordings.

Clinician Dashboard View - Columns	
Name	Last Name, First Name
Date of Birth	DD Month, YYYY
Patient ID	Alphanumeric ID assigned by Clinic/Hospital
Last Recording	MM/DD/YYYY of Most Recent Recording
Recordings Pending Review	Count (#)
Patient Status	Onboarding Complete, Pending, or Update Required



Finding Patient Record

You may find a patient record by using the **Search tool**, Selecting the Letter associated with the patient's last name (e.g. S for Smith), or scrolling through the table.



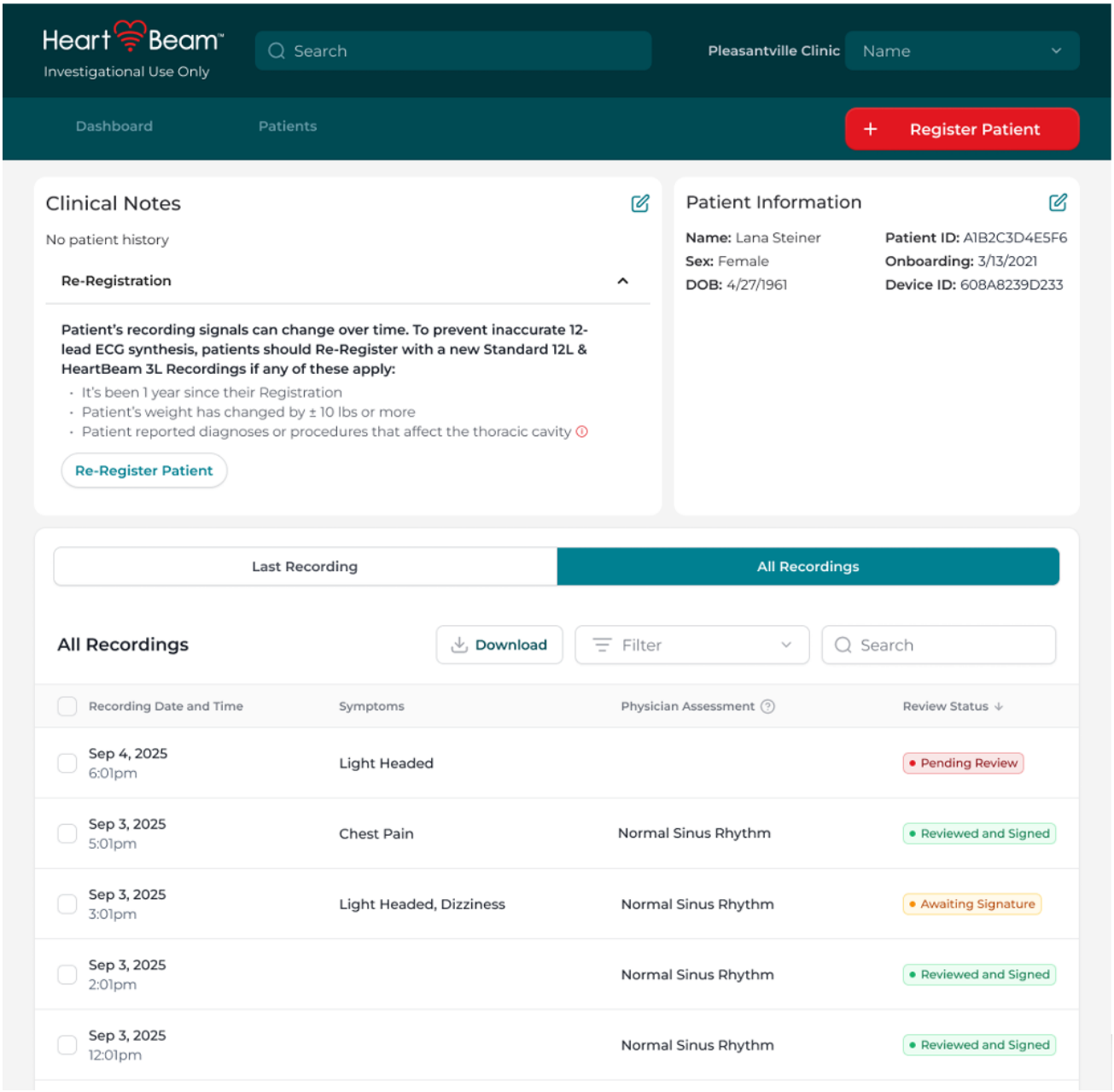
Patient Summary – Reviewing All Available Recordings

The **Patient Summary** includes a table listing of **All Assessment Recordings** for the patient, including their Assessment AIMIGo 3-Lead ECGs and their Assessment Synthesized 12-Lead ECGs.

NOTE: If a patient has not yet completed their onboarding the Onboarding Status will display as ***Pending***.

Patient Summary View - Columns	
Recording Date and Time	Timestamp of when the recording was completed using the AIMIGo Device
Symptoms	Patient logged symptoms associated with the recording
Physician Assessment	Clinician Assessment after review
Review Status	Clinician Review Status: Reviewed and Signed, Awaiting Signature, Pending Review

To view a recording simply click on the desired row. This will open the **ECG Viewer** window where you may toggle between the 3-Lead Assessment and 12-Lead Assessment recording view.



NOTE: You may click **Patients** tab to return to the Patient Dashboard and review the list of all your patients.

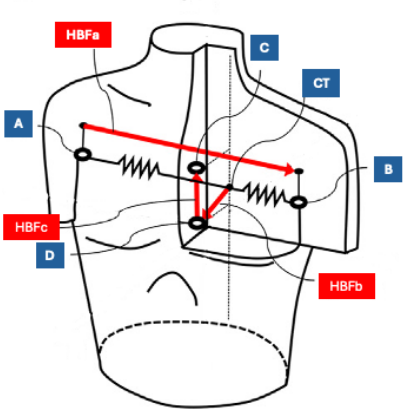
ECG Viewer – Leads & Device Electrodes

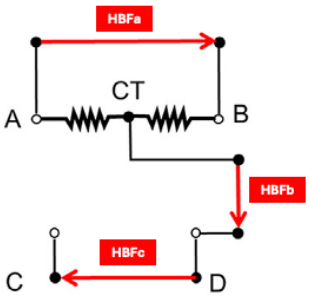
The system records cardiac electrical signals using three separate leads to capture the heart's electrical activity from three directions. Each lead gathers unique information, and together they provide a comprehensive overview of the heart.

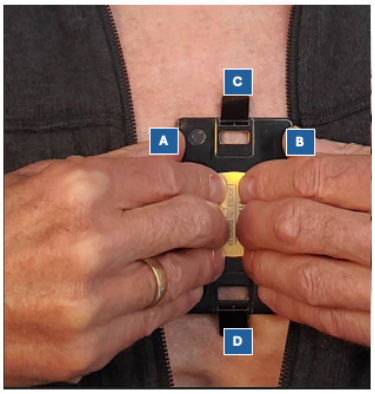
NOTE: While the three leads are representing different directions, these leads are not orthogonal between each other, are not collected according to "Frank" lead system, and do **not** represent a Vectorcardiograph.

Within the **ECG Viewer** 3-Lead window, three leads are presented: HBFa (“Lead a”), HBFb (“Lead b”), and HBFc (“Lead c”). These leads are based on electrodes that contact the Right (“A”) and Left (“B”) Thumbs and the Upper (“C”) and Lower (“D”) chest.

- HBFa / Lead a correlates with Standard Lead I (Right (“A”) to Left (“B”) Thumb Electrodes)
- HBFb / Lead b is a non-standard lead, front to back (Lower Chest electrode (“D”) to the approximate Central Terminal (CT) of the heart)
- HBFc / Lead c is a non-standard lead, head to toes (Upper (“C”) to Lower (“D”) Chest Electrodes)







ECG Viewer – Reviewing the 3-Lead ECG

The ECG Viewer displays the selected ECG Recording:

NOTE: The CRM Filter is applied to all recordings. The CRM filter includes methods to reduce Electromyographic (EMG) and Baseline Wander noise. These filters cannot be disabled by the user. For a description of these filters see Appendix A.

CAUTION: Filters applied may impact the ECG signal morphology, including significant attenuation of low-level atrial activity (P-waves / Flutter-waves), which may result in inability to discriminate certain types of arrhythmias (e.g., Atrial Fibrillation/Atrial Flutter). The ECG report produced by HeartBeam AIMIGo is not intended for analysis of the T-wave or other morphological ECG evaluation.

To return to the Patient Record view click **Go Back**.

ECG Viewer Functions

The **ECG Viewer** displays the ECG recording you have selected from the patients **Patient Record** window.

3-Lead ECG / 12-Lead ECG Toggle View (A)

The Assessment 3-Lead ECG ("3-Lead") is enabled by default. You may review the Assessment 12-Lead ECG ("12-Lead") by clicking the **12 Leads** button.

3-Lead and 12-Lead View – Skip Ahead (B)

Within the 3-Lead and 12-Lead View you may skip ahead to shift the strip ahead by 5 or 10 seconds. Click **Skip 5s** or **Skip 10s** as needed.

3-Lead View – Filtering (C)

Within the 3-Lead View you may toggle the 60Hz filter on or off. The 60Hz filter helps to remove powerline interference.

NOTE: the CRM Filter is enabled ON all recordings by default. The CRM filter includes methods to reduce Electromyographic (EMG) and Baseline Wander noise. These filters cannot be disabled by the user. For a description of these filters see Abbreviations & Definitions section.

Print Function (D)

Within either the 12-Lead or 3-Lead View you may click the **Print** button to generate a PDF copy of the current view.

(A) 3-Lead/12-Lead Toggle | **(B) Skip Ahead** | **(C) Filter** | **(D) Print to PDF**

ECG Viewer – Reviewing the Assessment 12-Lead ECG

⚠ **WARNING**: The synthesized 12-L ECG output is contraindicated for the assessment of any urgent, serious, or life-threatening conditions or arrhythmias. The synthesized 12-L ECG output is solely intended for manual assessment of normal sinus rhythm and the following non-life-threatening arrhythmias: sinus arrhythmia, sinus tachycardia, sinus bradycardia, atrial premature complexes, atrial fibrillation, and ventricular premature complex.

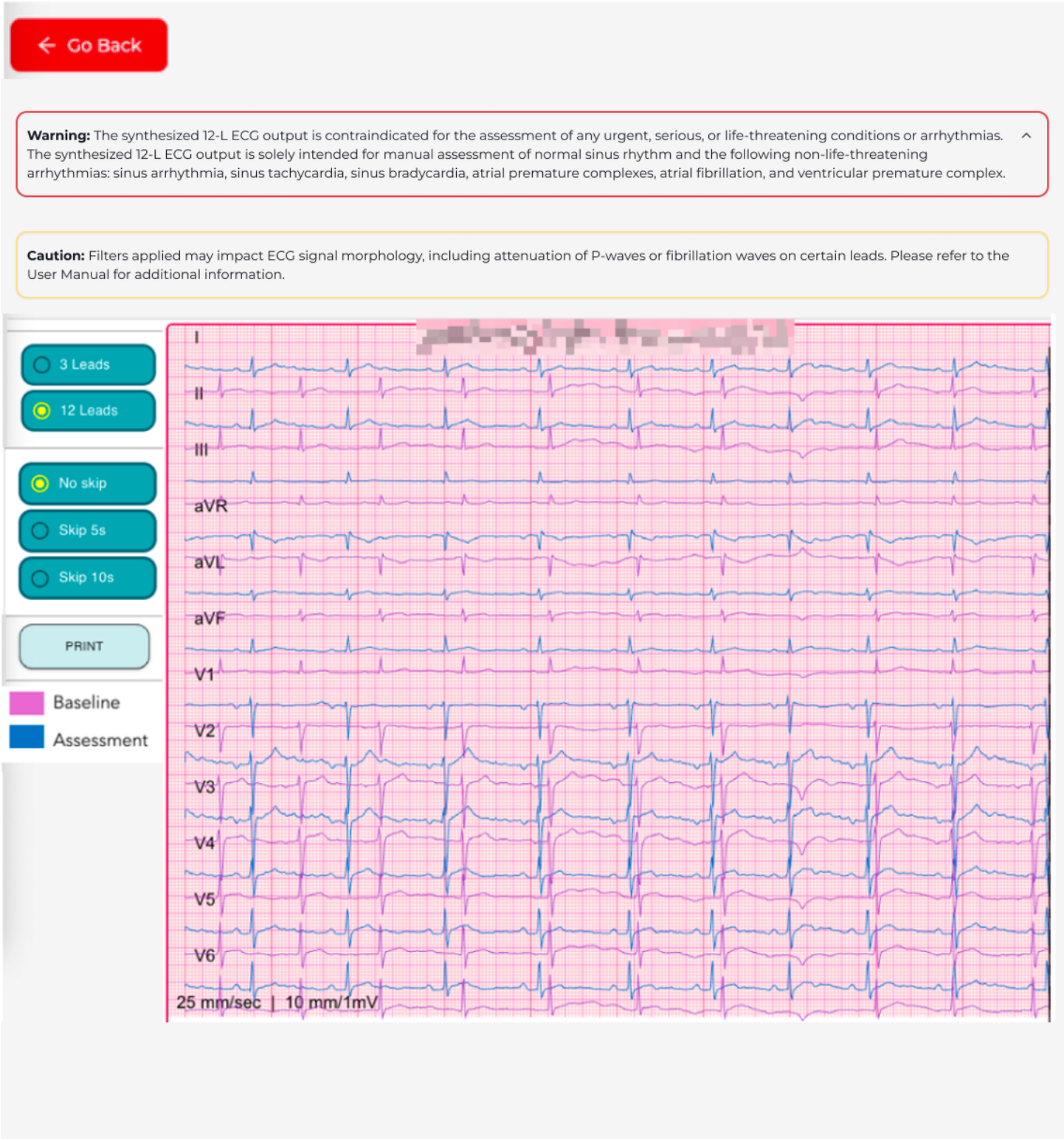
An Assessment 12-Lead ECG is an output of the AIMIGo 12-L ECG Synthesis Software that is generated for assessment (both for asymptomatic, routine monitoring recordings and symptomatic recordings purposes).

You may review the Assessment 12-Lead ECG ("12-Lead") by clicking the **12 Leads** button to toggle from the 3-Lead view. The Assessment synthesized 12-Lead ECG (presented in Blue) reflect a patient's current ECG status and is overlaid with the Baseline Synthesized 12-Lead ECG (Presented in Purple) for assessment of clinically relevant changes. For a full description of the recordings see Abbreviations & Definitions section.

NOTE: The CRM Filter is applied to all recordings. The CRM filter includes methods to reduce Electromyographic (EMG) and Baseline Wander noise. These filters cannot be disabled by the user. For a description of these filters see Appendix A.

CAUTION: Filters applied may impact the ECG signal morphology, including significant attenuation of low-level atrial activity (P-waves / Flutter-waves), which may result in inability to discriminate certain types of arrhythmias (e.g., Atrial Fibrillation). The ECG report produced by HeartBeam AIMIGo is not intended for analysis of the T-wave or other morphological ECG evaluation.

NOTE: The synthesized 12-Lead ECG (including PDF reports) is not intended to replace traditional methods of diagnosis or standard of care, and no clinical action should be taken solely based on the device output.



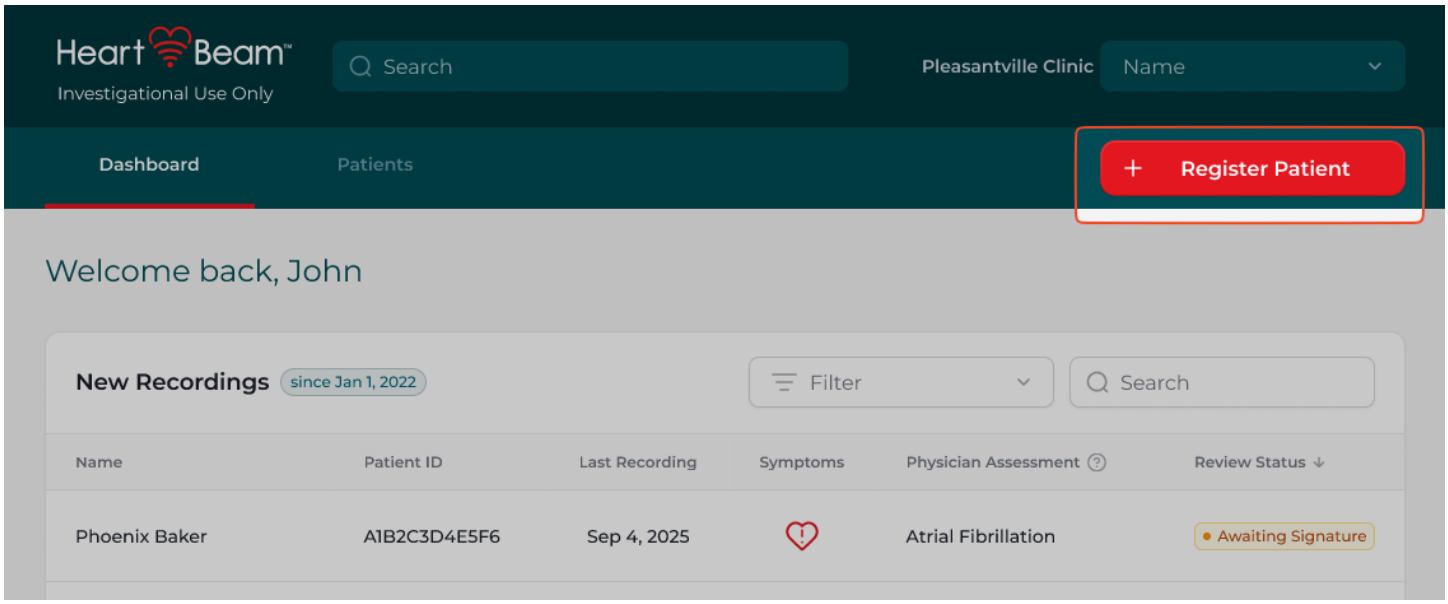
Click **Go Back** to return to the Patient Record view.

Patient Registration & Onboarding

After prescribing the HeartBeam AIMIGo device to your patient you must register them in the Clinician Portal, assign their device, and upload a Reference Standard 12-Lead ECG captured from the EDAN SE-1515 DX-12. The patient will complete the onboarding process on their mobile device.

Registering a New Patient

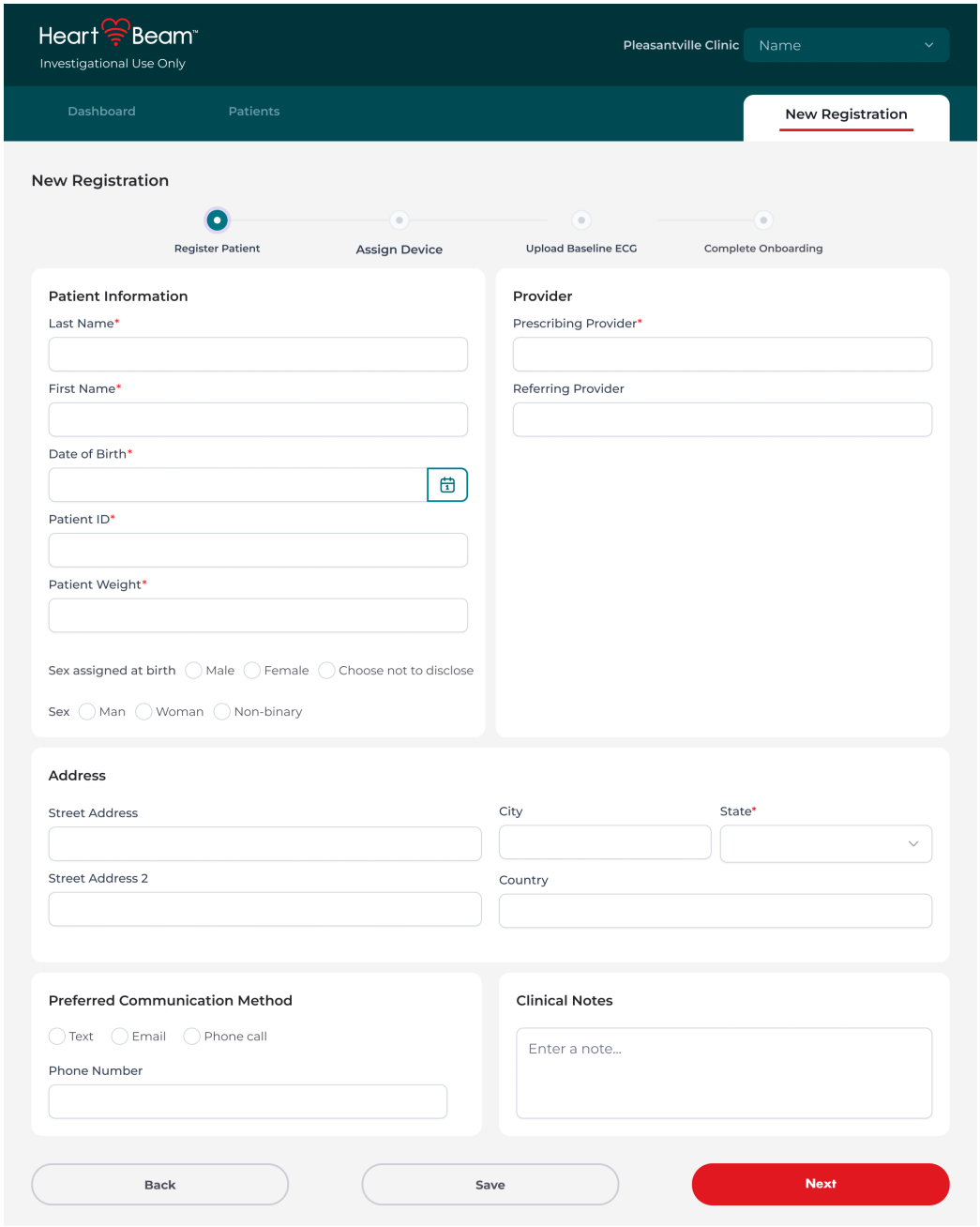
To begin a new patient registration, click **+ Register Patient** from the Patient Dashboard.



In the **New Registration** window on enter the Patient Information on the **Register Patient** page. Ensure that the Required fields are completed.

- Last Name
- First Name
- Date of Birth
- Patient ID
- Patient Weight
- Prescribing Physician

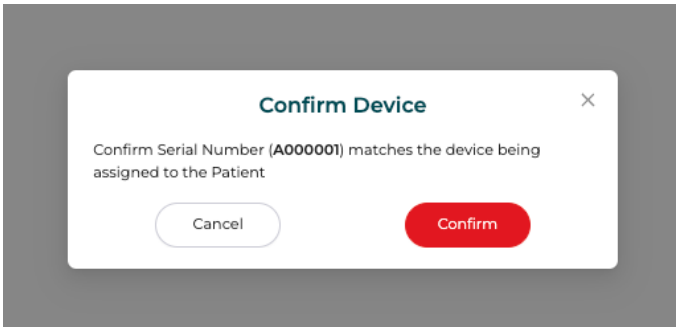
Other fields are optional, click **Next** to continue.



Assigning an AIMIGo Device

In the **Assign Device** page, enter the **Serial Number** (“SN”) from the HeartBeam AIMIGo device being provided to the patient. The Serial Number is found on the back of the device packaging as well as the AIMIGo device label (e.g. SN A000001). Click **Next** to continue.

Confirm the SN matches the device being registered and click **Confirm**.



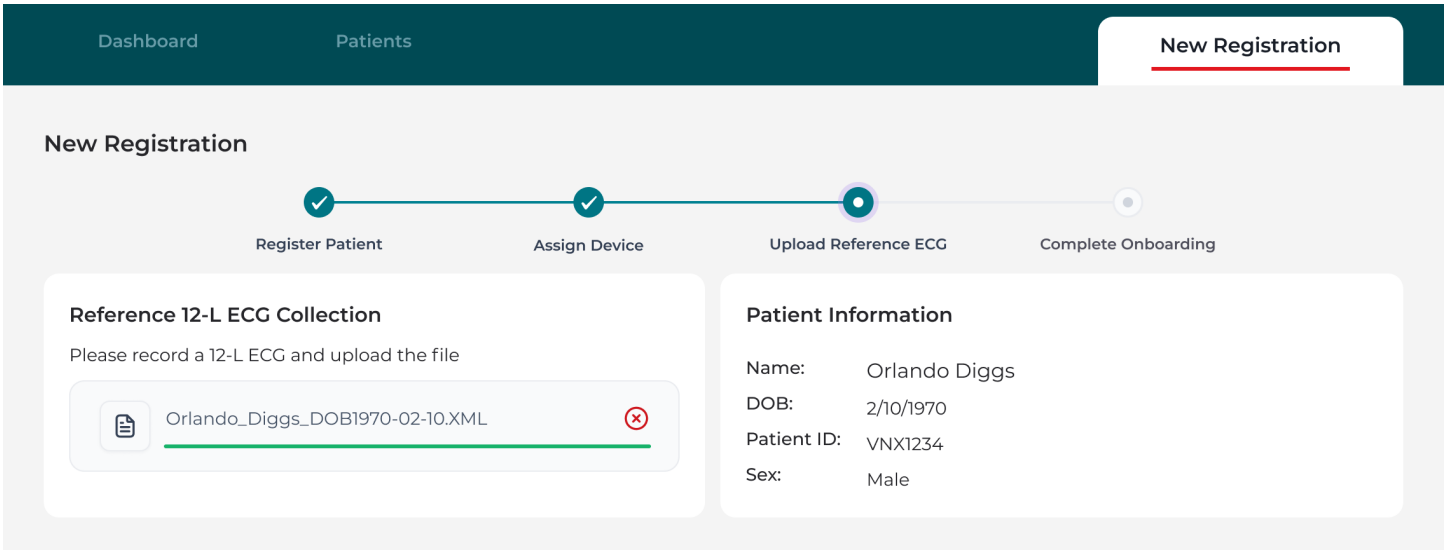
Uploading a Standard 12-Lead ECG

In the **Upload Standard ECG** page, you may drag and drop the 12-Lead .XML file from your computer file explorer window or click the **Click to Upload** link to open the file explorer and select the .XML file directly.

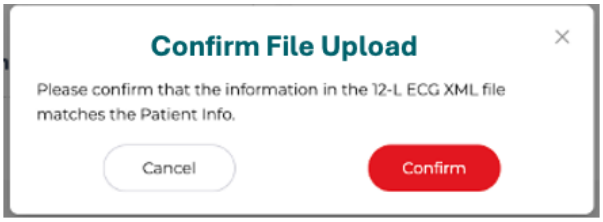
CAUTION: the 12-Lead Synthesis feature relies on the correct patient XML file being uploaded. When uploading, ensure that the XML file matches the Patient Information on the screen.

CAUTION: the 12-Lead Synthesis feature relies on a compatible file (in XML format) being uploaded from the EDAN SE-1515 DX-12. If the file is not accepted the system will generate an error message to try again. Contact HeartBeam Support for assistance in ensuring compatibility with the HeartBeam Portal and configuring your 12-Lead ECG machine.

Once the XML file has been uploaded the file name is displayed.



Click **Next** to continue, then confirm the XML file matches the Patient Information and click **Confirm**.



Review Patient Information & Mobile App Download

In the **Complete Onboarding** page enter the patient's mobile phone number and click 'Verify'. The patient will use their mobile phone number as part of their login credentials on their mobile app.

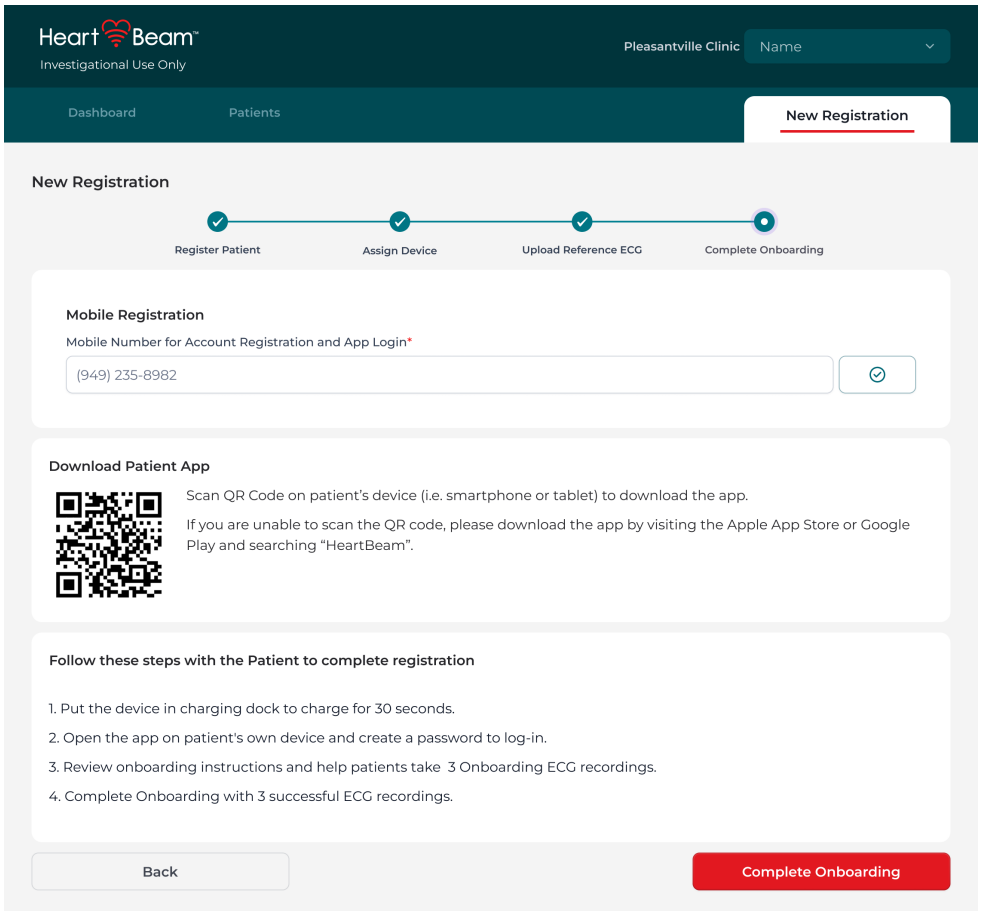
Below the Mobile Registration there is a QR code to download the HeartBeam AIMIGo Mobile Application from the Google Play Store (for Android users) or the Apple App Store (for iPhone users). The patient may scan the QR code using their mobile device camera to access the app for download. Alternatively, the patient may manually search the respective app store for the mobile application.

Review the Patient information for accuracy, then click **Complete Onboarding** to continue.

Patient Onboarding

The HeartBeam AIMIGo Mobile Application will guide the patient through the remainder of their onboarding process. This includes updating their login credentials, learning to charge the device, pair it to the mobile device via Bluetooth, and completing three AIMIGo 3-Lead ECG recordings. Click **Done** to close the registration window.

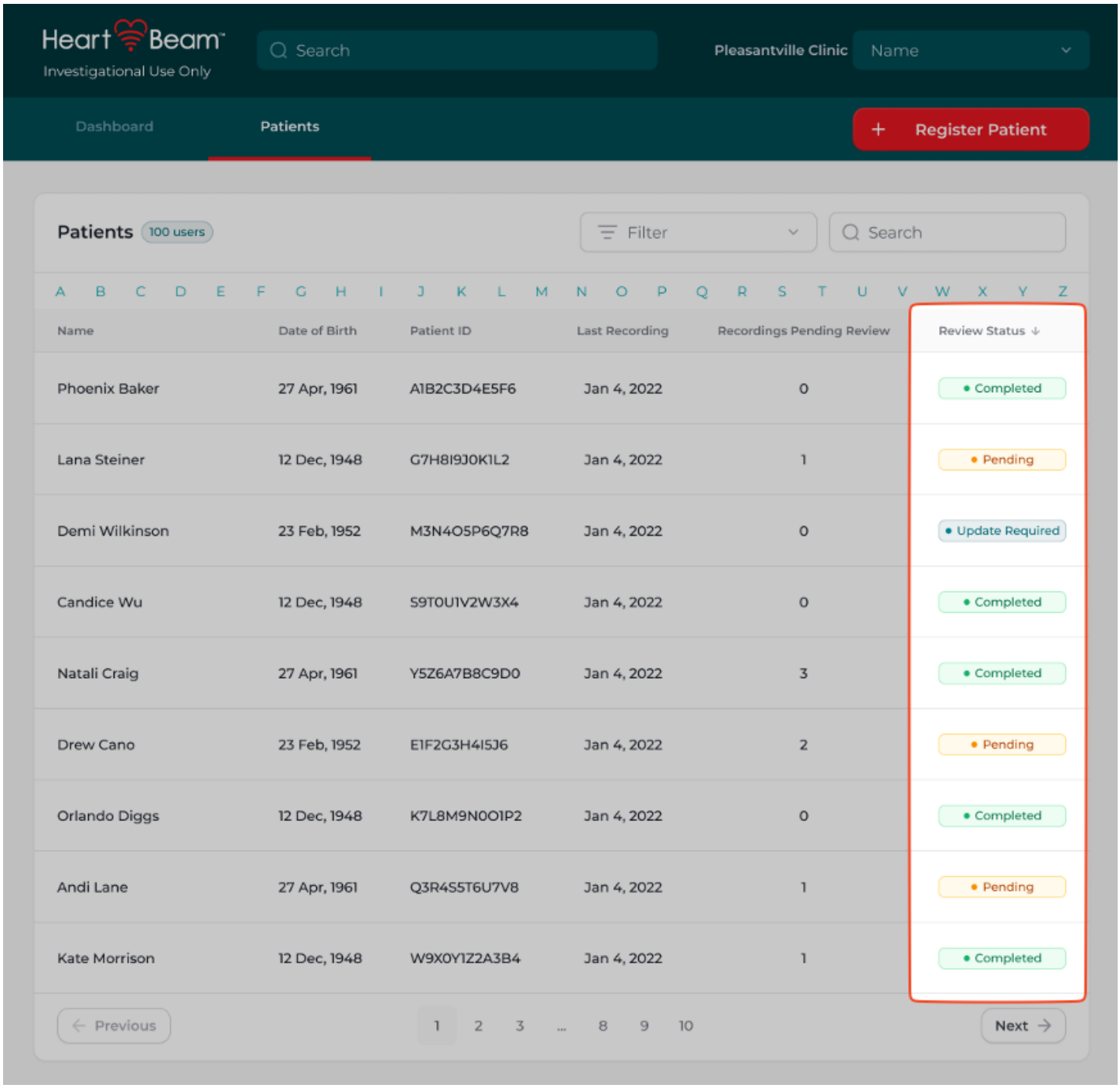
CAUTION: Patients should not complete Patient Onboarding if they are feeling unwell or are experiencing any cardiac related symptoms (such as heart palpitations, dizziness, light headedness, etc.).



Patient Onboarding Status

Once the patient has completed their onboarding steps their **Onboarding Status** will be updated on the Patient Dashboard from **Pending** to **Complete**. This status is also displayed in the Patient Record in Patient Information window.

NOTE: AIMIGo Assessment recordings are only available after the patient has completed onboarding.



When to initiate a Patient Re-Registration

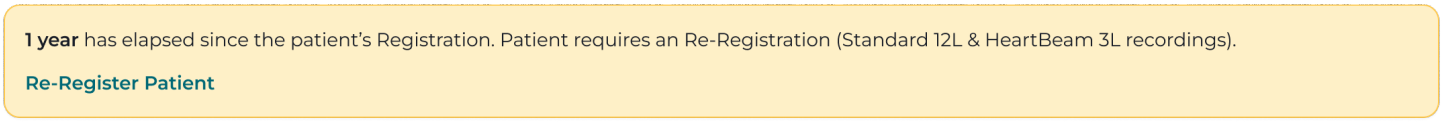
A patient's personalized transformation matrix (PTM) may require renewal over time or under certain circumstances that may affect the tissue composition in the thorax area. These changes may impact the electrical signal propagation from the AIMIGo device recordings, which are required for PTM generation (and subsequently, 12-Lead Synthesis). To renew the PTM you will follow the Patient Re-Registrations steps update the patient profile with new recordings.

A Patient Re-Registration may be required when the following has occurred:

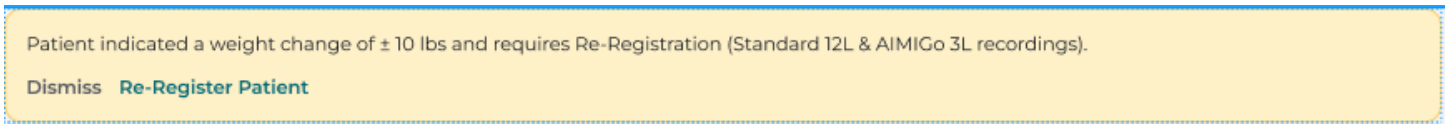
- A minimum of **1 year** has elapsed since the last Onboarding Recording Session.
- Your patient has experienced a weight change (gain or loss) of **at least 10 lbs**.
- Clinical circumstances that may impact tissue composition in the thoracic cavity have occurred:
    - Occurrence of changes in fluid or air in the lungs. This includes, but is not limited to the following:
        - Pulmonary Edema
        - Chronic Obstructive Pulmonary Disease (COPD)
        - Emphysema
        - Atelectasis
        - Pleural Effusion
        - Pneumothorax
        - Hemothorax
        - Tumors or Masses in the Thoracic Cavity

PTM Notifications & Reminders

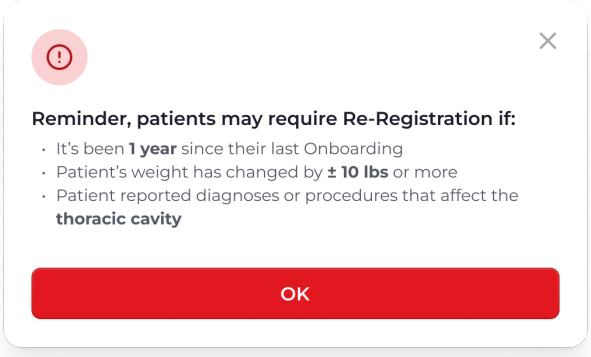
The Portal will display the below notification when **1 year** has elapsed since their onboarding/last PTM update:



The Portal will display the below notification when the patient has logged a weight change (**at least 10 lbs**) from the Patient Application:



Note: The Portal will provide periodic reminders to proactively review your patient medical records for these occurrences. Care should be taken to periodically review patient medical records for any changes that may warrant a new PTM appointment:



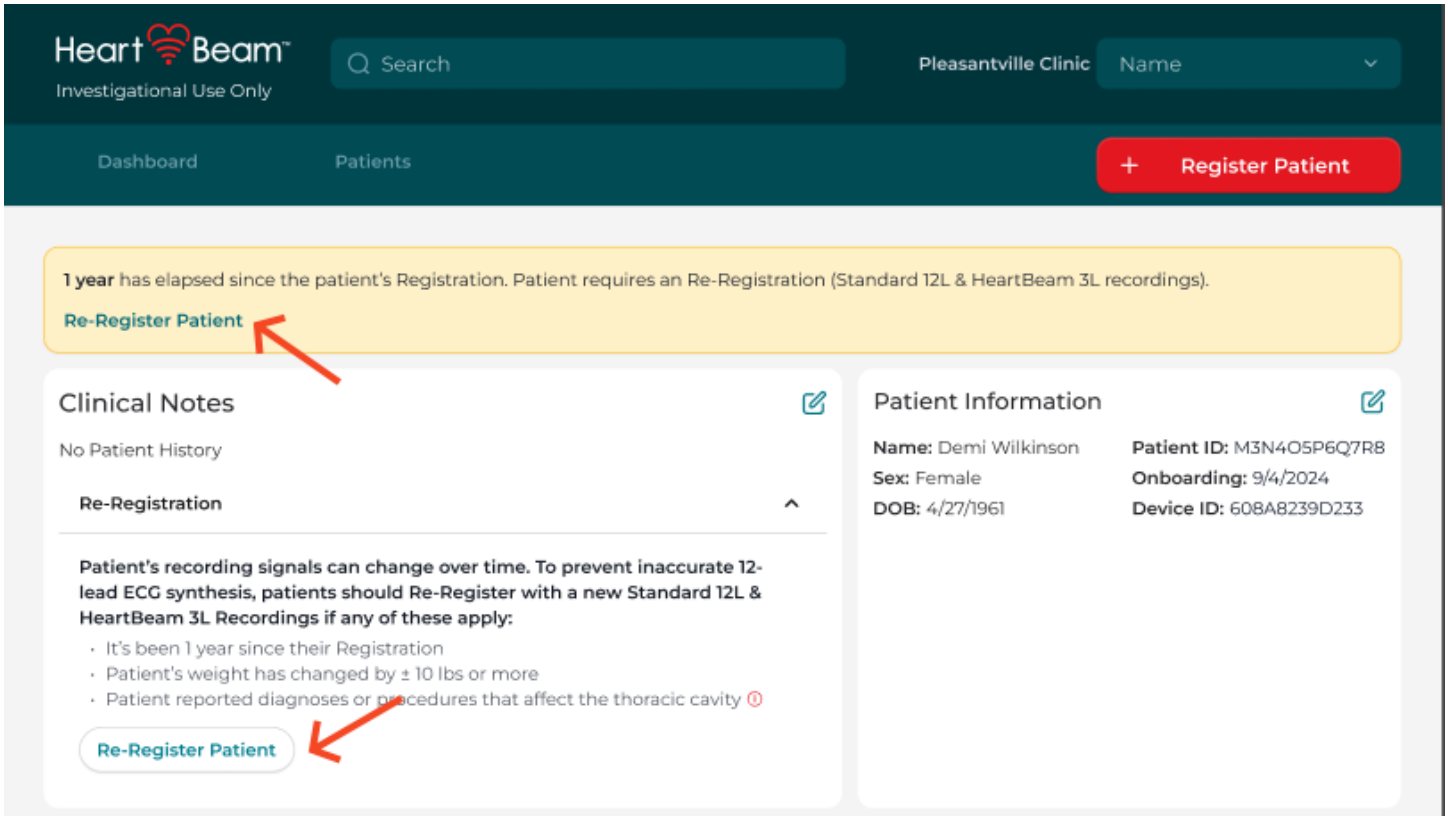
How to Perform a Patient Re-Registration

Once you have determined that a Patient Re-Registration is necessary, initiate the Re-Registration process then schedule an appointment with the patient in a timely manner.

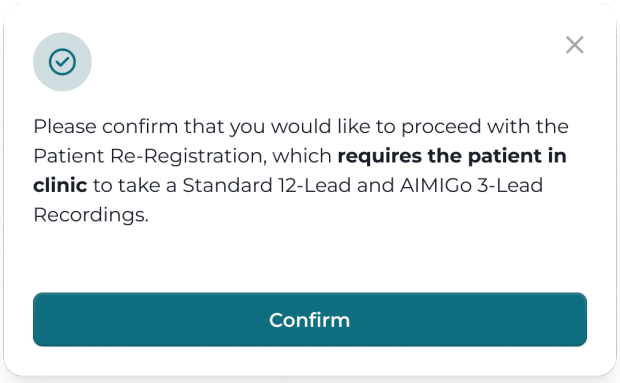
Note: It is important to initiate the process in a timely manner to ensure the PTM remains as accurate as possible.

Initiate the Patient Re-Registration Process

To initiate the Patient Re-Registration process, you may either select '**Re-Register Patient**' in the notification bar (if available, in the case of weight change or annual update) or select '**Re-Register Patient**' under the Clinical Notes window.



Confirm that you would like to initiate the Patient Re-Registration by clicking '**Confirm**' in the pop-up window:



Completing the Patient Re-Registration Process (3-Steps)

1. *Update Patient Weight*

First, enter the Patient weight within the Patient Information Window.

2. *Upload new Standard 12-Lead ECG*

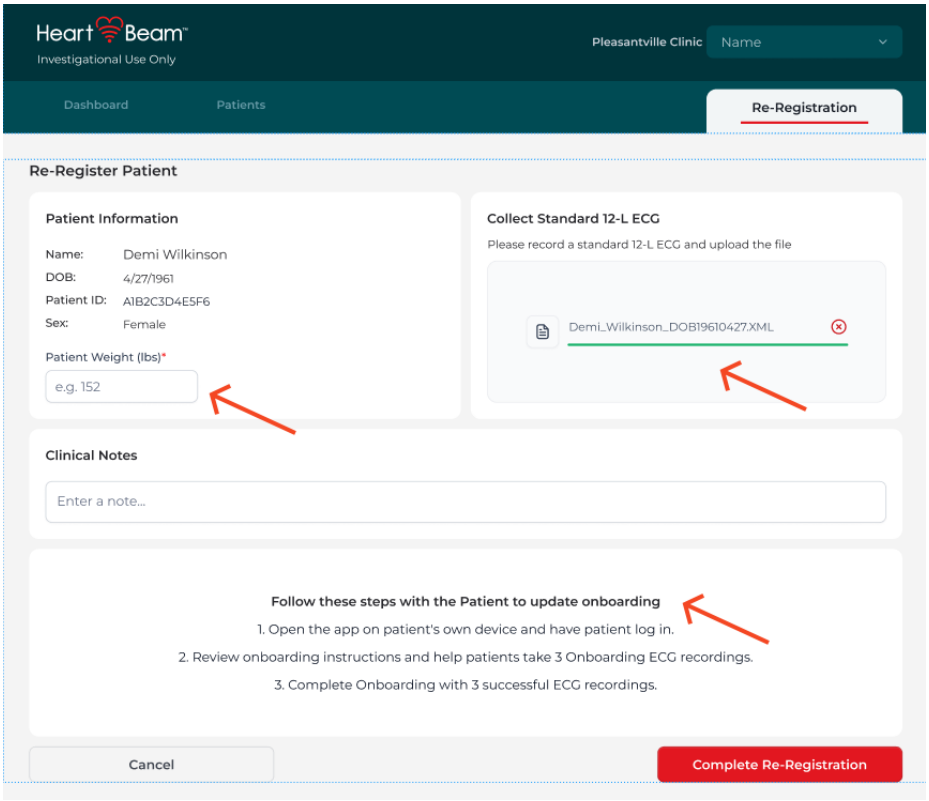
Collect a new standard 12-Lead ECG recording from the EDAN SE-1515 DX-12, saved as an XML file. You may drag and drop the Standard 12-Lead ECG .XML file from your computer file explorer window or click the '**Click to upload'** link to open the file explorer and select the .XML file directly.

CAUTION: the 12-Lead Synthesis feature relies on the correct patient XML file being uploaded. When uploading, ensure that the XML file matches the Patient Information on the screen.

CAUTION: the 12-Lead Synthesis feature relies on a compatible file (in XML format) being uploaded from the EDAN SE-1515 DX-12. If the file is not accepted the system will generate an error message to try again. Contact HeartBeam Support for assistance configuring your 12-Lead ECG machine to export compatible files.

3. *Complete new AIMIGo 3-Lead Onboarding Recordings*

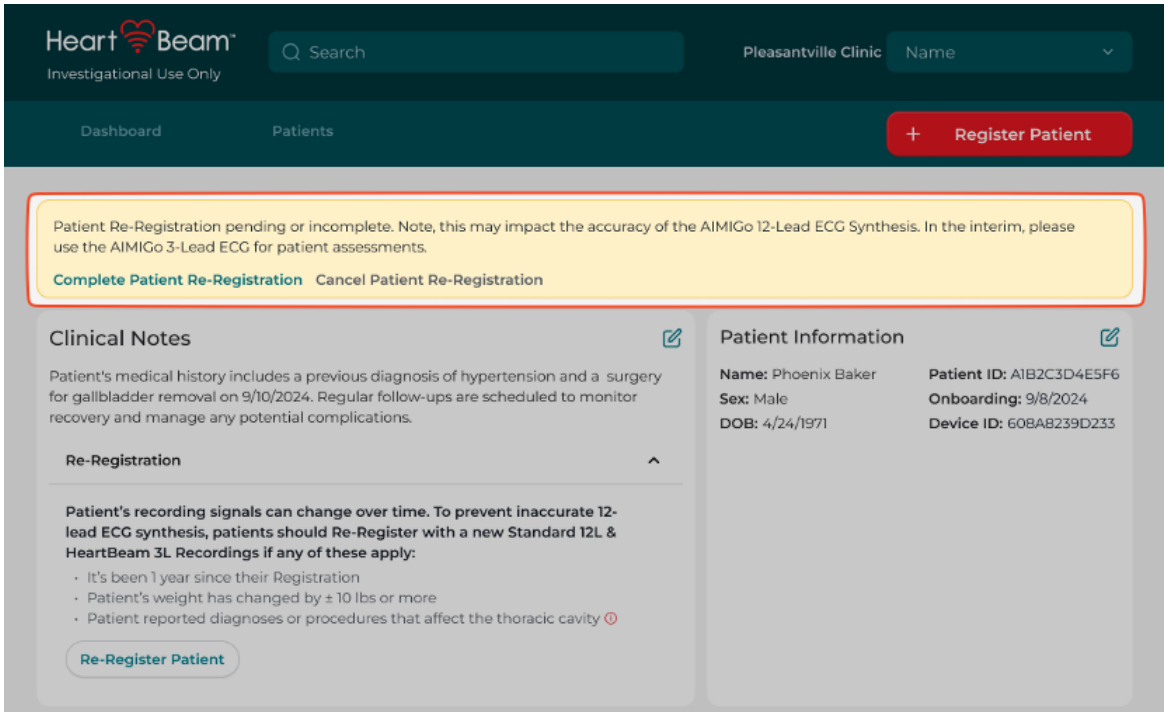
Assist Patient in completing three AIMIGo 3-Lead recordings using the Patient Application and AIMIGo device. [See D-10001 HeartBeam AIMIGo Patient User Manual for more information.]



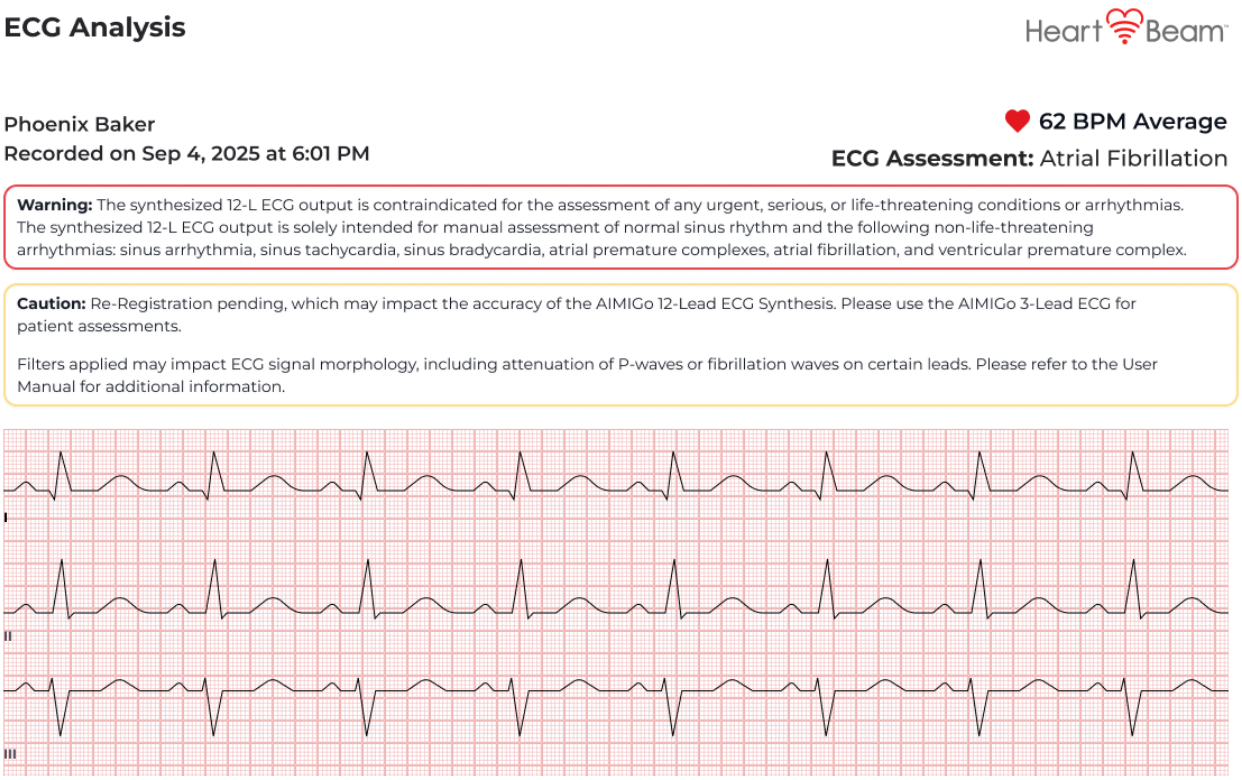
The '**Complete Re-Registration**' button will highlight red once the patient has completed their new AIMIGo recordings. Click to complete the process.

Patient Assessment Recordings Uploaded before the Re-Registration is Complete

While the timely scheduling of a patient appointment to complete the Re-Registration is encouraged, the patient may still upload AIMIGo Assessment recordings from home before the process has been completed in clinic. For these interim recordings the portal will caution that ***"Patient Re-Registration pending or incomplete. Note, this may impact the accuracy of the AIMIGo 12-Lead ECG Synthesis. In the interim, please use the AIMIGo 3-Lead ECG for patient assessments."*** Click '**Complete Patient Re-Registration**' to complete the process. See the *ECG Viewer – Reviewing the 3-Lead ECG* section for more details about the 3-Lead View.



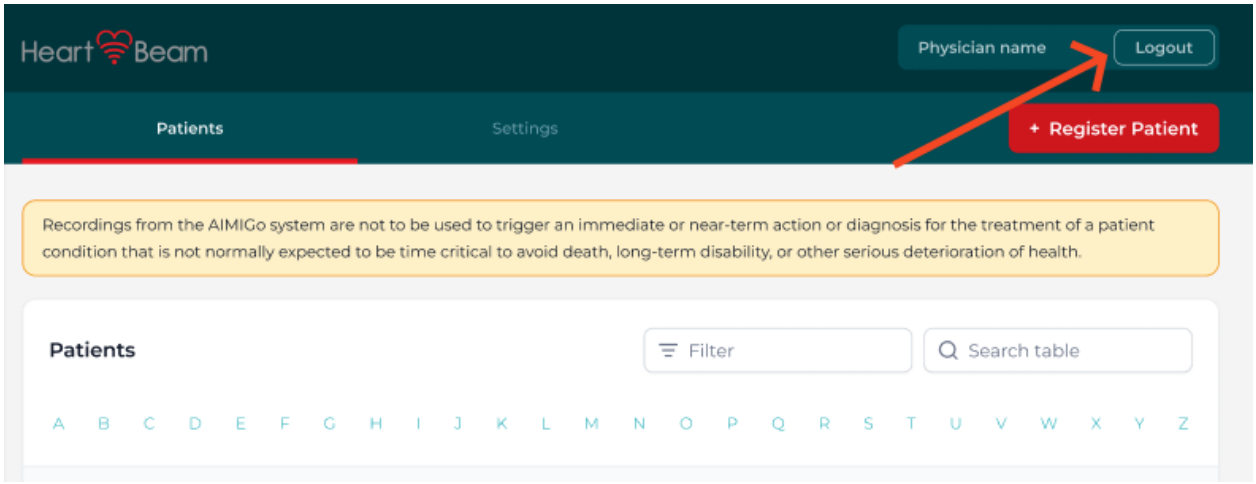
This Caution will also be present on the ECG Viewer and Reports:



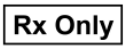
Logging Out of the Portal

To log out of the Clinician Portal, click '**Logout**' at the top right corner of the screen.' This will securely end your session.

NOTE: As a best practice, log out of the portal whenever you have completed use of the portal. Additionally, the Portal will automatically log out after 10 minutes of inactivity.



Symbols & Definition

Symbol	Description	Notes
	Warning: Consult Accompanying Documents	
	Consult instructions for use	
	Manufacturer	HeartBeam, Inc.
	Type BF Applied Part	
IP52	Ingress Protection Rating	Device protected against limited dust ingress and dripping water up to 15° from vertical
	Keep Dry	Device packaging should be kept dry
	For Prescription Use Only (U.S.)	
	Warning: MR-Unsafe. Do not use the equipment near an MRI machine / MRI scan room.	
	Date of Manufacturer	e.g. MM-DD-YYYY; 01-01-2025
	Lot / Batch Number	e.g. LOT XXXX
	Medical Device	
	Unique Device Identifier (UDI)	Both human and machine readable
	Serial Number	e.g. A000001

REF	Catalog or Model Number	e.g. 2002A
	Non-Sterile	
	Single Patient Multiple Use	
	Storage Temperature Limit	
	Do not use if package is damaged	
	Do Not dispose with household waste	

Customer Support Contact Information

For assistance in setting up, using, or maintaining the AIMIGo Device, or to report any unexpected operating events, contact Customer Service:

Customer Support Toll-free number: ***1-(844) 4-HEARTB*** 1-(844)-443-2782

Customer Support E-mail: **Support@heartbeam.com**

Mail to: **HeartBeam Inc., 2118 Walsh Ave., Ste 210, Santa Clara, CA 95050**

Manufacturer

HeartBeam, Inc.

2118 Walsh Ave. Ste 210

Santa Clara, CA 95050

www.heartbeam.com

Appendix A – EMG and Baseline Wander Filtering

EMG

Electromyographic (EMG) noise refers to unwanted interference generated by muscle activity that contaminates the ECG signal. This noise can obscure the underlying cardiac activity, making it challenging to accurately interpret the ECG recording. EMG noise typically manifests as high-frequency spikes or fluctuations in the ECG signal, often occurring during movements or muscle contractions. To mitigate the effects of EMG noise, HeartBeam has developed an enhanced filter referred to as the Iterative Regeneration Method (IRM), a novel method for efficient EMG-noise suppression. The main hypothesis behind the method is that the temporary removal of the dominant ECG components (QRS complexes and T waves) which enables the extraction of the noise with the minimum alteration to the signal. Filters applied may impact the ECG signal morphology, including significant attenuation of low-level atrial activity (P-waves / Flutter-waves), which may result in inability to discriminate certain types of arrhythmias (e.g., Atrial Fibrillation/Atrial Flutter).

Baseline Wander

Baseline wander is a low-frequency noise that can distort the true signal, often caused by patient movement, respiration, or poor electrode contact. Cubic spline filtering is a mathematical technique used to correct baseline wander in electrocardiogram (ECG) signals and other physiological recordings. This approach is the foundation of the HeartBeam approach to baseline wander removal. The filter applied may impact the ECG signal, including T wave amplitude and morphology. Filters applied may impact the ECG signal morphology, including significant attenuation of low-level atrial activity (P-waves / Flutter-waves), which may result in inability to discriminate certain types of arrhythmias (e.g., Atrial Fibrillation/Atrial Flutter).