General Information

Contact Information

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F15-01-02 Rev G

Indications for Use

The HEMOTAG® CardioPulmonary Assessment System (CPAS), when used with HEMOTAG® sensor on the chest wall, is intended for use on adults 22 years of age and older in acquiring, analyzing and reporting ECG and heart sound data and to provide interpretation of the data in an integrated report for consideration by physicians.

The HEMOTAG® recording may be obtained at any location specified bya physician including home, hospital or clinic. The device is intended foruse only under the direct supervision of a physician.

The HEMOTAG® CardioPulmonary Assessment System (CPAS) can assess left ventricular systolic function, severe left ventricular systolic function, systolic pulmonary artery pressure, left ventricular diastolic function, and Atrial Fibrillation.

(1) The HEMOTAG® CardioPulmonary Assessment System (CPAS) device is intended to be an aid to diagnosis and treatment;
(2) Use of HEMOTAG® CardioPulmonary Assessment System (CPAS) should be under the supervision of a prescribing healthcare providerand is intended to be interpreted by a trained healthcare professional; and
(3) The device is not intended to be a replacement for an echocardiogram.

Contraindications

- Apply the HEMOTAG Device only to intact and clean skin. Do not apply over open wounds, lesions, infected or inflamed areas.
- Do not use lotions, oils or sprays on skin location where you will place the HEMOTAG Device.
- Do not dispose of the HEMOTAG Device. Return the Device to your health care provider, or mail to Aventusoft.
- Do not disassemble the Device.
- Keep away from other electronic devices as they may interfere with the wireless connectivity of the Device.
- Do not defribilate with device attached.
- Keep device away from children.
- Do not use in the presence of flammable gasses.
- Do not use if the device is damaged or broken.
- Do not heat above 60° C (140° F).
- Do not immerse in water or any kind of liquids or cleaning fluids.
- Do not use in a wet environment.
- Do not attempt to utilize the HEMOTAG Device while charging. The Hemotag device will not transmit or operate while charging.

Conventions & Notations in this Manual

Conventions

Bold text indicates a button or key that you touch or press.

Notations

Warning icons idenfity conditions or practices that could result in injury to patients or users.

Caution icons identify conditions of practices that could result in damage to equipment or other property.

Note icons provide additional information about a feature or process.

Tip icons convey helpful information about how to use the HEMOTAG device.

Confidential and Proprietary

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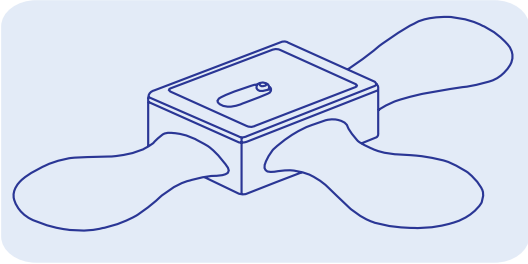
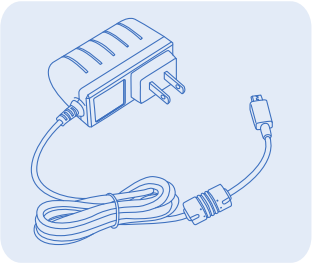
The HEMOTAG Kit

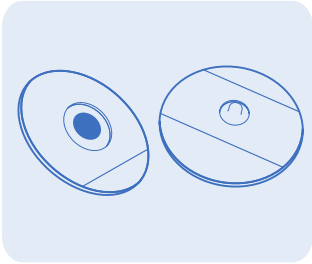
If for any reason you are missing one of the components listed below, contact Aventusoft at 954.399.3335.



HEMOTAG Device



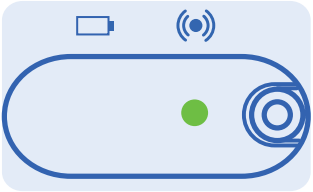
Charging Cable
with Adapter



Disposable Electrodes x100

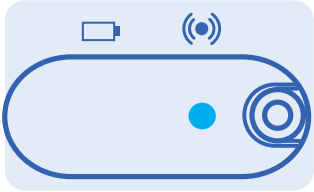
HEMOTAG Device Lights

The color and pattern of lights on the HEMOTAG Device indicate the status of the device.



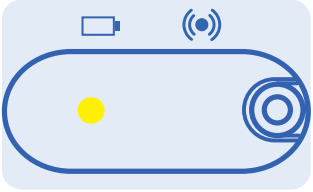
Solid green - connected to HEMOTAG App

Flashing green - turned on, looking for Bluetooth connection



Solid blue - collecting sensor data from patient

Flashing blue - transmitting data to HEMOTAG App



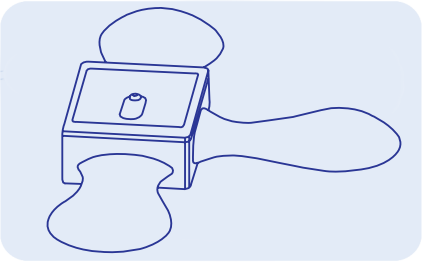
Solid yellow - charging

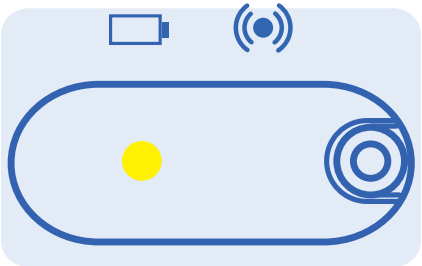
Using the HEMOTAG System

1. Setting Up

Charge the HEMOTAG Device using the Charging Cable. All lights will go off when the HEMOTAG Device is fully charged. (The battery light will display flashing yellow when low on power).

NOTE: Do not attempt to utilize the HEMOTAG Device while charging. The HEMOTAG Device will not transmit or operate while charging.





While your HEMOTAG Device is charging, take this time to set up the HEMOTAG App on your smartphone.

On your smartphone, open the introductory email to create your free account, with an email and password.

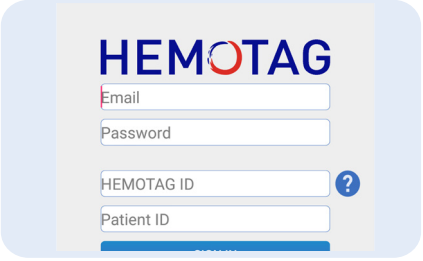
On your smartphone, click the desired iOS or android product link in the introductory email.

Download & Install HEMOTAG App from your smartphone's app store. Launch the HEMOTAG App and sign in to your account, using the HEMOTAG ID: from the HEMOTAG Box.

2. Launch the HEMOTAG App

Use your smartphone to launch the HEMOTAG App. Sign in to the app, using your email, password, and the HEMOTAG ID, located on the HEMOTAG, or located on the box.

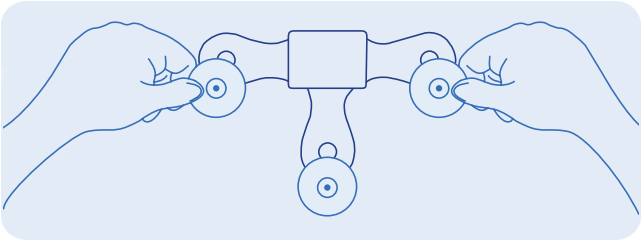
Stay within 3 feet of your smartphone in order for the HEMOTAG App to properly receive your heart data.



For Healthcare professionals only: Enter your patients medical record number in the "Patient ID".

3. Attach Electrodes to the HEMOTAG Device

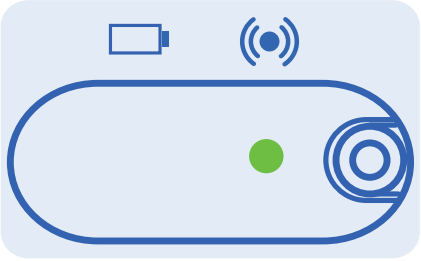
Take out the packaged electrodes and snap them to the HEMOTAG Device, using the center snaps and attaching to the arms of the device.



Using the HEMOTAG System

4. Turn on the HEMOTAG Device

Turn on the HEMOTAG Device by **long pressing** the **center power button.** The Device will begin broadcasting, waiting to connect to the HEMOTAG App, and the right green LED will start flashing.



5. Attach the HEMOTAG Device to your chest.

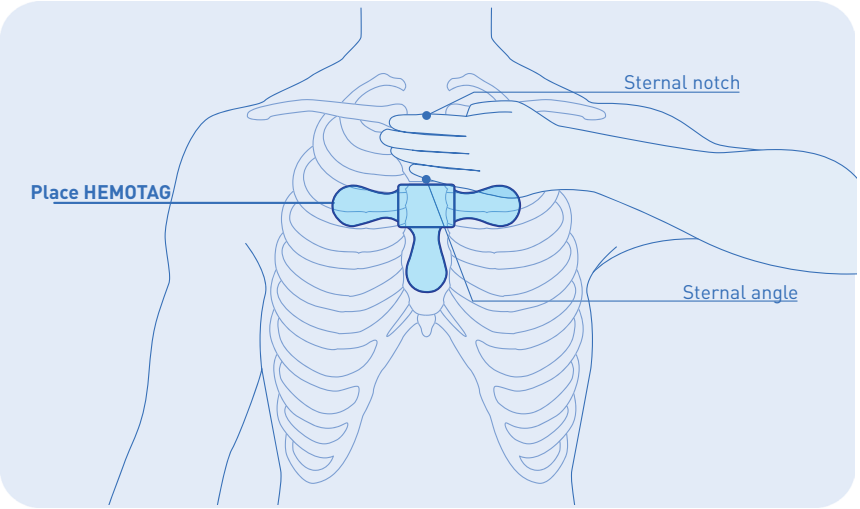
Prep your skin! Remove any and all hair in the placement location, and thoroughly clean the area with soap and water. Do not apply lotions, oils, or other topical ointments.

Peel away the adhesive backing on the electrode.

Place the HEMOTAG Device on the shown location on your chest.

Four fingers below the sternal notch (i.e. Index finger at the start of the bone, below the notch).

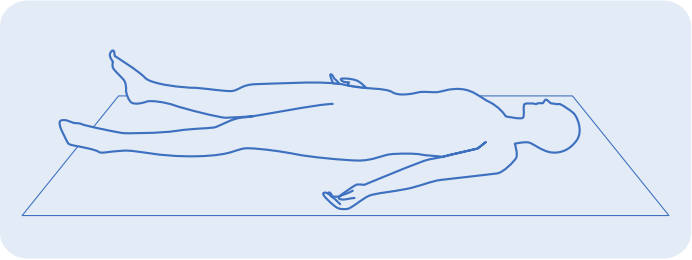
Place HEMOTAG below the fourth finger (At the sternal angle, or second intercostal), centered on the sternum bone.



If you have skin allergies, consult your doctor for different electrodes.

6. Lie Down

With the HEMOTAG Device ready, lie down on a comfortable surface, such as a bed. You want to be as still as possible in order for the HEMOTAG Device to record an accurate reading.



Using the HEMOTAG System

Try to keep your smartphone within 3 feet of the HEMOTAG Device. If something occurs that disrupts the data stream (no battery charge, no connection), the HEMOTAG App will show the necessary indications visually. See Appendix D.

Keep the HEMOTAG Device charged.

If your smartphone's Bluetooth is off, it won't be able to connect to the HEMOTAG Device. Make sure Bluetooth is on while using the HEMOTAG Device.

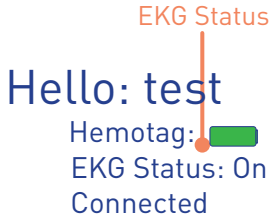
7. Collect and Report HEMOTAG Data

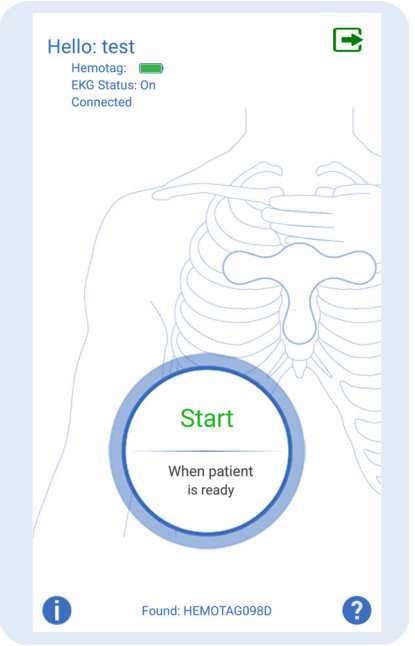
If connection to HEMOTAG device is successful, the battery icon on the HEMOTAG App screen will indicate it is connected to the HEMOTAG. If the HEMOTAG Device is properly placed, the EKG status: ON will appear, and the **Start** text will turn green to indicate that you can start the data capture.

Press the **Start** button to begin the 30second data capture, followed by data transfer to the smartphone.

A percentage completion wheel will indicate the amount completed.

At the end of the session, an orange **Done** button will appear. Press to finish.

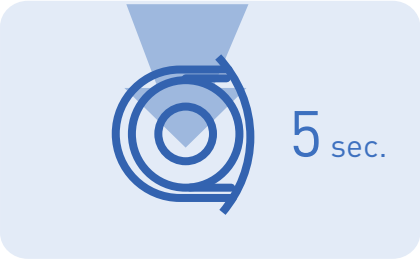




8. Turn off the HEMOTAG

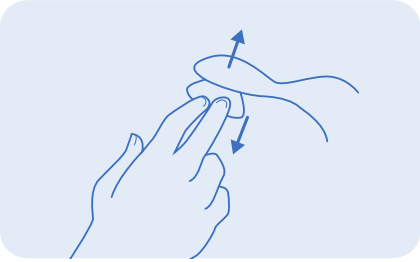
Your HEMOTAG Device will automatically turn off after each session.

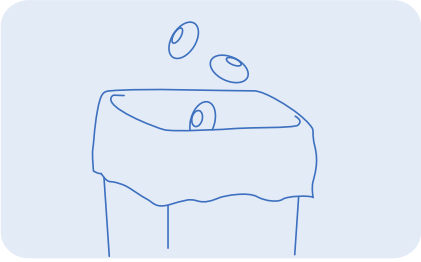
To manually turn off the HEMOTAG Device, press and hold the **center power button** for at least 5 seconds.



9. Remove the Electrodes from the HEMOTAG Device

Hold the electrodes against your skin and lift the arms of the HEMOTAG Device until the electrodes snap off one at a time. Discard the used electrodes.





Appendix A: Specifications

HEMOTAG specifications

Shelf life	24-months
Battery Capacity	110mAh typical
Battery Charger Power Requirement	100-240 VAC, 50-60Hz
Battery Type	Rechargeable Li-polymer
Battery Voltage	3.7 VDC
Operating Temperature	10°C/50˚F to 45°C/113˚F
Battery Operation Time (typical)	8 - 12 hours between charges
Storage Temperature (Power Off)	-25°C/-13˚F to 70°C/158˚F
Operating Humidity	10% to 90%
Storage Humidity	30% to 75% (excluding condensation)
Operating/Storage Pressure	700-1060 hPa
Digital Resolutions - ECG - Accelerometer	 12 bits 20 bits
Sampling Rates - ECG - Accelerometer	 488.25Hz 488.25Hz
Measurement Ranges - Heart Rate - Respiration - Accelerometer	 25 to 240 bpm 0 to 30 breaths/min ±2g range in x,y,z directions
Data Storage - Capacity -Type	 60 seconds recording Internal NAND Flash
Dimensions	6.5"L x 3.7"W x 0.6"D
Weight	35g
Communications Type	Bluetooth TM Class II with QoS Best Effort between HEMOTAG and phone
BLE Cybersecurity	AES 128-bit encryption

Warnings

This product is prescription-use only.

Aventusoft should not be contacted in the case of medical emergencies. If you experience anything not outlined in this manual, contact your doctor immediately. If you are having a medical emergency, call 911.

If you require assistance with usage, application, or technical issues, contact Aventusoft at 954.399.3335.

Remove the HEMOTAG Device before swimming, bathing, or performing similar activities, and re-attach the HEMOTAG Device afterwards.

Keep the HEMOTAG Device and electrodes outside of the MRI scanner room. This device presents a projectile hazard.

If you have any known skin irrtants or hypersensitivities, consult your doctor before using the HEMOTAG Device.

Latex Information:
The HEMOTAG Device and/or packaging material are not formulated with and do not contain natural rubber. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

The HEMOTAG Device may not be suitable for patients with extremely fragile skin or patients with open wounds/lesions at or immediately adjacent to electrode and sensor positions. The Device may not be appropriate for patients that have skin allergies or are otherwise sensitive to the disposable electrodes and/or the HEMOTAG Sensors used with the system.

Warnings

- Use only Ag/AgCl-type ECG electrodes with the HEMOTAG Sensors. Other types of electrodes might result in misleading results and incomplete HEMOTAG Device or ECG reports.
- There are no serviceable parts in the HEMOTAG Device. Do not open the Device to change the Battery or modify the Device. Use only the included Charging Cable to recharge the internal Battery.
- Do not use the tip of a pen to touch the HEMOTAG power button because it can damage the switch. Use only your fingers.
- Do not disassemble or incincerate.
- Do not charge except as specified in this manual.
- Do not crush.
- Do not perform any type of sterilization procedure on the HEMOTAG Device components.
- The conductive parts for electrodes and associated connectors for type BF applied parts should not contact other conductive parts including earth.
- For proper disposal of the device, contact the appropriate authorities.

Symbols

The following symbols may appear on the HEMOTAG Device as well as the included accessories.

REF — Part number/ catalog item

SN — Serial number

LOT — Lot number

Rx Only — Prescription-use only

Manufacturer

Date of Manufacture

Not defib-proof type of CS equipment

Consult accompanying documents

Instruction manual must be read

IP22 — Protection against fingers/objects not > 80mm length and 12mm diameter.
Protection from verticle dripping water.

ECG electrode

LATEX FREE — Contains no latex

Sensor pouch

Sensor box

Temperature limitation (operating)

Humidity limitation

Type BF applied part

FCC ID: 2AQS4-HT17999999
This device complies with Part 15 of 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.

Appendix B: Electromagnetic environment

The HEMOTAG Device is suitable for use in the specified electromagnetic environment. The purchaser or user of the HEMOTAG Device should assure that it is used in an electromagnetic environment as described below:

Emissions

RF emissions CISPR 11	Group 1	The monitor or HEMOTAG uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The monitor or HEMOTAG is suitable for use in domestic establishments and in establishments directly connected to the low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions EIC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Changes or modifications not expressly approved by Aventusoft, LLC. could void the user's authority to operate the equipment.

Immunity

Standard	Test Description	Test Level/Limits
IEC 61000-4-3	Radio Frequency Electromagnetic Field Amplitude Modulated	80 MHz to 2.7 GHz 3V/m 80% AM 1kHz
	Spot frequency tests	385 MHz (18 Hz Pulse mod) 27 V/m, 450 MHz (1 kHz sine FM +/-5 kHz dec) 28 V/m, 710, 745 & 780 MHz (217 Hz Pulse mod) 9 V/m, 810, 870 & 930 MHz (18 Hz Pulse mod) 28 V/m, 1.720, 1.845, 1.970 & 2450 GHz (217 Hz Pulse mod) 28 V/m, 5.240, 5.500 & 5.785 GHz (217 Hz Pulse mod) 9 V/m
IEC 61000-4-4	Electrical Fast Transients	±2.0kV AC Mains
IEC 61000-4-5	Surge	1kV Line to Line (D M) 2kV Line to PE (CM)
IEC 61000-4-6	Radio Frequency Common Mode	0.150 to 90 MHz 3Vrms (6 Vrms in ISM bands) 80% AM 1kHz
IEC 61000-4-8	Power Frequency Magnetic Field	30A/m
IEC 61000-4-11	Voltage Dips and Interruptions	0% of Vnom 0.5 cycles (Phase angles 0, 45, 90, 135, 180, 225, 270 & 315)
		0% of Vnom 1.0 cycle
		70% Vnom 25 cycles
		0% of Vnom 250 cycles

Appendix C: LED Light Table

LED Displays	What do the HEMOTAG lights mean?
	HEMOTAG is off.
	Power-on sequence, attempting to connect with smartphone. Stay within 3 feet of smartphone.
	HEMOTAG connected to HEMOTAG App on smartphone.
	HEMOTAG capturing cardiac data.
	HEMOTAG transmitting cardiac data.
	Electrodes do not have good contact with skin. Check if plastic lining has been removed. Press firmly on the skin. Try replacing all three electrodes with new ones.
	Battery charging.
	Low battery. Connect HEMOTAG to charging cable. NOTE: The right "Broadcast LED" may be illuminated in any state.
	Flashes once, Device powers off after timeout time to save battery.
	Hardware error. Turn off HEMOTAG and restart. If error happens consistently, send HEMOTAG back to manufacturer.

Light off Light steady on Light flashing

Appendix D: HEMOTAG App Guide

There are a total of three screens on the HEMOTAG App: the splash screen, login screen, and main screen.

Figure 1: Splash Screen

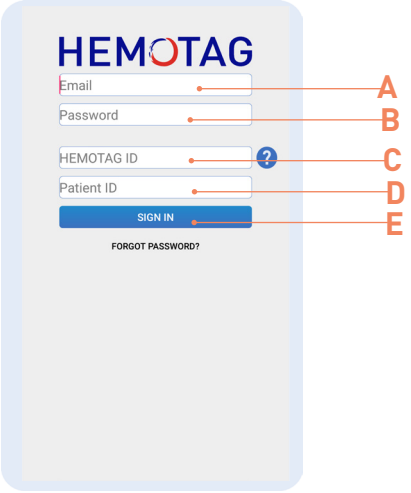


Figure 2: Login Screen

The user will first be greeted with the splash screen. After the app loads, the user can review the introduction screens. Press the Login button at anytime. This is where the user must provide identification information as well as the Devices information to access the HEMOTAG Device's service.

A. Email: User's identification in the cloud server.

B. Password: User's password in the cloud server.

C. HEMOTAG ID: The alphanumeric characters from the box. Case insensitive.

D. Patient ID: Enter patient's Medical Record Number.

E. Sign In: Submit the login request to the cloud server.

The Patient ID is an optional field.

Appendix D: HEMOTAG App Guide

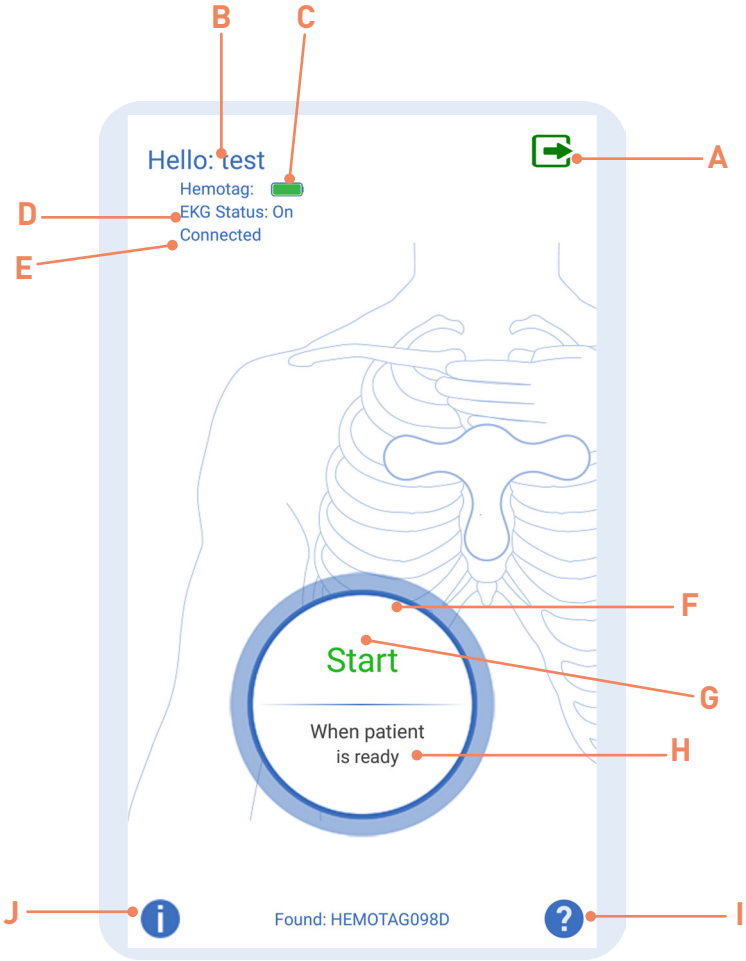


Figure 3: Main Screen

A. Exit Button: Stop the current activity and exit the app.

B. Welcome Indicator: Shows the username.

C. Device Battery Level Status Bar: Indicates the device battery level informaton when the device is powered on and connected.

D. EKG Status Indicator: Indicate whether device is connected and EKG is detected on or not.

E. Top Status Indicator.

F. Main Button: Press to start data collection. After the data collection process is finished, press to exit the app. During the data collection and transfer, the progressive bar will show the percentage of data collection and data transfer.

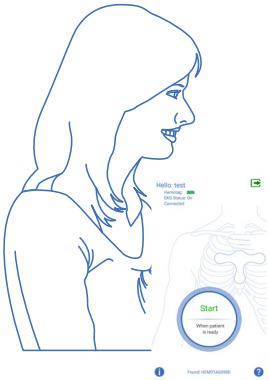
G. Indicators on the Button.

H. Bottom Status Indicator.

I. Help Menu Button.

J. Device Information Button.

A Simplified Approach to Patient Care



Patient Cardiopulmonary Assessment

Cardiopulmonary Assessment

Secure wireless Transmission of Data

HEMOTAG Cloud

Secure HIPAA-compliant cloud platform

High Availability Cloud Environment

Secure HIPAA-Compliant Data Storage

Automated Analysis of Heart Sounds and ECG for Cardiopulmonary Assessment

Simplifies the need for IT and Healthcare Resources

Clinician HEMOTAG Dashboard

Customize notifications Threshholds specific to Patients

Patient Specific Reports and Data Trends

Monitor threshholds for: Bradcardia, tachycardia Systolic Time Ratio, Myocardial Performance Index, Electromechanical Activation Time

Handle Data Review in Bulk

Easy Monitoring of Events based on Urgency

Multiple levels of administrative access to simplify tasks

Figure 4: HEMOTAG Ecosystem

The HEMOTAG System can be operated by either a healthcare professional or the patient.

How the HEMOTAG System Works

The complete HEMOTAG Cardiopulmonary Assessment System (CPAS), as shown on page 5, consists of components to record and collect your Heart Sounds and ECG data. The Device includes software that communicates over an encrypted Bluetooth link with a smartphone App to transmit data over an SSL link to a secure HIPAA compliant web-dashboard for storage analysis and reporting. The data is available to be accessed and reviewed by your health care professionals.

The HEMOTAG measures the heart rate in beats/minute, by dividing 60 with the calculated average RR duration from the 30second 1-lead ECG signal.

Cleaning & Storing the Device

Cleaning the HEMOTAG Device

If you see visible dirt on the HEMOTAG Device: Use a sterile 70% isopropyl alcohol (IPA) pad and thoroughly wipe in a circular motion, for a minimum of 30 seconds, all outer surfaces of the HEMOTAG Device. Ensure excess alcohol does not run into or collect in seams or crevices. Allow the Device to air dry. If visible soil remains, repeat the above steps using a new, sterile IPA pad until the HEMOTAG Device is visibly clean.

If using same HEMOTAG on multiple patients clean/disinfect between uses.

Servicing/Maintenance

No operator maintenance is required. If device requires servicing or maintenance contact aventusoft LLC at the info provided on page 2 of these instructions.

Storing the Device & Charging Cable

Store the Device in its box when not in use or for long-term storage or during travel.

Wait approximately @ ambient temperature 20°C for 1 hour to warm up/ cool down to the appropriate operating temp of 10°C to 45°C per spec page 13, to enable the device.

For charging the HEMOTAG device, connect the provided charging cable as shown.

Frequently Asked Questions

Why does the smartphone HEMOTAG App show a number pad and ask for a HEMOTAG ID? Enter the alphanumberic HEMOTAG ID from your HEMOTAG Device. The HEMOTAG ID is also available on the HEMOTAG Box Sleeve.

Why does the smartphone HEMOTAG App fail to log in? Verify you are entering the full email address (e.g. you@company.com). Verify you are entering your correct password. Verify you are entering the alphanumberic HEMOTAG ID from the back of your HEMOTAG Device. Verify your smartphone has Internet connectivity. If this problem persists, reset your password using the 'Forgot password?' link on the HEMOTAG app login page. Or by visiting https://dashboard.hemotag.com

Why is the Collect button grayed out (disabled) on the HEMOTAG Smartphone Application screen? The button will change to blue (enabled) once the Device is connected and ready to record. Follow the instructions in the Instructions for Use Manual to connect HEMOTAG Device to HEMOTAG App. Ensure Bluetooth is turned ON in the smartphone. If this problem persists, contact 954.399.3335.

Why does the smartphone display 'Transmitting data' with a progress wheel for an extended period of time after the Collect button was pressed? The Heart sound and ECG data collected on the HEMOTAG Device takes a significant amount of time to download the stored data to the HEMOTAG Application followed by a short upload time to send data to the secure cloud. Keep the smartphone within 3 feet of the powered on HEMOTAG Device until the status displays Done. Ensure the smartphone is connected to the internet, required to transmit the captured data to the cloud.

Why does the smartphone vibrate and display 'ECG not detected' message on the screen and the ECG icon is not green? The Device is unable to get reliable skin contact. Ensure all three ECG electrodes are snapped to the Device and the clear adhesive backing on each electrode is removed. Verify the Device adheres securely to the skin. Verify the Device positioning on the chest. If the message continues to display, you may need to replace the ECG electrodes. If this problem persists, contact 954.399.3335.

Does the smartphone require Internet connectivity? Yes, during the HEMOTAG Data capture the smartphone will need to be connected to the internet, either WiFi or the data service plan. The recorded heart sounds and ECG data is approximately 120kbytes which is transmitted to the online cloud server.

Where can I view the reports provided by my HEMOTAG Device? Contact your doctor to obtain all your reports.

Why does the charging light not illuminate when the Device is plugged to the charger? If the Device is fully charged, the light will only illuminate briefly. Check the power connections on the charger.

Can I capture the HEMOTAG Data anytime during the day? Yes, it is okay to use the HEMOTAG anytime during the day. Please follow the doctors prescription for the time of data capture and the frequency.

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