



Babson Diagnostics ART Sample Preparation Device

User Manual

Table of Contents

Babson Diagnostics Art Sample Preparation Device	1
Preface	4
Scope of Supply.....	4
Accident Prevention	5
Precautions.....	5
Symbols.....	6
Safety and Regulatory Considerations	7
Intended Use and Characteristics	8
Regulatory Labels and Warnings.....	9
FCC Statements.....	11
Safety Practices	12
Technical Data.....	13
Directives, Standards and Guidelines.....	14
Functions and Features.....	15
Mains Supply	15
Installation	16
Before Setting Up	17
Transporting the Art Sample Preparation Device.....	18
Installation	20
Power On	21
User Events and Responses.....	23
Device Basics	24
Control Panel.....	25
Caddy / Base Inventory Lights	26
Events and Audio Responses.....	28
Operation	34
Switch on Art Sample Preparation Device	35

Collection.....	35
Tube Deposit	39
Tube Mixing.....	40
Centrifugation	40
Storage.....	42
Maintenance and Care.....	43
Cleaning.....	44
Preventative Maintenance	45
Troubleshooting and Servicing.....	46
User Troubleshooting	46
Contacting Babson Customer Service.....	47
Babson Field Service Engineer on Site Servicing.....	48

Preface

Before starting to use the Art Sample Preparation Device, read through the instruction manual carefully and follow the instructions. It provides vital information about the following aspects of the Art Sample Preparation Device.

- Regulatory considerations and Labeling
- Technical Data
- Installation
- User Events and Responses
- Operation
- Maintenance and Care
- Troubleshooting

The information contained in this instruction manual is the property of Babson Diagnostics; it is forbidden to copy or pass on this information without explicit approval.

Scope of Supply

Article Number	Quantity	Check
Art Sample Preparation Device - Base	1	
Art Sample Preparation Device - Caddy	1	
Cartridges	2	
PCM Pack(s)	2	
Instruction Manual	1	

Accident Prevention

Prerequisite for the safe operation of the Art Sample Preparation Device is a safe work environment and proper instruction for the user.

Precautions

To ensure safe operations of the Art Sample Preparation Device, the following general safety regulations must be followed:

- Do not manipulate safety devices
- Do not manipulate the device unless as a trained Babson employee
- The Art Sample Preparation Device should be operated by trained specialist only
- The Art Sample Preparation Device should be used for its intended use only
- Plug the Art Sample Preparation Device only into sockets which have been properly grounded
- Do not move either part of the Art Sample Preparation Device while it is running
- Do not lean on the Art Sample Preparation Device
- Do not touch the mechanical components of the Art Sample Preparation Device and do not make any changes to the mechanical components
- Never use the Art Sample Preparation Device if the parts of its cover panels damaged or missing
- Do not touch the electronic components of the Art Sample Preparation Device or alter any electronic components
- Please observe the safety instructions

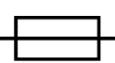
Please pay particular attention to the following aspects:

- Location of Art Sample Preparation Device Base: well-ventilated environment, set up on a rigid surface with adequate load-bearing capacity
- Location of Art Sample Preparation Device Caddy: set up on a rigid surface with adequate load-bearing capacity

Symbols

You may encounter these symbols either on the device or throughout this manual. They represent warnings, conditions, identifications, instructions, and regulatory agencies.

TABLE 1. Symbols

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	General Warning, Caution, Risk of Danger	~	Alternating Current (ac)		Consult Instructions for Use
SN	Serial Number	REF	Catalog Number		Electric Shock
	Power Off Power On		Manufacturer and Date of Manufacture		Hand Crush/ Pinch Point
	Fuse		Biohazard		

Safety and Regulatory Considerations

Intended Use and Characteristics

The Art Sample Preparation Device is an electromechanical in-vitro diagnostics device according to the In-Vitro Diagnostics Directive 98/79/EC. It serves as a sample preparation device used to automate the mixing, centrifugation, and refrigeration of capillary blood samples for chemistry and hematology testing. The Art Sample Preparation Device is not an analyzer and does not produce test results. The Art Sample Preparation Device is intended to be used by a trained healthcare worker in ancillary healthcare settings such as pharmacies, walk-in clinics, or similar non-traditional healthcare settings. The Art Sample Preparation Device will not be distributed or sold and or be accessible to the general public.

The user-friendly control panel makes it easy to scan the collection tube barcodes for chain of custody tracking, collection tube identification, sample mixing, sample clotting storage and timing, sample centrifugation, and sample storage for temperature-controlled transportation.

The Art Sample Preparation Device is intended for use only with the Becton, Dickinson, and Company's BD Microtainer(R) Easy Collect Capillary EDTA and Easy Collect Capillary SST(TM) capillary blood collection devices, which are used to collect capillary blood from the customer's fingertip; the EDTA will be mixed, and the SST will be mixed, and centrifuged by the Art Sample Preparation Device. The device is intended to be able to process up to 60 tubes per day across multiple customers.

The Art Sample Preparation Device will communicate securely with external data processing via the Internet.

Art Sample Preparation Device Portable Collection Component (Caddy)

The Art Sample Preparation Device includes a portable component, called the Caddy, that can be operated while either attached to the stationary component or detached and operated in a different location. The trained healthcare worker interacts with the portable collection component to perform the initial sample collection steps according to the Dandelion collection procedure and CLSI standards.

This component includes the following:

- User Interface
- Barcode Scanner
- Sample Mixer

Art Sample Preparation Device Stationary Preparation Component (Base)

Art Sample Preparation Device includes a stationary component, called the Base, that receives samples from the portable component. The Base automates additional sample preparation steps according to the Dandelion collection procedure and CLSI standards.

Additionally, the Base contains one ethernet port and one USB port. The ethernet port is used to provide an opening to the Art Sample Preparation Device for a standard ethernet cable connection interface. This hard connection will allow the Art Sample Preparation Device the ability connect to the facilities wide area network. The USB port is used to provide a Babson Service Engineer an opening to the Art Sample Preparation Device for a standard USB cable connection interface. This interface allows the Babson Service Engineer the ability to connect their diagnostic laptop to service the device.

This component includes the following:

- Transporter
- Centrifuge
- Storage cooler
- Ethernet Port
- USB Port

Regulatory Labels and Warnings

A general label appears on the back of the Art Sample Preparation Device. It displays the Art Sample Preparation Device serial number, model number, power requirements, and manufacturer's information.

FIGURE 1-1. Serial Number and Voltage Label Base

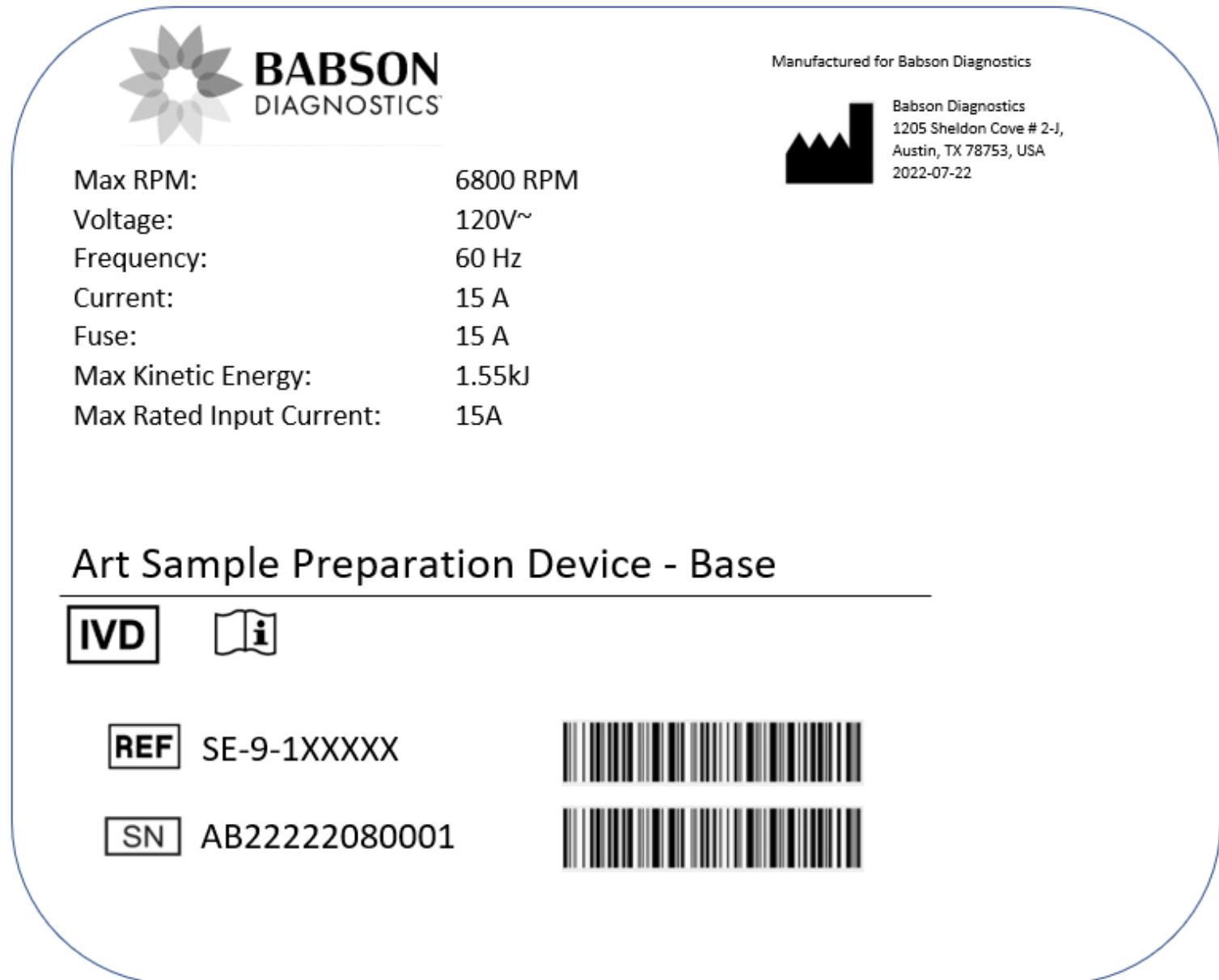
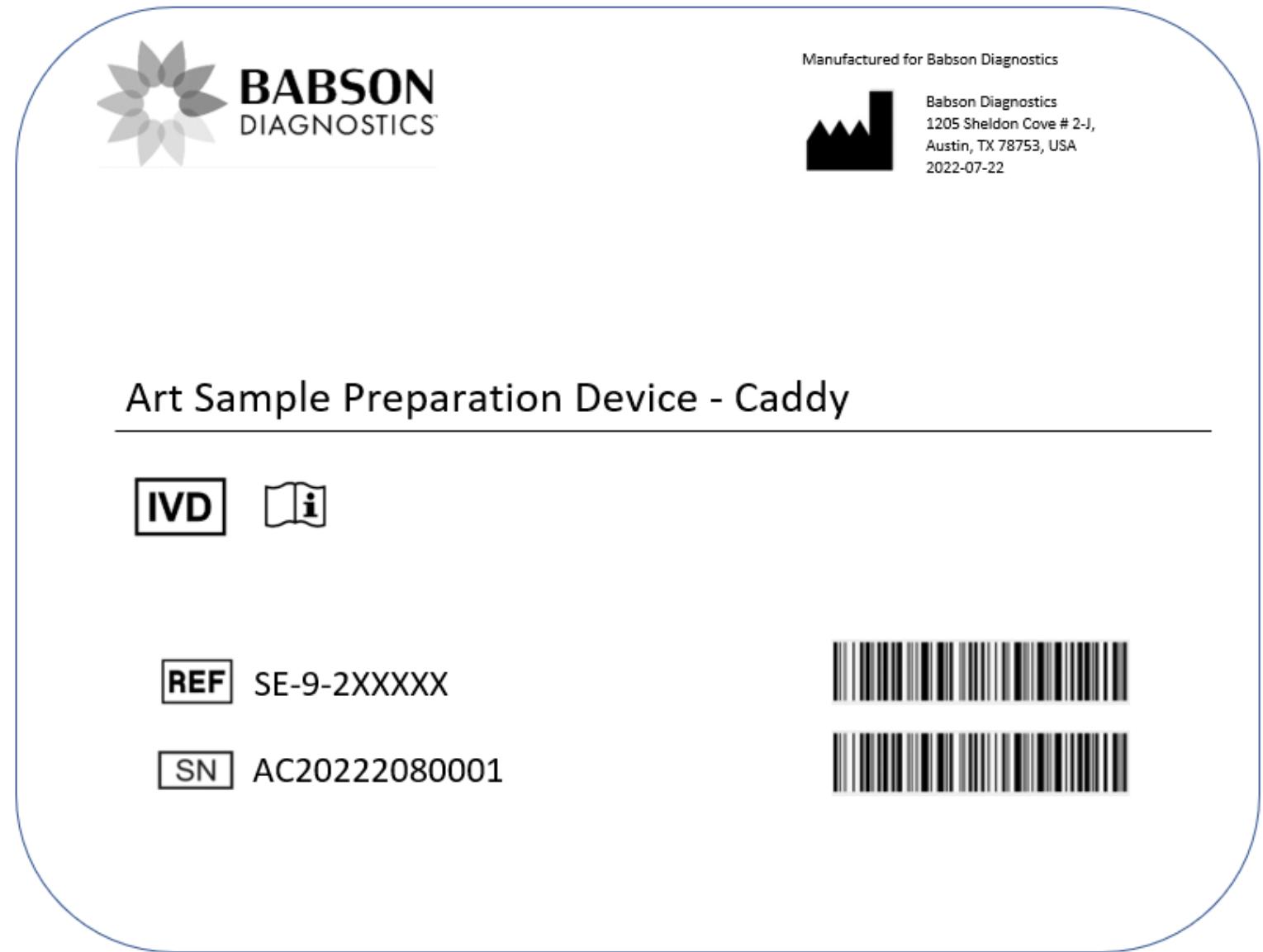


FIGURE 1-2. Serial Number Label



The Art Sample Preparation Device has been tested by F2 Labs and SGS and complies with safety requirements for the United States.



FCC Statements

Changes or modifications not expressly approved by Babson Diagnostics could void the user's authority to operate the equipment.

This device contains WiFi Module
FCC ID: 2A83TWFASPD

RFID Module
FCC ID: 2A83TRFASPD

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.

The Federal Communications Commission warns that changes or modifications of the radio module within this device not expressly approved by Babson Diagnostics could void the user's authority to operate the equipment.

To comply with FCC's RF radiation exposure requirements, the antenna(s) used for this transmitter must be installed such that a minimum separation distance of 20 cm is maintained between the radiating element (antenna) & any user's or bystander at all times and must not be co-located or operating in conjunction with any other antenna or transmitter.

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

Safety Practices

Electromagnetic Compatibility:

Art Sample Preparation Device complies with emission and immunity requirements as designated by the SGS listing mark.

WARNING:



Do not use this instrument near sources of strong electromagnetic radiation, for example, unshielded intentional RF sources, as these may interfere with the proper operation.

WARNING:



Always handle Art Sample Preparation Device according to Babson instructions so avoid any possible interference from its electromagnetic fields.

Technical Data

The technical data of the Art Sample Preparation Device is listed in the following table:

Table 1-1 Technical Data Art Sample Preparation Device

Feature	Value
Overvoltage Category	II (2)
Pollution Degree	2
Heat Dissipation	55W
Max Speed n_{max}	6800 RPM
Min Speed n_{min}	0 RPM
Max RCF value at n_{max}	4417xg
Max Kinetic Energy	1.55kJ
Noise Level at Max Speed	<60 Dba measured at 1 meter over 1 minute
Temperature Setting Range	18C-25C
Dimensions	Height – 27.5 in Width – 10.25 in Depth – 24 in
Weight	Empty Base (no cartridge, PCM, or sample chamber): 94 lbs
Ethernet Port	Number of Ports: 2x RJ45 Transmission Performance: Cat. 6 Class E up to 250 MHz Transmission Rate: 10/100 Mbit/s and 1/10 Gbit/s
USB Port	USB 2.0 Current Rating: 1.5A Contact Resistance: 30mΩ Dielectric Withstanding Voltage: 500 VAC

Directives, Standards and Guidelines

Table 1-2. Directives, Standards and Guidelines

Tension / Frequency	Produced and inspected according to the following standards and guidelines
120V 60Hz	21 CFR 862.2050 product code JQC UL/IEC 61010-1 UL/IEC 61010-2-020 UL/IEC 61010-2-101 EN ISO 13485 FCC CFR 42 Part 15, subpart B FCC 15.247 FCC 15.209 CLSI GP44-A4

Functions and Features

The following table gives an overview of the important functional and performance characteristics of the Art Sample Preparation Device.

Table 1-3. Functions and Features

Component / Function	Description / Features
Structure/ Housing	Zinc plated steel and polycarbonate
Chamber	Mic-6 and Zinc plated steel
Motor	AC Induction Motor
Drive	Variable speed drive
Keys and Display	Easy to clean keypad and display surface
Controls	Microprocessor-controlled
Internal Memory	Most recent data is saved
Mixing Arm Profiles	Software controlled
Centrifugation Profiles	Software controlled

Mains Supply

The following table contains an overview of the electrical connection data for the Art Sample Preparation Device. This data is to be taken into consideration when selecting the mains connection socket.

Table 1-4. Electrical connection data of the Art Sample Preparation Device.

Cat.	Mains Voltage	Frequency	Rated Current	Power Consumption	Equipment Fuse	Building Fuse
5120.2007.0	120 V ± 10 %	60 Hz	12 A	1200 W	15 AT	15 AT

Installation

Before Setting Up

1. Check the Art Sample Preparation Device packaging for any shipping damage.
2. Inform the shipping company and Babson Diagnostics immediately if any damage is discovered.
3. Make certain that the setup site is appropriate:
 - For indoor use
 - Secure location protected from tampering
 - Private or semi-private area
 - Operating temperature of 18°C - 25°C
 - Operating relative humidity of 10-80% non-condensing
 - Operating altitude up to 2400 m above mean sea level
 - Ensure available electrical power outlet of 115 VAC / 15+ A circuit with protective earthing and easy accessibility
 - Ensure available area of approximately 40.5" L x 16" W x 29" H which includes clearances of 3" sides and back, 14" front, and 1.5" top.
 - The Art Sample Preparation Device shall be placed on a hard floor, level, and able to withstand the weight of the Art Sample Preparation Device
 - Requires network access; either wired network jack with internet access or Wi-Fi



CAUTION Do not replace provided mains power cord with inadequately rated cord



CAUTION Ensure the power cord is easily reachable during setup

Transporting the Art Sample Preparation Device

- The Art Sample Preparation Device will arrive in 2, corrugated cardboard overpacks. One containing the Art Sample Preparation Device Base and the other containing the Art Sample Preparation Device Caddy.

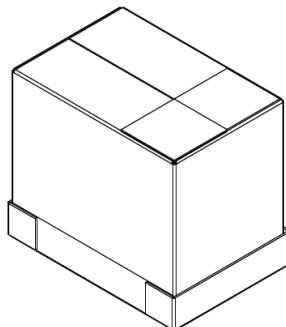


Figure 2-1. Art Sample Preparation Device Overpack

- It is recommended that the Base overpack be lifted by two people and should be moved mechanically. Be careful the overpack is not punctured during any necessary moving.
- Always lift the Art Sample Preparation Device Base at both sides.
- The Art Sample Preparation Device can be damaged by impacts.
- Remove the packaging.

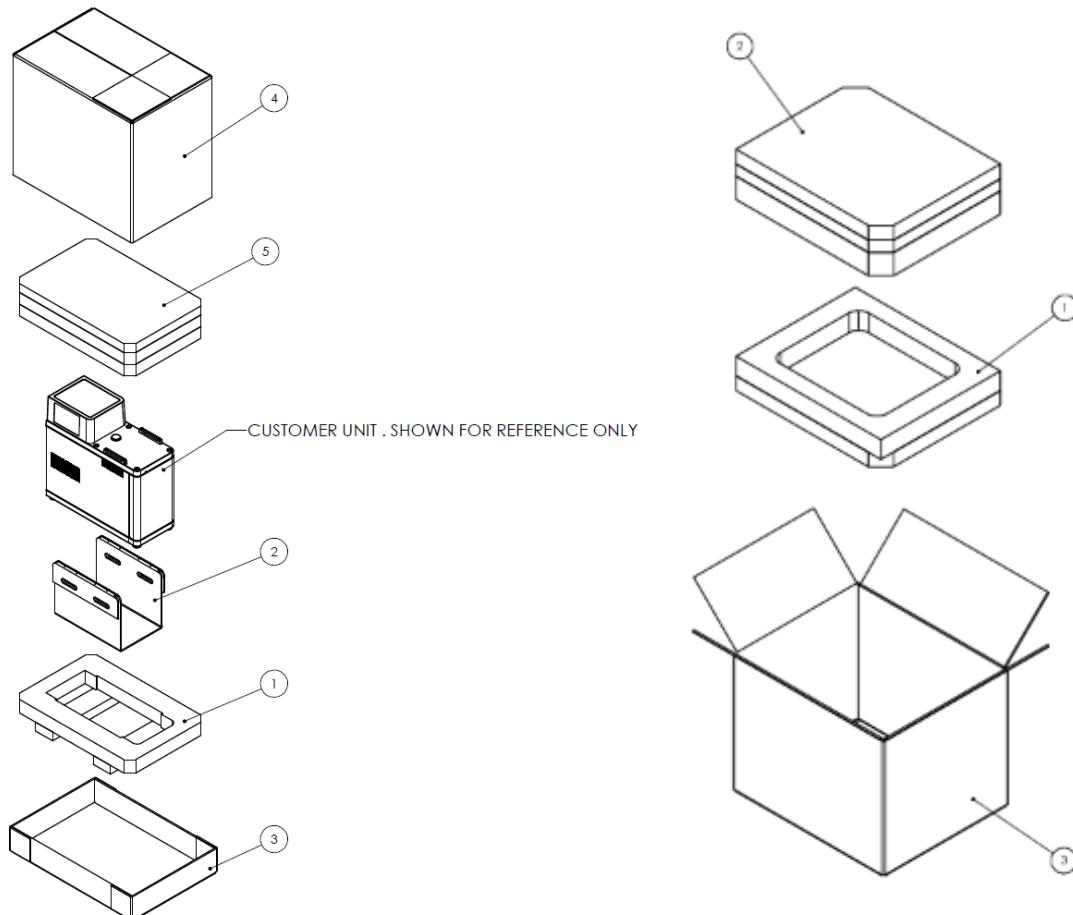


Figure 2-3. Inside the Overpack. Art Sample Preparation Device Base (L) and Art Sample Preparation Device Caddy (R)

Item	Description
Base	
1	Foam base assembly
2	DC corrugated insert
3	Tray
4	Box – HSC
5	Top foam assembly
Caddy	
1	Foam base assembly
2	Top foam assembly
3	Box - RSC

Installation

A trained field service engineer will be present to install the Art Sample Preparation Device. They will provide a soft installation to get the device in the correct status. Along with the soft install, they will ensure that:

- The device is setup to an internet connection
- The device is up to date on software
- All configurable files are set or adjusted as necessary,

Once all the above is established a sample will be run through to confirm successful operation.

Power On

Mains Connection

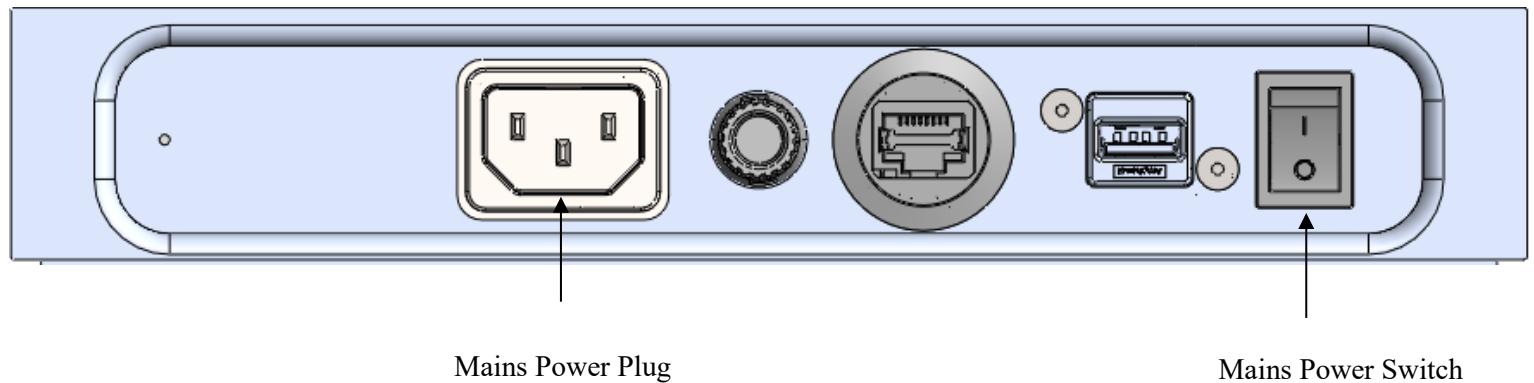


Figure 2-4. Mains Connection

1. Turn off the power supply switch on the back (press "O").
2. Plug the Art Sample Preparation Device into grounded electrical sockets only.
3. Make sure that the voltage and frequency correspond to the figures on the rating plate.
4. Establish the connection to the power supply with the connecting cable
5. Turn on the power supply switch on the back (press "I").

Storage

- Before storing the Art Sample Preparation Device and the accessories it must be cleaned and if necessary disinfected and decontaminated.
- Store the Art Sample Preparation Device in a clean, dry, dust-free location.
- Do not store outside.
- Avoid direct sunlight.

User Events and Responses

Device Basics

If your collection area has enough room for the sample preparation device to be next to the collection table, you can decide to collect with the caddy still on the base.

Otherwise, to start a collection, undock the caddy by using its handle to lift it up off the base. Carry it to the collection area.

If you can, dock the caddy back onto the base in between every customer so it can transfer the samples right away. If you don't have time, dock when all six inventory lights are on, showing that the caddy is full.

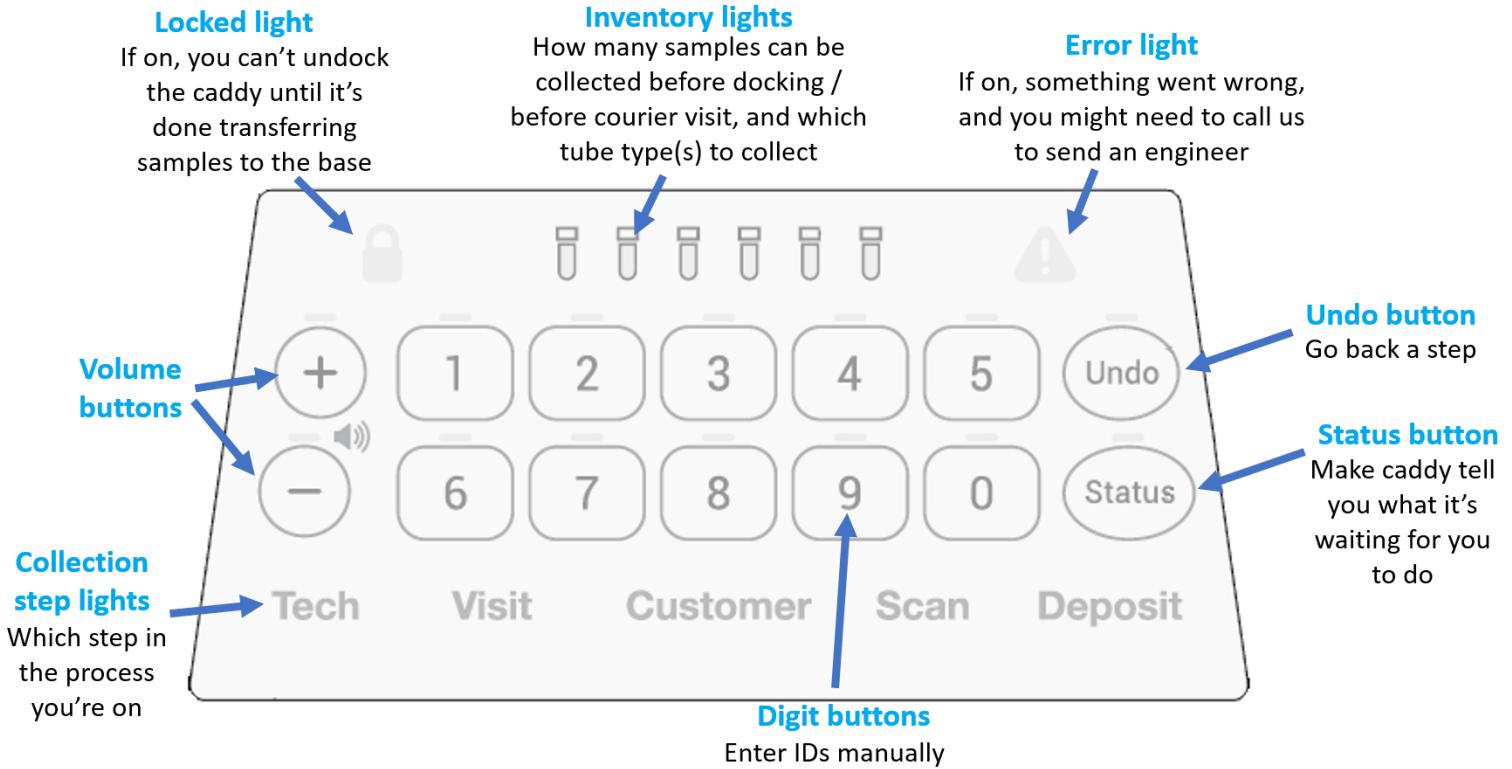
The caddy is the portable part that holds collection supplies, verifies IDs, and mixes samples. It can hold up to 6 samples before needing to dock and transfer them to the base.

The base is the stationary part that centrifuges and refrigerates samples. It can hold up to 60 samples before needing a courier to change out its coolers.



Control Panel

The control panel contains the keys and displays of the Art Sample Preparation Device, located on the Caddy (only the power switch is located on the back of the device).



Caddy / Base Inventory Lights

When base is not nearing full, the caddy lights will be represented as seen below:



Caddy is empty and can hold 6 samples.



Caddy is holding 4 samples and you can collect 2 more before docking.



Caddy is holding 5 samples and you can collect 1 more before docking. If it's a one-tube collection, you can proceed, but if it's a two-tube collection, you have to dock first.



Caddy is full and needs to be docked before the next collection to free up space.

When base is nearing capacity (40 tubes) the tube lights will be represented as seen below. The red indicates insufficient capacity to perform a collection.



Caddy is holding 2 samples. The base can only hold 4 more. You can only collect 2 more samples until the courier comes.



Caddy is holding 2 samples. The base can only hold 3 more. If it's a one-tube collection, you can proceed, but if it's a two-tube collection, you can't proceed until the courier comes.



Caddy is holding 2 samples and the base can only hold 2 more. You can't collect any more samples until the courier comes.



Caddy is empty, but the base is full. You can't collect any more samples until the courier comes.

Additional light configurations for collection:



This customer needs a gold tube.



This customer needs a lavender tube.



This customer needs a gold tube and then a lavender tube.



Caddy is holding 2 samples and the base can only hold 4 more.
This is the last customer before the courier comes, and they need a gold tube and then a lavender tube.

Events and Audio Responses

The following audio and non-audio responses to the user are:

State	Event	Mutable	Art Sample Preparation Device Audio Response	Art Sample Preparation Device Visual Response
Tech ID State	Invalid Tech ID	No	I don't recognize that Tech ID. Please try again.	Tech light flashes 3x
	Before any input: Status button pushed	No	Remember, the Tech ID is 8 digits. The Base can accept xx more samples.	No Visual Indicator
	After partial manual entry: Status button pushed	No	Remember, the Tech ID is 8 digits. You have entered Z digits. The Base can accept xx more samples.	No Visual Indicator
	Before any input: Undo button pushed	N/A	No Audio	Tech light flashes 3x
	SST tube in Caddy and has been clotting for 45 minutes.	No	It is important that you dock the Caddy in the next XX minutes. *Audio plays every 120 seconds. Device status is inactive.	Tube lights flash 5x. Repeats with same frequency as audio message.
	SST tube in Caddy and has been clotting for 55 minutes.	No	Reminder! It is important that you dock the Caddy in the next XX minutes. *Audio plays every 60 seconds.	Tube lights flash 5x. Repeats with same frequency as audio message.
SST tube in Caddy and has been clotting for 65 minutes.		No	The Caddy needs to be docked before starting the next visit. Please dock the caddy now. The Sample will expire in XX minutes* Audio plays every 30 seconds.	Tube lights flash 5x. Repeats with same frequency as audio message. User is blocked from any functionality. If any key is pressed the audio and non-audio response plays.
	SST tube in Caddy and has been clotting for 70 minutes.	No	The Caddy needs to be docked before starting the next visit. Please dock the Caddy now. The sample will expire in XX minutes* Audio plays every 10 seconds. In between audio messages the Caddy beeps.	Tube lights flash 5x. Repeats with same frequency as audio message. User is blocked from any functionality. If any key is pressed the audio and non-audio response plays.
SST tube in Caddy and has been clotting for 75 minutes.		No	The Caddy needs to be docked before starting the next visit. It is urgent to dock to prevent expiration, please dock the caddy now.	User is blocked from any functionality. If any key is pressed the tube lights flash 5x and the audio and non-audio
	SST tube in Caddy and has been clotting for 75 minutes.	No		

State	Event	Mutable	Art Sample Preparation Device Audio Response	Art Sample Preparation Device Visual Response
Initial State	SST tube in Caddy and has been clotting for 75+ minutes.		The Caddy needs to be docked before starting the next visit. Please dock the caddy now. A sample has expired.	response plays. User is blocked from any functionality. If any key is pressed the tube lights flash 5x and the audio and non-audio response plays.
	After partial manual entry: Undo button pushed	N/A	No Audio	Tech light flashes 3x. and entry is cleared.
	Undo button pushed for 3 sec	N/A	No Audio	Tech light flashes 3x (nothing else happens. Nothing to abort)
	Device status is inactive message returned from sunflower.	No	Device status is inactive.	No Visual Indicator
	Valid Tech ID	Yes	The Tech ID is accepted.	Tech light turns off. visit light turns on
Sleep Mode	Caddy goes into sleep mode	No	The Caddy has been inactive for a while. it is going into sleep mode now to conserve battery life. *Repeat every minute	Slowly pulse the tech ID light
Battery Low	Battery gets below configurable level	No	The battery is critically low. Please dock the caddy now before performing additional functions. *Repeat every minute	Error light turns red. User is blocked from all functionalities. If any key is pressed this message gets played.
	Battery gets critically low during a visit	No	The battery is critically low. Please dock the Caddy to continue this visit. If the Caddy is not docked within 60 seconds the visit will be cancelled.	Error light turns red. If the Caddy is not docked within 60 seconds the visit is cancelled.
Visit ID State	Invalid Visit ID	No	I don't recognize that Visit ID. Please try again.	Visit Light Flashes 3x
	Before any input: Status button pushed	No	Remember, the Visit ID is 8 digits. The Base can accept xx more samples.	No Visual Indicator
	Close to timeout	No	The caddy has been inactive for a while. For security, this visit will time out soon. Press any button for more time.	No Visual Indicator
	Timeout occurs	No	For security, the visit will time out now. You will need to enter your Tech ID to begin again. * This message gets prepended to the status message while in the tech ID state following this event	Visit ID light turns off and Tech ID light turns on
	After partial manual entry: Status button pushed	No	Remember, the Visit ID is 8 digits. You have entered Z digits. The base can accept xx more samples.	No Visual Indicator
	Before any input: Undo button pushed	N/A	No Audio	Visit light turns off. Tech ID light turns on.
	After partial manual entry: Undo button pushed	N/A	No Audio	Visit light flashes 3x and

State	Event	Mutable	Art Sample Preparation Device Audio Response	Art Sample Preparation Device Visual Response
Customer ID State	Undo held for 3 sec while in Visit ID State	No	You are about to cancel the visit, are you sure you want to cancel? Press 1 for No or 0 for Yes	entry is cleared No Visual Indicator. If one is pushed, then the visit light flashes 3x. If 0 is pushed, then the visit light turns off and the Tech ID light flashes 3x.
	Valid Visit ID	Yes	The Visit ID is accepted.	Visit light turns off. Customer light turns on.
	Invalid Customer ID	No	I don't recognize that Customer ID. Please try again.	Customer Light Flashes 3x
	Before any input: Status button pushed	No	Remember, the Customer ID is 8 digits. The Base can accept xx more samples.	No Visual Indicator
	Close to timeout	No	The caddy has been inactive for a while. For security, this visit will time out soon. Press any button for more time.	No Visual Indicator
	Timeout occurs	No	For security, the visit will time out now. You will need to enter your Tech ID to begin again. * This message gets prepended to the status message while in the tech ID state following this event	Customer ID light turns off and Tech ID light turns on
	After partial manual entry: Status button pushed	No	Remember, the Customer ID is 8 digits. You have entered Z digits. The Base can accept xx more samples.	No Visual Indicator
	Before any input: Undo button pushed	N/A	No Audio	Customer light turns off. Visit light turns on.
	After partial manual entry: Undo button pushed	N/A	No Audio	Customer light flashes 3x and entry is cleared
	Undo held for 3 sec while in Customer ID State	No	You are about to cancel the visit, are you sure you want to cancel? Press 1 for No or 0 for Yes	No Visual Indicator
	Valid Customer ID	Yes	The Customer ID is accepted.	Customer ID light turns off and scan light turn on
Scan State	Scanning lavender when gold type is needed	No	It looks like a gold tube is needed instead. Please review.	Scan light and gold tube light flash 3x
	Scanning Gold when lavender is needed	No	It looks like a lavender tube is needed instead. Please review.	Scan light and lavender tube light flash 3x
	Status button pushed during Scan State. Gold tube expected	No	Please scan a gold tube. The Base can accept xx more samples.	No Visual Indicator
	Status button pushed during Scan State. Lavender tube expected	No	Please scan a lavender tube. The Base can accept xx more samples.	No Visual Indicator
	Close to timeout	No	The caddy has been inactive for a while. For security, this visit will time out soon. Press any button for more time.	No Visual Indicator
	Timeout occurs	No	For security, the visit will time out now. You will need to enter your Tech ID to begin again. * This message gets prepended to the status message while in the tech ID state following this event	Customer ID light turns off and Tech ID light turns on
	First tube: Undo Pushed	N/A	No Audio	Scan light turns off and customer light turns on.
	Non first tube: Undo pushed	No	Cannot go back to customer step once first sample has been processed. To cancel visit hold undo for 3 seconds	Scan light flashes 3x

State	Event	Mutable	Art Sample Preparation Device Audio Response	Art Sample Preparation Device Visual Response
Deposit State	Undo held for 3 sec while in Scan State	No	You are about to cancel the visit, are you sure you want to cancel? Press 1 for No or 0 for Yes	No Visual Indicator. If one is pushed, then the scan light flashes 3x. If 0 is pushed, then the scan light turns off and the Tech ID light flashes 3x.
	Valid Tube Scan	Yes	The sample scan is accepted	Scan light turns off. Deposit light turns on.
	Status button pushed during Deposit State. Gold tube expected	No	Please deposit the gold sample into the Caddy. The Base can accept xx more samples.	No Visual Indicator
	Status button pushed during Deposit State. Lavender tube expected	No	Please deposit the lavender sample into the Caddy. The Base can accept xx more samples.	No Visual Indicator
	Close to timeout	No	The caddy has been inactive for a while. For security, this visit will time out soon. Press any button for more time.	No Visual Indicator
	Timeout occurs	No	For security, the visit will time out now. You will need to enter your Tech ID to begin again. * This message gets prepended to the status message while in the tech ID state following this event	Customer ID light turns off and Tech ID light turns on
	Undo Pushed	N/A	No Audio	Deposit light turns off and scan light turns on.
	Undo held for 3 sec while in Deposit State	No	You are about to cancel the visit, are you sure you want to cancel? Press 1 for No or 0 for Yes	No Visual Indicator. If one is pushed, then the deposit light flashes 3x. If 0 is pushed, then the deposit light turns off and the Tech ID light flashes 3x.
	If wrong tube type expecting gold	No	It looks like this is the wrong sample color. Please remove and deposit the correct gold sample.	Gold sample light flashes 3x
	If wrong tube type expecting lavender	No	It looks like this is the wrong sample color. Please remove and deposit the correct lavender sample.	Lavender sample light flashes 3x
	If wrong barcode but correct tube type	No	This barcode doesn't seem to match. To continue with this sample, press any number. Otherwise please remove and deposit the correct sample.	Gold or lavender sample light flashes 3x. Whichever is expected.
	Deposit Accepted	Yes	The sample is accepted.	Deposit light turns off. Sample light starts alternating its color between blue and either gold or lavender (Whichever is applicable)
Error State	Insurmountable Error State	No	There appears to be a service issue. Service is required.	Error light turns on

State	Event	Mutable	Art Sample Preparation Device Audio Response	Art Sample Preparation Device Visual Response
Mix State	Undo held for 3 sec while in mix state and still have a tube to collect	No	You are about to cancel the visit, are you sure you want to cancel? Press 1 for No or 0 for Yes	No Visual Indicator. If one is pushed, then the scan light flashes 3x once the mix cycle is complete. If 0 is pushed, then the Tech ID light flashes 3x once the mix cycle is complete.
	Tube still in mixer arm after mix cycle	No	Sample transfer into inventory was unsuccessful. Remove the sample and inspect it. If there are no apparent issues reinsert the sample to try again. Or you can try a new sample by pushing zero.	If zero is pushed, then go back to the scan state.
	Undo held for 3 sec no further tubes to collect	No	The visit is complete and cannot be cancelled.	No Visual Indicator
	Undo pushed	N/A	No Audio	No Visual Indicator
	Status button pushed during mix state	No	Please wait while the sample is processed. The base can accept xx more samples.	No Visual Indicator
Caddy Full	Caddy Full. Any input	No	The caddy is full! Please dock the caddy to free up space before continuing.	No top lights illuminated (cannot login). Inventory lights flash 3x
Art Sample Preparation Device Full	Art Sample Preparation Device Full. Any input	No	The Base is full! It will need to be emptied before it can take more samples.	No top lights illuminated (cannot login). Red inventory lights flash 3x
Caddy Close to Full	Caddy can hold one more tube, so allows login, but after Visit ID, Caddy realizes it's a two-tube collection.	No	It looks like this visit needs more samples than the Caddy has room for. Please dock the caddy to free up space.	Inventory lights flash 3x. Visit light turns off and tech light turns on
Art Sample Preparation Device Close to Full	Art Sample Preparation Device can hold one more tube, so Caddy allows login, but after Visit ID, Caddy realizes it's a two-tube collection.	No	It looks like this visit needs more samples than the Base has room for. It will need to be emptied to free up space.	5 red inventory lights flash 3x. Visit light turns off and tech light turns on. 5 red inventory lights flash 3x.
Transferring Samples	Caddy is docked with samples in inventory	N/A	No Audio	No top steps are illuminated. Lock light illuminates. Inventory lights de-illuminate when each tube transfers. If Caddy is docked while processing a visit normal sample transfer behavior

State	Event	Mutable	Art Sample Preparation Device Audio Response	Art Sample Preparation Device Visual Response
				occurs and resumes at the same state and visit it was in when it was docked. The current visit is not affected by docking.

Operation

Switch on Art Sample Preparation Device

1. Turn on the power switch on the back of the device.
2. The device performs a self-check of its software.
3. The Art Sample Preparation Device will identify its current state to the User.

Collection

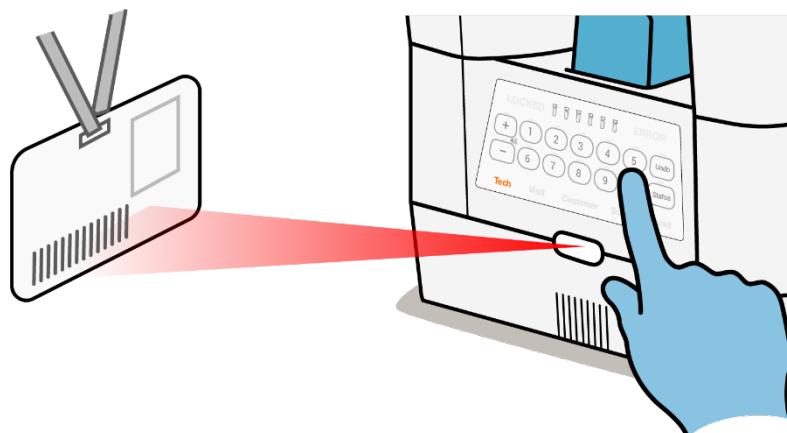
Prior to sample collection, the collection technician will don gloves and PPE adhering to local workplace safety and environmental requirements and proceed to scan or enter using the User Interface, see section “[Control Panel](#)”, the unique collection tech ID, visit ID, and customer ID. This confirms the collection tech identity, test order confirmation number (determining which tubes need to be collected), and customer’s identity. These steps electronically link the tube barcode with the customer order to prevent labeling errors and enables Art Sample Preparation Device to alert the user if the wrong type of tube has been selected.

The collection tech will collect one or more samples using sample collection device(s) according to the Dandelion Collection Procedure.

1. Tech ID
 - a. All collection techs will have unique tech IDs. Scanning or entering your tech ID will log you in to start a collection.



The caddy’s “Tech” light means it’s ready for this step.



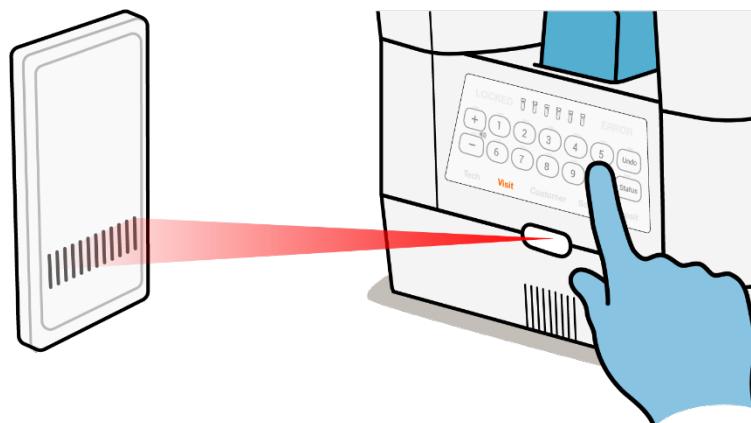
Scan the barcode on your employee badge or enter your tech ID number.

2. Visit ID

- a. When customers order tests, they will get an 8-digit order confirmation number called a visit ID. This tells the caddy which type of tube(s) they will need. Scan the barcode on the customer's phone or enter the number.



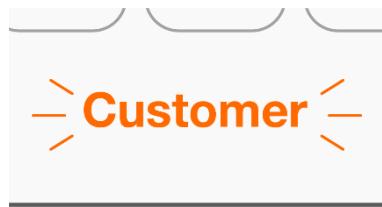
The caddy's "Visit" light means it's ready for this step.



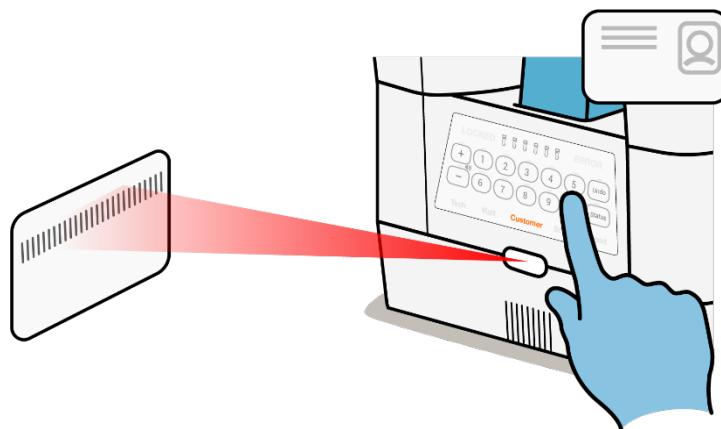
Scan the barcode on the customer's phone or enter the visit ID number.

3. Customer ID

- a. The customer's birth date is their customer ID. The caddy will confirm that this is the same person who ordered the tests for the visit ID. If this is the wrong person, it will not let you proceed.



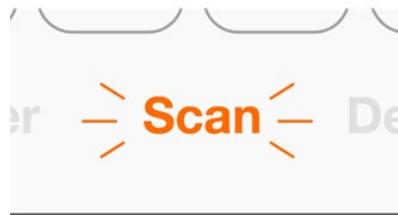
The caddy's "Customer" light means it's ready for this step.



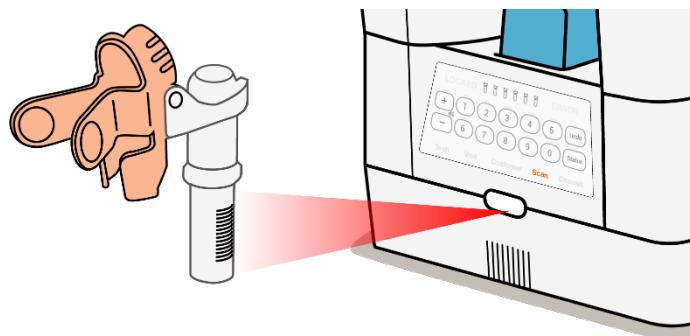
Scan the barcode on the customer's driver's license or enter their birth date (DDMMYYYY).

4. Scan Barcode of Tube – In conjunction with hand warming

- a. When the finger cuff and the finger are fully dry, look at the indicator lights on the hand warmer to know when you can scan the tube.
- b. For a gold tube, scan when the gold light stops flashing and turns solid on the hand warmer.
- c. For a lavender tube, scan when the lavender light stops flashing and turns solid on the hand warmer.



The caddy's "Scan" light means it's ready for this step.



Scan the tube's barcode using the caddy's barcode scanner. The caddy will check the type of tube (gold or lavender) and either confirm that you may proceed or ask you to choose the other tube type.

Tube Deposit

1. After taking the cuff and sample off the finger:
2. Use your right thumb to close the sample's lid; you will hear a click. Push in the sample door on the caddy and place the sample inside where you should hear another audible click. This places the tube into the mixer. Let go of the sample door so that it can close.



The caddy's "Deposit" light means it's ready for this step.



WARNING Do not reach into the caddy sample door. The caddy sample door is drawn shut automatically.



CAUTION To protect sample quality, aim for the shortest time possible between blood passing the bottom fill line and placing the sample in the caddy



CAUTION Blood samples used within the centrifuge are considered biohazardous. Adhere to local workplace safety and environmental requirements regarding handling biohazardous materials.

Tube Mixing

The mixer within the Art Sample Preparation Device, reads the barcode of the sample to ensure the correct sample preparation steps are taken. The mixer ensures that the blood is properly mixed with additives in the tube by inverting the sample the correct number of times. The mixing action replicates the manual mixing actions specified in the collection device IFU to ensure that mixing steps are performed consistently. Mixing parameters are pre-set and cannot be modified by the user. The Art Sample Preparation Device's mixer delivers energy to the collection tube device in the form of a mechanical mixing action which is consistent with conventional tube mixing approaches such as manual inversion, vortexing, rolling, and shaking.

After mixing is complete and when the portable collection component is docked onto the stationary preparation component, the Art Sample Preparation Device transfers the sample(s) into the internal transporter. For lavender samples, the transporter moves the samples directly to the storage cooler. For gold samples, the transporter holds the samples for a specific amount of time to ensure each sample is fully clotted prior to centrifugation.

Alerts and Errors

For possible user alerts or errors, see section "[Events and Audio Responses.](#)"

For possible alerts and/or errors that cannot be readily resolved from the audio prompts, it is recommended that the user try to manually reset the device.

Users do not have to troubleshoot the device. All activities are automatically logged, and errors will attempt to automatically resolve. Otherwise, a field service engineer will automatically be made aware of the error and come service your device.

Centrifugation

Automation of the clotting time ensures that samples are not centrifuged too early or too late, both of which can cause preanalytical sample quality errors.

After a gold sample has fully clotted, the Art Sample Preparation Device transfers the sample into the centrifuge. The centrifuge spins the sample according to the parameters specified in the collection device IFU to ensure that centrifugation is performed correctly. After centrifugation, Art Sample Preparation Device transfers the sample to the storage cooler. All settings of the centrifuge are pre-set and cannot be modified by the user.

Art Sample Preparation Device's centrifuge delivers energy to the collection device in the form of relative centrifugal force (g). The centrifugation process is consistent with conventional centrifugation, which typically operates in the range of 2,000-15,000 g.



WARNING Do not mix or centrifuge flammable/explosive materials and or materials that react chemically when sufficiently mixed

Alerts and Errors

For possible user alerts or errors, see section "[Events and Audio Responses.](#)".

For possible alerts and/or errors that cannot be readily resolved from the audio prompts, it is recommended that the user try to manually reset the device.

Users do not have to troubleshoot the device. All activities are automatically logged, and errors will attempt to automatically resolve. Otherwise, a field service engineer will automatically be made aware of the error and come service your device.

Storage

Art Sample Preparation Device's storage cooler holds collected samples in a temperature-controlled compartment at 2-8°C, in a manner consistent with the collection device IFU. The storage cooler can be removed from Art Sample Preparation Device and transported to a CLIA laboratory for analysis. Using a removable storage cooler helps avoid temperature excursions during transfer to the laboratory.

Maintenance and Care

Cleaning

For the sake of personal, environmental, and material protection, it is the Babson couriers' responsibility to clean the Art Sample Preparation Device on a regular basis per the relevant Babson Diagnostics work instruction.

In the event of blood contamination:

- Use a soft cloth to wipe out of the surfaces.
- Never use caustic cleaning agents such as soap suds, phosphoric acid, bleaching solutions, or scrubbing powder.
- A tuberculocidal or diluted bleach solution can be used to wipe down the surface.

In the case of accidental spills, the user is to adhere to local workplace safety and environmental requirements.

Maintenance	Recommended Interval
Cartridge	Daily or when polluted
Art Cartridge Environment	Daily or when polluted
Art Sample Preparation Device Chassis	Daily or when polluted
Outside of Ventilation Vents	Daily or when polluted



CAUTION Before using any cleaning or decontamination methods except those recommended by Babson, users should check with the Babson that proposed method will not damage the equipment.



CAUTION Refrain from using any other cleaning or decontamination procedure than those recommended by Babson, if you are not entirely sure that the intended procedure is safe for the equipment.

If in doubt, contact Babson Diagnostics Customer Service.

Preventative Maintenance

The pharmacy (pharmacist or pharmacy technician) will not need to perform any preventive maintenance of the Art Sample Preparation Device.

The Art Sample Preparation Device will be serviced twice a year as determined by Babson. A field service engineer will be deployed to the site and check the following:

- The electrical equipment
- The suitability of the set-up site
- The safety
- Mixing arm profile which includes number of inversions, mixing angle, speed, acceleration, max speed.
- Centrifuge profile which includes acceleration, speed, max speed

Troubleshooting and Servicing

Contents

User Troubleshooting

If errors do not self-resolve attempt to restart the device.

Caddy

For issues involving the Caddy hold down the status button to restart the caddy. If restart is successful, the Caddy should re-initialize. Do not attempt to do anything with the Caddy until it has fully re-initialized. If restart is unsuccessful or does not resolve the issue encountered contact Babson customer service.

Base

For issues involving the Base switch power down the device by using the switch on the back of the device. Once powered down remove the power cord and wait 15 seconds. After 15 seconds reconnect the power cord and power back on the device. Allow the base to initialize, a solid green light at the front of the Base will indicate ready for use. If restart is unsuccessful or does not resolve the issue encountered contact Babson customer service.

Contacting Babson Customer Service

When contacting Babson customer service, please provide the serial no. of your device. This information can be found on the label on the back panel of the Base.

SN AB22222080001



2x/PRODUCT CODE (Art Base – AB)
5x/JULIAN YEAR (2 digit for year
and 3 digits for day)
3x/CONFIGURATION
3x/DAY BUILD NUMBER

Babson Field Service Engineer on Site Servicing

When an error occurs and does not automatically resolve or when Babson customer service is contacted, a Field Service Engineer will be notified and deployed to the site. A Field Service Engineer will troubleshoot and repair the Art Sample Preparation Device as captured in the Field Service Guide. The Field Service Guide will dictate safe and proper techniques for troubleshooting and repair.

Potential risks that the Field Service Engineer may encounter while servicing is:



ELECTRIC SHOCK Before attempting to disassemble any components ensure device is powered down and disconnected from power unless otherwise specified in the Field Service Guide



HAND PINCH OR CRUSH Before attempting to disassemble any components ensure device is powered down and disconnected from power unless otherwise specified in the Field Service Guide

Risks associated with repair will be mitigated by proper training to the Field Service Guide.

Upon completed repair / servicing the Field Service Engineer will run diagnostic tests to ensure the device is in an operable and safe state.



CAUTION Cleaning and decontamination may be necessary as a safeguard before laboratory centrifuges, rotors, and any accessories are maintained, repaired, or transferred.



Babson Diagnostics
1205 Sheldon Cove #2-J
Austin, TX, 78753
USA

BabsonDx.com/Art Sample Preparation Device

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