Vivio® System

Instructions for Use



Table of Contents

1 Symbols and Definitions 5

1.1 Symbols 5

2 Warnings and Precautions 6

3 System Specifications 9

4 Introduction 10

4.1 Device Description 10

4.2 Product Description 11

4.2.1 Controls and Functional Elements 12

4.3 Intended Use/Indications For Use 14

4.4 Expected Life 14

4.5 Intended Duration of Application 14

4.6 Disposal/Recycle 14

5 Set Up 14

5.1 Transport and Unpacking 14

5.2 Check System for Damage Prior to Use 14

6 Overview of Vivio System App 15

7 Vivio App Navigation 15

7.1 Account Signup & Sign In 15

7.2 Accessing the IFU 15

7.3 Accessing Settings 15

8 Instructions 15

8.1 Vivio System Overview 15

8.2 Patient Preparation and System Use 16

8.2.1 Placement of the EKG Patch 16

8.2.2 Placement of the Arm Cuff 17

8.3 Selecting and Connecting System Components 17

8.3.1 Powering the Arm Cuff and EKG Patch On/Off 17

8.3.2 Starting the Vivio App 17

8.3.3 Connecting the Vivio App to the Arm Cuff and EKG Patch via Bluetooth 18

8.4 Completing a Recording 18

8.5 Unsent Recordings 18

8.6 Results Screen 18

8.6.1 Results & Interpretation 19

8.7 Disconnecting the System 19

8.8 Cleaning the Arm Cuff and EKG Patch 19

- **Arm Cuff 19**

- **EKG Patch 20**

8.9 Charging the Arm Cuff and EKG Patch Battery 20

9 Summary of Clinical Study 20

10 Clinical Use Considerations 22

11 Updating Software 22

11.1 Arm Cuff 22

11.2 EKG Patch 22

11.3 Vivio App 22

12 EMC Declaration 22

13 Product Support 26

14 Troubleshooting 26

15 Servicing 30

16 Warranty 30

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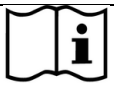
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1 Symbols and Definitions

1.1 Symbols

The following symbols appear on the Vivio System product and/or packaging.

Table 1. Explanation of Symbols Used

Symbol	Meaning
	Manufacturer
	Date of Manufacture
	Catalog number
	Serial number
	Batch code
	Caution: US federal law restricts this device to sale by or on the order of a physician.
	Recycle, do not throw in trash
	Wireless communication
	Temperature limit When on the carton, these are the shipping and storage limits. If on the device, these are the limits during use.
	Humidity limitation When on the carton, these are the shipping and storage limits. If on the device, these are the limits during use.
	Electronic instructions for use
	Consult instructions for use. Indicates the need for the user to consult the instructions for use.
	Refer to instructions for use
	Type BF applied part
IP22	Enclosure protects from momentary dripping water and finger access to electronics
	Orient towards the patient's right side
	Orient towards the patient's left side

2 Warnings and Precautions

Read this document completely and follow the instructions exactly. An electronic copy of this document is also available on the Vivio App. Refer to the tablet instructions for using the tablet. Refer to the electrode instructions for using the electrodes.

Warnings, Precautions, and Notes – Patient Characteristics

For reader convenience, the Warnings, Precautions, and Notes included throughout this instructions for use document, that are specific to patient characteristics, have been compiled into the following table (Table 2). Additional Warnings, Precautions, and Notes related to the safe and effective use of the Vivio System follow.

Table 2. Warnings, Precautions, and Notes – Patient Characteristics

Category	Patient Characteristic	IFU Reference	Vivio System Instructions for Use Section
WARNING	Intravascular access or therapy, arterio-venous (A-V) shunt/fistula	Warning: Application of the Cuff on any limb where intravascular access or therapy, or an arterio- venous (A-V) shunt/fistula is present, can cause temporary interference with blood flow and could result in injury to the patient.	This table
	Mastectomy or lymph node dissection	Warning: Application of the Cuff and its pressurization on the arm on the side of a mastectomy or history of axillary lymph node dissection may result in injury to the patient	This table
	Implantable electrical cardiac devices, including pacemakers	Warning: Not intended and should not be used in the presence of implantable electrical cardiac devices, including pacemakers.	This table
	Open lesion, visible blood, or body fluids	Warning: Do not use the Vivio System if any of the following are true: Open skin lesions or any visible blood or body fluids at the site of Arm Cuff or EKG Patch placement. Warning: Application of the Cuff or EKG Patch over a wound or bodily fluids can cause further injury.	This table
NOTE	Arm size	Do not use if Arm size is different from the Arm Cuff specifications. Supported Arm Cuffs are for use with patient arm circumferences between 22 and 42cm or 38 and 54 cm.	8.2 Patient Preparation and System Use
	Inability to take blood pressure on left arm	Rest left forearm on a flat surface so that the center of the arm is at the same height as the heart. With the left palm up, wrap the Cuff around the upper arm about 0.5 in (1-2 cm) above the inside of the elbow.	8.2.2. Placement of the Arm Cuff

Category	Patient Characteristic	IFU Reference	Vivio System Instructions for Use Section
	Devices (i.e., Continuous Glucose Monitors, Insulin Pump, Drug Patch, etc.) interfering with direct placement of Vivio System on skin	Place the Cuff directly against the skin (i.e., do not place over devices such as Continuous Glucose Monitor, Insulin Pump, Drug Patch, etc.), as objects between the skin and Cuff may cause a measurement error.	8.2.2. Placement of the Arm Cuff

Electrical Warnings

Warning: Prior to defibrillating the patient, remove the Vivio System from the patient.

Warning: Not intended and should not be used in the presence of implantable electrical cardiac devices, including pacemakers.

Warning: The battery used in the Vivio System may present a risk of burn, toxic fumes, or environmental contamination if mistreated. Do not crush, heat above 70°C (158°F) or incinerate. Do not leave in extremely low air pressure.

Warning: Prior to applying to the patient, the EKG Patch and Electronics Enclosure must be disconnected from the charging power supply plugged into mains.

General Warnings

ADJUNCT WARNING: This device is intended only as an adjunct in patient assessment. The Vivio System is intended to be used along with clinically relevant information to aid a clinician in arriving at a diagnosis of heart failure.

Warning: No modification of any device or app in the Vivio System is allowed.

Warning: In very busy environments with multiple receiver devices and transmit devices working in Bluetooth, WIFI, or cellular there is the possibility that data on the Vivio System is interrupted from an interfering transmitter. In such cases try to locate the offending source and establish distance from it, remove it from the vicinity, or power it off during use of the Vivio System.

Warning: Kinking of the connection tubing can cause continuous Cuff pressure resulting in blood flow interference and injury to the patient. Avoid compression or restriction of the connection tubing.

Warning: Too frequent measurements can cause injury to the patient due to blood flow interference.

Warning: Pressurization of the Cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.

Warning: Check that operation of the Arm Cuff does not result in prolonged impairment of the patient's blood circulation.

Electromagnetic Warnings

Warning: Do NOT use the Vivio System during high frequency surgical procedures!

Warning: Use of accessories and cables other than those specified, with the exception of accessories and cables sold by Ventric as replacement parts, may result in increased emissions or decreased electromagnetic immunity of the system and result in improper operation.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Portable radio-frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) generally should be used no closer than 30 cm (12 inches) to any part of the System, including cables specified by the manufacturer. Otherwise, degradation of the

performance of this equipment could result.

Warning: The Vivio System has NOT been evaluated for use in an MRI environment. Therefore, the Vivio System should NOT be taken into an MRI environment.

General Precautions

Follow all instructions carefully. The Vivio System may be susceptible to certain attack vectors where a malicious actor may gain unauthorized access to the system, which may result in compromise of protected health information (PHI), data integrity, and device functionality. Do not disassemble or modify the Vivio System. Improper use and handling can create hazards, cause damage and/or compromise the device cybersecurity configuration implemented for the Vivio System.

To help keep the Vivio System secure:

- Use good cyber security practices to prevent unauthorized access to the Vivio System.
    - Network access required for using the Vivio System should be set up with security configurations that utilize, at a minimum, WPA2 or WPA3 protocol.
    - Follow all password requirements (At least 8 Characters with 1 Uppercase and Lowercase Character)
    - Update your password on a regular basis (e.g., Every 3 months or when your device may have been compromised)
    - Never share your login information.
    - Protect your tablet with up-to-date antivirus software.
- For customer-provided iPads, keep iOS on your iPad up to date (v16.0 or above).
    - Remove any iOS versions that are no longer supported.
    - Never jailbreak your iPad because you leave it open to the malware it was designed to be protected against.
- For customer-provided iPads, keep the Vivio App up to date.
    - Apple App Store will alert users that a new version is available for installation on the next use of the Vivio App.
- Turn Bluetooth off when not in use. If you keep Bluetooth active, a hacker may be able to discover what other devices you connected to before, spoof one of those devices, and gain access to your device.
- Do not leave the paired Vivio System devices (Arm Cuff and EKG) or iPads signed into the Vivio App unattended.
- Do not use any software not authorized by Ventric Health with the Vivio System. Only the following software has been authorized by Ventric Health:
    - Apple, Inc. iPad OS Version 16.0 or higher
- The Vivio System device does not perform cybersecurity event detection nor event logging for cybersecurity-related events.

Ventric Health is committed to safeguarding device cybersecurity by establishing an active cybersecurity monitoring program. Please contact support if you believe your device has experienced a cybersecurity attack. Ventric Health will inform users of any cybersecurity events that may affect the device and detail any updates or actions needed by the user.

Monitor the Vivio System and patient during the entire session. It is the responsibility of the end user

to identify, analyze, evaluate, and control risks, including if the end user connects the Vivio System to a tablet that operates other devices.

If a cybersecurity event is detected or suspected, stop usage of the Vivio System and contact support for help.

Rogue and malware programs running on the tablet used to communicate with the Vivio System components might interfere with the intended function of the device, therefore it is highly recommended to protect the tablet with an antivirus program to reduce the risks of virus program infections. Always keep this program up to date. Report any unexplained malfunction of the Vivio System to the Manufacturer; when cybersecurity updates from the manufacturer are available, the manufacturer will contact you and schedule an update.

3 System Specifications

Table 3. Technical Information – Vivio System

Type designation	**Vivio System**	
	Arm Cuff Electronics Enclosure	**EKG Patch**
Charging (remove charger prior to use on patient)		
Rated line voltage when charging	100 – 240 V, 50/60 Hz	100 – 240 V, 50/60 Hz
Rated current when charging	1 A	1 A
Protection against electric shock	Class II (double insulated, no reliance on protective earth)	Class II (double insulated, no reliance on protective earth)
Operating		
Power	Internally powered	Internally powered
Network connection speed	The minimum recommended upload speed for the Vivio System is 5000 Kbps	
Transport conditions		
Temperature	-25°C to 70°C (-13°F to 158°F)	-25°C to 70°C (-13°F to 158°F)
Relative humidity	0 % to 90 %	0 % to 90 %
Storage conditions		
Temperature	-5°C to 35°C (23°F to 95°F)	-5° C to 35°C (23°F to 95°F)
Relative humidity	0 % to 90 %	0 % to 90 %
Operating conditions		
Ambient Temperature	5°C to 40°C (41°F to 104°F)	5°C to 40°C (41°F to 104°F)
Relative humidity	0 % to 90 %	0 % to 90 %
Dimensions and weight		
Electrode Separation	Not Applicable	8 cm

Type designation	Vivio System	
	Arm Cuff Electronics Enclosure	**EKG Patch**
Dimensions	Length: 14.12 cm (5.56 in) Width: 9.91 cm (3.90 in) Height: 4.45 cm (1.75 in)	Length: 11.73 cm (4.62 in) Width: 4.67 cm (1.84 in) Thickness: 1.60 cm (0.63 in)
Weight without power supply (approx.)	14 oz	4 oz
Vivio System LVEDP Estimate Parameters		
Sensitivity	80% in detecting LVEDP $>$ 18 mm Hg	
Specificity	83% in detecting LVEDP $\leq$ 18 mm Hg	

4 Introduction

4.1 Device Description

The Vivio System consists of:

- Arm Cuff comprised of a Cuff, Electronics Enclosure, and Power Supply
- EKG Patch with a Power Supply
- Vivio System Software Application (Vivio App) that runs on an off-the-shelf computer tablet

Data is collected non-invasively at the brachial artery and via a single channel, two electrode EKG Patch. A Cuff is attached to the patient's upper arm as if taking a blood pressure measurement. The Cuff is connected to the pneumatic pump within the Electronics Enclosure. Two off-the-shelf electrodes are attached to the snap connections on the bottom of the EKG Patch and then connected on the left side of the patient's chest. Both the Arm Cuff and EKG Patch are powered on by pressing and releasing their respective power buttons. The Vivio App is opened on an off-the shelf computer tablet, and the on-screen prompts are followed to connect the Arm Cuff and the EKG Patch. The user is prompted to enter required patient and user data, initiating a recording session. Data from the recording session is processed by a proprietary algorithm and results reported on the computer tablet.

The Vivio System is designed for use by qualified healthcare professionals.

4.2 Product Description

The “Vivio System” or “System” comes with the following components:

- Arm Cuff (Cuff, Electronics Enclosure, and Power Supply)
  - Cuffs support the following arm sizes:
    - Regular- arm circumferences between 22 to 42 cm
    - Extra Large (XL) – arm circumferences between 38 and 54 cm



Figure 1. Arm Cuff (Regular Cuff, XL Cuff, Electronics Enclosure, Power Supply)

- EKG Patch and Power Supply

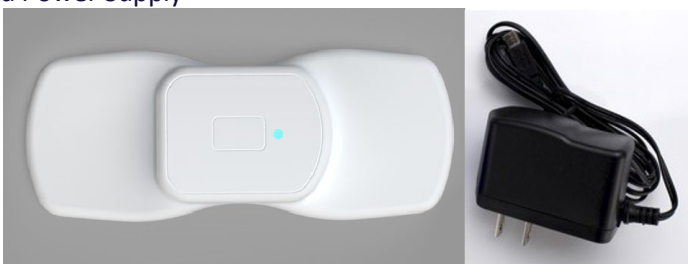


Figure 2. EKG Patch (EKG Patch, Power Supply)

- Vivio App (Installed on user computer tablet)
- Vivio System Convenience Case



Figure 3. Convenience Case

The following accessories are needed to use the Vivio System:

- Two Electrode Adhesive pads (Any standard electrode pads may be used. The EKG Patch has been validated with 3M 2560 Red Dot Multi-Purpose Monitoring Electrodes.)
- Computer tablet meeting the requirements in Table 4. Tablet Requirements:

Table 4. Tablet Requirements

Software Minimum Specifications	
Reference	**Details**
Operating System (OS)	iPad OS Version 16.0 or higher
Cellular and Wireless	Wi-Fi (802.11a/b/g/n/ac); simultaneous dual band (2.4GHz and 5GHz); HT80 with MIMO Bluetooth 5.0 technology – enabled Built-in GPS/GNSS Cellular (optional)
Hardware Minimum Specifications: iPad mini manufactured on or after March 18, 2019 meeting the technical specifications defined here: https://support.apple.com/en_US/specs/ipad	

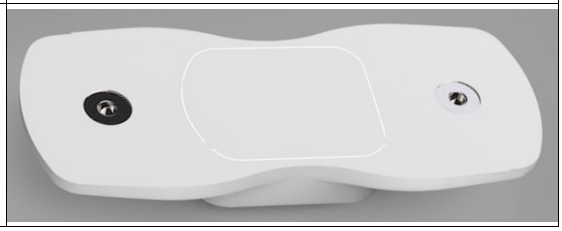
4.2.1 Controls and Functional Elements

Table 5. Vivio System Arm Cuff

Power On/Off Button	
Charging Port	
Electronics Enclosure Cuff Attachment Port	

Regular Cuff (circumference 22 to 42 cm)	
XL Cuff (circumference 38 to 54 cm)	

Table 6. Vivio System EKG Patch

Power On/Off Button	
Charging Port	
EKG Patch Electrode Snaps	

Electrodes Attached to EKG Patch	

4.3 Intended Use/Indications For Use

The Vivio® System is indicated to non-invasively estimate whether left ventricular end-diastolic pressure (LVEDP) is above or below 18mmHg. This measurement can aid in the diagnosis of heart failure when used by qualified healthcare professionals as an adjunct alongside other clinically relevant information. For use in adults only.

4.4 Expected Life

Two years beyond the year of the Date of Manufacture listed on the device (e.g., if Date of Manufacture listed on the device is 2024-07-08, the device would be able to remain in use for all of 2025 and 2026 or until December 31, 2026).

4.5 Intended Duration of Application

The Vivio System is intended to be used for up to:

- 3 minutes of recording

4.6 Disposal/Recycle

Contact Ventric for information on collection and disposal of the Vivio System.

5 Set Up

5.1 Transport and Unpacking

Upon receiving the System, confirm that all components of the Vivio System have been received.

If return shipment is required, use original packaging.

Retain the packaging materials. You will need to use the packaging if you return the Vivio System.

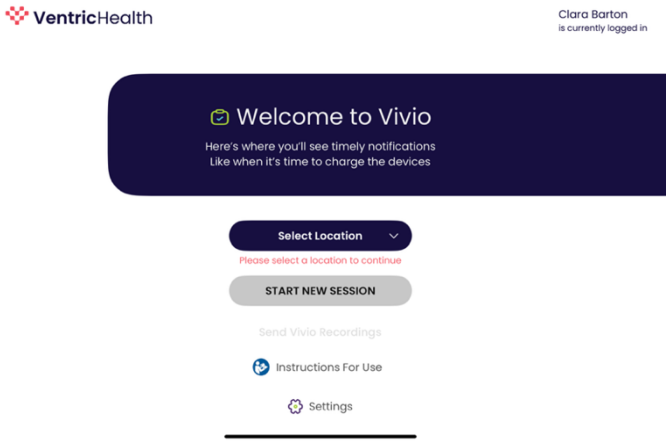
Fully charge all system components prior to first use.

5.2 Check System for Damage Prior to Use

Prior to each use, inspect the Arm Cuff and EKG Patch (including power supplies). Damage could result in injury to the patient or user due to sharp edges or exposed electronics. In the event any component appears damaged, do not use the System. Contact Ventric for replacement.

6 Overview of Vivio System App

Table 7. Overview of Vivio System App

Vivio App Icon	
Vivio System Instructions for Use and Settings Icon and Vivio App Initiation Screen	

7 Vivio App Navigation

When using the Vivio App, follow on-screen instructions.

7.1 Account Signup & Sign In

Open the Vivio App and sign up for an account. Enter email address. A one-time passcode will be sent to this email for account creation. Enter first name, last name, and confirm email address. Enter a unique password.

For future logins, a one-time passcode is only required when prompted.

7.2 Accessing the IFU

The user may access the IFU through the Vivio App by pressing “Instructions For Use”.

7.3 Accessing Settings

Press “Settings” to access the Vivio App Settings menu.

The Settings menu contains the Vivio App Version and Unique Device Identifier.

The Settings menu also contains a button for the user to log out of the Vivio App.

8 Instructions

8.1 Vivio System Overview

The Vivio® System is indicated to non-invasively estimate whether left ventricular end-diastolic pressure (LVEDP) is above or below 18mmHg. This measurement can aid in the diagnosis of heart failure when used by qualified healthcare professionals as an adjunct alongside other clinically relevant information. During the recording session the Vivio System is collecting arterial blood pressure waveforms from the Arm Cuff and electrocardiographic waveforms from the EKG Patch.

The Vivio System algorithm interprets information contained in these waveforms to provide an estimate of the patient's LVEDP as described in Section 8.6 below. Clinical users of the Vivio System should understand the basic principles regarding the derivation of the LVEDP estimate as well as the strengths and limitations of research conducted to date as described in Section 9 below.

8.2 Patient Preparation and System Use

Disconnect the Vivio System components from any external power supply prior to attaching to patient.

If needed, clip excessive hair.

If skin is oily or has lotion on it, wash with soap and water and dry thoroughly with a towel. Thoroughly dry the skin to ensure the EKG Patch has adequate skin contact.

Do not use the Vivio System if any of the following are true:

- Open skin lesions or any visible blood or body fluids at the site of Arm Cuff or EKG Patch placement
- Arm size is different from the Arm Cuff specifications. Supported Arm Cuffs are for use with patient arm circumferences between 22 and 42cm or 38 and 54cm. Please refer to the labeling on the Cuff for specified circumference.

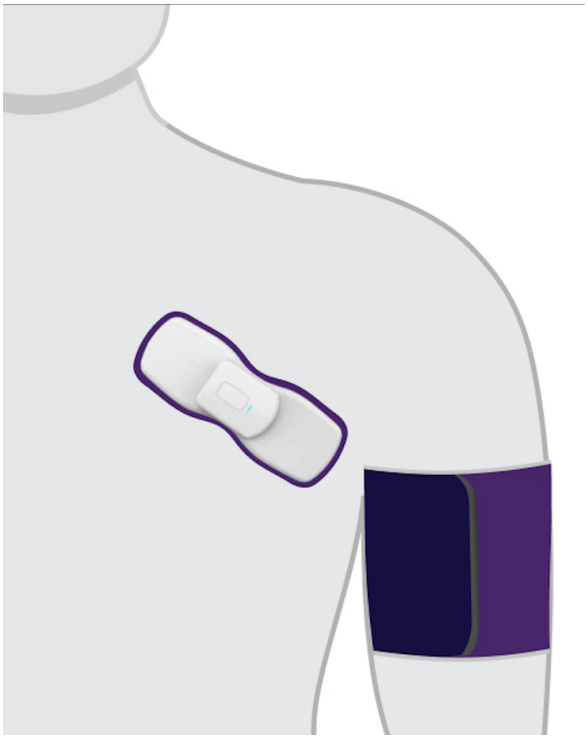


Figure 3. EKG Patch & Arm Cuff on Patient

8.2.1 Placement of the EKG Patch

Snap two electrode adhesive pads onto the EKG Patch. Remove the protective layer from the electrode pads.

Below the left collarbone, place the EKG Patch with the "R" side electrode on the side closest to the patient's sternum in the 1st intercostal space and the "L" side electrode closest to the patient's left arm in the 2nd intercostal space so that the EKG Patch is angled downward in the direction of the left arm.

NOTE: The curved profile of the thicker, center section of the EKG Patch should be facing toward the left arm as opposed to the flat profile which should be facing toward the sternum.

Activate the pressure sensitive adhesive by running a finger over the wings of the EKG Patch, tracing the pattern of the attached electrode pads.

8.2.2 Placement of the Arm Cuff

The patient should be sitting comfortably with back and legs supported. The patient's legs should be uncrossed and their feet flat on the floor.

Rest left forearm on a flat surface so that the center of the arm is at the same height as the heart. With the left palm up, wrap the Cuff around the upper arm about 0.5 in (1-2 cm) above the inside of the elbow. Place the Cuff directly against the skin (i.e., do not place over devices such as Continuous Glucose Monitor, Insulin Pump, Drug Patch, etc.), as objects between the skin and Cuff may cause a measurement error. Secure Cuff around arm. The Cuff should be snug but not too tight. Again, make sure Cuff is aligned at heart level.

Attach the Cuff to the Electronics Enclosure by pushing the metal connector on the end of the Cuff tubing onto the metal connector on the Electronics Enclosure until it clicks or is locked into place.

As possible, allow 5 minutes before taking a reading. The patient should be encouraged to relax and remain still.

NOTE: In the event of an emergency requiring the release of pressure from the Arm Cuff remove the Cuff from the patient or disconnect the Electronics Enclosure from the Cuff.

8.3 Selecting and Connecting System Components

8.3.1 Powering the Arm Cuff and EKG Patch On/Off

To power on the unit, hold the on/off button until the LED turns on. A blue flashing LED indicates the unit is in ready mode. A solid red LED or the unit not powering on indicates the battery needs to be charged.

After ten minutes the Arm Cuff will automatically power off if it has not connected with a EKG Patch.

After ten minutes the EKG Patch will automatically power off if it has not connected with an Arm Cuff and the Vivio App.

To power off the unit, hold the on/off button until the LED turns off.

8.3.2 Starting the Vivio App

Open the Vivio App on the tablet by tapping the Vivio App icon. Use the following on-screen prompts:

- Select location
- Select "Start New Session"
- Complete Patient ID, Patient Date of Birth, and Patient First and Last Name.
    - The Patient ID must only contain alphanumeric characters, hyphens, and colons. Only alphanumeric characters can be in the first and last position of the Patient ID.
- Complete the name of the ordering provider.
- Complete patient information

- Select “Next”

8.3.3 Connecting the Vivio App to the Arm Cuff and EKG Patch via Bluetooth

Bluetooth connection between the Arm Cuff and EKG Patch and between the EKG Patch and Vivio App is required to conduct a recording session.

Devices available for pairing will be displayed in the Available Devices list. The names displayed will match the serial numbers listed on the back of each device.

If the devices have been previously connected with the tablet, they will automatically connect again.

Device connection can be tested in the Vivio App Settings.

If the devices need to be re-paired with the tablet, or are being paired for the first time, complete the following on-screen steps:

- Choose the EKG Patch and Arm Cuff devices. The names displayed will match the serial numbers listed on the back of each device.
- Once the devices have been selected, they will automatically pair with the Vivio App
  - If pairing to the tablet for the first time, accept the Bluetooth connection request pop-up.
- Once the devices have paired the “Start Recording” button will be accessible
- Confirm the battery percentage of the EKG Patch and Arm Cuff devices once the battery levels have been updated on the Vivio App.

8.4 Completing a Recording

Press “Start Recording”. The recording session process will start and the Vivio App will display three steps that will be completed:

- In the first step labeled “Calibrating” the Cuff will inflate in order to calibrate to the patient.
- In the second step labeled “Recording Heart Data” the Cuff will inflate in three steps of increasing pressure. It is important for the patient to remain still throughout the sequence.
- In the final step labeled “Finishing Up” the Cuff will deflate and the recorded data will be sent for processing if there is an internet connection.
- If there is no internet connection, the user will have the option to complete the KCCQ-12 Questionnaire. This data will be stored as part of the Unsent Recording.

8.5 Unsent Recordings

To send Unsent Recordings, an internet connection is required. Connect to the internet and press “Send Vivio Recordings” from the Home Screen. Press “Send Now” to send the recording for processing. Upon completion of the process, the results will be displayed on the Results Screen (see Results Screen section). Upon completion of the results screen and results interpretation process and if there are additional recordings to send, the Vivio App will return to the Unsent Recordings. Repeat the process to send additional unsent recordings.

The Vivio App can store a maximum of 20 unsent recordings. Once the maximum number of unsent recordings is reached, no additional recording sessions may be performed until the number of unsent recordings is under 20.

8.6 Results Screen

If the tablet is connected to the internet, the results of the Vivio System recording will be displayed along with the information entered in Section 8.3.2.

- If the patient’s LVEDP is equal to or lower than 18 mmHg the Vivio App will display “LVEDP is lower than 18 mmHg”

- If the patient's LVEDP is higher than 18 mmHg the Vivio App will display "LVEDP is higher than 18 mmHg"
- If the information collected during the recording session was unable to be processed, the Vivio App will inform the user.

ADJUNCT WARNING: This device is intended only as an adjunct in patient assessment. The Vivio System is intended to be used along with clinically relevant information to aid a clinician in arriving at a diagnosis of heart failure.

In the event that the user is not presented a result due to lost internet connection, please contact Ventric for cloud retrieval.

8.6.1 Results & Interpretation

To record interpretation of the results, perform the following:

- Enter interpretation notes, if desired
- When LVEDP is higher than 18 mmHg, select the option to skip or complete the KCCQ-12 Questionnaire. When LVEDP is lower than 18 mmHg, the KCCQ-12 Questionnaire may be completed. If completing the KCCQ-12 Questionnaire, answer all questions and select "COMPLETE".
  - NOTE: Ventric Health uses simple calculations routinely used in clinical practice for the KCCQ-12 score. The Kansas City Cardiomyopathy Questionnaire (KCCQ-12) is an internationally accepted and widely used health-related quality of life assessment tool for patients with chronic heart failure.
  - NOTE: By selecting the Spanish option, a Spanish version of the KCCQ-12 Questionnaire is available for Spanish-speaking patients.
- Select "Done"

The interpretation data will be sent to Ventric Health for storage if there is an internet connection. If there is no internet connection, the recording session and KCCQ-12 information will be saved as an Unsent Recording, however, the other portions of the Results & Interpretation form should be completed once internet connection is re-established.

8.7 Disconnecting the System

Once the recording session is completed, removing the EKG Patch from the patient can be accomplished by following one of the techniques outlined below:

- Carefully detach the EKG Patch from the electrodes and then slowly peel back the electrodes in the direction of hair growth, while supporting the skin adjacent the electrode with the other hand.
- Carefully detach the EKG Patch by slowly peeling back the electrodes in the direction of hair growth, while supporting the skin adjacent the electrode with the other hand. Remove the electrodes from the EKG Patch.

Detach the Cuff from the Electronics Enclosure prior to removing the Cuff from the patient. While holding the Electronic Enclosure in one hand, pull back on the shell of the metal connector to release it from the Electronic Enclosure. Remove the Cuff from the patient. Power down both the EKG Patch and the Arm Cuff after each use. Avoid tightly folding the Cuff and tightly coiling the attached tubing as such treatment may shorten the life of the components.

8.8 Cleaning the Arm Cuff and EKG Patch

You must clean the Arm Cuff and EKG Patch after every use.

- Arm Cuff

After each use, clean the Cuff per standard of care. The Electronics Enclosure should be wiped down after each use with a soft dry cloth moistened with 70% isopropyl alcohol.
Do not wash or immerse the Arm Cuff or other components in water.

- EKG Patch

After each use, use a soft dry cloth moistened with 70% isopropyl alcohol to wipe down the EKG Patch. At least weekly and if soiled, clean with disinfectant wipes.

8.9 Charging the Arm Cuff and EKG Patch Battery

NOTE: The system components should only be charged with the Ventric-provided power supply plugged into mains power. Position the Arm Cuff or EKG Patch so that it is easy to disconnect the power supply.

While charging, the LED will flash green and when fully charged, the LED will be solid green. A solid red LED indicates that the battery is low, and the unit should be charged immediately.

The battery charge level is indicated in the upper right corner of the Vivio App next to the unit serial number.

9 Summary of Clinical Study

Ventric conducted a prospective validation study to characterize the relationship of Ventric's non-invasive Vivio System for the estimation of elevated left ventricular end-diastolic pressure (LVEDP) as compared to gold-standard invasive LVEDP obtained via the Millar Mikro-Cath (Cath Lab Cohort) as well as reference-standard non-invasive echocardiographic indices (Aged Healthy Cohort). An additional non-aged healthy cohort was enrolled without the use of a reference comparator (Non-Aged Healthy Cohort).

Study overview and LVEDP:

Ventric conducted a prospective clinical validation study involving a total of 195 subjects enrolled across 9 sites. The subjects were categorized into three cohorts: Cath Lab, Aged Healthy and Non-Aged Healthy. A description of the subjects enrolled by cohort is provided in Table 8 below. The study was conducted in accordance with Good Clinical Practice standards (GCP), and all applicable regulatory requirements.

Subjects enrolled in the Cath Lab Cohort (N=75) consisted of subjects indicated for diagnostic left heart catheterization across 7 clinical sites in the United States. During the routine catheterization procedure a gold standard high-fidelity Millar Mikro-Cath catheter was used to measure post-A wave LVEDP. Forty (40) of the subjects in the Cath Lab Cohort had LVEDP as determined by the Mikro-Cath above 18 mmHg and 35 subjects had LVEDP equal to or lower than 18 mmHg. The patients enrolled in the Cath Lab Cohort were older (mean age of 65) and sicker than the general population with a mean LVEDP of 19 mmHg. To address issues related to spectrum bias two additional cohorts were enrolled in order to assure the full spectrum of LVEDPs was analyzed.

Patients enrolled in the Aged Healthy Cohort (N = 40) consisted of subjects with no known significant cardiovascular disease and were determined to be true negatives (i.e. LVEDP ≤ 18 mmHg) if they met the echocardiographic indices listed in Table 9 below. The subjects enrolled in the Aged Healthy Cohort were similar in age to the Cath Lab Cohort (mean age of 63).

Patients enrolled in the Non-Aged Healthy Cohort (N=80) consisted of subjects with no known cardiovascular disease or risk factors and were presumed to be true negatives (i.e. LVEDP ≤ 18 mmHg) given their age and lack of risk factors for elevated LVEDP. The subjects enrolled in the Non-Aged Healthy Cohort were younger than the Aged Healthy and Cath Lab Cohorts (mean age of 28).

Results :

- The primary efficacy objectives for the study were met: sensitivity of 80% (64% to 91%) and

specificity of 80% (73% to 86%).

- There were no unanticipated adverse events or reported serious adverse events.
- The primary endpoints are the sensitivity and specificity of the Vivio System to detect elevated (> 18 mmHg) versus non-elevated LVEDP in the combined Cath Lab, Aged Healthy and Non-Aged Healthy Cohorts. For the Aged Healthy and Non-Aged Healthy Cohort we assume that the true LVEDP is <= 18 mmHg, that is, we are assuming they are true negatives, as described in more detail above.

Table 8. Demographics and Baseline Characteristics of Analyzed Validation Subjects

	Cath Lab (75)	Aged Healthy Control (40)	Non-Aged Healthy Control (80)
Gender (M; F)	51 M (68%) 24 F (32%) 0 Unknown (0%)	14 M (35%) 26 F (65%) Unknown (0%)	45 M (56%) 34 F (43%) 1 Unknown (1%)
Race	0 American Indian or Alaskan Native (0%) 2 Asian (3%) 12 Black or African American (16%) 1 Native Hawaiian or Other Pacific Islander (1%) 57 White (76%) 3 Other (4%) 0 Unknown (0%)	0 American Indian or Alaskan Native (0%) 23 Asian (58%) 1 Black or African American (3%) 0 Native Hawaiian or Other Pacific Islander(0%) 13 White (33%) 3 Other (8%) 0 Unknown (0%)	1 American Indian or Alaskan Native (1%) 10 Asian (13%) 8 Black or African American (10%) 1 Native Hawaiian or Other Pacific Islander (1%) 48 White (60%) 8 Other (10%) 4 Unknown (5%)
Ethnicity	1 Hispanic or Latino (1%) 74 Not Hispanic or Latino (99%) 0 Unknown (0%)	3 Hispanic or Latino (8%) 37 Not Hispanic or Latino (93%) 0 Unknown (0%)	24 Hispanic or Latino (30%) 43 Not Hispanic or Latino (54%) 13 Unknown (16%)
Mean Age (years) (SD)	65.1 (11)	62.8 (6.3)	27.6 (7.6)
Mean Height (cm) (SD)	173.1 (9.4)	161.1 (9.9)	172.8 (11.1)
Mean Weight (kg) (SD)	88.7 (17.5)	64.2 (14.6)	76.8 (20.1)
Mean Body Mass Index (kg/m2) (SD)	29.6 (5.5)	24.5 (3.4)	25.6 (5.7)
Mean LVEDP (mmHg) (SD)	20.3 (7.8)	-	-

Table 9. Aged Healthy Cohort Echocardiographic Indices

Normal ejection fraction ≥50% and ≤70%
Normal average E/e' ≤ 15
Normal maximum LA volume/BSA (mL/m2) ≤ 34
No moderate of severe aortic valve stenosis
No severe mitral valve stenosis

10 Clinical Use Considerations

Clinical users of the Vivio System should understand the basic principles regarding the derivation of the LVEDP estimate as well as the strengths and limitations of research conducted to date. As noted above, the Vivio System LVEDP was found to correlate closely with invasively measured LVEDP. This device is intended only as an adjunct in patient assessment and is to be used along with other clinically relevant information. It is recommended that users carefully consider the clinical conditions and evaluate other clinically relevant information when interpreting results of the Vivio System.

11 Updating Software

To maintain the product cybersecurity requirements, update the Vivio System Software when prompted.

11.1 Arm Cuff

Ventric will send out replacement devices with updated firmware in the event of a necessary software update to the Arm Cuff device.

11.2 EKG Patch

Ventric will send out replacement devices with updated firmware in the event of a necessary software update to the EKG Patch device.

11.3 Vivio App

It is recommended to have the tablet's battery level at 20% or above to update the Vivio App.

If a new version of the Vivio App is available in the App store, an Apple generated alert will pop up in the Vivio App upon launch of the Vivio App. The User should always select Yes when asked if they want to update to the latest version of the Vivio App to ensure the Vivio System works as intended and has the latest cybersecurity updates configured.

12 EMC Declaration

The Arm Cuff and EKG Patch both contain Bluetooth communication module with:

- FCC ID: RYYEYSHJN
- IC ID: 4389B-EYSHJN

The Arm Cuff and EKG Patch comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) These devices may not cause harmful interference, and (2) these devices must accept any interference received, including interference that may cause undesired operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) generally should be used no closer than 30 cm (12 inches) to any part of the System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The Vivio System has been designed to be electromagnetically compatible with other devices. In the unlikely event the Vivio System interferes with other devices or that other devices interfere with the operation of the Vivio System, try the following:

- Move the Vivio System and other devices farther away from each other.
- Move the cords from the Vivio System and other devices as far apart as possible.
- If the cords from other devices must cross cords from the Vivio System, try to have them cross at right angles (+). Running parallel (||) may increase interference.
- Plug the other devices or the Vivio System components into different outlets. If possible, plug them into outlets on different circuits.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The Vivo System is intended for use in the electromagnetic environment specified below. The user of this should make sure it is used in such an environment.

Table 10. Guidance and manufacturer's declaration – electromagnetic emissions

Emissions Test	**Compliance**	**Electromagnetic Environment-Guidance**
RF Emissions CISPR 11	Group 1	The Vivio System uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Vivio System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 11. Guidance and manufacturer's declaration - electromagnetic immunity part 1

Test and Method	Test Levels	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV and ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV and ±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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Power Lines: ±0.5 kV and ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV and ±2 kV line(s) to earth Signal Lines: ±2 kV line(s) lines(s) to earth	Power Lines: ±0.5 kV and ±1 kV line(s) to line(s) ±0.5 kV, ±1 kV and ±2 kV line(s) to earth Signal Lines: ±2 kV line(s) lines(s) to earth	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
	0 % UT; 1 cycle, and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle, and 70 % UT; 25/30 cycles Single phase: at 0°	
	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle	
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.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Table 12. Guidance and manufacturer's declaration - electromagnetic immunity part 2

Test Method	Test Levels	Compliance Levels	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 V outside ISM bands [b] 6 V in ISM bands [b] 150 kHz to 80 MHz	3 V outside ISM bands [b] 6 V in ISM bands [b]	Portable and mobile RF communications equipment should be used no closer to any part of the Vivio System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = [3.5/10]$\sqrt{P}$ 150 kHz to 80 MHz d = [3.5/10]$\sqrt{P}$ 80 MHz to 800 MHz d = [7/3]$\sqrt{P}$ 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. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

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 strengths 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 the Vivio System is used exceeds the applicable RF compliance level above, the Vivio System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Vivio System.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
c. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

13 Product Support

Contact Ventric for assistance in setting up, using, or maintaining the Vivio System or to report any unexpected operations or events.

14 Troubleshooting

Table 13. Failures and Troubleshooting Steps

Failure	Error & Troubleshooting Steps
No Locations Found	No Locations Found Please contact Ventric Health Support for help (support@ventrichealth.com).
Patient Not Found	Patient Not Found Patient ID : XXXXX Date of Birth : MM/DD/YYYY Please recheck patient ID and Date of Birth Press Continue: To ACCEPT entries Press Go Back: To correct entries
Arm Cuff Battery Low	Arm Cuff solid Red LED Arm Cuff Battery charge is below 10%. Please charge the device to keep using it.
EKG Patch Battery Low	EKG Patch solid Red LED. EKG Patch Battery charge is below 10%. Please charge the device to keep using it.
Bluetooth Connection Failure	Bluetooth connection is lost. Restart both devices. Then, go to “Select Other Devices” to reconnect.
Bluetooth Pairing Failure	One or more devices could not pair. Please do the following: • Make sure the devices are powered on. If a device does not power on, please make sure the device is charged. • Restart both devices to reconnect. If error continues, please do the following: • Go to the tablet Bluetooth settings • Remove/forget the devices • Go to the App • Attempt Bluetooth pairing/connection
EKG Patch Signal Failure	The EKG Patch does not provide a signal. Please do the following: • Remove the Patch. • Replace the electrodes. • Check placement and angle of the Patch. • Check to see if the electrodes are making good contact with the skin.

Failure	Error & Troubleshooting Steps
Arm Cuff Pump or Pneumatics Failure	There is a problem with the Arm Cuff. Please do the following: • Restart both devices. • Check the Arm Cuff connection. If the error continues, please contact Ventric Health Support for help (support@ventrichealth.com).
Arm Cuff Pump or Pneumatics Failure	The Arm Cuff does not provide a signal. Please do the following: • Check the position of the Arm Cuff on the patient's arm. • Restart the Arm Cuff. If the error continues, please contact Ventric Health Support for help (support@ventrichealth.com).
Arm Cuff Data Failure	There is a problem with the Arm Cuff data. Please do the following: • Restart both devices. • Check the Arm Cuff connection. If error continues, please contact Ventric Health Support for help (support@ventrichealth.com).
Arm Cuff Initialization Error	Baseline blood pressure could not be obtained during calibration. Please do the following: • Power off/on Arm Cuff and EKG patch. • Check to make sure the patient's arm circumference is within the range defined on the Arm Cuff. • Retry the recording. If the error continues, please contact Ventric Health Support for help (support@ventrichealth.com).
Arm Cuff Pressure Neared Regulatory limit	Maximum Pressure Exceeded Error Remove devices from patient. Contact Ventric Health Support before use (support@ventrichealth.com).
Arm Cuff values lie out of bounds of the accepted ranges	The pressure is out of range. Please do the following: • Pause before repeating the test. • Make sure the patient is sitting still in a supported position, with their feet flat on the floor, and their arm resting on a flat surface by their side, at heart level. • Keep the arm as still as possible. No talking Do not repeat the test more than once.

Failure	Error & Troubleshooting Steps
Patient movement during data collection (rendering pressure signal inadequate for analysis)	Movement is detected during the test. Please do the following: • Pause before repeating the test. • Make sure the patient is sitting still in a supported position, with their feet flat on the floor, and their arm resting on a flat surface by their side, at heart level. • Keep the arm as still as possible. No talking. • Do not repeat the test more than once. If there was no patient movement and this error repeats, please contact Ventric Health Support for help (support@ventrichealth.com).
Recording manually stopped	The recording will be stopped. Are you sure you want to end the recording? SELECT YES, END RECORDING No, keep recording
"Skip" KCCQ-12 Questionnaire selected after it was started	"Skip Questionnaire" has been selected after data was entered into the KCCQ-12 questionnaire. If you proceed this data will be lost. To Save this data select "Cancel" and unselect "Skip Questionnaire". To proceed without the KCCQ-12 data select "Continue"
Complete KCCQ-12 Questionnaire Without Internet Connection	Session Complete No internet Connection. Click "Continue" to complete KCCQ-12 Questionnaire
No internet connection when confirming patient, uploading a recording, uploading interpretation, or receiving results	Internet Connection Error The recording data has been saved on the App. Please connect the tablet to the internet. Go to the Unsent Recordings screen and send the data.
Issue processing results	There was a problem processing the result. The data is saved to Unsent Recordings. Please do the following: • Go to the Unsent Recordings screen. • Send the data. • Finish the result screen. If the error continues, contact Ventric Health Support for help. (support@ventrichealth.com).
Maximum number of unsent recordings reached	You cannot save any more recordings. Please connect the tablet to the internet. Go to the Unsent Recordings screen and send the data. This must be done before starting a new recording.

Failure	Error & Troubleshooting Steps
Result Error (Generic)	The result is inconclusive. Please do the following: • Pause before repeating the test. • Make sure the patient is sitting still in a supported position, with their feet flat on the floor, and their arm resting on a flat surface by their side, at heart level. • Keep the arm as still as possible. No talking. • Do not repeat the test more than once.
Result Error (Arm Cuff Issue)	Arm Cuff data is inconclusive. • Remove and reapply Cuff. Make sure Cuff is properly positioned and fitted. • Patient should not move or flex their arms, hands or fingers during the Vivio Test. • Do not repeat the test more than once.
Result Error (EKG Patch Issue)	EKG Patch data is inconclusive. • Ensure nothing is blocking contact between skin and electrodes. • Re-check EKG Patch placement. • Do not repeat the test more than once.
Result Error (Repeat occurrence)	Data is inconclusive. Error may be due to patient's underlying physiology. Unlikely to get a result in this session.
Test Result is received	If "Test Result" is received, this indicates that a test session was run utilizing a patient ID that starts with: • "Test" • "test" • any consecutive number of zeroes with no other digit in that number (i.e, 000000). When a test session is run, the result will only show "Test Result". To receive an LVEDP result, a real patient ID must be entered.
Invalid one-time passcode	The code you entered is invalid.
Invalid email when signing up for account in the Vivio App	Email is not valid.
First Name not entered when signing up	First Name is required
Last Name not entered when signing up	Last Name is required
First and Last Name not entered when signing up	First and Last Name are required

Failure	Error & Troubleshooting Steps
Unregistered email when signing up for account in the Vivio App	Your email address is not yet registered to access the Vivio app. Please contact Ventric Health Support at support@ventrichealth.com and include the following details so we can assist you: First and last name, Email address, Organization, Title
Email address already in use	The email address provided is already in use. Try signing in or use “Forgot Password” to reset your password.
Password does not meet minimum requirements	Your password must contain: At least 8 characters. At least 3 of the following: • Lower case letters (a-z) • Upper case letters (A-Z) • Numbers (0-9) • Special characters (e.g., !@#$%^&*)
Password mismatch when signing up for account in the Vivio App	Passwords don’t match.
Incorrect username or password when logging in or problem with authorization	Wrong email or password.
Login Session Expiration	The login session has expired. Please log back in to finish the recording.
No internet connection	The device cannot connect to the Internet. Please contact your IT team.
Code 403 Error	There is problem with the Vivio device. Please contact Ventric Health Support for help (support@ventrichealth.com). Please include the Error Code 403.

15 Servicing

Vivio System components do not require any calibration. Refer to section 11 for software maintenance activities. For faults and repairs, please contact Ventric.

16 Warranty

The Vivio System and/or related materials are provided “AS-IS” WITHOUT WARRANTY OF ANY KIND INCLUDING ANY WARRANTIES OF PERFORMANCE OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE (as set forth in UCC §23212-2313) or for any purpose whatsoever, however used. In no event shall Ventric be liable for any damages and/or costs, based on the condition of the Vivio System or related materials including but not limited to incidental or consequential damages of any kind, including economic damage or injury to property and lost profits, regardless of whether Ventric shall be advised, have reason to know, or in fact shall know of the possibility.