Inmedix
INNOVATIVE MEDICAL DISCOVERY

CloudHRV™ System

Instructions for Use

REF 68481

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Contents

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1 Device Overview

The Inmedix CloudHRV™ System acquires approximately 5 minutes of 3-lead electrocardiographic (ECG) data from a patient lying supine and at rest to measure heart rate variability (HRV). The raw cardiac electrical signals are detected using four standard ECG electrodes applied to the wrists and ankles of the patient and a custom 4-lead wire (one reference) ECG cable assembly.

The ECG data collected from the patient are transmitted to a cloud-based service hosted by Inmedix, where proprietary mathematical algorithms calculate HRV. The CloudHRV™ System outputs are used as an aid by clinicians who are accustomed to evaluating HRV as a part of their overall medical assessment.

Figure 1: The CloudHRV™ System comes with its own 12 V Power Adapter, ECG Cable Assembly, introductory ECG electrodes, and IFU

1.1 Base Enclosure and Sensor

Figure 2: The Base Enclosure storage compartment can be used to store the ECG Cable Assembly

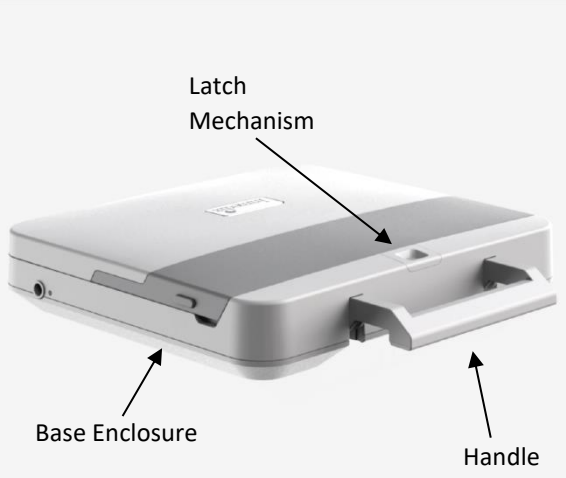


Figure 3: The Base Enclosure latch secures the lid when closed

The Base Enclosure is used to house the device's internal components including the Sensor battery and the Sensor (main Printed Circuit Board [PCB]). On the left-hand back corner, the Base Enclosure has a Power Adapter Port and a Sensor Power Button to sleep or wake the internal components (Figure 2). A compartment in the Base Enclosure provides the connection port for the ECG Cable Assembly and may be used to store the cable when the device is stowed (Figure 2). The Base Enclosure has a handle to carry the device, adjacent to the latch mechanism (Figure 3).

1.2 Tablet

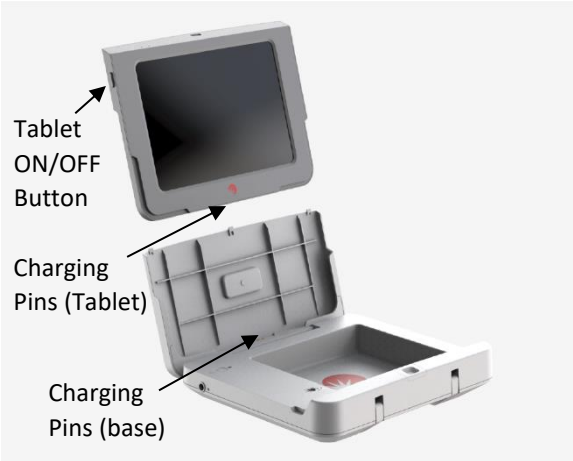


Figure 4: The Tablet may be used when docked or hand-held

Figure 5: Presentation mode allows for a range of angles

The Tablet (Apple iPad), which is permanently housed in a protective case (Figure 5), forms part of the lid and can slide in and out of the Base Enclosure (Figure 4). A bezel in the back of the Tablet case also provides the option for the Tablet to be placed in presentation mode (Figure 7). A button on the top left-hand side of the Tablet turns the Tablet ON/OFF (Figure 4). When the Tablet is docked in the lid, magnets hold the Tablet in place, which enables the Tablet to charge (Figure 6). The Tablet charges via the charging pins, which interface with the Sensor at the location illustrated in Figure 4. The Tablet connects to the Sensor using a Bluetooth connection. This allows the Tablet to be used whether it is docked or hand-held. Closing the lid of the Base Enclosure when the Tablet is docked will put the Tablet in sleep mode.

Figure 6: Magnets hold the Tablet in place when it is charging

Figure 7: The bezel on the back of the Tablet allows for the Tablet to be used in presentation mode

1.3 ECG Cable Assembly

Figure 8: ECG Cable Assembly is assembled from the Patient Lead Wires (left) and Trunk Cable (right)

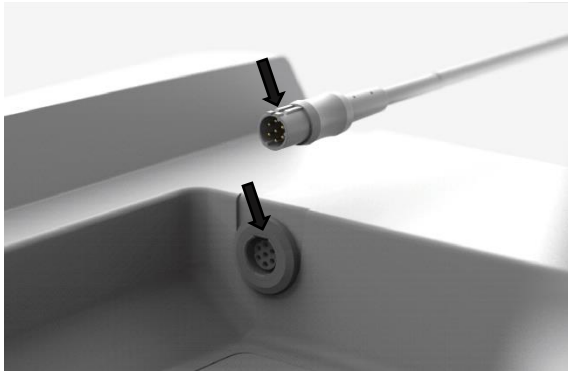


Figure 9: The ECG Cable Assembly connector is keyed to provide the proper orientation for connection with the ECG Cable Assembly Connection Port on the Base Enclosure.

The CloudHRV™ System can only be used with the supplied 4-lead ECG Cable Assembly. The Cable Assembly contains two pieces, the Trunk Cable and the Patient Lead Wires (Figure 8). Prior to use the Trunk Cable and the Patient Lead Wires are connected. The cable connector has a “notch” to indicate the cable orientation (Figure 9) to attach it to the ECG Cable Assembly Connection Port on the Base Enclosure.

1.4 Power Adapter

Figure 10: Power Adapter provided with the CloudHRV™ System

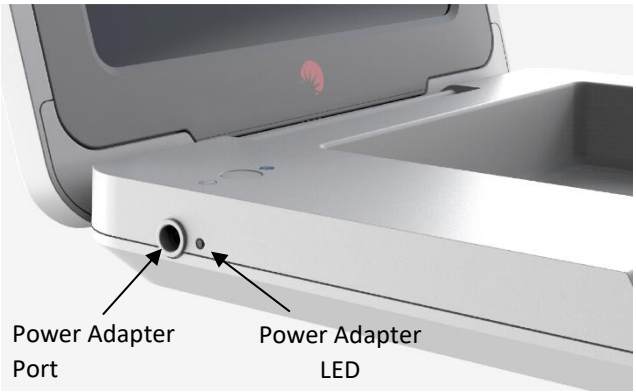


Figure 11: Power Adapter Port

The CloudHRV™ System comes with its own 12 V Power Adapter (Figure 10). The Power Adapter connects to the wall and to the Power Adapter Port on the left-hand side of the Base Enclosure (Figure 11).

1.5 Graphical User Interface (GUI)

Figure 12: Splash screen displayed momentarily when the app is launched

Figure 13: The patient list is the home screen for the CloudHRV™ application

The Graphical User Interface (GUI) allows users to interact with the system. The CloudHRV™ application runs on a Tablet and is launched via an icon on the Tablet. The application enables users to manage patient records, create new patient profiles, conduct tests, and view test results.

2 Intended Use

The Inmedix CloudHRV™ System is intended to acquire, display, and record electrocardiographic information (ECG) to measure heart rate variability (HRV). These measurements are not intended for any specific clinical diagnosis. The clinical significance of HRV must be determined by the physician.

3 Indications for Use

The Inmedix CloudHRV™ System is intended to acquire, display, and record electrocardiographic information (ECG) to measure heart rate variability (HRV) in patients with normal sinus rhythm. These measurements are not intended for specific clinical diagnosis. The clinical significance of HRV must be determined by the physician.

3.1 Patient Population

The intended patient population are adults, 22 years of age and older in normal sinus rhythm.

4 Contraindications

The CloudHRV™ System has the following contraindications:

- Use on patients with a heart being actively controlled by a pacemaker.

5 Use Environment

The CloudHRV™ System is intended to be used in a stationary, professional healthcare facility, such as an outpatient medical clinic, away from RF communication equipment (including peripherals such as antenna cables and external antennas).

6 General Information

This Instructions for Use (IFU) describes the use of the CloudHRV™ System.

All intended operators of the CloudHRV™ System shall fully read and understand this Instructions for Use (IFU).

6.1 Contact Inmedix

Inmedix, Inc.
17837 First Avenue South, #6,
Normandy Park, WA 98148, USA

+1 206-466-3349 (+1 206-INMEDIX)
support@inmedix.com

6.2 Cybersecurity Information

The Tablet requires a passcode for access. The passcode used should not be easily guessable and only shared with individuals that require access to the device.

The device should be connected to a private network, not used for guest connections, that is protected with a password and WPA2 security.

The device, when not in use, should be stored in a locked area or cabinet to prevent any tampering with the device by unauthorized personnel.

Please refer to the customer portal for important cybersecurity information. The customer portal can be navigated to via www.inmedix.com.

7 Symbols and Descriptions

Symbol	Description
	**Warning** Indicates important safety information for hazards that could cause moderate injury.
	**Caution** Indicates safety information for hazards that could cause minor injury or cause damage to the device or peripheral equipment.

NOTE	**Note** Indicates information to which the user should pay special attention.
REF	**Catalog or Orderable Part Number** Indicates the manufacturer's catalog or part number.
SN	**Serial Number** Indicates the manufacturer's serial number.
UDI	**Unique Device Identifier** Indicates the Unique Device Identifier including the Automatic identification and data capture (AIDC) and human-readable information.
LOT	**Lot Number** Indicates the manufacturer's lot number.
MAC	**Media Access Control Address** Indicates the MAC address of the device, used to identify the device on a network.
	**Quantity** Indicates the number of components in the package.
	**Date of Manufacture** (Year-Month-Date) Indicates the original manufacture date for this device.
	**Manufacturer** Indicates the name and address for the manufacturer of this device.
	**Class II Equipment** Indicates the device meets the safety requirements specified for Class II equipment according to IEC 61140.
IP20	**Degree of Protection** Indicates protection of solid foreign objects of 12.5 mm diameter and greater, and no protection against water.
	**Prescription Use Only** Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	**Waste Stream Disposal Status** Indicates electronic products must not be disposed of in the general waste stream.

	**Direct Current** Indicates the device is suitable for direct current only.
	**Polarity of DC Power Connector** Indicates the positive and negative connections of the DC power adapter.
	**Resistor** Indicates the resistance of the current limiting device(s) in series with each wire lead (located within the Yoke).
	**Power Button** Indicates the ON/OFF button for the device.
	**Defibrillation-Proof Type CF Applied Part** Indicates a defibrillation-proof Type CF applied part complying with IEC 60601-1.
	**Fragile, Handle with Care** Indicates the device can be broken or damaged if not handled carefully.
	**Keep Dry** Indicates the device needs protection from moisture.
	**This Way Up** Indicates the orientation of the system.
	**Temperature Limit** Indicates the temperature limits to which the device can be safely exposed.
	**Humidity Limitation** Indicates the range of humidity to which the device can be safely exposed.
	**Atmospheric Pressure Limitation** To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	**Consult Instructions for Use** Indicates that the user should read the IFU prior to using the device.
	**Refer to Instructions for Use** Indicates that the user must read the IFU prior to using the device.

8 Notes, Cautions and Warnings

Caution and warning iconography is used to draw attention to use related information that may result in harm or damage to the device or other equipment. There are three (3) kinds of statements: **Notes**, **Cautions** and **Warnings**.

8.1 Warnings

Warnings

- The CloudHRV™ System is not intended to be used to prescribe specific patient treatment plans.
- Do not use the ECG waveforms and results output displayed by the CloudHRV™ System for diagnosing or monitoring cardiovascular conditions.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment
- The Sensor battery is not replaceable. Replacement of the Sensor battery may result in injury. Contact Inmedix for servicing.
- There are no user serviceable parts. Contact Inmedix if service is required.
- Avoid use of the CloudHRV™ System adjacent to or stacked with other equipment, failure to do so may 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 1 m (40 inches) to any part of the CloudHRV™ System, including cables specified by the manufacturer. Failure to do so may result in degradation of the performance of this equipment.
- Use only the ECG cable provided by Inmedix. Protection of the CloudHRV™ System against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate ECG cables. Using incorrect ECG cables may result in decreased defibrillation energy delivered to the patient, damage to the device, or electric shock to the operator or other persons.
- Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

8.2 Cautions

Cautions

- The CloudHRV™ System must only be used by qualified health professionals.
- Only use the 12 V Power Adapter provided with the device for charging the Sensor battery. Use of other power adapters may damage the device or result in minor electric shock.
- Do not use a damaged Power Adapter cord / Power Adapter. Contact Inmedix for a replacement. Inspect the power cord and Adapter before use. Use of a damaged Power Adapter or cord may result in minor electric shock and / or damage to the device.
- Only use single-use ECG electrodes with the CloudHRV™ System. Remove ECG electrodes immediately after test completion.
- Do not apply ECG electrodes over open wounds, lesions, infected, or inflamed areas. The ECG electrodes should be applied only to intact, clean skin. Failure to do so may damage the skin.
- Do not use the CloudHRV™ System and its accessories in the presence of high magnetic fields.
- Do not spill fluids on or near the device and its accessories. The device has no protection against fluids. Exposure to fluid may damage the device or result in injury.
- Avoid touching the exposed charging pins when the Tablet is undocked. Do not touch the charging pins on the base and the patient simultaneously. Refer to Figure 4 for the location of the charging pins. Contact with the charging pin may result in minor electric shock.
- If the device or its components are dropped or mishandled, unplug the device, and perform a visual inspection to check for damage. If there is obvious or suspected damage, discontinue use, handle with care, and contact Inmedix for servicing or replacement.
- Do not use a defibrillator while the CloudHRV™ System is connected. If the device is exposed to a defibrillation voltage, the ECG cable should be replaced prior to the next use, and the CloudHRV™ System should be power cycled.
- While it is not expected that other devices are applied to the patient while a CloudHRV™ System measurement is being performed, if additional medical devices are applied or present, there will be an additive effect and the permissible electrical leakage current value may be exceeded.
- Ensure that the latch is closed and that it is not inadvertently opened during transportation. Failure to do so may result in the lid opening, the Tablet and/or ECG Lead Set dropping, resulting in damage.

8.3 Notes

NOTES

- Answering “Yes” to any of the Patient screener questions will not prevent the system from performing a measurement. This information is only used for the physician’s reference when reviewing the results to understand the patient’s state at the time of measurement.
- Performing two consecutive measurements on a patient may produce inaccurate ECG readings due to the patient entering a state of rest.
- If a measurement must be repeated and the patient enters into a state of rest, the patient should be asked to walk for 5-10 minutes before attempting a new measurement.
- The Tablet must be docked in the Base Enclosure lid for the Tablet’s battery to charge. No additional cables are required or available to charge the Tablet.
- Refer to the ECG electrode manufacturer’s labeling for safety information.

- To avoid noise interference, avoid routing the patient ECG cable in parallel or in contact with any other cables that may carry mains power or signals.
- Occasional momentary high electric field events, such as Electrostatic Discharge (ESD), Electrical Fast Transients (EFT) or Surges (when AC/DC adapter is plugged in), defibrillation, etc. may affect the device's input. For the duration of the momentary event, the displayed waveform may appear distorted, and the device would be available for normal use within 10 s after the event has completed.
- Conductive parts of the ECG electrodes and associated connectors on the ECG cable, including the neutral electrode, should not contact any other conductive parts including earth.
- When fully discharged (0%), the Sensor battery should take 4-5 hours to fully recharge (100%). The Sensor battery should be sufficiently charged and unplugged prior to initiating a measurement for optimal conditions. However, a measurement may be initiated while the Sensor battery is plugged in and charging.
- While in storage, the system should be recharged at a minimum of every 6 months to prevent the battery from being severely depleted.
- Connection of the device to an IT network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties. Risks should be identified, analyzed, evaluated, and controlled. Subsequent changes to the IT network could introduce new risks and require additional analysis. Changes to the IT network include changes in the IT network configuration, connection of additional items to the IT network, disconnecting items from the IT network, update of equipment connected to the IT network, and upgrade of equipment connected to the IT network.

9 System Setup

9.1 Unpacking the System

WARNING: Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The CloudHRV™ System package includes:

- CloudHRV™ Base Enclosure
- CloudHRV™ Tablet with Inmedix CloudHRV™ Application. The Tablet is housed within a secure protective case and is detachable from the Base Enclosure.
- CloudHRV™ ECG Cable Assembly (Trunk Cable and Patient Lead Wires)
- Power Adapter
- ECG Electrodes (QTY 30) – Refer to section 18.8 for ECG electrode recommended replacements
- Instructions for Use (IFU)

To unpack the CloudHRV™ components:

1. Carefully remove all components from the shipping packaging.
2. Inspect each part to ensure there are no signs of damage.
3. Dispose of packaging in accordance with the facility guidelines.

There are no special installation requirements.

CAUTION: Ensure that the latch is closed and that it is not inadvertently activated during transportation. Failure to do so may result in the lid opening, the Tablet and/or ECG Cable Assembly dropping, resulting in damage to the device.

9.2 Powering and Charging the System

CAUTION: Only use the 12 V Power Adapter provided with the device for charging the Sensor battery. Use of other power adapters may damage the device or result in minor electric shock.

The system is packaged with a partially charged battery and should be fully charged prior to the first use. When exposed to temperatures outside of the recommended operating temperature stabilize the device for at least 1 hour prior to charging.

To charge the System:

1. Connect the supplied Power Adapter to a wall power outlet and to the Power Adapter Port. Ensure that the adapter is accessible to allow disconnection from the power outlet if isolation is required.
2. When the Sensor battery is charging and the Sensor is powered (section 9.4), the Adapter Port LED will blink green, and when the Sensor battery is fully charged, the Adapter Port LED will stop blinking and remain steady green until it is unplugged.

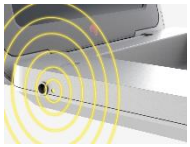
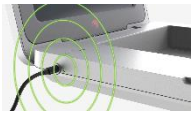
   Table 1 summarizes the Adapter Port LED behavior when the Sensor is powered on.

NOTE: When fully discharged (0%), the Sensor battery should take 4-5 hours to fully recharge (100%). To ensure optimal measurement conditions the Sensor battery should be sufficiently charged and system unplugged prior to initiating a measurement. However, if necessary, a measurement may be initiated while the system is plugged in and charging.

NOTE: While in storage, the system should be recharged at a minimum of every 6 months to prevent the Sensor battery from being severely depleted.

NOTE: The Adapter Port LED is operational when the Sensor is powered on (section 9.4). The battery status is not available when the device is in sleep mode.

Table 1: Adapter Port LED states and meaning (Sensor is powered on to view the Adapter Port LED)

Colors	Adapter Port LED	Meaning
	Light is off	The Sensor battery is not charging, and the battery level is above 25%.
	Yellow light is blinking slowly (once every 2.5 seconds)	The Sensor battery level is below 25%. This serves as an early indication that the device should be charged soon.
	Yellow light is blinking quickly (2.5 times every second)	The Sensor battery is not charging, and the battery level is below 5%. The Sensor should be plugged in. The Sensor battery level is insufficient for reliably completing a measurement. The Sensor will NOT connect to the Tablet.
	Green light is blinking (Sensor is plugged in)	The Sensor is plugged in, and the Sensor battery is charging.
	Green light is steady (Sensor is plugged in)	The Sensor is plugged in, the Sensor battery is fully charged.

9.3 Powering and Charging the Tablet Battery

The Tablet is packaged in a power off state but should be charged prior to first use.

To charge the Tablet battery:

1. Insert the Tablet into the Base Enclosure lid and ensure it is properly seated (the Tablet must be contacting the charging pins in the Base Enclosure lid, Figure 6).
2. Ensure the Power Adapter is connected to the Power Adapter Port and is plugged in (see Section 9.2).
3. If the Tablet does not begin the power up sequence, the Tablet battery may have fully depleted during storage. Wait a few minutes with the Tablet connected and try again.
4. When the Tablet is charging, the battery icon in the corner of the Tablet screen will display the charging status next to the battery level (Figure 14 and Figure 15).

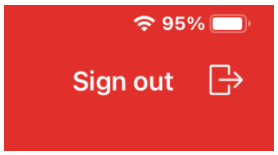


Figure 14: Tablet battery level

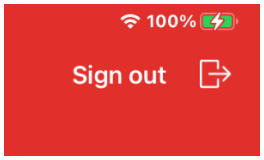


Figure 15: Tablet battery icon while charging

> ***NOTE:*** The Tablet must be docked in the Base Enclosure lid for the Tablet's battery to charge. No additional cables are required or available to charge the Tablet.

9.4 Powering on the system

The Tablet and the Sensor are turned on separately. To power on the system:

1. Press the Sensor Power Button to power on the Sensor (Figure 2). The Sensor Power LED will be illuminated blue (flashing or solid).
2. Press the Tablet Power Button to power on the Tablet (Figure 4)

9.5 Connecting the Tablet to a Wireless Network

The Tablet must be connected to the internet via Wi-Fi to communicate with the Inmedix Cloud.

To connect the Tablet to your wireless network:

1. Swipe down on the top right of the screen to open the general menu.
2. Press and hold the Wi-Fi icon to open the connection menu.
3. Press and hold the Wi-Fi icon in the connection menu to view all available networks.
4. Select the appropriate network for your facility from the list of networks. Inmedix recommends connecting to a private network, not used for guest connections, that is protected with a password and WPA2 security.
5. Enter the password for the network.
6. Press **Join**.

If you have successfully joined the network, a checkmark will appear next to the network name.

9.6 Accessing the CloudHRV™ Application

After the device has been unpackaged and charged, it needs to be associated with the clinic where it will be used.

1. Look for the CloudHRV™ application thumbnail (Figure 16).
2. Select the thumbnail to launch the application. You will be presented with the log-in screen (Figure 17).
3. Enter the **Email** and **Password** associated with the Inmedix account you were provided and press the **Log in** button.

There may be one or multiple email addresses associated with a clinic or hospital. Using any of the email addresses to authenticate will provide access to the application.

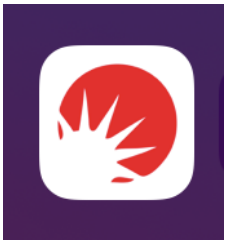


Figure 16: CloudHRV™ application thumbnail

Figure 17: Clinic Log-in screen

10 Use Instructions

CAUTION: The CloudHRV™ System must only be used by qualified health professionals.

10.1 Introduction

This section describes how to set up and operate the Inmedix CloudHRV™ System. The basic workflow for performing a CloudHRV™ assessment is as follows:

1. Power on the CloudHRV™ system.
2. Log in to the CloudHRV™ application.
3. Ready the Tablet and the Sensor to be connected (via Bluetooth)
4. Select the patient to be assessed.
5. Complete the patient screener.
6. Prepare and connect the patient.
7. Complete the measurement.
8. Disconnect the patient.
9. Review the assessment results.
10. Log out of the CloudHRV™ application.
11. Powering off the CloudHRV™ system.

For a description of the device and its user interfaces, refer to section 1. When operating the CloudHRV™ System, it should be placed on a clean, flat surface.

10.2 Power on the CloudHRV™ System

1. Ensure the Sensor battery and Tablet battery are sufficiently charged (see Sections 9.2 and 9.3).
2. Power on the Sensor and the Tablet (see Section 9.4)

10.3 Logging in to the CloudHRV™ Application

1. Select the CloudHRV™ Application thumbnail to launch the application (see Section 9.6).
2. Once booted, the CloudHRV™ Application will display the **User Login** screen (Figure 18).
3. Select the **User name** or email, enter the **Password** you were provided and press the **Log in** button.
   If you have lost or forgotten your password, refer to section 14 for troubleshooting instructions.

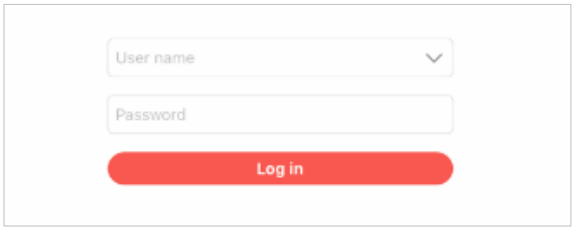


Figure 18: User Login screen

4. Upon successful log in, the CloudHRV™ Application will display the **Patient List**[1] screen (home screen, Figure 19).

[1] The patient data that appears in this document are fictitious protected health information (PHI). No personally identifiable information is shown.

Figure 19: Patient List screen (home screen)

	Patient List Screen Elements
1	Settings button: Used to navigate to the Settings screen.
2	New Patient (“+”) button: Used to create a new patient profile.
3	Synchronization button: Spinning arrows indicate the CloudHRV™ application is synchronizing with the data on the Cloud. Last synchronized date and time is displayed below.
4	Patient List headers: Clicking a column header will activate the sorting function. An upward arrow indicates ascending order, and a downward arrow indicates descending order.
5	Sign out button: Used to log the current user out of the CloudHRV™ application.
6	Search field: Can be used with first name, last name, date of birth (DOB), or Medical Record Number (MRN) to filter the Patient List.

10.4 Connecting the Tablet to the Sensor

The Tablet and the Sensor work together to acquire patient measurement data for processing and display. The two parts of the system connect wirelessly through Bluetooth. Before a measurement can be initiated, the Tablet must be connected to the Sensor. Normally this will occur automatically.

To establish the Bluetooth connection:

1. If the Sensor has not been already powered on, press the Sensor Power Button momentarily (1-2 second).
2. The Sensor Power Button LED will blink blue. This indicates that the Sensor is advertising a Bluetooth signal.

3. The Tablet and Sensor will automatically pair when the system is at the **Patient Screener** or **Connect Cables** screen. This will be confirmed by the blue LED changing from blinking to a steady illuminated state. The Connection Status on the Tablet will also display a "Connected" message.
4. If you are unsure a Sensor has been selected or would like to check which Sensor has been chosen, select the **Settings Button** on the **Patient List** screen and following the directions given in section 11 or section 14.1.4.

Error! Reference source not found. Table 2 below summarizes the Sensor Power LED behavior.

Table 2: Sensor Power Button LED states and state meanings

LED State Visual	LED State Description	LED State Meaning
	LED is off	The Sensor is in a low power state and not advertising a Bluetooth signal. The Tablet cannot be paired with the Sensor when the LED is off. Press the Sensor Power Button momentarily (1-2 seconds) to power on the Sensor.
	LED is blinking blue slowly	The Sensor is advertising a Bluetooth signal. It is ready to connect to the Tablet, but the Tablet has not yet recognized the signal. ***NOTE:*** The Tablet will only attempt to connect to the Sensor when the system is at the **Patient Screener** or **Connect Cables** screen. ***NOTE:*** Refer to Troubleshooting section 14.1.4 for difficulty pairing the Tablet to the Sensor.
	LED is steady blue	The Tablet and the Sensor are connected via Bluetooth. The system is ready to perform a measurement.

10.5 Selecting the Patient for Assessment

To perform an assessment, the patient profile must exist in the system.

The following subsections provide instructions for adding a new patient profile to the system or selecting an existing patient profile from the **Patient List** screen.

10.5.1 Adding a New Patient

If the patient is not yet in the system, the following steps can be used to create a new patient profile and add it to the system. This patient profile may be selected later from the **Patient List** screen (Figure 19) for future assessments.

1. Click the **New Patient ("+")** button at the top of the **Patient List** screen and confirm by pressing **Create new**.

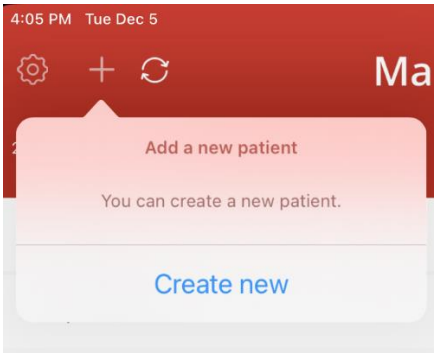


Figure 20: New Patient ("+") button

2. The **New Patient Profile** screen will be displayed. Refer to the patient's medical chart to complete the patient profile form, confirming that all information is up to date. Fields marked with an asterisk (*) are mandatory for creating a new patient in the system.

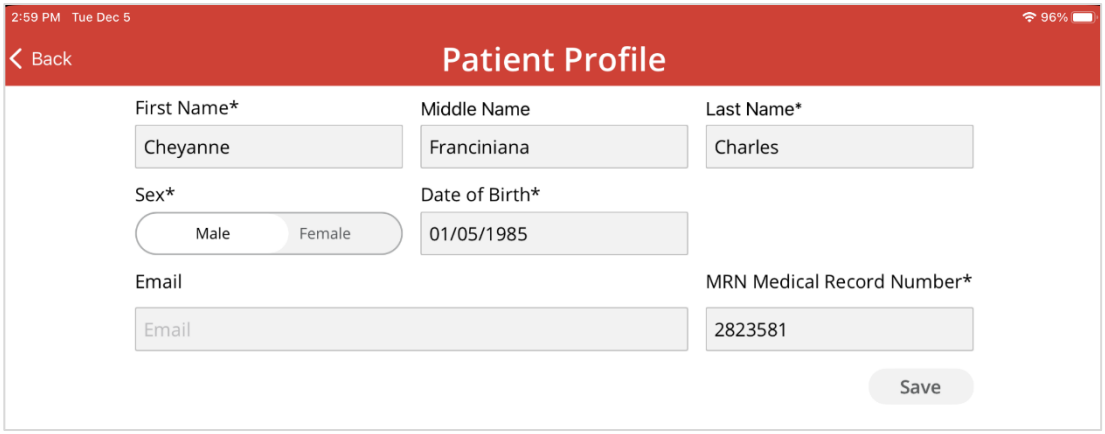


Figure 21: New Patient Profile screen

3. Press the **Save** button to add the patient to the system.
4. Once the form has been completed, the **Patient History** screen will be displayed with no previous assessment results (Figure 22).
5. Press the **New Assessment** button at the top of the **Patient History** screen to proceed to the **Patient Screener** screen (Figure 25).

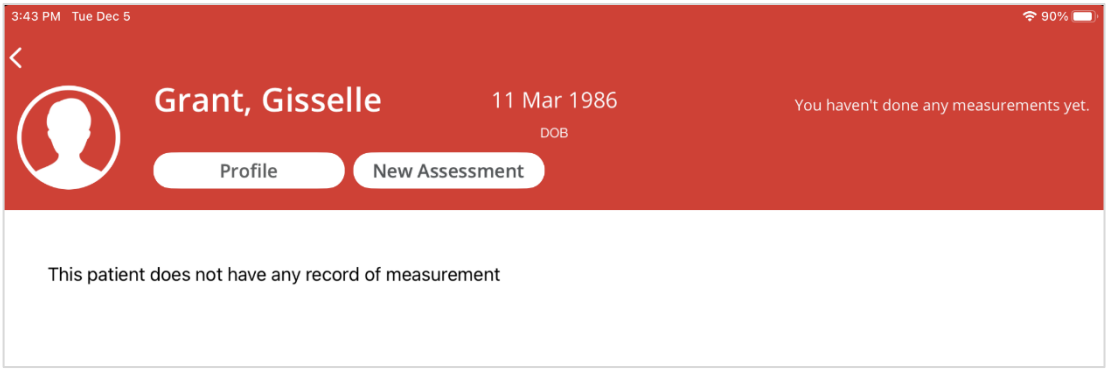


Figure 22: Patient History screen (new patient)

10.5.2 Updating or Selecting an Existing Patient

If the patient is already in the system, the following steps can be used to select the patient profile from the **Patient List** screen (Figure 19).

1. Identify the patient within the list of patients (refer to Figure 19). The column headers may be used to sort and filter the list for efficiency. A search box is also available, which allows the user to search for a patient name, date of birth, medical reference number, or the date of their last assessment.
2. Select the name of the patient (or the patient row) from the list.
3. The **Patient History** screen will be displayed with previous assessment results (Figure 24).
4. Press the **Profile** button to update the patient's information. This will bring up the patient's information, which can be edited (Figure 23).

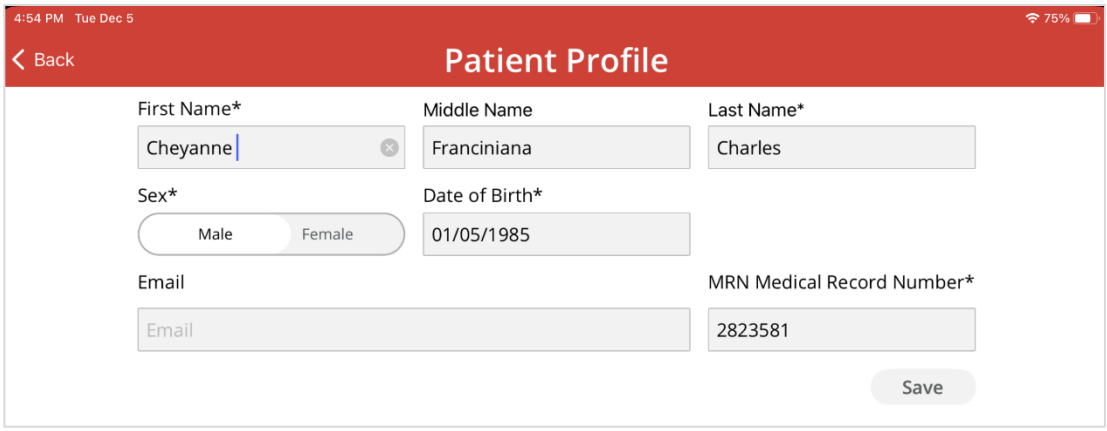


Figure 23: The Patient Profile can be edited

5. Press **Save** after making changes to the **Patient Profile**, and the system will return to the **Patient History** screen (Figure 24).
6. Press the **New Assessment** button at the top of the screen to proceed to the **Patient Screener** screen (Figure 25).

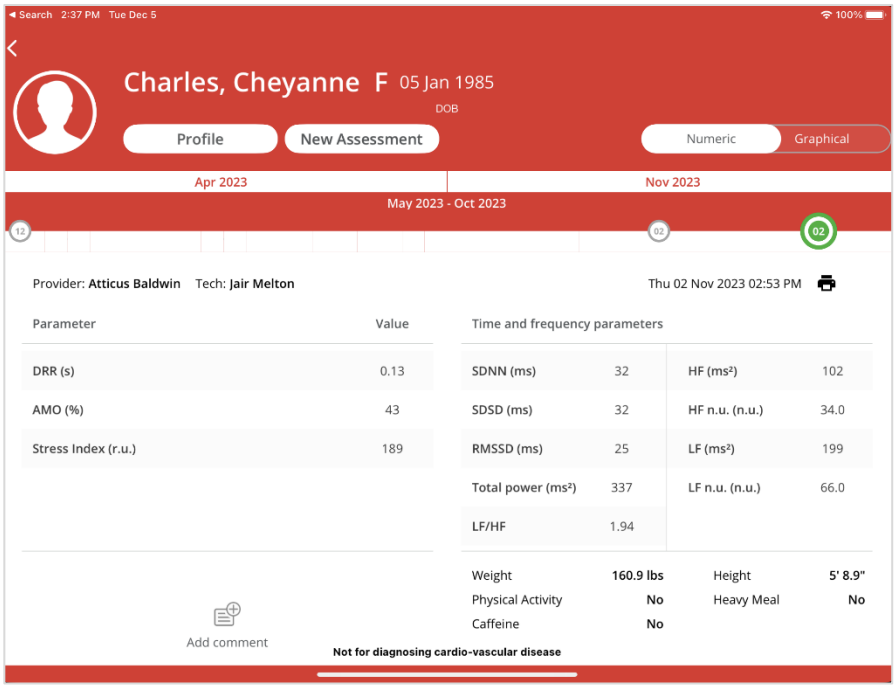


Figure 24: Patient History screen (existing patient)

10.6 Completing the Patient Screener

Once a patient has been selected and a new assessment has been initiated, the CloudHRV™ application will display the **Patient Screener** screen (Figure 25). A form is provided to collect information about the clinic, operator, and patient to associate with the assessment. The Sensor will automatically connect with the Tablet via Bluetooth.

1. Ensure that the Sensor has connected with the Tablet, indicated by the text in the upper right side of the screen (Figure 25) and section 10.4.
2. Complete all fields for the patient screener.
3. Press the **Continue** button to proceed to the **Connect Cables** screen.

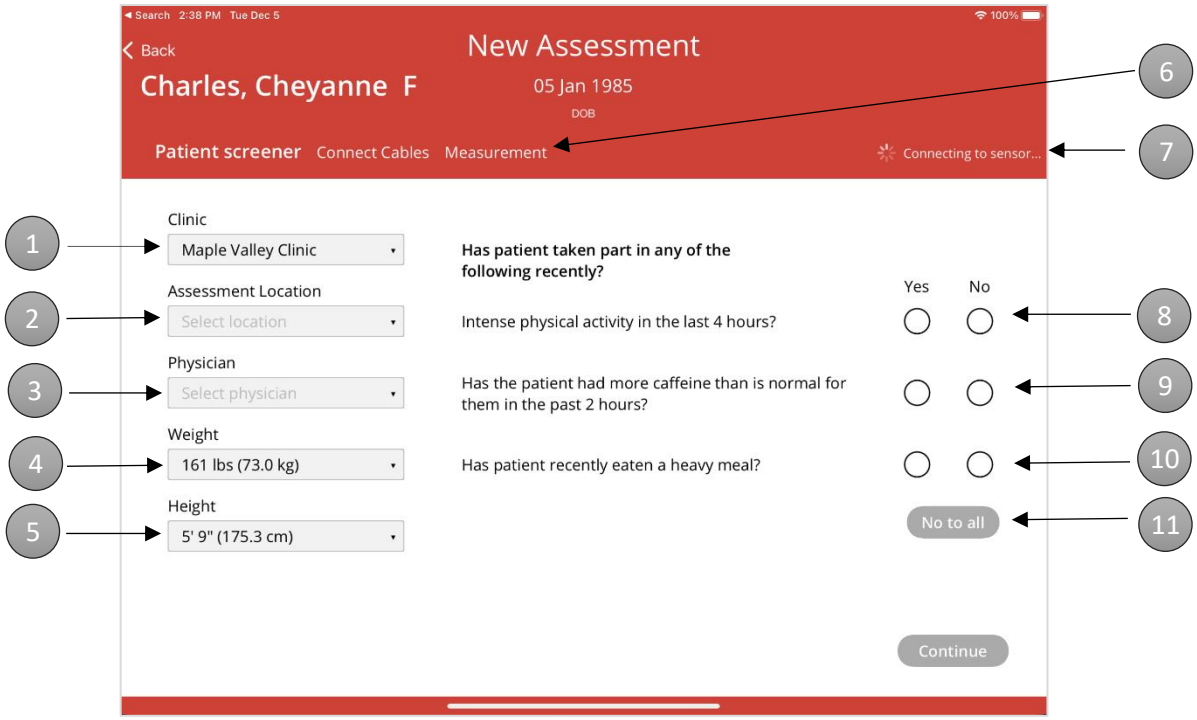


Figure 25: Patient Screener

	Patient Screener Elements
1	Clinic dropdown: Used to select the name of the clinic where the Tablet is registered. This field is automatically filled.
2	Assessment Location dropdown: Used to specify the type of location where the assessment will take place.
3	Physician dropdown: Used to identify the name of the physician that ordered the assessment.
4	Weight dropdown: Used to enter the weight of the patient on the day of the assessment.
5	Height dropdown: Used to enter the height of the patient on the day of the assessment.
6	New Assessment tabs: Used to indicate (in bold) the current stage of the patient assessment workflow.
7	Connection status: Used to indicate whether the Sensor is in the process of connecting or has successfully connected to the Tablet.
8	Physical activity option buttons: Used to indicate whether the patient has recently participated in intense physical activity (have they exerted themselves or been significantly more active than normal?).
9	Caffeine option buttons: Used to indicate whether the patient has recently consumed significant amounts of caffeine (more than they normally consume).
10	Heavy meal option buttons: Used to indicate whether the patient has recently eaten a heavy meal.
11	No to all button: Used to select “no” for all three of the above buttons (items 8-10).

NOTE: Answering "Yes" to any of the Patient screener questions will not prevent the system from performing a measurement. This information is only used for the physician's reference when reviewing the results to understand the patient's state at the time of measurement.

10.7 Preparing and Connecting the Patient

CAUTION: Only use single-use ECG electrodes with the CloudHRV™ System. Remove ECG electrodes immediately after test completion.

Do not apply ECG electrodes over open wounds, lesions, infected, or inflamed areas. The ECG electrodes should be applied only to intact, clean skin. Failure to do so may damage the skin.

Before applying an ECG Electrode to the patient, ask the patient if they have known allergies to the electrode adhesion material. Ensure the skin is intact and free from lotions or cosmetics before applying the ECG electrode.

Ensure that the patient is lying comfortably supine in a position that can be maintained without effort for the duration of the measurement. Arms and legs should be fully supported. Patient motion during measurement may result in excessive measurement "noise" and a rejected measurement session.

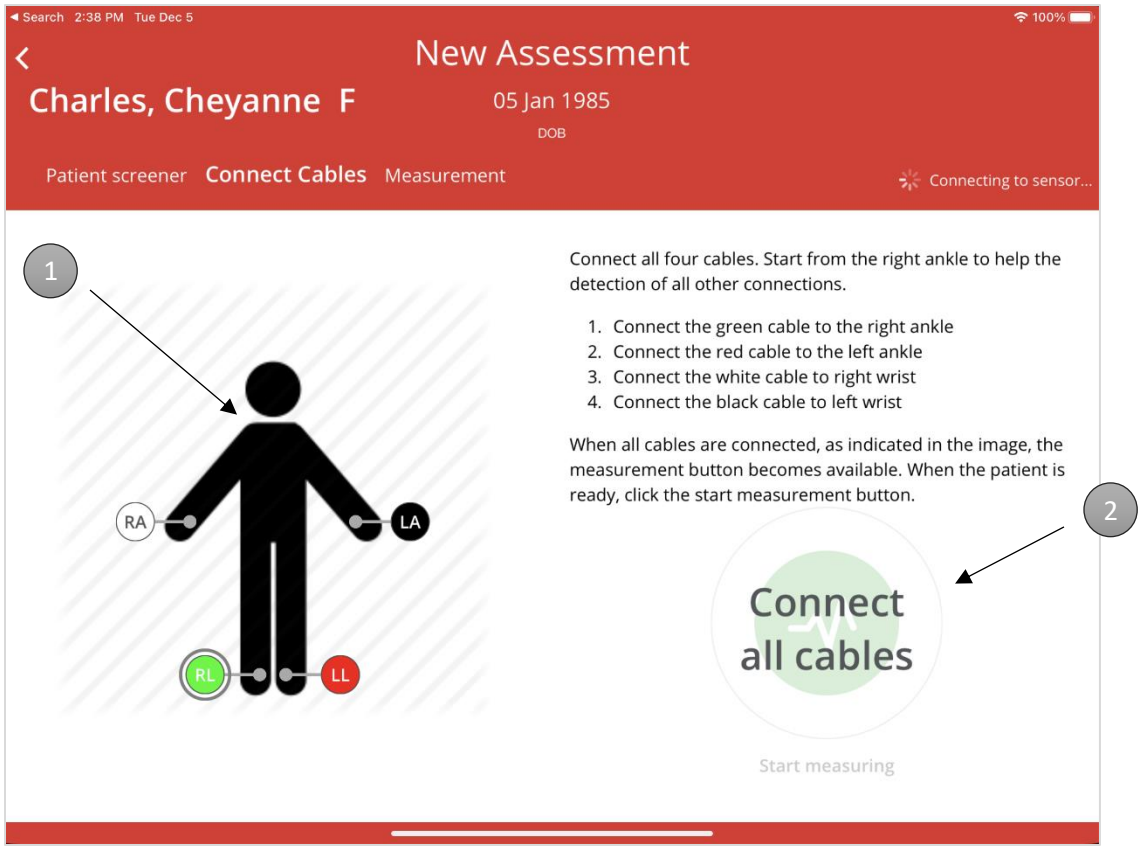


*Figure 26: The **Connect Cables** Screen gives instructions on how to apply ECG leads to the patient*

	Connect Cables Screen Elements
1	Diagram that illustrates where to connect each Patient Lead Wire and the status of each connection. When the lead wire is connected correctly, the location will be enclosed with a green circle.
2	Indicator that displays the status of the Patient Lead Wire connections. Changes from "Connect all cables" to "Start Measurement" when ready.

While the **Connect Cables** screen is displayed (Figure 26), perform the following steps to connect the patient to the Sensor:

1. Place one ECG Electrode on the patient at each of the following 4 locations (Figure 27, Figure 28):
    a. Inside the patient's left wrist,
    b. Inside the patient's right wrist,
    c. Inside the patient's left ankle, and
    d. Inside the patient's right ankle.
2. If they are not already assembled, connect the two pieces of the ECG Cable Assembly (Trunk Cable and Patient Lead Wires) to each other (Figure 8).

3. Connect the Trunk Cable plug to the ECG Cable Assembly Connection Port of the Base Enclosure (Figure 9).
4. Connect the green Patient Lead Wire, indicated for the right leg (RL), to the ECG Electrode applied to the inside of the patient's right ankle (over the tibia for easier attachment).
5. Connect the red Patient Lead Wire, indicated for the left leg (LL), to the ECG Electrode applied to the inside of the patient's left ankle (over the tibia for easier attachment).
6. Connect the white Patient Lead Wire, indicated for the right arm (RA), to the ECG Electrode applied to the inside of the patient's right wrist (over the radius for easier attachment).
7. Connect the black Patient Lead Wire, indicated for the left arm (LA), to the ECG Electrode applied to the inside of the patient's left wrist (over the radius for easier attachment).

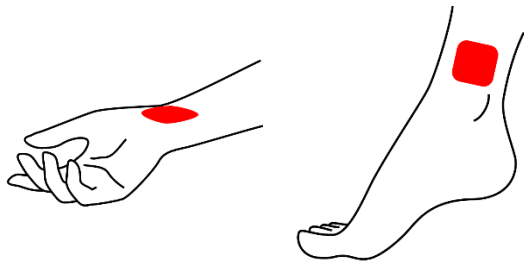


Figure 27: Connect the ECG Electrode to the inside of the patient's wrists and ankles

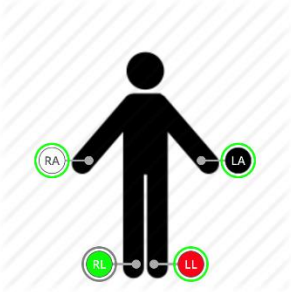


Figure 28: The Connect Cables screen displays a diagram illustrating where to connect each Patient Lead Wire and the status of each connection

8. When the system detects a signal from all the Patient Lead Wires, the **Connect all cables** message will no longer be displayed (Figure 29), and the green **Start measuring** button (Figure 30) will become enabled. Avoid applying pressure to the ECG Electrodes and Patient Lead Wires once the patient is connected.

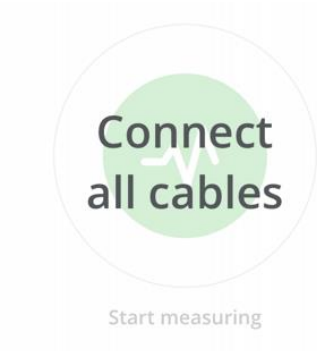


Figure 29: The system is looking for the signals from the Patient Lead Wires

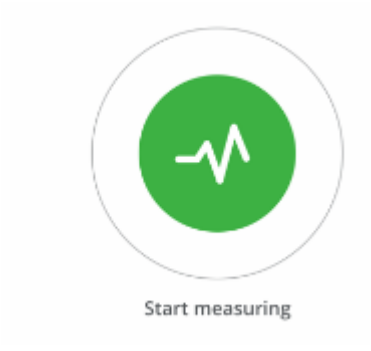


Figure 30: The system has detected the signals from the Patient Lead Wires and is ready to start the measurement

9. Remind the patient to remain calm and refrain from speaking or moving during the measurement.
10. Press the **Start measuring** button to proceed to the **Measurement** screen to initiate ECG data acquisition.

NOTE: Conductive parts of the ECG electrodes and associated connectors for ECG cable, including the neutral electrode, should not contact any other conductive parts including earth.

10.8 Completing the Measurement

WARNING: The CloudHRV™ System is not intended to be used to prescribe specific patient treatment plans.

Do not use the ECG waveforms displayed by the CloudHRV™ System for diagnosing or monitoring cardiovascular conditions.

The system will perform the measurement over 5 minutes (Figure 31). For the acquisition to be successful, it must collect 5 minutes of continuous data. During the measurement, the patient must remain supine, calm, and refrain from talking and moving. Coughing, sneezing, or movement will impact the signal quality and may result in a “rejected” measurement.

NOTE: During the measurement, the patient must remain supine, calm, and refrain from talking and moving. Failure to do so may result in in excessive measurement “noise” and a rejected measurement session.

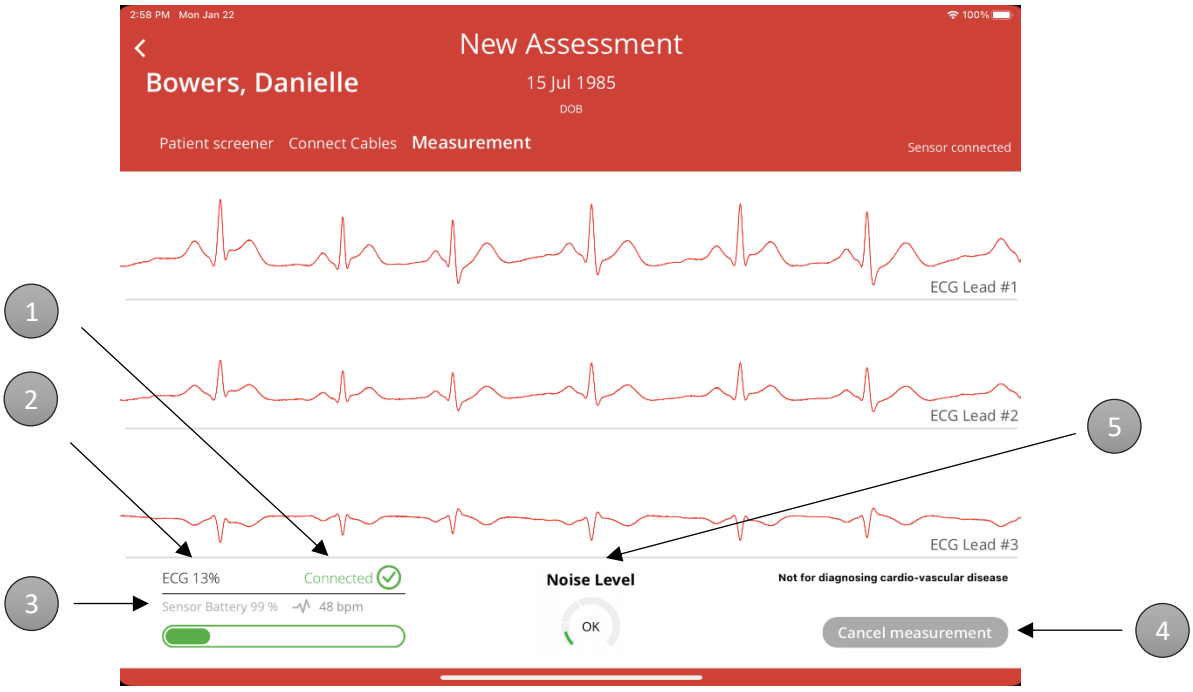


Figure 31: The Measurement Screen displays the progression of the measurement

	Measurement Screen Elements
1	Bluetooth connection icon: Used to indicate the status of the Sensor and Tablet Bluetooth connectivity. It is either displayed as **Connected** or is not displayed at all.
2	Measurement progress bar and percentage: Used to indicate how much of the 5-minute measurement has been completed.
3	Sensor battery icon: Used to indicate the Sensor battery charge level. Patient heart rate icon: Used to indicate the patient's heart rate in beats per minute (bpm).
4	**Cancel measurement** button: Used to prematurely end a measurement in progress. Selecting this will bring up a confirmation dialog box to confirm intent.
5	**Noise Level:** Indicates the noise level of the ECG signal. Green indicates normal, yellow indicates medium noise threshold has been exceeded for 10 seconds and red indicates high noise threshold has been exceeded for 10 seconds.

Once the measurement is complete, the system will automatically upload the acquired data to the Inmedix Cloud and display the **Results Screen** (Figure 32) with the results of the latest assessment.

The acquired data will not be uploaded or stored if the measurement cannot be completed successfully. Refer to Troubleshooting, section 14, if you are experiencing difficulties completing a measurement.

NOTE: Completion of a measurement is indicated by the display of the Results Screen with the results from the current session.

10.9 Disconnecting the Patient

Once the measurement is complete and the **Results Screen** is displayed (Figure 32), the Patient Lead Wires and ECG Electrodes can be removed from the patient.

Electrodes should be removed gently to prevent damage to the patient's skin. The electrodes are single use and must be disposed of in accordance with the local facility protocol.

10.10 Reviewing Assessment Results

WARNING: The CloudHRV™ System is not intended to be used to prescribe specific patient treatment plans.

Do not use the ECG waveforms and results output displayed by the CloudHRV™ System for diagnosing or monitoring cardiovascular conditions.

Results from the HRV assessment can be displayed in numerical or graphical form in the **Results Screen** (Figure 32, Figure 33).

10.10.1 Navigating the Results Screen

Numerical Results Screen:

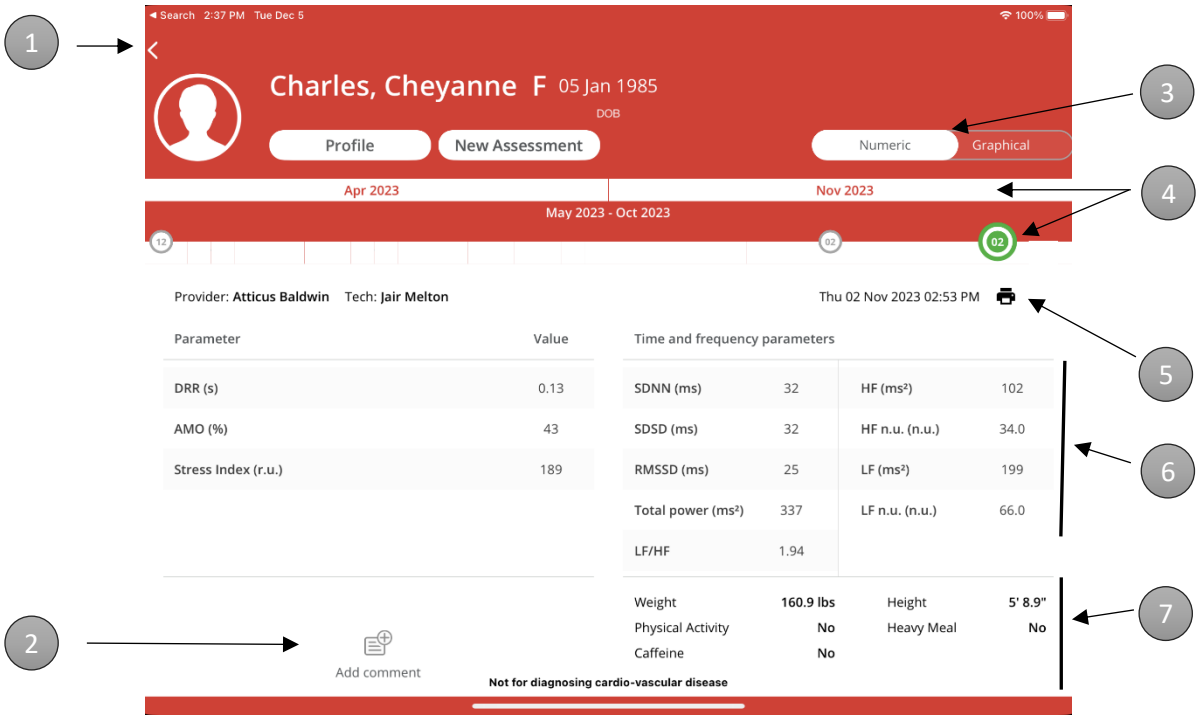


Figure 32: Results screen (Numeric) is displayed immediately following the measurement

	Results Screen Elements (Numeric)
1	Back button (**<**): Returns to the patient list screen.
2	**Add comment** button: Brings up a window where comments can be added or edited.
3	**Numeric** / **Graphical** toggle button: Changes the presentation style of the measurement results.
4	Timeline with measurement dates: Displays historical assessments and allows the user to select and view any past measurements.
5	Print button: Displays the print window with relevant settings.
6	HRV numerical results. Refer to Table 3.
7	Patient biometrics and patient screener results

Heart rate variability parameters displayed on the **Results Screen** are explained in Table 3 below.

Table 3: Heart rate variability parameters (alphabetical order)

Term/Variable (units)	**Definition**
AMO (%)	The mode amplitude (AMO) is the proportion of all RR intervals that correspond to the most

Term/Variable (units)	Definition
	frequent RR interval (mode, MO), measured as a percentage. AMO is a geometric estimate of HRV; as AMO increases, HRV decreases, since there is more consistency across the distribution of RR intervals.
DRR (s)	The breadth of the main distribution of RR intervals, measured in seconds (s). DRR is a geometric estimate of HRV; as DRR increases, HRV increases, since the distribution of RR intervals spans a greater range of values.
HF(ms^2)	Absolute power of the high-frequency band (0.15–0.4Hz)
HF n.u. (n.u.)	HF power in normalized units. Relative value of high-frequency power in proportion to the total power minus VLF (HF/(Total Power–VLF)x100).
LF (ms^2)	Absolute power of the low-frequency band (0.04–0.15 Hz).
LF n.u. (n.u.)	LF power in normalized units. Relative value of low-frequency power in proportion to the total power minus VLF (LF/(Total Power–VLF)x100).
LF/HF	Ratio of LF-to-HF power
MO	Timing of the most populous bin (peak distribution) from the R-R histogram
RMSSD (ms)	Square root of the mean of the sum of the squares of differences between adjacent NN intervals
SDNN (ms)	Standard deviation of all NN intervals
SDSD (ms)	Standard deviation of differences between adjacent NN intervals
Stress Index (r.u.)	The Stress Index is a geometric estimate of HRV reflecting the cardiac system response to physical and mental loads (cardiovascular system stress). The Stress Index tends to rise when sympathetic activation increases and conversely it tends to decrease when parasympathetic activation increases.
Total power (ms^2)	The sum of the power output across the entire frequency range of the ECG waveform
VLF (ms^2)	Absolute power of the very low frequency band (0.003 – 0.04 Hz)

Graphical Results Screen:

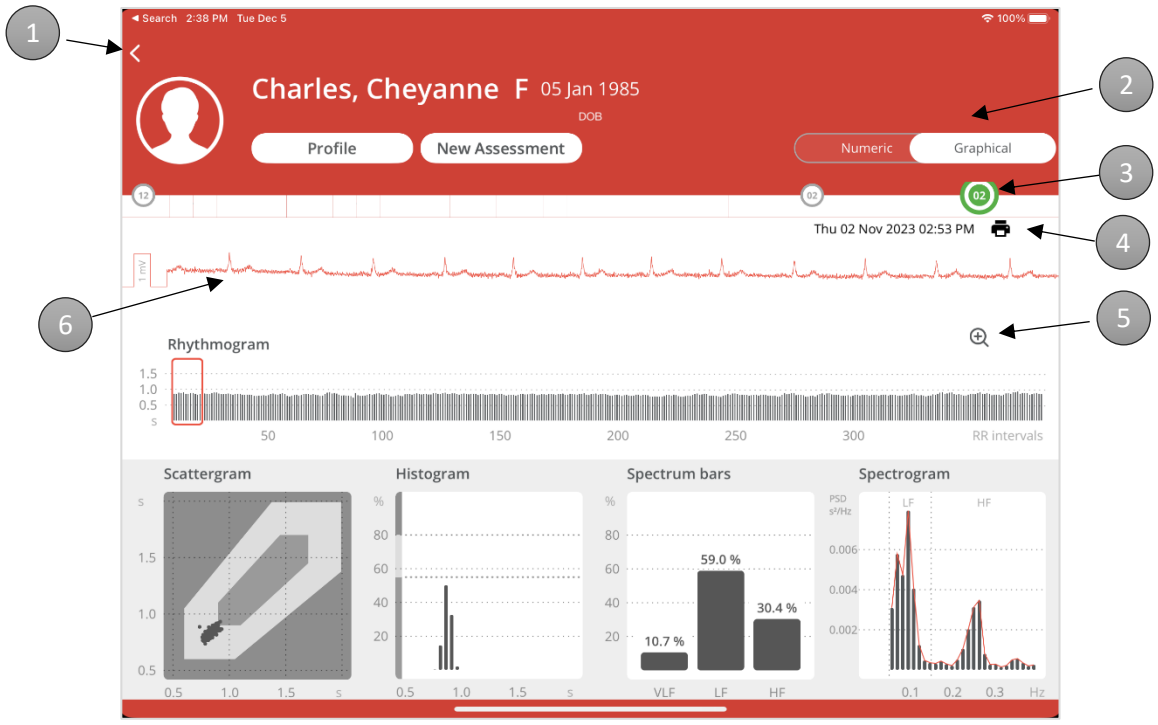


Figure 33: Results screen (Graphic), accessed by scrolling down or pressing the Numeric / Graphic toggle button

	Results Screen Elements (Graphical)
1	Back button (<): Returns to the patient list screen.
2	**Numeric** / **Graphical** toggle button: Changes the presentation style of the measurement results.
3	Timeline with measurement dates: Displays historical assessments and allows the user to select and view any past measurements.
4	Print button: Displays the print window with relevant settings.
5	Magnifying glass allows the ECG waveform to be enlarged
6	Displays the ECG waveform from lead I

The Rhythmogram, Scattergram, Histogram, Spectrum bars and Spectrogram are different visual presentations of the HRV data:

Rhythmogram

The rhythmogram illustrates each R-R interval during the data capture time. The rhythmogram has two axes: the y-axis represents the time of the R-to-R intervals in seconds; the x-axis represents the intervals number.

Scattergram

The scattergram is used to visualize and quantify the correlation between two consecutive data points. Each R-R interval is plotted against the previous R-R interval. Each dot on the graph incorporates the information on the interval duration of two consecutive R-to-R intervals. For each dot, the value on

the y axis is the first R-R interval and the value on the x axis is the next interval. The unit of measurement for both the x and the y axis is in seconds.

Histogram

The histogram provides a visual representation of the distribution of the data. Each bar represents the overall percentage of R-R intervals that fall within the width of the bar. Percentage is indicated on the y-axis and time in seconds is indicated on the x axis.

Spectrum bars

The spectrum bars graph illustrates the percentage contribution of very low-frequency (VLF), low frequency (LF) and high frequency (HF) power with respect to the total power. Percentage is indicated on the y axis and VLF, LF and HF are indicated on the x axis.

Spectrogram

The spectrogram is a histogram of the power across the measured frequency range. The histogram provides a visual representation of the distribution of the data. Dashed lines indicate the LF and HF bands.

10.10.2 Accessing Previous Assessments

All historical data is kept with the patient's profile. To view previous assessments, use the timeline function at the top of the screen. The timeline displays the month and date for each assessment. The historical data is selected by clicking on the date (circle). A green circle around the date indicates the date of the assessment currently displayed on the screen.

10.10.3 Adding Comments

The **Add comment** button can be used to include notes, observations, or any information relevant to the measurement that should be considered with the results (Figure 34). Comments can be added to the most recent measurement or a past measurement. To add a comment:

1. Press the **Add comment** area in the lower left corner.

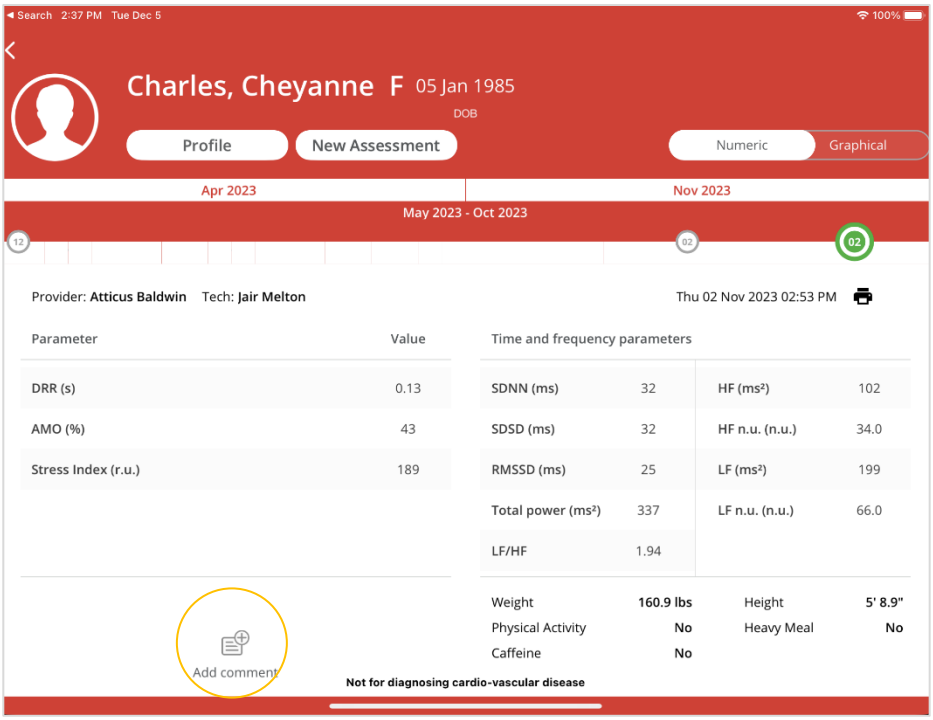


*Figure 34: **Add comment** function is located on the bottom left-hand side of the assessment **Results Screen***

2. Type the comment, up to 221 characters (Figure 35).
3. Press **Done**, the comment will then be saved and displayed in the comments section (Figure 36).
4. Press **Back** to return to the **Results Screen** without updating the comment section.

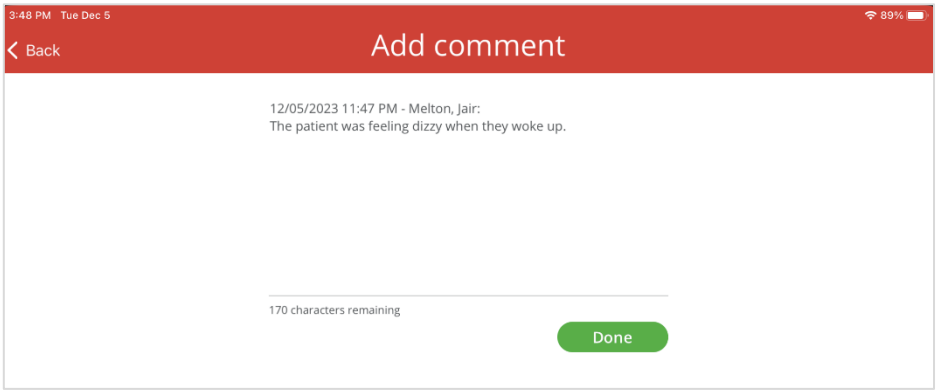


Figure 35: Add comment screen

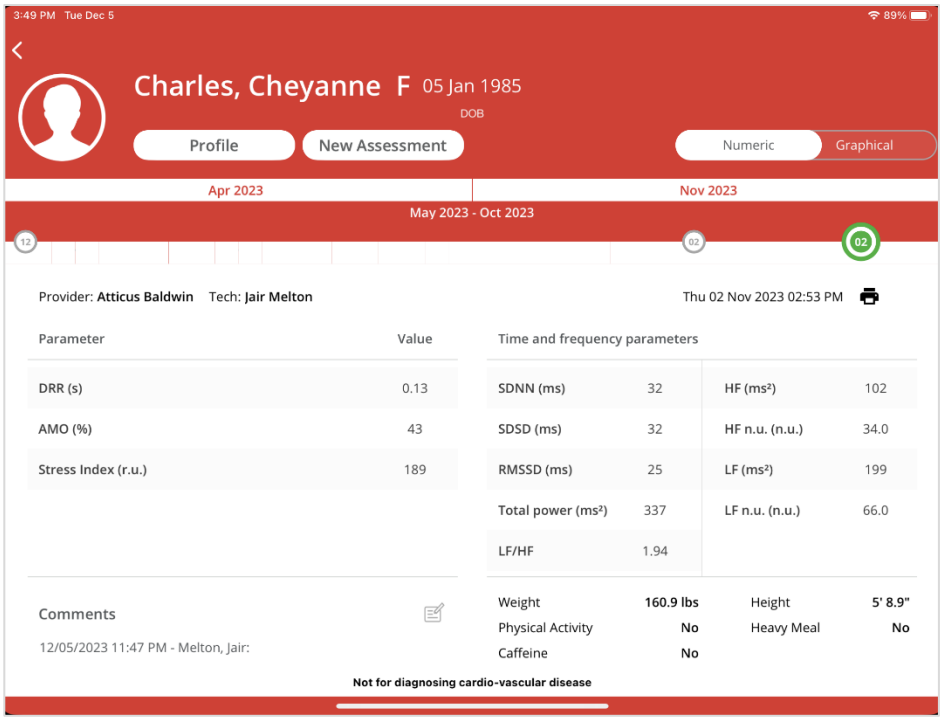


Figure 36: Comments are displayed in the comments section below with the date and time stamp as well as user name

10.10.4 Printing Assessment Results

To obtain a printed copy of an assessment:

1. Click the Print button (printer icon) located below the timeline, on the right-hand side (Figure 37).

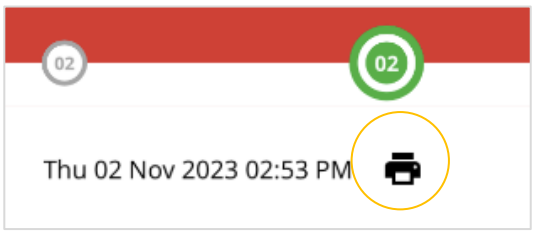


Figure 37: Printer button to access printing functions

2. Select the **Printer** you want to use.
3. Indicate the number of **Copies** and **Paper Size**.
4. Press **Print**.

10.11 Logging Out of the CloudHRV™ Application

After the assessment it is recommended that the device operator log off. To log off:

1. Go the **Patient List** screen using the back button (**<**) in the top left-hand corner.

2. Press the **Sign out** button on the top right-hand corner. The system will ask you to confirm, press **OK** (Figure 38).

Figure 38: Sign out dialog box requires the confirmation before logging out the user

The device will display the login screen for the next user to enter their credentials.

10.12 Powering Off the CloudHRV™ System

To power off the Tablet:

1. Go to Settings.
2. Select General.
3. Scroll to the bottom of the options under General and select Shut Down.
4. Slide the power switch at the top of the screen to the right to shut down the Tablet.

To power off the Sensor:

1. Momentarily press the Sensor Power button (Figure 2) to place the Sensor in sleep mode (when the blue light is continuously illuminated or blinking).

The Sensor will automatically enter sleep mode if it is left unconnected for 5 min.

11 Settings

The **Settings** screen can be accessed from the **Patient List** screen using the **Settings** button in the top left-hand corner (Figure 19).

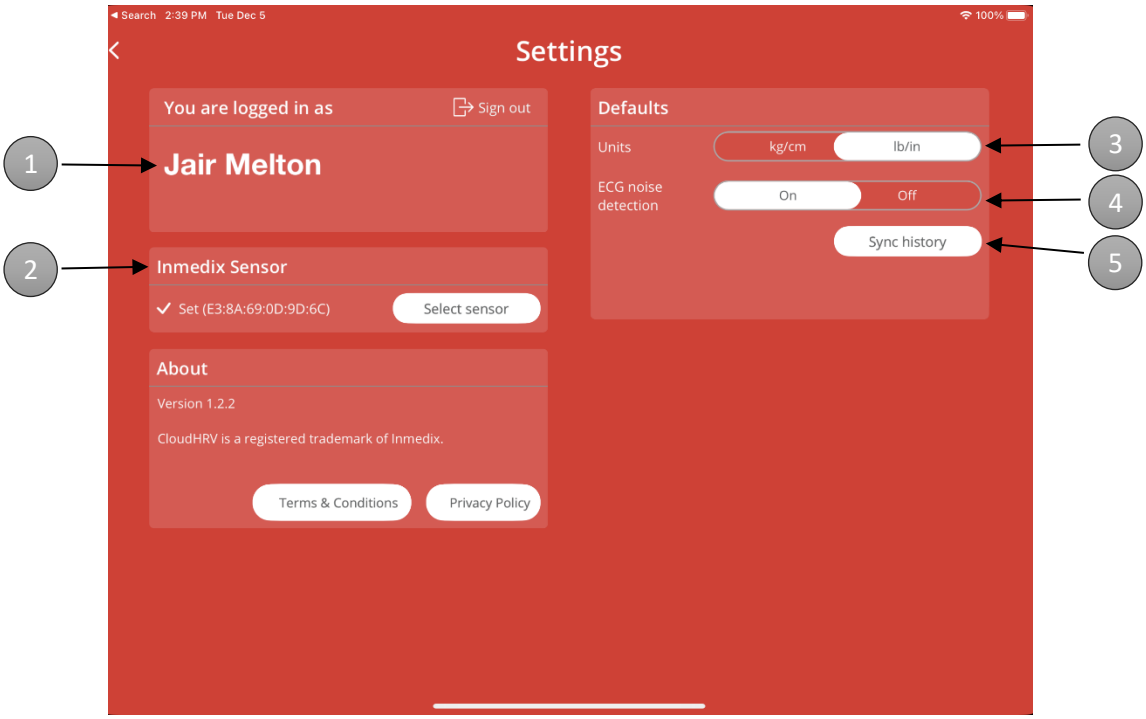


Figure 39: Settings screen

	Settings Screen
1	Name: Displays the name of logged-in user.
2	Inmedix Sensor: Displays the MAC Address of the Sensor the Tablet is paired with and provides the option to **Select sensor** if the Tablet is not paired.
3	Units: Toggles between metric and imperial system for the weight and height units (**kg/cm** and **lb/in**).
4	ECG noise detection: **On/Off** allows the user to select whether they want the noise detection feature displaying the level of noise on the measurement screen during the measurement.
5	**Sync history** button: Brings up a list of the dates and times the Tablet synchronized its data with the Inmedix Cloud.

Press the **Sensor Select** button to select the Sensor**.** Instructions on how to connect to a Sensor are provided on the **Select Sensor** screen (Figure 40).

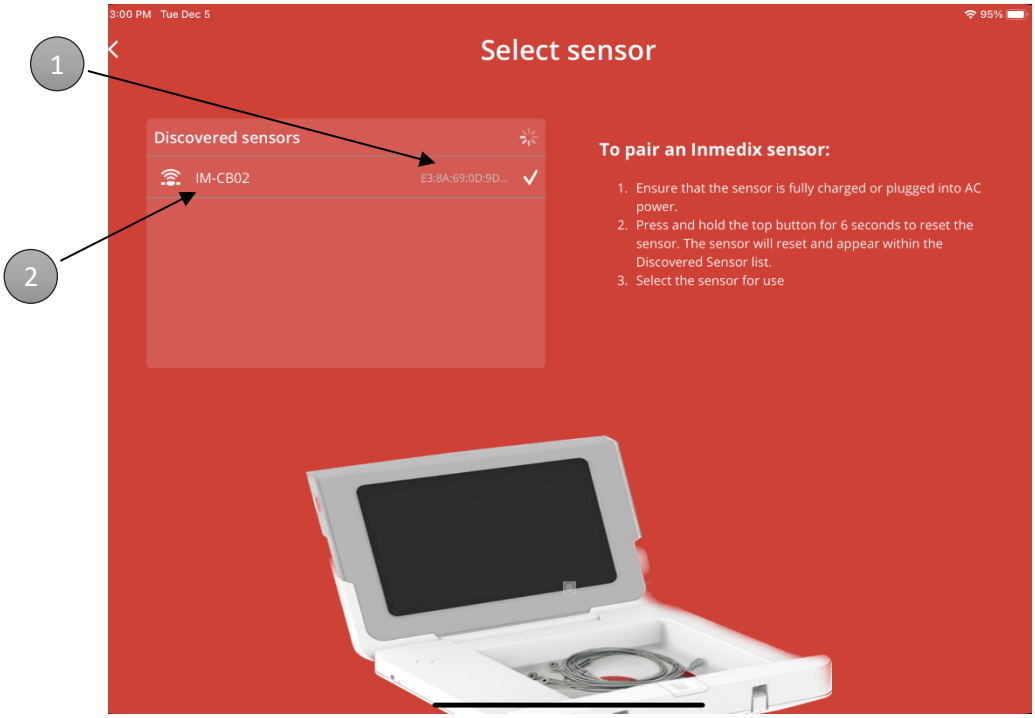


*Figure 40: **Select Sensor** screen*

	Select Sensor Screen
1	MAC address
2	Sensor number

12 Cleaning

	**CAUTION:** Do not spill fluids on or near the device and its accessories. The device has no protection against fluids. Exposure to fluid may damage the device or result in injury.

The CloudHRV™ System must be cleaned between uses. The recommended cleaning product for the ECG Cable Assembly, Base Enclosure, and Tablet screen is 70% IPA.

1. Spray a clean cloth with 70% IPA or obtain 70% IPA wipes.
2. Remove the Tablet and wipe all surfaces of the Base Enclosure and Tablet.
3. Wipe all cables, including the trunk cable, the yoke and the electrode snaps and place in the Base Enclosure compartment or on a clean surface.

The device is considered cleaned when there are no visible signs of dirt or contamination. Repeat cleaning using above steps until this is achieved.

13 Storage

Inmedix recommends storing the device when not in use in a locked area or cabinet to prevent any tampering with the device by unauthorized personnel.

It is recommended the device be left charging when not in use. If the Sensor battery is completely depleted, it will require approximately 4-5 hours to charge completely. The Tablet must be docked in the Base Enclosure lid for the Tablet's battery to charge; it cannot be charged independently.

For longer term storage, the device should be fully charged, and the Tablet should be powered down. Charge both the Tablet battery and Sensor battery to 100% power, then shut them down by following the directions in section 10.12. The Power Adapter and ECG cable should be placed inside the device and the device should be closed and placed in a dry location away from direct sunlight.

The Tablet and Sensor batteries will deplete over time. When the device is brought out of storage, it must be equalized to operating temperature then recharged before use.

The environmental conditions permitted for storage can be found in section 18.2.

NOTE: While in storage, the system should be recharged at a minimum of every 6 months to prevent the battery from being severely depleted.

14 Troubleshooting

14.1 Common Issues

14.1.1 Device Not Connected to Wi-Fi

The CloudHRV™ System cannot be operated if it is not connected to the Internet. To connect the device to the internet or to change the network the device is connected to, perform the following steps:

1. Go to the Tablet Settings > Wi-Fi.
2. Toggle Wi-Fi setting to “On”.
3. Select the appropriate network from the networks list.
4. Enter the password for the network.
5. Press “Join”.

14.1.2 No User ID

To log-in to the device, you need a Username, Password and email address. These must be set-up by Inmedix. For technical support contact the Inmedix help desk at +1 (206) 466-3349.

For information on clinic user creation or management contact the Inmedix help desk at +1 (206) 466-3349 or refer to the Inmedix Management Portal.

14.1.3 Forgotten Password

If you forget your device password, you will need to access your user profile on the Inmedix website.

1. Enter your username or email address on the login screen and select the “Forgot Password” button.
2. Open the email from Inmedix Support and follow the link provided to rest your password.

14.1.4 Tablet is Not Paired with the Sensor

The Sensor and the Tablet must be paired to perform a measurement. To pair the Tablet with the Sensor, follow these steps:

1. Press the Sensor Power Button to turn the Sensor on (Figure 2).
2. On the Tablet, go to the **Patient List** page and press the **Settings** button.
3. Look for the Inmedix Sensor header and press the **Select sensor** button and follow the directions (refer to section 11).
4. Hold the Sensor Power Button for 6 seconds to reset the Sensor.
5. Verify the MAC address of the Sensor by checking the label on the bottom of the device.
6. On the Tablet, select the MAC address of the correct Sensor.
7. Once the Sensor is paired with the Tablet, the MAC address of the Sensor will appear beneath the Inmedix Sensor heading on the **Settings** page.
8. Proceed with the Patient Assessment.

14.1.5 Level of Charge for the Sensor is Insufficient to Perform an Assessment

If the Sensor battery is completely depleted the device will not turn on. If the Sensor Power Button is pressed, the Adapter Port LED will flash yellow momentarily to indicate the device must be plugged in.

1. Connect the device to its Power Adapter and ensure the Power Adapter is connected to power.
2. The Adapter Port LED will start to blink green, indicating the Sensor battery is charging. Wait 2 to 3 minutes and proceed with pairing the Sensor to the Tablet.

14.1.6 Low ECG Signal Quality or Patient Movement

If the system detects a low signal quality, it may cancel the measurement. To prevent low signal quality or persistent noise:

1. Disconnect the Power Adapter and use the CloudHRV™ System on battery power.
2. Ensure the ECG electrodes are properly applied to the patient's wrists and ankles as outlined in section 10.7. If the ECG electrodes appear to be peeling off or were not applied in the proper location, remove the electrodes, and replace with new ECG electrodes.
3. Connect the Cables.
4. Ensure there is no tension on the Patient Lead Wires and that they are securely connected to the ECG electrodes.
5. Remind the patient to remain supine and still for the entire duration of the measurement. Even small movements such as scratching or handling a cell phone will reduce the signal quality.
6. Proceed with a new measurement.
7. If low ECG signal quality persists, check the environment for any devices that may cause interference. Increase the distance between the CloudHRV™ System and any devices that may be causing interference. Proceed with a new measurement.

14.1.7 Wireless Communication Issues

If you are experiencing issues with wireless communication, try one or more of the following:

1. Run the device on battery power only (disconnect the Power Adapter).
2. Position the CloudHRV™ System away from other devices.
3. Turn off any adjacent devices.
4. Ensure the ECG Cable Assembly and Power Adapter cable are not run alongside any other power or signal cables.

14.1.8 Device Not Connected to Printer

To connect the CloudHRV™ System to a printer, or change the default printer it's connected to:

1. Ensure the CloudHRV™ System and the printer are connected to the same Wi-Fi network.
2. Go to the Tablet Settings > Wi-Fi.
3. Select the printer from the networks list.
4. Press "Join".
5. Print by following the instructions in section 10.10.4.

14.1.9 Tablet Not Charging when Connected to the Sensor

The Tablet is designed to charge its battery whenever the Tablet is docked in the Base Enclosure lid and the Sensor is connected to power.

1. Ensure the Sensor is connected to power and that the Adapter Power LED is steady or blinking green.
2. Slot the Tablet into the Base Enclosure lid, making sure it slides all the way into the case so the pins will come into contact with the charging pads on the bottom of the Tablet protective case.
3. Monitor the Tablet screen for a charging indication. If the battery was fully depleted, it may take a few minutes for the Tablet to power on.

14.2 System, Error, and Fault Messages

Table 4: System, Error, and Fault Messages and Actions to Resolve

Category	Message	Description	Action
Login Screen	"Please fill email"	Username instead of email	Re-login using email and password.
	"Please enter valid user"	Email instead of username	Remove email from username box, select correct username then enter password and log in.
	"The internet connection appears to be offline."	Bad connection	Disconnect and reconnect. Check connection strength. Move device closer to the router.
	iPad crash report	Random crash	Submit a crash report and restart the app.
Sync Errors	"Upload status, one or more files cannot be uploaded."	Cannot upload	There is an error with the named files and they cannot be uploaded. No corrective actions can be taken at this time. Contact Inmedix for support.
	"No network"	No network connection	Reconnect the internet and try again.
Sensor Connect Errors	"Can not connect to sensor"	Cannot connect to Sensor	Press the Sensor Power Button to start the Sensor and check if the Sensor is connected. If the connection is not automatically reconnecting, cancel the assessment and restart.
Recording Errors	"ECG device disconnected"	Lost connection to Sensor	Restart the Sensor and reconnect.
	"Measurement cancelled"	Noise	Investigate the source of the noise (patient movement, bad lead connection). Select "try measuring again" to restart assessment after corrective action taken.

Category	Message	Description	Action
			If message occurred while unit is powered from the supplied power adapter, disconnect the adapter and attempt the measurement again while running off of battery.
	"ECG cable disconnected"	Cable disconnected	Reconnect disconnected cable or lead, select "try measuring again".
	"ECG measurement problem"	Connection issues	Make sure Tablet is close to the Sensor to reduce risk of communication issues. Select "Try measuring again". Try positioning device further away from other data communication devices such as tablets, cell phones, networking equipment, etc.
Post Recording Errors	"No network"	No connection	Check the Tablet internet connection. Attempt to reconnect the Tablet to the internet. If internet is reconnected press "Try Again". If the error persists or if the internet connection cannot be restored press "Calculate Later" to save the data to upload later.
	"Error, failed to upload the assessment data"	Failure to upload	The data cannot be uploaded. Verify connection to the internet. Repeat measurement if issue is not resolved.

15 Maintenance

	**WARNING:** There are no user serviceable parts. Contact Inmedix for servicing.
	**WARNING:** The Sensor battery is not replaceable. Replacement of the Sensor battery may result in injury. Contact Inmedix for servicing.

The CloudHRV™ System should be plugged in overnight to ensure the batteries are fully charged at the beginning of each day. The CloudHRV™ System should also be inspected for visible damage daily before use.

15.1.1 Device serial number

To locate the serial number of the CloudHRV™ System, refer to the label located on the bottom of the device (Figure 41).

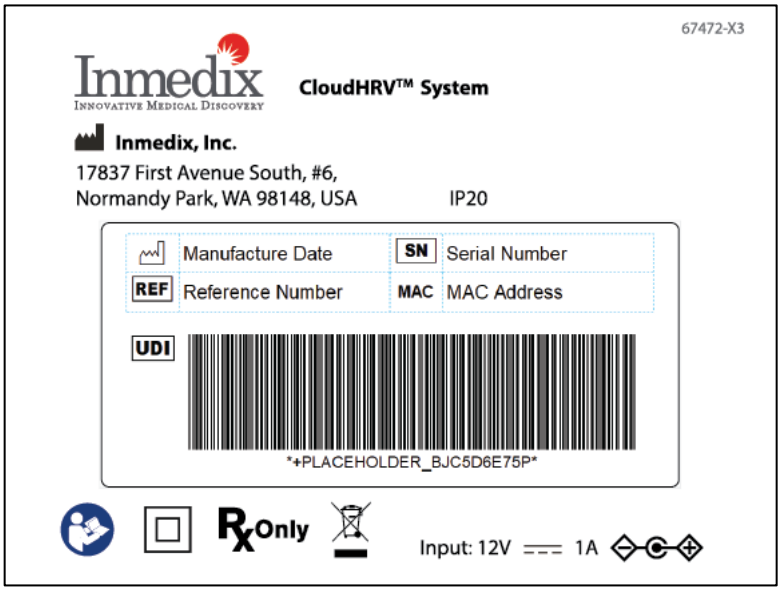


Figure 41: CloudHRV™ System Device Label

16 Accessories

The ECG electrodes supplied with the CloudHRV™ System are Medi-Trace™ 530 Diaphoretic Foam Electrodes. The CloudHRV™ System requires single use ECG electrodes. To replace electrodes, purchase additional Medi-Trace™ 530 Diaphoretic Foam Electrodes, or equivalent, from a third-party retailer.

17 Device Return and Disposal

The expected service life of the CloudHRV™ System is 2 years. When the device has reached the end of its life, it must be returned to Inmedix. Package the device with all accessories and ship to the following address:

Inmedix, Inc.
17837 First Avenue South, #6,
Normandy Park, WA 98148, USA
www.inmedix.com

18 Technical Description

18.1 Operating Classifications

Protection against electric shock	Class II ME equipment, externally powered when charging, internally powered when on battery, type CF applied part. This ECG lead set meets the requirements of the standard, ECG Trunk Cables and Patient Lead Wires (ANSI/AAMI EC53). This cable is intended for multi-patient use.
Protection against harmful ingress of water or particulate matter	IP20: ingress protection against solid objects greater than 12.5 mm
Method(s) of sterilization	No sterilization required
Suitability for use in an oxygen-rich environment	Not intended for use in oxygen-rich environments
Mode of operation	Continuous operation

This product complies with the following North American safety standards:

Placeholder for 60601-1 Certification Marking

18.2 Environmental

The CloudHRV™ System is intended to be used only in weather-protected professional healthcare facilities, such as outpatient medical clinics.

Operating Temperature	15°C to 30°C
Operating Humidity	10% to 90% RH (non-condensing)
Operating Pressure	10 to 15.3 psi (70 kPa to 106 kPa)

Transportation Temperature	-15 to 40°C
Transportation Humidity	10% to 90% RH (non-condensing)
Transportation Pressure	10 to 15.3 psi (70 kPa to 106 kPa)

Storage Temperature	15°C to 30°C
Storage Humidity	10% to 90% RH (non-condensing)
Storage Pressure	10 to 15.3 psi (70 kPa to 106 kPa)

18.3 Power

Input Power	Rated Input of Power Adapter: 120VAC, 60 Hz. Meets requirements of IEC 60601-1 ed. 3.2, 2MOPP isolation to mains. Rated input of Sensor: 12VDC, 12W
Internal Batteries (Sensor and Tablet)	The operating time for the CloudHRV™ System is a minimum of 10 sessions over 8 hours (150 minutes total use time, 330 minutes sleep mode). Battery life of the tablet varies with usage, including screen brightness. **Sensor** Recharge time (from depletion to 90%): 4-5 hours (when not in use) Expected battery life: 2 years **Tablet** Recharge time (from depletion to 90%): 5-10 hours Expected battery life: 2 years If when fully charged, the Tablet cannot be used to take a measurement without being plugged in, the battery needs to be replaced. Contact Inmedix for replacement.

18.4 Wi-Fi Internet Connection (Apple iPad)

Purpose of the Connection	To access cloud-based data.
Required Characteristics of the Wi-Fi network	TCP/IP based network, minimum 100 Mbps.
Required Configuration of the Wi-Fi network	WPA2 security with password recommended. No other configuration required (pass through).
Technical and Security Specifications of the Network Connection	Requires TLS1.3.
Wi-Fi receive and transmit frequencies supported	802.11ax, 2.4GHz, 5GHz band

Wi-Fi Transmitter Effective Radiated Power (ERP)	< 30.0 dBm
Intended Information Flow	See Figure 42 below
Hazardous Situations Resulting from Failure of the IT Network	Delay in treatment (negligible harm).

18.5 Bluetooth Sensor to iPad Connection

Purpose of the Connection	To stream functional data from the sensor.
Technical Specifications of the Sensor's Bluetooth Radio	Bluetooth® 5 Low Energy, IEEE 802.15.4-2006, 2.4 GHz transceiver
Sensor Receiver operating frequency band, data rate	2.4000 GHz to 2.4835 GHz, 2Mbps
Sensor Transmitter operating frequency band, data rate	2.4000 GHz to 2.4835 GHz, 2Mbps
Sensor transmitter Effective Radiated Power (ERP)	-0.25 dBm

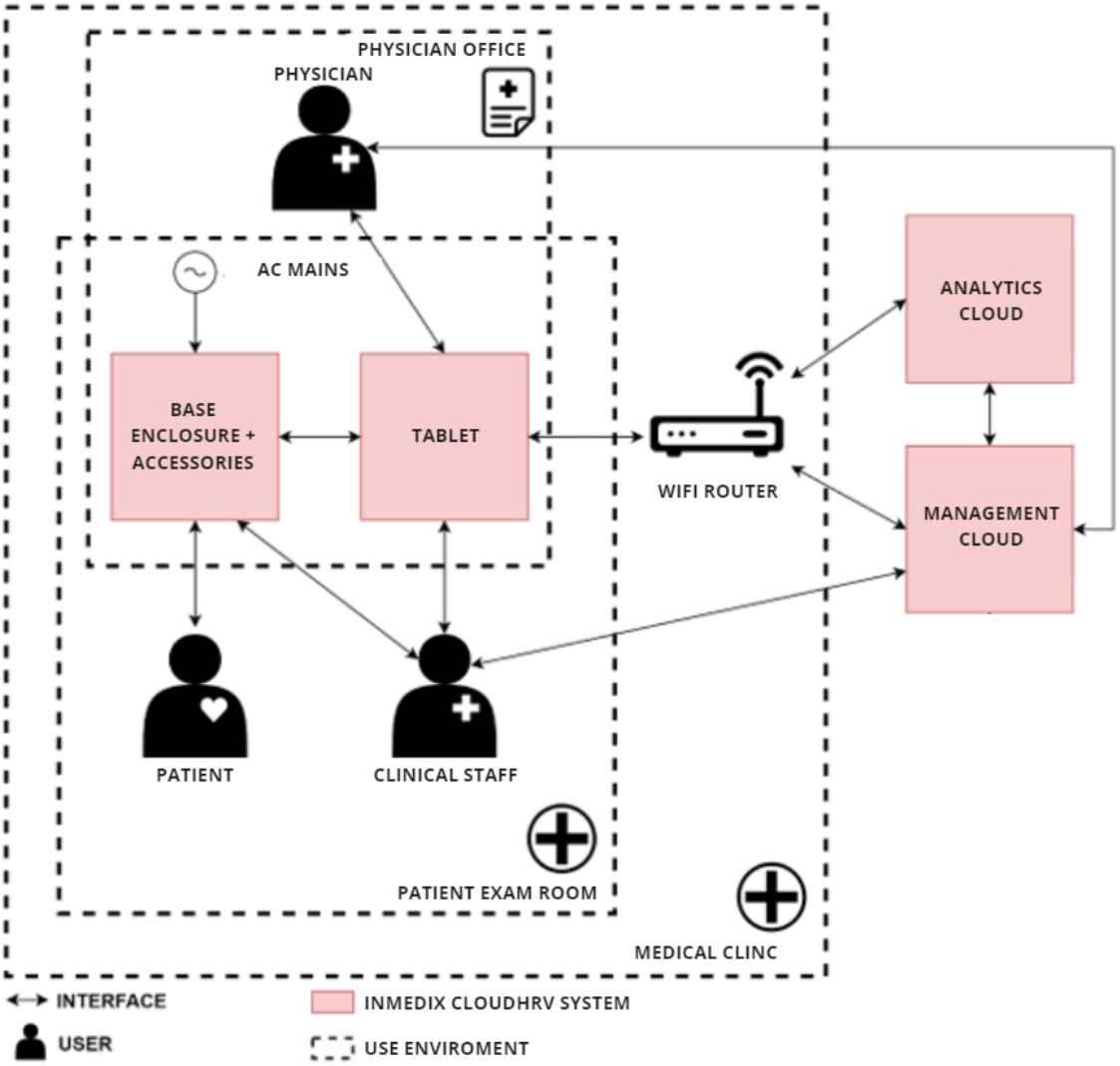


Figure 42: Operational context diagram for the CloudHRV™ System

18.6 ECG Data Acquisition and Performance Characteristics

ECG Front End	Internal ECG front end, provides 3 simultaneously Sampled channels, Lead I, II, III, DC coupled with Right Leg Drive.
Applied Part Protection Level	Type CF
Amplitude Resolution	9.155 µV
Sampling rate	500 samples/s

Dynamic Range	AC Differential: +/-5 mV DC Offset: +/- 280 mV
Data Frequency Range	0.44Hz to 131 Hz
Common mode rejection	>130 dB
Input Impedance	>100 MΩ @ 10 Hz (defibrillator protected)
Patient Leakage Current	<10 µA normal condition (NC) <50 µA single fault condition (SFC)

The essential performance of the CloudHRV™ System is that it does not store nor display a result if its inputs are affected to the extent that it cannot produce a result within its stated accuracy/performance. Essential performance is still maintained when faults result in the unavailability of the device, a failed/automatically halted measurement, an issue with the system temporarily losing function, requiring system reset, and loss of communications.

NOTE: Occasional momentary high electric field events, such as Electrostatic Discharge (ESD), Electrical Fast Transients (EFT) or Surges (when AC/DC adapter is plugged in), defibrillation, etc. may affect the device's input. For the duration of the momentary event, the displayed waveform may appear distorted, and the device would be available for normal use within 10 s after the event has completed.

There are no additional instructions or testing required to confirm or maintain essential performance.

18.7 Electromagnetic Compatibility

The following sections contains the manufacturer's declarations for the CloudHRV™ System electromagnetic emissions, electromagnetic immunity, and recommended separation distances between the CloudHRV™ System and portable/mobile RF communications equipment.

WARNING: Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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

The measured emission characteristics of the CloudHRV™ System make it suitable for operation in industrial areas and hospitals. Radiated and conducted emissions are below limits outlined in CISPR 11 for a Class A, Group 1 device.

The CloudHRV™ System design has been subjected to electromagnetic radiation and disturbances using methods and levels specified in IEC 60601-1-2:2014+AMD1:2020. It has shown no reaction to electromagnetic disturbances, within the limits stated below, that could affect the device's ability to maintain basic safety and essential performance.

Immunity Type	**Test Method**	**Achieved Professional Healthcare Facility Environment Immunity Level**	**EMC Environment and Guidance**
Electrostatic Discharge	IEC 61000-4-2:2008	Voltage (Contact): ± 8 kV Voltage (Air): ± 15 kV	Portable and mobile RF communications equipment should be used no closer to any part of the CloudHRV™ System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2 √p d = 1.2 √p 80 MHz to 800 MHz d = 2.3 √p 800 MHZ to 2.5 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 strength from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the
Radiated RF Immunity	IEC 61000-4-3:2006 +AMD1:2007+AMD2:2010	Field: 3V/m Frequency: 80 MHz–18 GHz Modulation: 80% AM at 1 kHz	
Radiated RF Immunity - Proximity Fields	IEC 61000-4-3:2006 +AMD1:2007+AMD2:2010	IEC 60601-1-2:2014+AMD1:2020 Table 9, ISM Intentional Transmitters. [1,3] 385MHz: 27 V/m, [2]450MHz: 10V/m, [1,4]710/745/780MHz: 9V/m, [1,3]810/870/930Mhz: 28V/m, [1,4]1720/1845/1970: 28V/m, [1,4]2450MHz: 28V/m, [1,4]5240/5500/5785MHz: 9V/m	
Electrical Fast Transient/Burst	IEC61000-4-4:2012	± 2 kV Repetition frequency: 100 kHz	
Surge Transient	IEC 61000-4 5:2014 +AMD1:2017	± 0.5 kV, ± 1 kV	
Conducted Immunity	IEC 61000-4-6:2013	3V, Frequency: 0.15 MHz–80 MHz, 6V in ISM and amateur radio bands between Frequency:0.15 MHz–80 MHz Modulation: 80% AM at 1 kHz	
Power Frequency Magnetic Fields	IEC 61000-4-8:2001	30A/m, 60Hz	

Immunity Type	Test Method	Achieved Professional Healthcare Facility Environment Immunity Level	EMC Environment and Guidance
Proximity Magnetic Fields	IEC 61000-4-39:2017	IEC 60601-1-2:2014+AMD1:2020 Table 11 134.2kHz, 2.1kHz pulsed modulation, 65A/m field 13.560MHz, Pulsed 50kHz, 7.5A/m	compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 
Voltage Dips	IEC61000-4-11:2004+AMD1:2017	0 % U_T; 0,5 cycle (AC Only) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	
Interruptions	IEC 61000-4-11:2004+AMD1:2017	0 % U_T; 250/300 cycle	

[1]The carrier is pulse modulated using a 50% duty cycle square wave signal.

[2]FM ± 5 kHz deviation 1 kHz sine

[3] Pulsed at 18Hz

[4] Pulsed at 217Hz

The deviations from IEC 60601-1-2:2020, and the associated allowances used are listed below. Clinical performance of the CloudHRV™ System may be affected by the following:

- Conductive disturbances on patient cables deviation:
  The length of patient cable (< 3m) makes it technically possible to route the ECG Cable Assembly in parallel with power cables for a significant percentage of its total length. The typical clinical environment assumes the Base Enclosure is to be positioned on a table, and the patient is supine on a bed. The extended ECG Cable Assembly is therefore intended to be routed in working areas where power supply cables do not exist.

> ***NOTE:*** Avoid routing the patient ECG Cable Assembly along with any other cables that may carry mains power or signals to avoid signal interference due to coupling.

- Industrial, Scientific, and Medical (ISM) radio band immunity:
  GMRS/FRS voice radio devices are not expected to exist in the CloudHRV™ System operating environment. Signal degradation occurs at typical 28 V/m test levels, simulating a 2W transmitter at 0.3m, though immunity is demonstrated at 10 V/m (the same transmitter at 0.85m).

NOTE: Position FRS/GMRS (common voice communication radios) operating in the 430-470MHz band, minimum 1m away from equipment, for transmitters 2W or less. For transmitters greater than 2W, the guidance and calculations in the Immunity table in this section may be used to determine minimum distance.

Users and operators of the CloudHRV™ System should be aware that radio frequency emissions are additive and, as such, the CloudHRV™ System must be located at a sufficient distance from transmitting devices to avoid interruption. Do not operate the CloudHRV™ System in a magnetic resonance (MRI) imaging environment.

For any questions or concerns relating to electromagnetic disturbances, contact the manufacturer.

18.8 FCC Certification

18.8.1 FCC Interference Statement (Part 15.105(a))

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

18.8.2 FCC Part 15 Clause 15.21:

"Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment"

18.8.3 FCC Part 15.19(a) [interference compliance statement]:

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

18.9 Replacement Components

The ECG electrodes are single use accessories that must be replaced by the user. Please contact Inmedix for additional information regarding purchasing other replacement components (Table 5).

Table 5: Replacement Components

Accessory Name	**Technical Information**
ECG Cable Assembly	Replacements sold by Inmedix
Power Adapter	Replacements sold by Inmedix
Tablet / Tablet protective case	Contact Inmedix
ECG electrodes	Replacements to be sourced by user Medi-Trace™ 530 Diaphoretic Foam Electrodes, or equivalent Adapter/connector type: Snap Electrical performance: Meets requirements of AAMI/ANSI EC12:2000 Biocompatibility: Meets ISO 10993-1

Appendix A: Glossary

Table A-1: Units of Measure

Term	Definition
bpm	Beats per minute
dBµV/m	Decibel-microvolt per meter
GHz	Gigahertz
Hz	Hertz
KHz	Kilohertz
kPa	Kilopascal
kV	Kilovolt
lbs	Pound
m	Meter
Mbps	Megabits per second
MHz	Megahertz
ms	Millisecond
ms^2	Millisecond squared
n.u.	Normalized units
psi	Pound per square inch
r.u.	Relative Units
s	Second
V	Volt
VAC	Alternating current voltage
V/m	Volt per meter
W	Watt
µA	Microamp
µV	Microvolt
°C	Degree Celsius

Table A-2: Technical Abbreviations

Term/Variable (units)	Definition
AMO (%)	The mode amplitude (AMO) is the proportion of all RR intervals that correspond to the most frequent RR interval (mode, MO), measured as a percentage. AMO is a geometric estimate of HRV; as AMO increases, HRV decreases, since there is more consistency across the distribution of RR intervals.
DOB	Date of Birth – the exact date on which an individual was born, including the year.
DRR (s)	The breadth of the main distribution of RR intervals, measured in seconds (s). DRR is a geometric estimate of HRV; as DRR increases, HRV increases, since the distribution of RR intervals spans a greater range of values.
ECG	Electrocardiogram – records the electrical signal from the heart.
GUI	Graphical User Interface
HF(ms^2)	Absolute power of the high-frequency band (0.15–0.4Hz)

HF n.u. (n.u.)	HF power in normalized units. Relative value of high-frequency power in proportion to the total power minus VLF (HF/(Total Power–VLF)x100).
HRV	Heart Rate Variability: "the conventionally accepted term to describe variations of both instantaneous heart rate and RR intervals"[2]
IFU	Instructions for Use – a form of medical device labeling that has use instructions.
LED	Light-Emitting Diode – a semiconductor diode which glows when a voltage is applied.
LF (ms^2)	Absolute power of the low-frequency band (0.04–0.15 Hz).
LF n.u. (n.u.)	LF power in normalized units. Relative value of low-frequency power in proportion to the total power minus VLF (LF/(Total Power–VLF)x100).
LF/HF	Ratio of LF-to-HF power
MRN	Medical Record Number – the number assigned to a patient's record to help with identification.
MO	Timing of the most populous bin (peak distribution) from the R-R histogram
PCB	Printed Circuit Board
RMSSD (ms)	Square root of the mean of the sum of the squares of differences between adjacent NN intervals
SDNN (ms)	Standard deviation of all NN intervals
SDSD (ms)	Standard deviation of differences between adjacent NN intervals
Stress Index (r.u.)	The Stress Index is a geometric estimate of HRV reflecting the cardiac system response to physical and mental loads (cardiovascular system stress). The Stress Index tends to rise when sympathetic activation increases and conversely it tends to decrease when parasympathetic activation increases.
Total power (ms^2)	The sum of the power output across the entire frequency range of the ECG waveform
VLF (ms^2)	Absolute power of the very low frequency band (0.003 – 0.04 Hz)

[2] Heart Rate Variability. (1996, March 1). *Circulation, 93*(5), 1043-1065.