HEMOTAG

Cardiac Monitoring System (CMS)

HEMOTAG User Guide

Model: HT-101

General Information

Contact Information

Aventusoft
3651 FAU Blvd.
Boca Raton, FL 33431

Phone:	(954) 399-3335
Hours:	9am - 5pm EST
General email:	info@hemotag.com
Service email:	service@hemotag.com
Website:	www.hemotag.com

User Guide Revision: F15-01-02 Rev C draft

Indications for Use

The HEMOTAG® Cardiac Monitoring System (CMS) acquires and reports single channel ECG data and vibrational waveforms produced by the heart contractions and transmitted to the chest wall.

This device may be used as a tool to measure the timing of part of the events in the cardiac cycle for adult population.

Trained Medical Professionals.

Use Restrictions

ESD: The device shall not be prescribed for use in an environment which might introduce electrostatic discharge into the device.

Device Shelf Life

The device shelf life is 2 years.

Conventions & Notations in this Manual

Conventions

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

Notations

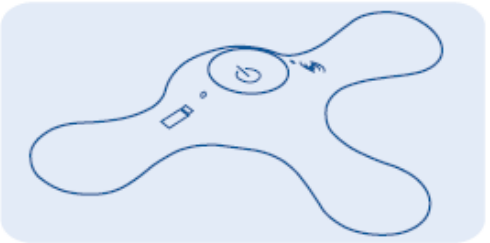
Notification of a condition that deserves attention.

Note icons provide additional information about a feature or process.

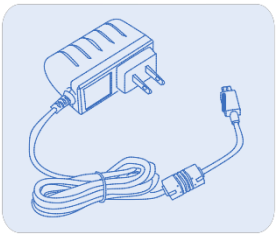
Tip icons convey helpful information about how to use the HEMOTAG device.

The HEMOTAG Kit

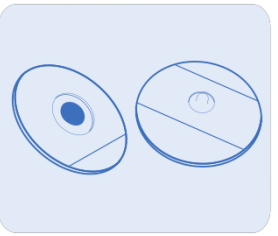
If for any reason you are missing one of the components listed below, contact Aventusoft at (954) 399-3335.



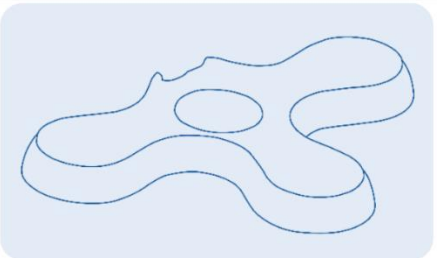
HEMOTAG Device



Power Adapter



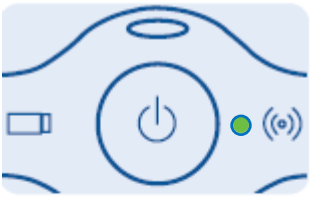
ECG Electrodes



Charging Base

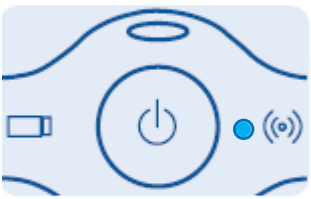
HEMOTAG Device Lights

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



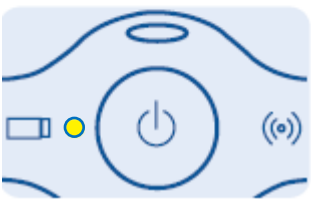
Solid green - connected to HEMOTAG App

Flashing green - turned on, looking for Bluetooth connection



Solid blue - collecting sensor data from patient

Flashing blue - transmitting data to HEMOTAG App



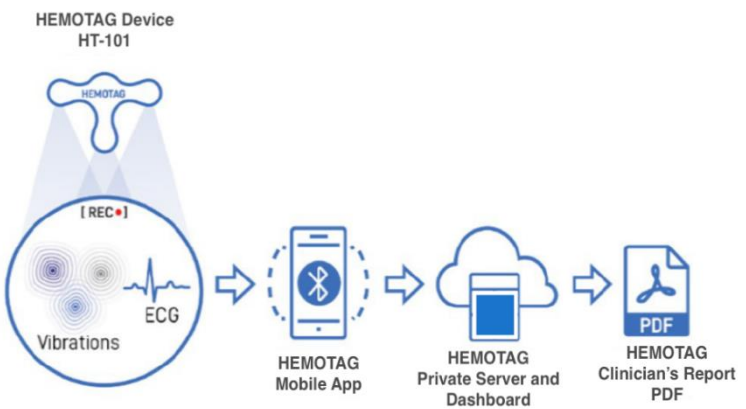
Solid yellow – device battery charging

Flashing yellow – low battery

Workflow Summary

Device Action	App Action
Set up the system (Section 1)	
Check device and charger for visible damage (Section 2)	
Apply electrodes to the device (Section 3)	
Apply device to patient (Section 4)	
Turn device on (Section 5)	
	Launch HEMOTAG App (Section 6)
	Report HEMOTAG Data (Section 7)
Turn off the HEMOTAG Device (Section 8)	
Remove the Electrodes from the HEMOTAG Device (Section 9)	
Clean between uses (Section 10)	

Data Flow



Using the HEMOTAG System

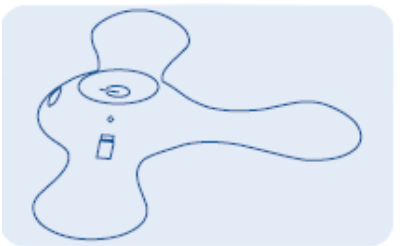
Assessing Device Fit and Suitability

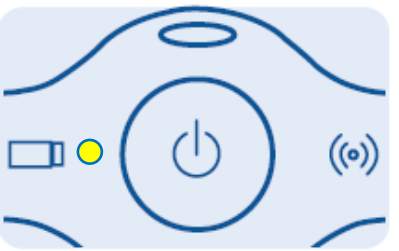
In the course of prescribing this device, the practitioner should conduct an assessment to ensure when fitted onto the patient's chest wall the device meets the intended use.

1. Setting Up

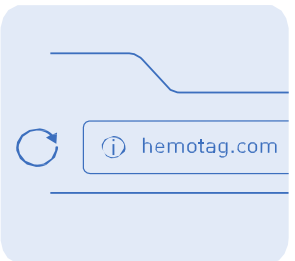
Charge the HEMOTAG Device using the charging base and cable provided. All lights will turn off when the HEMOTAG Device is fully charged. The battery light will display a flashing yellow light when battery is.

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



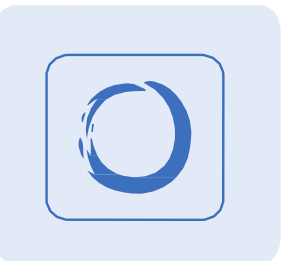


While the HEMOTAG Device is charging, set up the HEMOTAG App on the smartphone.



Using a smartphone, open the introductory email to create an account, with an email and password.

Select the desired iOS or Android product via the link sent in the introductory email. Download and install the HEMOTAG App.



Launch the HEMOTAG App and sign into the account, using the HEMOTAG ID from the HEMOTAG Device.

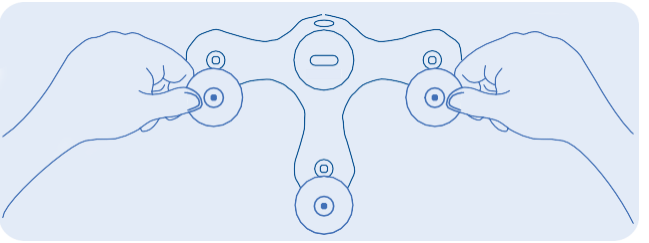
2. Visual

Perform a visual inspection of the device looking for signs of deterioration (i.e., corrosion, discoloration, pitting, cracked housing or arms). Continued use of a device that exceeds its use life may result in reduced effectiveness, malfunction, or increased risk of infection from damaged device materials.

3. Attach Electrodes to the HEMOTAG Device

Take out the packaged electrodes, peel off the plastic on the bottom of electrode, and snap them to the HEMOTAG Device, using the center snaps and attaching to the arms of the device.

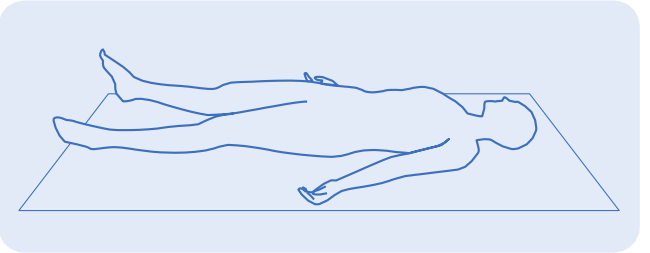
NOTE: The device has been tested to work with Telectrode T716 electrodes.



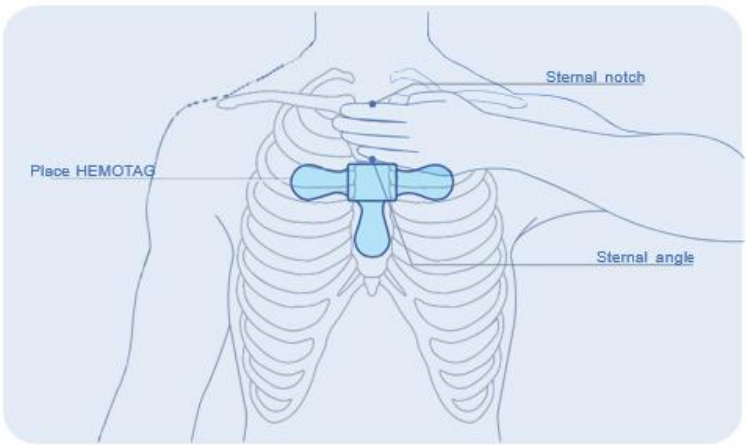
4. Attach the HEMOTAG Device to the Patient's Chest

Skin Preparation: Prepare the skin according to the manufacturer electrode instructions. Assure skin integrity and monitor for adverse reactions to the electrode.

Place the HEMOTAG Device on the shown location on the patient's chest. The patient must be positioned in supine position for the remaining duration of the test.

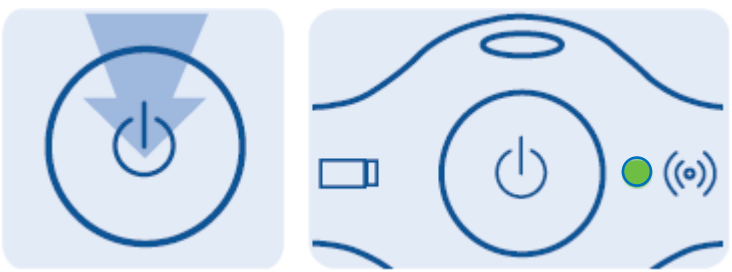


Place HEMOTAG Device four fingers below the Sternal Notch and between the Sternal Notch (second intercostal) and Sternal angle, centered on the Sternum bone.



5. Turn on the HEMOTAG Device

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



Using the HEMOTAG System

Try to keep your smartphone within 3 feet of the HEMOTAG Device. If the data flow is disrupted (e.g. no battery charge or no connection), the HEMOTAG App will show the necessary indications visually.

Keep the HEMOTAG Device charged.

Assure that Bluetooth is turned "ON" on your smartphone.

6. Launch the HEMOTAG App

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

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

Enter your patient's medical record number in the "Patient ID" field.

7. Collect and Report HEMOTAG Data

Once the Bluetooth connection is established, the center button on the HEMOTAG App will indicate it is connected to the HEMOTAG.

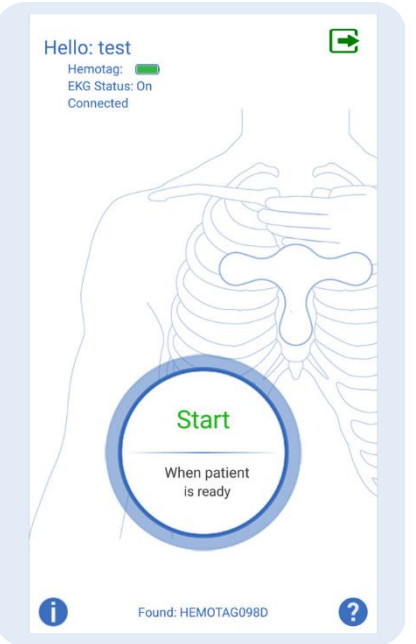
Once HEMOTAG device is properly placed on the chest, the ECG status: ON will appear, and the Start text will turn green.

The HEMOTAG App uses the "ECG" abbreviation which is a synonym for "EKG" commonly in medical field.

Press the Start button to indicate the patient is ready, followed by data transfer to the smartphone.

A percentage completion wheel will indicate the progress.

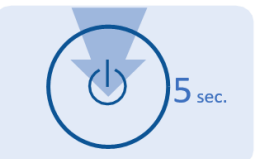
At the end of the session, an orange Done button will appear. Press it to finish.



8. Turn off the HEMOTAG

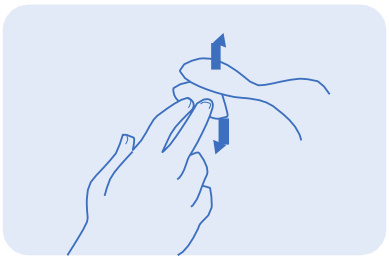
The HEMOTAG Device will automatically turn off after each session.

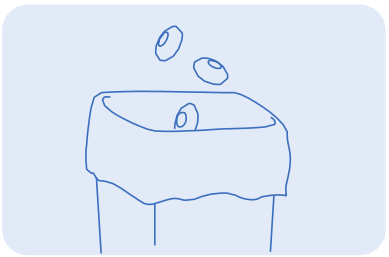
To manually turn off the HEMOTAG Device, press and hold the center power button for at least 5 seconds.



9. Remove the Electrodes from the HEMOTAG Device

After the session is complete, remove the device and electrodes by holding the electrodes against the patient's skin and lifting the arms of the HEMOTAG Device until the electrodes snap off one at a time. Discard the used electrodes.





Protect the HEMOTAG device from inadvertent contact with electrically conductive objects.

10. Cleaning between uses:

Manually clean the device with friction and a 70% isopropyl alcohol pre pad. Wipe down the backside of the HEMOTAG using a circular motion. Sequentially wipe the arms of the HEMOTAG and then the center to completely wipe the entire surface. If visible soil remains, repeat cleaning step until device is visibly clean. Allow the device to air dry before next use.

The HEMOTAG can be used 2 years or 2500 cleanings (whichever one comes first).

Appendix A: Specifications

HEMOTAG specifications

Shelf Life	24-months
Battery Capacity	80mAh nominal
Battery Charger Power Requirement	100-240 VAC, 50-60Hz
Battery Type	Rechargeable Li-Ion Polymer
Battery Voltage	3.7 VDC
Operating Temperature	50˚F to 113˚F (10°C to 45°C)
Battery Operation Time (typical)	8 - 12 hours between charges
Storage Temperature (Power Off)	-4˚F to 113˚F (-20°C to 45°C)
Operating Humidity	10% to 90%
Storage Humidity	30% to 75% (excluding condensation)
Operating/Storage Pressure	700-1060 mb
Measurement Ranges - Accelerometer	±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	1.25oz (35g)
Communications Type	Bluetooth TM Class II with QoS Best Effort between HEMOTAG and phone
BLE Cybersecurity	AES 128-bit encryption
Device Placement	Device placement has been verified with displacement of up to one inch deviation from target location.

Warnings

This is a prescription-only device

Call 911 in case of medical emergencies

For assistance with usage, application, or technical issues, contact Aventusoft at (954) 399-3335

MR Unsafe: Keep the HEMOTAG Device and electrodes outside of the MRI scanner room

Not Defibrillation-Proof
Remove the HEMOTAG device and its electrodes before external cardiac defibrillation

- There are no serviceable parts in the HEMOTAG Device. Do not open the HEMOTAG Device.
- Keep HEMOTAG Device out of reach of children and pets.
- Use only the included Charging Base and Cable to recharge the internal Battery as defined in Section 1.
- Do not disassemble or incinerate.
- Do not perform any type of sterilization procedure on the HEMOTAG Device components.
- For proper disposal of the device, contact the appropriate authorities.
- WARNING: No modification of this equipment is allowed. WARNING: Do not modify or attach any other devices to the HEMOTAG.
- The HEMOTAG device is not intended to be used with any external third-party analysis software.
- No external wires should be connected to the HEMOTAG Device while it is attached to the body

Symbols

The following symbols may appear on the HEMOTAG Device and accessories.

Unique Device Identification

Manufacturer

Type BF

Prescription-use only

Instruction manual must be read

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

Temperature limitation (operating)

Humidity limitation

Not defibrillation-proof type of CS equipment

FCC ID: 2AQS4-HT101
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 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 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 could void the user's authority to operate the equipment.

Note: This equipment has been tested and complies with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules, which provide reasonable protection against harmful interference in a residential installation. This equipment generates radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to radio communications, although there is no guarantee that interference will not occur. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to relocate the receiving antenna or increase the separation between the equipment and receiver.

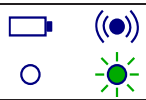
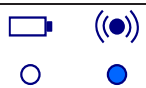
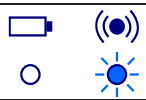
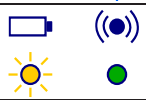
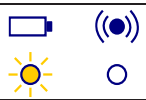
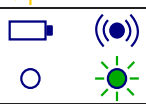
Immunity

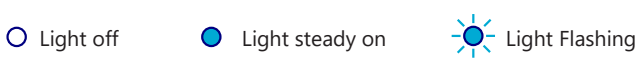
Standard	Test Description	Test Level/Limits
IEC 61000-4-3	Radio Frequency Electromagnetic Field Amplitude Modulated	80 MHz to 2.7 GHz 10V/m 80% AM 1kHz
	Spot frequency tests	385 MHz (18 Hz Pulse mod) 27 V/m, 450 MHz (18 Hz Pulse mod) 28 V/m, 710, 745 & 780 MHz (217 Hz Pulse mod) 9 V/m, 810, 870 & 930 MHz (18 Hz Pulse mod) 28 V/m, 1720, 1845, 1970 & 2450 MHz (217 Hz Pulse mod) 28 V/m, 5240, 5500 & 5785 MHz (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 (DM) 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

Warning: The HEMOTAG Device has not been tested for immunity to known sources of electrical interference including but not limited to diathermy, lithotripsy, electrocautery, RFID, electromechanical anti-theft systems or metal detectors, the presence of which may affect device operation.

Warning: Portable RF communications equipment should be used no closer than 12 inches (30 cm) to any part of the HEMOTAG Device. Otherwise, degradation in performance could result.

Appendix C: LED Light Table

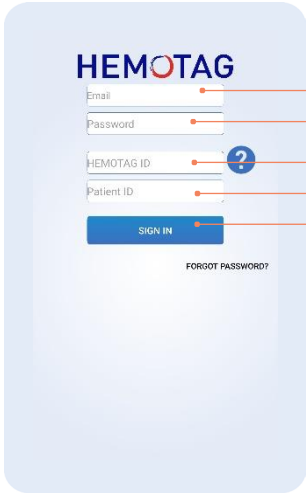
LED Displays	What do the HEMOTAG lights mean?
	HEMOTAG is off
	Power-on sequence, attempting to connect with smartphone. Stay within 3 feet of smartphone.
	HEMOTAG connected to HEMOTAG App on smartphone.
	HEMOTAG capturing cardiac data.
	HEMOTAG transmitting cardiac data.
	Electrodes do not have good 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. Place HEMOTAG on charging base. 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.



Appendix D: HEMOTAG App Guide

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

Splash Screen



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 any time. 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 identification number.

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

The Patient ID field is optional.

The Main Screen

A. Welcome Indicator: Shows the username.

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

C. ECG Status Indicator: Indicate whether device is connected and ECG is detected on or not.

D. Top Status Indicator.

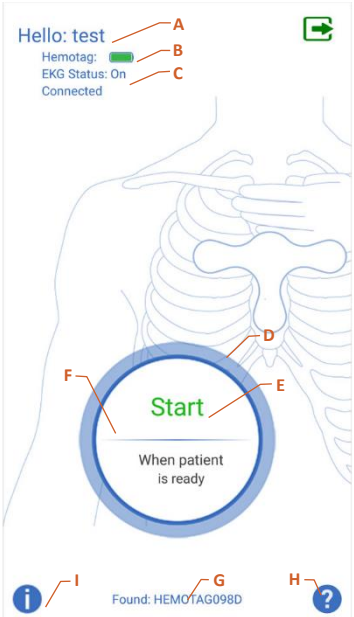
E. Main Button: Press to start to indicate patient is ready for test. After the data collection process is finished, press to exit the app. During the data collection and transfer, the progressive bar will show the percentage of data collection and data transfer.

F. Indicators on the Button.

G. Bottom Status Indicator.

H. Help Menu Button.

I. Device Information Button.



The Help Menu

By pressing the Help (?) Menu Button, the App will show the Help Menu on top of the Main Page.

The Device Information Button

By pressing the Device Information Button, the App will show the Device Information pop up window.

How the HEMOTAG System Works

The complete HEMOTAG Cardiac Monitoring System (CMS), 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.

Data Acquisition Quality of Service (QoS)

The HEMOTAG Cardiac Monitoring System (CMS) data acknowledgment system confirms data exchanged between the device and the Hemo App. Should data repeatedly fail to be properly exchanged, in a matter of a few seconds, the session will be terminated. Users can then attempt to restart the process.

Cleaning the Device

Manually clean the device with friction and a 70% isopropyl alcohol pre pad. Wipe down the backside of the HEMOTAG using a circular motion. Sequentially wipe the arms of the HEMOTAG and then the center to completely wipe the entire surface. If visible soil remains, repeat cleaning step until device is visibly clean. Allow the device to air dry before next use.

The HEMOTAG can be used for 2 years or 2500 cleanings (whichever comes first).

Servicing/Maintenance

No operator maintenance is required. If device requires servicing or maintenance, contact Aventusoft at the info provided on page 2 of this User's Guide.

Frequently Asked Questions

Why does the smartphone HEMOTAG App ask for a HEMOTAG ID?

Enter the alphanumeric 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 the correct password. Verify you are entering the correct alphanumeric 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 Collection button was pressed?

The Heart sound and ECG data collected on the HEMOTAG Device takes a significant amount of down to download the stored data to the HEMOTAG Application followed by a short upload time to send data to the secured 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 Wi-Fi or the data service plan.

Where can I view the reports provided by my HEMOTAG Device?

Contact your doctor to obtain all your reports.

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 doctor's prescription for the time of data capture and the frequency.

Storing the Device & Charging Cable

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

Wait approximately @ ambient temperature 20°C for 1 hour to warm up/ cool down, the enabled HEMOTAG Device.

To charge the HEMOTAG Device, connect the provided charging cable to charging base and place HEMOTAG onto the base as shown.