

# HOUND<sup>®</sup> CANNABIS BREATHALYZER Collect + Send User Manual



1



The HOUND® CANNABIS BREATHALYZER is intended to detect recent cannabis use. It does not measure whether, or how much, a person is impaired. It is intended solely for use in employment, law enforcement, and insurance settings. It should not be used for any medical or therapeutic purposes, or for any Federal drug testing programs, such as programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military.

DISCLAIMER: Neither the manufacturer, the distributor, nor the owner accepts liability or responsibility due to any action or claim arising from the reading produced by the HOUND<sup>®</sup> CANNABIS BREATHALYZER, whether used correctly or incorrectly.

For more information, contact Hound Labs Support at 888.310.FAIR (3247) or <a href="mailto:support@houndlabs.com">support@houndlabs.com</a>.



# TABLE OF CONTENTS

1	INTRO	ODUCTION4
	1.1	Product Features
	1.2	Product Components
2	OPER	ATIONAL OVERVIEW 10
	2.1	Touchscreen Buttons + Icons
	2.2	Initial System Setup
	2.3	Wi-Fi Set-up
	2.4	Date and Time Set-up
	2.5	Operating Conditions
	2.6	Performing a Collection
	2.7	Reviewing Completed Collections
	2.8	Canceling a Collection
	2.9	Powering Down the Base Station
	2.10	Cleaning and Maintenance
	2.11	Used Component Disposal
	2.12	Storage
	2.13	Error Messages
	2.14	Test Integrity and Accuracy
3	EXPL	ANATION OF SYMBOLS 47
4	LIMIT	ATIONS AND WARNINGS 48
5	WAR	RANTY 48

3



# 1 INTRODUCTION

The HOUND<sup>®</sup> CANNABIS BREATHALYZER – Collect + Send captures THC in breath. Captured THC is stored and stabilized in tamper-evident, single-use cartridges for processing. Cartridges are sent to a qualified laboratory partner for processing using Liquid Chromatography Mass Spectrometry (LC-MS). This user manual provides a step-by-step guide for how to configure and use the HOUND<sup>®</sup> CANNABIS BREATHALYZER.



- 1.1 Product Features
- Limits detection to use that may impact an employee's workday.
- Provides on-site collections with lab-based results.
- Only detects cannabis if it has been used within a few hours of the collection.
- Measures THC (the psychoactive compound in cannabis) in breath.
- The smart base station facilitates a paperless collection process with seamless laboratory integration.
- Ensures sample integrity with packaged, tamper-evident, single-use cartridges.





Figure 1: Components Diagram



#### **Base Station**

- Equipped with a touchscreen that displays prompts throughout the collection process.
- Integrated barcode scanner.
- Internal components facilitate collections in 2-3 minutes.
- Connects to donor and air cartridges.



#### Assisted Compression Equipment (ACE)

- Assists collectors in compressing cartridges following a collection.
- Mounts to either a desk or tabletop.
- Integrated cradle holds the cartridge in place during compression.
- Ensures cartridges are completely and uniformly compressed following completion of the collection.





#### Donor Cartridge

- Captures donor breath for LC-MS testing at a laboratory.
- Single-use, disposable mouthpiece facilitates donor breath collection.
- Connects to pre-assembled connector tubing.
- Single-use and tamper-evident.
- Identifiable by a unique cartridge ID (aka specimen ID).



#### Connector

• Single-use component used to connect the donor cartridge to the base station to facilitate breath collection.





#### Air Cartridge

- Captures an air sample of the collection environment for LC-MS testing at a laboratory.
- Single-use and tamper-evident.
- Identifiable by a unique cartridge / specimen ID.
- Connects to the air cartridge fitting on the top of the base station.





# 2 OPERATIONAL OVERVIEW

The HOUND<sup>®</sup> CANNABIS BREATHALYZER – Collect + Send captures THC in breath. Collections can be completed in five easy steps:

- 1. Create collection event
- 2. Connect cartridges
- 3. Collect breath sample
- 4. Complete collection
- 5. Certify + ship to lab

Breath and air samples are captured in their respective cartridges during the collection. Processing of the cartridges to determine the presence and, if applicable, amount of THC must occur at a laboratory using LC-MS technology.

#### 2.1 Touchscreen Buttons + Icons

Button	Name	Function
$\bigcirc$	Hound Logo	Select to enter the System Menu page
Â	Home	Select to return to the main collection information entry screen
←)	Back	Select to return to the previous screen
((r·	Wi-Fi	Displays Wi-Fi connection status
.11	Cellular	Displays cellular connection status
	Ethernet	Displays ethernet connection status
R	Retriever™	Displays status of connection to Retriever™ online results portal



#### 2.2 Initial System Setup

Open and remove the HOUND<sup>®</sup> CANNABIS BREATHALYZER base station, power cord, styluses, and the system start-up card from the shipping packaging.

NOTE: Retain original shipping materials for use in future reshipment if needed.



Insert the power cord connector into the power cord connection point on the back of the base station. Plug the power cord into a standard 120V outlet. Once the power cord is plugged in at both ends, press the power button until it illuminates, indicating that the base station is powering on.

NOTE: The base station will take several seconds to boot up after the power button is pressed. During this time, the screen will remain blank.





While powering on, the base station will progress through several start-up screens, including the Hound Labs disclaimer and welcome screens, until it reaches the log in screen.

Upon first use, use the included stylus to enter the default local base station administrator log in on the log in screen. Enter the username (admin) and password (admin) in the Username and Password fields, respectively. Select the checkbox certifying the completion of collector training and select the LOGIN button.

If training has not been completed, visit the Hound Labs Learning Management System page to access collector training: <u>https://houndlabs.talentlms.com/index</u>.

			08:04 PDT 10/04/2023	R ₽ 11 ?
		Log In		
Username				]
Password				]
Confirm y your emp http://ww	ou have comp loyer. Hound L w.houndlabs.c	leted Hound Labs collector abs collector resources ca com/collector-portal/	training as required by n be accessed at	
SHU	TDOWN	ADD GUEST USER	LOGIN	



After logging in with the default password, the system will require a password reset for the local base station administrator account.

	System Admin	08:04 PDT 10/04/2023 限 🚠 💷 🗢
	Ch	ange Password
1	Current Password New Password Confirm Password The new password mus	t be at least 8 characters in length, contain
	at least 1 upper cas following spe	e, 1 lower case, 1 numeric and 1 of the cial characters: !@#\$%^&* []{}?<>
	RESET	CANCEL

The base station will provide guidance during the password reset process, including minimum password format requirements. To access symbols, press the shift key on the keyboard.

NOTE: This password is unique to the system and must be retained for future use as the local base station administrator. In the event this password is forgotten or lost, contact Hound Labs Support for assistance.



Following the password reset, the base station will return to the Log In screen. Log in to the system using the local base station administrator username and the newly created password. Upon log in, the base station will advance to the collection information entry screen.

System Admin	08:05 PDT 1	0/04/2023 Ŗ 占 🖽 🏹
Lab Account Number		]
Donor ID		Verified By 🔻
Donor First Name		]
Donor Last Name		]
Donor Date of Birth		]
Donor Phone Number		Send CCF?
Donor Email Address		]
Reason for Testing	Select Test Reason 🔹	]
Remarks		]
An account number n	nust be scanned or entered to proceed wit	h collection.
	SCAN CARTRIDGE BEGIN COLLEC	CTION

The HOUND<sup>®</sup> CANNABIS BREATHALYZER supports three different modes of connectivity to communicate with the Hound Labs Retriever<sup>™</sup> results portal: ethernet, Wi-Fi, and cellular. Ethernet and Wi-Fi are the preferred modes of connectivity, as they will offer the most stable connection to the Hound Labs Retriever<sup>™</sup> results portal. In environments where ethernet and/or Wi-Fi connectivity are not available, the HOUND<sup>®</sup> CANNABIS BREATHALYZER is configured to automatically utilize cellular networks for connection to the Hound Labs Retriever<sup>™</sup> results portal.

To set up Wi-Fi, proceed to section 2.3.

The system can also be updated to reflect the local time zone. To configure the system Date and Time, proceed to section 2.4.



If a Wi-Fi connection is not available or desired, navigate to the system menu by selecting the Hound Labs logo in the upper left-hand corner of the screen. Once on the system menu screen, select Log Off. Then confirm intent to log off. The system is now set up and ready to perform a collection.

$\bigcirc$	System Admin	08:05 PDT 10/04/2023 Ŗ 占 🚚 🗢
	Log Off	
	About	
	User List	
	Collection Results	
	Setup	
	System Test	
	Restart	
	Shutdown	
	Update	
←]	Change Root Password	Â



#### 2.3 Wi-Fi Set-up

Once configured, the HOUND<sup>®</sup> CANNABIS BREATHALYZER can utilize ethernet, local Wi-Fi, or cellular connectivity to enable the required connection to the Hound Labs Retriever<sup>™</sup> results portal. The ability to set up Wi-Fi access is limited to the local base station administrator and system administrators.

Ensure the system is powered on. Log in using either the local base station administrator account or a user account with system administrator privileges.

Once logged in to the base station, select the Hound Labs logo in the upper left-hand corner of the collection information entry screen to enter the system setting screen.

On the base station system menu, select Setup to access the setup menu.

$\bigcirc$	System Admin	08:05 PDT 10/04/2023 <u>R</u> 🚠 🗐 🛜
	Log Off	
	About	
	User List	
	Collection Results	
	Setup	
	System Test	
	Restart	
	Shutdown	
	Update	
<del>(</del> )	Change Root Password	Â



In the setup menu, select Wi-Fi to open the Wi-Fi configuration page. Ensure Wi-Fi State is set to Enabled.

$\bigcirc$	System Admin		08:05 PDT 10/04/2023 🔞 占 💷 🗢
		Setup	
	Date and Time		
	Backlight		
	Network		
	Wi-Fi		
	Cellular		
	Retriever Service		
<del>(</del> )	Reset Database		Â

Select the Network field to see a drop-down list of available networks. Select the desired Wi-Fi network from the list. If the network is not visible, select the FIND NETWORKS button on the bottom left of the screen. Once the desired network is selected, enter the appropriate password in the Wi-Fi password field and select the CONNECT button.

$\bigcirc$	System Admin		08:06 PDT 10/04/2023 🔞 🛔 🔒	
		Wi-Fi		
	State Network: Password:	Enabled Fios-HS9cK	▼	
	Address:			
€)	FIND NET	WORKS	CONNECT	Â



The base station will surface a pop-up window indicating it is connecting to the Wi-Fi network.

	System	Admin		08:07 PDT 10/04/20	23 R 占 🗐 🛜
	C	Vifi Connect	Ni-Fi		
	Stat Net Pas Add	Connecting to Fios-HS9cK			
<del>(</del> )		FIND NETWORKS		CONNECT	Â

If the connection is successful, the pop-up window will disappear, and no error messages will appear. Upon successful connection, select the HOME button icon in the lower right-hand corner of the screen to return to the collection information entry screen.



#### 2.4 Date and Time Set-up

The Date and Time can be manually configured through the system menu. The ability to set Date and Time is limited only to the local base station administrator and system administrators.

Ensure the system is powered on. Log in using either the local base station administrator account or a user account with system administrator privileges.

Once logged in to the base station, select the Hound Labs logo in the upper left-hand corner of the collection information entry screen to enter the system setting screen.

On the base station system menu, select Setup to access the setup menu.

$\bigcirc$	System Admin	08:05 PDT 10/04/2023 限 🚠 💵 🛜
	Log Off	
	About	
	User List	
	Collection Results	
	Setup	
	System Test	
	Restart	
	Shutdown	
	Update	
←]	Change Root Password	Â



In the setup menu, select Date and Time to open the Date and Time setting screen.



If the base station has connectivity via ethernet, Wi-Fi, or cellular, the date and time can be set automatically by pressing the SET FROM NIST button on the lower left side of the screen. After pressing the SET FROM NIST button, press the APPLY button on the lower right side of the touchscreen. Check in the upper right-hand corner of the screen to confirm that the settings have been applied. After the Date and Time settings have been confirmed, select the HOME button located in the bottom right-hand corner of the screen to return to the collection information entry screen.



If manual entry of the date and time is desired, or if the 'Set from NIST' button does not function as intended, the date and time may be manually set. On the Date and Time setting screen, enter the hour, minute, and second in the appropriate fields to set the system time. Time may be adjusted to 12- or 24-hour formats using the drop-down list options in the Format fields.

Select the Date field and enter the current date (MM/DD/YYYY).

Select the Time Zone field for a drop-down list of available time zones. Select the correct time zone for your location. Once all fields are correctly entered, select the APPLY button to implement on the system.

System Admin		08:07 PDT 10/04/2023 <u>R</u> 🛔 🗐 🛜
	Date and Time	
Hou	8	
Minute	7	
Second	45	
Forma	24 Hour 🔻	
Date	10/04/2023	
Time Zone	America/Los_Angeles	▼
←) SET FRO	MNIST	

Check in the upper right-hand corner of the screen to confirm that the settings have been applied. After the Date and Time settings have been confirmed, select the HOME button located in the bottom right-hand corner of the screen to return to the collection information entry screen.

## 2.5 Operating Conditions

The HOUND<sup>®</sup> CANNABIS BREATHALYZER should be operated at temperatures between 15-30°C (59-86°F) and a range of 20-80% relative humidity (RH).



## 2.6 Performing a Collection

#### STEP 1. CREATE COLLECTION EVENT

- Ensure the power cord is firmly connected to the base station and that the system is plugged in.
- Turn on the system using the power button on the back of base station, pressing the button for several seconds, or until the LED light illuminates.
   NOTE: The base station will take several seconds to boot up after the power button is pressed. The base station touchscreen will be blank while the system is powering on.
   WARNING: Do not unplug the base station while the system is running. For proper power down instructions, refer to Section 2.9.

		08:04 PDT 10/04/202	3 <u>R</u> 🖞 ''' 🕹
	Log In		
Username			]
Password			]
Confirm you your employ http://www.	I have completed Hound Labs over the second se	ollector training as required by Irces can be accessed at I/	
SHUT	ADD GUEST US	ER LOGIN	

• When fully powered on, the system will show the Log In screen.

• Using the provided stylus, enter your assigned username and password into the fields on the Log In screen.

NOTE: Type in slashes when entering date of birth. To access symbols, press the shift key on the keyboard.

- Select the checkbox on the Log In screen to confirm you have been trained on the use of the HOUND<sup>®</sup> CANNABIS BREATHALYZER.
- Select the LOG IN button to log in to the base station.
- Once successfully logged in to the base station, the system will advance to the collection information entry screen.



- Explain the collection procedure to the donor.
- Instruct the donor to empty mouth of gum, food, tobacco, etc., prior to collection.
- Industry best practice is to ask the donor to wait a minimum of ten minutes before collecting a breath sample and to observe the donor to ensure their mouth is empty for the entire waiting period.

NOTE: Select the speech bubble in the bottom right corner of the touchscreen to add remarks at any point during the collection.

- Select the Lab Account Number field on the base station touchscreen. WARNING: The barcode scanner light will be red when activated. Do not stare into the beam.
- Enter the Lab Account Number or scan the barcode on the donor's collection authorization form using the integrated barcode scanner on the side of the base station. NOTE: When scanning, position the label at an angle approximately three inches from the scanner.

NOTE: For new account numbers, the base station will require the Lab Account Number to be entered twice.

NOTE: If the donor does not present an authorization form, the collector should contact the ordering employer or department to confirm the order and the cannabis breath test account number for laboratory testing.

System Admin	08:05 PDT 10	0/04/2023 R 占 📖 🗢
Lab Account Number		
Donor ID		Verified By 🔻
Donor First Name		]
Donor Last Name		]
Donor Date of Birth		]
Donor Phone Number		Send CCF? 🔻
Donor Email Address		]
Reason for Testing	Select Test Reason 🛛 🗸 🗸	]
Remarks		]
An account number n	nust be scanned or entered to proceed with	n collection.
VIEW WORKLIST	SCAN CARTRIDGE BEGIN COLLEC	CTION



- Confirm the scanned Lab Account Number(s) match the value printed on the donor's collection authorization form (if a form is presented).
- If the values on the base station screen match the printed value on the donor's authorization form, select the CONFIRM button on the touchscreen to return to the collection information entry screen.

$\bigcirc$	System Admin		08:08 PDT 10/04/2023 <u>R</u> 🛓 🗐 🛜		
Account Validation					
	Entered Account ID: 1234567890				
	Re-Enter Account ID:				
	Unable to validate the entered Account ID.				
Please re-scan or re-enter the Account ID to confirm the validity of this account.					
	CANCEL				
$\bigcirc$	System Admin		08:08 PDT 10/04/2023 R 🚠 📶 🛜		
Account Validation					
	Entered Accour	nt ID: 12345678	90		
Re-Enter Account ID: 1234567890					
The entered Account IDs match.					
Press "Confirm" to verify the validity of this Account ID.					
	CANCEL				

HOUND LABS<sup>®</sup>

- After scanning is complete, the donor's authorization form can be discarded per company policy.
- Verify the donor's photo ID and select a method of verification on the touchscreen. NOTE: Reference employer policy for acceptable forms of verification (e.g., employer representative, driver's license, passport, employee photo ID).
- Enter the donor ID, first and last name, date of birth, phone number (if available), email address (if available), and reason for testing on the base station touchscreen. NOTE: Options for Reason for Testing include: Pre-employment, Random, Reasonable Suspicion, Post-Accident, Return-to-Duty, Follow-up, Pre-Access, Medical, and Other.
- Ask the donor if they want to receive a link to the donor copy of the CCF; then select the donor's preferred method of delivery from the dropdown menu, titled SEND CCF?. NOTE: Options for SEND CCF? dropdown include: No, By Text, By Email, and By Both.

System Admin	08:08 PDT 1	0/04/2023 <u>R</u> 占 🗐 🛜
Lab Account Number	1234567890	]
Donor ID		Verified By 🔻
Donor First Name		]
Donor Last Name		]
Donor Date of Birth		]
Donor Phone Number		Send CCF? 🔻
Donor Email Address		]
Reason for Testing	Select Test Reason 🛛 🗸	]
Remarks		]
All information fie	lds must be complete to proceed with a co	ollection.
	• SCAN CARTRIDGE BEGIN COLLEG	CTION

System Admin	08:10	DPDT 10/04/2023 佷 占 💷 🛜
Lab Account Number	1234567890	
Donor ID	123456789abc	Photo ID 🛛 🔻
Donor First Name	John	
Donor Last Name	Donor	
Donor Date of Birth	01/01/1985	
Donor Phone Number	(123)456-7895	By Both 🔻
Donor Email Address	john.donor@dono.com	
Reason for Testing	Random	$\checkmark$
Remarks	Remark	
A donor cartridge	ID must be scanned or entered to s	tart collection.
	SCAN CARTRIDGE BEGIN	COLLECTION



NOTE: Remarks is not a required field unless the collector selects 'OTHER' as the reason for testing.

NOTE: Selecting 'OTHER' as the reason for test will require manually entering a comment in the "Remarks" text field prior to proceeding with the collection.

• Collector advises the donor to remain seated during breath collection.

STEP 2. CONNECT CARTRIDGES

- Collector puts on appropriately fitting nitrile or equivalent gloves and wears them for the entire collection process.
- NOTE: It is recommended to use new gloves for each collection.
- Ask the donor to select a breath collection package.
- Check the use-by date printed on the package label and confirm that the package has not expired.
- Inspect the package for any signs of tampering or damage. If signs of tampering or damage are evident, collector should set it aside and instruct the donor to select a different collection package. Inspect the new package to ensure that it has not expired and shows no signs of damage or tampering.
- Open the collection package and remove the donor cartridge (with connector preattached), air cartridge, individually-packaged mouthpiece, and tamper-evident seals. WARNING: Do not remove cellophane wrappers from cartridges until after collection. NOTE: The air cartridge does not have a connector.

NOTE: The air cartridge does not require the use of a mouthpiece during collection. NOTE: Collection package contents should remain in the donor's view throughout the entire collection process.

NOTE: Keep the cartridges clean and dry after opening the packaging to ensure proper test results. Use immediately after opening.

• Confirm the cartridge barcode printed on the white donor cartridge label (aka donor sample barcode) matches the cartridge barcode printed on the yellow air cartridge label (aka air sample barcode).

WARNING: The barcode scanner light will be red when activated. Do not stare into the beam.

• Select the Scan Cartridge button on the touchscreen and use the barcode scanner built into the base station to scan the cartridge barcode printed on either the donor or air cartridge.

NOTE: When scanning, position the label at an angle approximately three inches from the scanner.



System Admin	08:10 Pi	DT 10/04/2023 R 占 🗐 ᅙ
Lab Account Number	1234567890	
Donor ID	123456789abc	Photo ID 🛛 🔻
Donor First Name	John	
Donor Last Name	Donor	
Donor Date of Birth	01/01/1985	
Donor Phone Number	(123)456-7895	By Both 🗨
Donor Email Address	john.donor@dono.com	
Reason for Testing	Random	▼
Remarks	Remark	
A donor cartridge	ID must be scanned or entered to star	t collection.
	· SCAN CARTRIDGE BEGIN CC	DLLECTION

- If the barcode does not scan properly, collector should enter the cartridge ID manually using the base station touchscreen and provided stylus.
- Confirm that the cartridge ID shown on the base station touchscreen matches the value printed on the donor and air cartridges.

NOTE: If the values on the base station screen match the printed value on the donor and air cartridges, collector should select the Accept button on the touchscreen to return to the collection information entry screen.

$\bigcirc$	System Admin	08:11 PDT 10/04/2023	R +
	Cartridge ID: HL123456789		
	If this is the correct cartridge ID, press If not, select the cartridge ID above to scan or enter	"ACCEPT" the correct cartridge	ID.
	АССЕРТ		

• Insert the air cartridge into the port on the top of the base station. WARNING: Hold the base of the air cartridge with two hands when inserting into the base station and take care to avoid compressing the cartridge by pressing on the top of the cartridge cover.



• Ensure the air cartridge is fully seated and not tilted relative to the port.



- Ensure the donor cartridge is firmly seated in the connector fitting.
   NOTE: When fully seated, the notches at the base of the cartridge should insert into the openings on either side of the fitting.
   NOTE: The donor cartridge should be connected to the connector at the end identified with a silver dot.
- If the donor cartridge is not fully seated and/or is tilted relative to the fitting, firmly push the cartridge into the fitting until it is fully inserted and seated. If necessary, remove the lower cellophane wrapping to adjust the cartridge at the connection point. Do NOT remove the upper cellophane wrapping until after the collection.





Attach the donor connector fitting to the port on the front of the base station.
 NOTE: To insert, collector should align the circular airflow ports in the connector fitting with the matching airflow ports in the base station. Attach the connector to the base station by inserting the fitting at an angle, first inserting the bottom edge, then tilting upward and pressing the fitting into the port.



#### STEP 3. COLLECT BREATH SAMPLE

- Depending on collector and/or employer processes, either the collector or the donor may hold the donor cartridge during the collection.
   NOTE: The cartridge should be held at the shrink wrap between the connector fitting and the cartridge to prevent misalignment during a collection.
- Give the donor the individually-packaged mouthpiece. Instruct the donor to remove the mouthpiece from its packaging; check to ensure the mouthpiece is free of obstruction.
- Instruct the donor to insert the mouthpiece into the round opening in the top of the donor cartridge, holding the cartridge by the cellophane wrap in the center to avoid compressing the cartridge.





• After ensuring all information has been entered, and both cartridges are connected, select the Begin Collection button on the base station touchscreen.

System Admin	08:11 Pi	DT 10/04/2023 R 占 🗐 🛜
Lab Account Number	1234567890	
Donor ID	123456789abc	Photo ID <
Donor First Name	John	
Donor Last Name	Donor	
Donor Date of Birth	01/01/1985	
Donor Phone Number	(123)456-7895	By Both 🗨
Donor Email Address	john.donor@dono.com	
Reason for Testing	Random	▼
Remarks	Remark	
	Press "Begin Collection"	
	SCAN CARTRIDGE BEGIN CC	DLLECTION

• The base station will then prepare internal pumps to facilitate the collection. NOTE: When the collection begins, the air collection pump will start immediately. The pump will stop once an air sample has been collected and may end before completion of the breath sample collection.





• Once the base station touchscreen indicates it is prepared for collection, instruct the donor to breathe into mouthpiece for approximately 2-3 minutes, pausing between breaths as needed.

NOTE: Collector should observe the collection to ensure the donor does not pull or tug the connector and the tubing is not overextended.

• The base station touchscreen will display a breath collection progress indicator. NOTE: The system power button and base station touchscreen should not be touched during sample collection.

System Admin	08:11 PDT 10/04/2023 <u>R</u> 🛓 🗐 🛜
COLLECTING SAMPLE	LAB ACCOUNT ID 1234567890
	CARTRIDGE ID HL123456789
<u> </u>	DONOR ID 123456789abc
8%	donor name <b>John Donor</b>
	reason for testing Random
<ul> <li>Donor breaths into the mouthpiece for approximately 2 minutes</li> <li>Donor may pause to inhale</li> </ul>	CANCEL COLLECTION

• Short pauses of up to 20 seconds between breaths are allowed. When pausing between breaths, a warning message with a countdown timer will appear on the base station touchscreen, instructing the donor to continue breathing to avoid invalidating the breath collection.





- Collector should not allow the donor to put anything in their mouth (including water) during the collection process. If this occurs, cancel the collection and follow employer policy for remediation.
- When the collection is complete and a breath sample has been successfully collected, the base station touchscreen will provide guidance for all post-collection steps.
- If a breath sample was not successfully collected (due to donor refusal, incomplete collection, cartridge error, system error, etc.), collector should follow the guidance provided on base station touchscreen.

NOTE: The decision about whether to reschedule the donor's collection should be determined based on employer policy.

• Upon completion of the breath collection, the collector instructs the donor to remove the single-use mouthpiece from the donor cartridge.

WARNING: Donor should secure the cartridge cover while detaching the mouthpiece to avoid removing the cover from the container.



- If the donor was holding the donor cartridge, the donor should return it to the collector and discard the mouthpiece.
- The base station will instruct the collector to prepare the cartridges for processing.
- Remove the lower cellophane wrapping from the connector fitting attached to the donor cartridge.

WARNING: Avoid compressing the cartridges while inserted in the base station or connector fitting to prevent system damage.

• Disconnect the donor cartridge from the connector by unclipping the connector fitting from the donor cartridge, holding the base of the cartridge securely as the fitting is removed.

NOTE: When properly removed, the cartridge will disconnect from the connector fitting. The fitting should not disconnect from the connector tubing.



- Remove the remaining upper cellophane wrapping from the donor cartridge.
- Disconnect the air cartridge from the base station, using two hands to grasp the base of the cartridge while removing.
- Remove the cellophane wrapping from the air cartridge.



• After disconnecting the air cartridge from the base station, select the NEXT button on the PREPARE SAMPLES FOR PROCESSING screen.





#### STEP 4. COMPLETE COLLECTION EVENT

- Ask the donor to initial the identified regions of the donor and air cartridge labels.
- Collector dates the identified regions of the donor and air cartridge labels (MM/DD/YYYY).

NOTE: Use a ballpoint pen to initial and date the cartridge labels.



• Select the NEXT button on the PREPARE SAMPLES screen.





 Insert the donor cartridge upright in the base of the desk-mounted Assisted Compression Equipment (ACE), making sure that it rests against the back of the ACE.
 NOTE: ACE installation instructions are available at <u>houndlabs.com/collector-portal</u>.



- Pull the ACE handle down and compress the cover of the cartridge until the ACE reaches its hard stop. The cartridge cover should come to rest at the base of the ACE fixture, indicating the donor sample is locked.
- Lift the handle of the ACE, remove the donor cartridge, and place it upright on a flat surface.
- Repeat the same ACE compression steps for the air cartridge.
- Disconnect the connector from the base station and discard the tubing. NOTE: To detach the connector, grasp the base of the connector fitting and tilt downward to remove from the port. NOTE: Pumps in the base station will conduct a 20-second purge cycle after the connector has been detached.

	System Admin	08:12 PDT 10/04/2023 (R
С	OLLECTING SAMPLE	LAB ACCOUNT ID 1234567890
	PROCESS CARTRIDGES	
	<ol> <li>Insert the donor cartridge into t cartridge until the ACE hits a ha</li> <li>Remove the donor cartridge fro flat surface.</li> <li>Insert the air cartridge into the until the ACE hits a hard stop.</li> <li>Remove the air cartridge from t surface.</li> </ol>	the ACE and compress the ard stop. Im the ACE and set upright on a ACE and compress the cartridge the ACE and set upright on a flat
	5 Disconnect the connector from	The nase station

- Secure the cover onto the donor cartridge by applying a tamper-evident seal to the cartridge. Apply the tamper-evident seal by placing the end of the seal in the center of the Hound Labs logo on the front of the cartridge, wrapping the seal down around the bottom to cover the larger center hole, and ending on the back surface of the cartridge.
- Apply the second tamper-evident seal to the air cartridge using the same placement technique.
- Place the locked donor and air cartridges with tamper-evident seals into a lab sample bag (laboratory specimen bag), seal the bag shut, and select the NEXT button on the PREPARE SAMPLES screen.





STEP 5. CERTIFY COLLECTION + SHIP SAMPLES

- Instruct the donor to read the certification statement and sign on the touchscreen certifying the collection is complete.
   NOTE: The donor may select the CLEAR button to reset the signature field and re-sign prior to accepting.
- Once the donor has signed the certification statement, instruct the donor to select the ACCEPT button.

	System Admin		08:12 PDT 10/04/2023 <u>R</u> 🛔 🗐 🛜		
	Donor Certification				
I certify that opened and	t I provided my specimen to the collector; I its components were in my view for the c and tamper evident seal applied; and th	that I have not adulterated it in luration of the collection, each a	any manner; the breath collection package was specimen cartridge was compressed (locked) in ring this collection and the label affired to each		
specimen o	artridge is correct.	at the information provided du			
	CLEAR	ACCEPT	CANCEL		

• Collector should sign on the touchscreen certifying the collection is complete and select the ACCEPT button.

	System Admin			08:12 PDT 10/04/2023 🔞 🚠 💵 🛜	
	Collector Certification				
I certify that compressed requiremen	at the specimen was provi d (locked), initialed, dated, ts.	ded to me by th , tamper evident	e identified donor, and ea t seal applied and release	ch specimen was collected, and the cartridges were d to a delivery service in accordance with applicable	
	CLEAF	2	ACCEPT		

- Place the lab sample bag it into an overnight shipping envelope and then attach a pre-printed laboratory shipping airbill.
- Release the samples to an approved delivery service for shipment to the laboratory for testing the same day as collection or the next business day.



NOTE: Samples should be delivered through FedEx only.

NOTE: If the package is not shipped the day of collection, the collector should follow company policy to secure the sample and store at room temperature until it is shipped.

NOTE: Do not unplug the base station while the system is running. For proper power down instructions, refer to Section 2.9.



#### 2.7 Reviewing Completed Collections

Collection results are housed in the Hound Labs Retriever<sup>™</sup> results portal. The base station will store collection results locally on the system until a stable connection to Retriever<sup>™</sup> is established and the results are uploaded. Once a collection is archived in Retriever<sup>™</sup>, the record is purged from the local machine.

Users can access unarchived collection records by selecting the Hound Labs logo in the upper left-hand corner of the screen to enter the system menu screen.

In the system menu screen, select Collection Results to open to collection database.

$\bigcirc$	System Admin	08:05 PDT 10/04/2023 限 🚠 💷 🗢
	Log Off	
	About	
	User List	
	Collection Results	
	Setup	
	System Test	
	Restart	
	Shutdown	
	Update	
<del>(</del> )	Change Root Password	Â



The results portal will display records for collections performed on the system that have not yet been uploaded to Hound Labs Retriever<sup>™</sup>.

$\bigcirc$	System A	dmin			08:13 PI	OT 10/04/2023 (	R
		Search:		A	I	•	•
DON	OR ID	DC	NOR NAME	DONOR DOB	DATE	REASON	STATUS
123456	5789abc	Donor, John		01/01/1985	10/04/2023	Random	Completed
<del>(</del> )							Â



## 2.8 Canceling a Collection

During a Collection:

At any point prior to the collector certification statement, a collection may be canceled by either the donor or the collector.

The cancelation process is initiated by selecting the CANCEL COLLECTION button on the base station touchscreen.

System Admin	08:11 PDT 10/04/2023 <u>R</u> 🛔 🗐 🛜	
COLLECTING SAMPLE	LAB ACCOUNT ID 1234567890	
	CARTRIDGE ID HL123456789	
<u> </u>	DONOR ID 123456789abc	
8%	DONOR NAME John Donor	
	REASON FOR TESTING	
<ul> <li>Donor breaths into the mouthpiece for approximately 2 minutes</li> <li>Donor may pause to inhale</li> </ul>	CANCEL COLLECTION	



HOUND® CANNABIS BREATHALYZER - User Manual



Selecting the CANCEL COLLECTION button will surface the CANCEL COLLECTION screen.

System Admin	08:15 PDT 10/04/2023 <u>R</u> 🛓 🗐 🛜
CANCEL COLLECTION	account 123456789
A cancellation reason must be selected to cancel this collection.	CARTRIDGE HL123456789
REASON FOR CANCELING	123456789abc
Select Cancel Reason 🗨	DONOR NAME John, Donor
REMARKS	REASON FOR TESTING Random
RESUME COLLECTION	CONFIRM CANCEL

On the CANCEL COLLECTION screen, select the Select Cancel Reason field to display a dropdown list of reasons for cancelation.

NOTE: Options for Reasons for Cancelation include Test Refused, Unable to Provide Specimen, System Error, and Other.

Select the Reason for Cancelation from the drop-down list.

NOTE: If Other is selected as a reason, you will be required to manually enter a comment or remark in the OTHER REASON REMARK field.

Once the reason for cancelation has been selected, the collection may be canceled by selecting the CONFIRM CANCEL button on the bottom right of the touchscreen.

If, at any point prior to confirming cancelation, the donor would like to resume the collection, the cancelation process can be aborted by selecting the RESUME COLLECTION button on the CANCEL COLLECTION screen. Selecting this button will return the collection to the screen previously displayed when the cancel collection process was initiated.



After canceling the collection, select the DISMISS button in the Collection Canceled screen to return to the collection information entry screen.

	System /	Admin	08:15 PDT 10/04/2	023 R 🛔 💷 🛜
		Info: 1007, Collection Canceled		
Di car	sco trid	Collection canceled. 10/04/2023 08:15:31 am DISMISS		he air nother



#### 2.9 Powering Down the Base Station

WARNING: DO NOT at any time unplug the base station while it is powering on or running. This may damage the system.

Several options are available for shutting down the system:

• From the Log In Screen:

Select the SHUTDOWN button in the bottom left of the Log In screen.

		08:04 PDT 10/04/2023	R + 11 ?	
	Log In			
Username				
Password				
Confirm you have completed Hound Labs collector training as required by your employer. Hound Labs collector resources can be accessed at http://www.houndlabs.com/collector-portal/				
SHU	ADD GUEST USER	LOGIN		

Select the CONFIRM button on the shutdown confirmation pop-up that surfaces. Allow the base station to fully power down prior to unplugging the power cord.



• User Logged In Screen:

Select the Hound Labs logo in the upper left of the screen to enter the system menu.

$\bigcirc$	System Admin	08:05 PDT 10/04/2023 <sub>R</sub> 🛔 🗐 🗢
	Log Off	
	About	
	User List	
	Collection Results	
	Setup	
	System Test	
	Restart	
	Shutdown	
	Update	
<del>(</del> )	Change Root Password	Â

In the system menu, select Shutdown. Select the CONFIRM button on the shutdown confirmation pop-up that surfaces. Allow the base station to fully power down prior to unplugging the power supply.

• The base station may also be manually powered down by holding the power button for several seconds.

#### 2.10 Cleaning and Maintenance

The base station should be cleaned by wiping all external surfaces with a non-abrasive cloth dampened with a solution of 70% isopropyl alcohol OR 70% ethanol.

WARNING: DO NOT spray cleaning solution directly onto the base station. WARNING: DO NOT submerge the base station in water or any other cleaning solution.

The HOUND® CANNABIS BREATHALYZER requires the base station be returned to Hound Labs after every 1,500 collections or one year, whichever occurs first, for routine service. Contact Hound Labs Support at https://houndlabs.com/support to schedule service.

The HOUND<sup>®</sup> CANNABIS BREATHALYZER does not require customer maintenance. Contact Hound Labs Support at <u>https://houndlabs.com/support</u> for all system maintenance and service questions.



#### 2.11 Used Component Disposal

Used cartridge covers, connectors, and mouthpieces can be discarded in standard waste streams. No special handling is required.

## 2.12 Storage

Unused cartridges should be stored at temperatures between 15-30°C (59-86°F). Cartridges may be used up until the use-by date marked on the collection package.

After use, collected samples should be transported to the laboratory via overnight shipping. Samples should be protected from impact and temperatures outside the range of 4-37°C (39.2-98.6°F) Collected samples are stable for a maximum of 7 days from the time of collection.

## 2.13 Error Messages

The HOUND® CANNABIS BREATHALYZER is designed to detect failures and help the user respond appropriately. In the event of an error status, users may see an error message on the base station that has a red warning icon. If an error message occurs, follow the instructions provided on the base station touchscreen. If the problem cannot be resolved, contact Hound Labs Support at <u>https://houndlabs.com/support</u>.

## 2.14 Test Integrity and Accuracy

The HOUND<sup>®</sup> CANNABIS BREATHALYZER is designed with several features to prevent the adulteration or falsification of test results.

- Unique cartridge ID number: Each cartridge is labeled with a unique sample ID number. This enables tracking of the test throughout the chain of custody.
- Single-use cartridges: Cartridges are single-use, and no component should be reused. Once a collection is performed and the sample is processed, the cartridge configuration is visibly altered and will not allow for reuse.
- Tamper-evident and resistant: Cartridges are delivered in sealed packaging. Any attempt to alter the cartridges or packaging prior to collection can be detected by visual inspection. The packaging should only be opened in the presence of the donor. Samples are stored within the cartridges. Attempts to access or adulterate the sample will damage the cartridge and result in visible evidence of tampering.

WARNING: Any opening in the cartridge that exposes the sample should be considered evidence of tampering.



# **3 EXPLANATION OF SYMBOLS**

LOT	LOT CODE
REF	CATALOG NUMBER
<b></b>	CONSULT INSTRUCTIONS FOR USE
$\sum$	USE BY
(	DO NOT REUSE
X	TEMPERATURE LIMITATION
Ť	KEEP DRY
	KEEP AWAY FROM SUNLIGHT
	MANUFACTURER



# 4 LIMITATIONS AND WARNINGS

FCC: Unique Identifier: HOUND® CANNABIS BREATHALYZER Contact Information: info@houndlabs.com Responsible Party: Hound Labs 46429 Landing Parkway Fremont, CA 94538

47 CFR § 15.19: 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.

47 CFR § 15.105: 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 their own expense.

# 5 WARRANTY

Please refer to your Hound Labs Master Service Agreement for information on warranty, repairs, and maintenance.





Sales: <u>https://houndlabs.com/connect-with-sales</u> Support: <u>https://houndlabs.com/support</u>

> houndlabs.com © 2023. Hound Labs, Inc. All Rights Reserved