Patient Instructions for Use

(User Manual)

Computerized Oral Prescription Administration (COPA) [coh-pah]

This “Instructions for Use” contains information on how to deliver prescribed oral medication

Sterling-BERK 0085 R33 Patient IFU

For Oral Use only

Indications for use: The Computerized Oral Prescription Administration System (COPA™) device is intended for use as an authenticated intended-user automated oral liquid prescription dispensing system. Oral liquid medications are dispensed, as prescribed by health care professionals, with dose size, dose frequency and dose restrictions, which are synchronized to the COPA by authorized dispensers via a remote management system (COPA MS). Following successful multi-biometric identification prior to each dose, medications are administered directly into the mouth of the intended user. In addition to dispensing, the COPA provides prescription-based messaging and reporting for patients, caregivers, and providers use in managing medication regimens.

Intended Operator: A patient who is a maintenance user of oral liquid medication

Contraindications: Persons prescribed a COPA through their physician who are afflicted with amelia, tetraplegia, upper extremity amputations, dysphagia, or who are visually impaired, non-English speaking, or illiterate, may be unable to use COPA or require the assistance of a caregiver for use. All Patient users should follow instructions on their prescription and medication label for additional warnings as to the medication being used with this product. For any questions or concerns regarding your medication please consult your doctor or pharmacist.

For assistance, if needed, in setting up, using or maintaining the COPA device or to report unexpected operation or events contact Berkshire Biomedical at 5950 Berkshire Ln, Ste 450 Dallas, TX 75225 or at (214) 389-1748 or Copainfo@berkbiomed.com.

Carefully read all instructions before use. Failure to follow instructions for use may result in Incomplete Dose or Inability to receive a dose (No Dose).

COPA Device Introduction

COPA is a hand held device using biometric identification technology to deliver timely and precise doses of prescribed liquid drug regimens to the intended user and through integrated cellular technology provide data reporting to the patient and their care team as to usage.

Table of Contents

Warnings and Precautions

WARNING	Indicates a potentially hazardous situation which if not avoided, may result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

Visually inspect all components for damage before use. Do not use the device that appears broken or damaged.

Do not use the device if the COPA SynCap appears broken or damaged.

Device must use bottle with COPA SynCap.

COPA SynCap cannot be removed from medication bottle.

Device can only be used by the person who is prescribed it.

Federal law Restricts this device's sale by or on the order of a physician.

Device cannot be used for more than one person.

COPA device is not safe to use in a MRI.

Only a pharmacist or qualified healthcare professional can set up device.

Do not remove medication bottle while dispensing.

Device must be put on airplane mode when traveling by airplane or above 6561ft (2000 meters).

Device cannot be used above 6561 ft (2000 meters) in altitude.

Keep device out of reach of children, pets or pests.

This device uses a Lithium ion battery. Do not puncture battery

Proximity to power line magnetic fields may impede device operation.

Keep portable and mobile RF communication equipment 12 inches from the COPA device.

Radio signals sent by COPA device may interfere with other medical devices. Tell your doctor if you use any other devices; such as pacemaker, insulin pump or pain relief device.

Do not disassemble the COPA device. Disassembling the device will damage and/or cause malfunctions. No modification of this equipment is allowed.

Do not drop COPA device or subject it to severe shock.

COPA device is water resistant but not waterproof; do not submerge COPA device in water or other liquids. See page 20 for more information.

Do not sterilize COPA device.

Do not place device in the dishwasher.

This device is not serviceable.

The cord packaged with this device presents a potential strangulation hazard.

Device contains small parts that when detached could result in choking.

Do not put fingers in area where the medication bottle is inserted, when no medication bottles are connected. Doing so may cause shock or injury.

Anesthetic Warning: This equipment not suitable for use in the presence of a flammable anesthetic mixed with air or oxygen or nitrous oxide.

Liquid medication will be dispensed directly into mouth. Do not inhale during delivery. Potential choking hazard.

COPA Device Components

COPA Device Kit

The COPA Device kit contains the following components:

COPA Device

Rinse Bottle

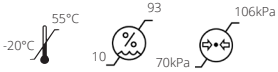
Clean Bottle

Charging Cable

Medication Bottles as shown in COPA device are prepared by Dispenser as prescribed.

General Use: Storage and Handling

Do not store device in direct sunlight or in high temperatures. In cold conditions, allow the device to warm to room temperature before use.



Device should be stored and transported between -4°F and 131°F (-20°C and 55°C), 10% to 93% humidity, and between 70 kPa and 106 kPa air pressure.

Store device in a dry location free of dust. Never submerge in liquid.

Do not store device near magnetic fields. Strong magnets may cause the COPA device to malfunction or cause the battery to discharge.

When transporting, unless being held or secured upright, ensure the unit is lying flat on a surface.

COPA device cannot be used without medication - defer to medication bottle for temperature to dispense medication.

One prepared medication bottle can be used in the device at a time; additional prepared medication bottles should be stored in accordance with the bottle label and specified instructions on the prescription information sheet room the drug manufacturer.

COPA device should be kept clean and free from debris. Clean mouthpiece before and after each use; see page 10 for complete instructions.

Device is not made with natural rubber latex. Discontinue use and contact your health care provider if you develop an allergic reaction to mouthpiece.

The maximum temperature of the COPA Device may be greater than 105°F (41°C) but less than 120°F (52°C) during normal use. A contact duration of less than 10 minutes, per occurrence, is recommended. A contact duration of less than 1 minute on and around the fingerprint sensor, per occurrence, is recommended. Special precautions may be considered for patients who are sensitive to higher temperatures.

General Use: Device Charging

COPA Device is powered by a recharageable internal battery

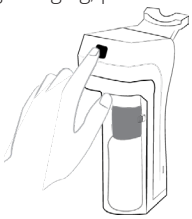
COPA device cannot dispense medication while charging.

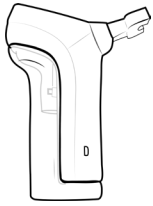
When COPA device is connected to the battery charger the COPA device and charger are not applied parts.
During normal use the entire COPA device, not while charging, is considered an applied part.

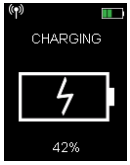
- ⚠ The use of a charger other than the one provided by Berkshire Biomedical could result in device malfunctions.
- ⚠ Battery in COPA device is rechargeable but battery cannot be replaced.
- ⚠ If battery is no longer charging or has other problems contact (214) 389-1748.
- ⚠ Do not plug or unplug the AC adapter into the electrical outlet with wet hands.
- ⚠ Do not overload power outlets. Plug the AC adapter into the appropriate electrical voltage outlet.
- ϟ Do not use extension cords. Plug the AC adapter directly into the electrical outlet.
- ⚠ Do not pull the power cord of AC adapter strongly.
- ⚠ Do not position the equipment (battery charger) so that it is difficult to disconnect from the electrical outlet.
- ⚠ The supplied USB charger is part of the COPA device equipment and should only be used to charge the COPA device.
- ⚠ Unplug the charger from the device to isolate the COPA device from mains power.

1 **To charge, plug the COPA charger into charging port.**

During charging, press the ON button to see the battery status bar.

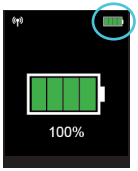




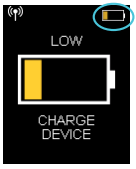


2 **When turned on, the battery status bar on the COPA device display always indicates the current level of charge.**

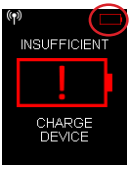
Dosing or any other function is not possible if COPA device has insufficient charge.



Unplug the device from the charger when the status bar reaches 100%. **Full charge takes approximately 2 hrs.**



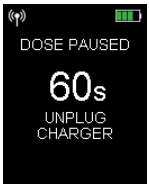
When the battery charge is down to 20% the device will begin to display a notice of low charge as a reminder device needs charging.



When the battery charge is down to 10% the device will begin to display a notice of insufficient charge as a reminder device needs charging. **COPA takes about 15 minutes to charge to minimum needed to take a dose.**

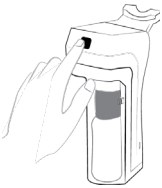
"IMPORTANT" Without sufficient charge device will not dose.

Keep device charged for optimal use. While plugged into charger the device will not dose. If you attempt to plug in a charger in the midst of a dose, the dose delivery will stop immediately. While taking a dose you will have 60 seconds to disconnect the charger and return the device to your mouth in order to resume dosing (see more info on dosing on pages 10 -12).



General Use: Device Display and Lights

Turn On Device



When turned on, COPA device display and lights work together to guide user through operation and dosing.

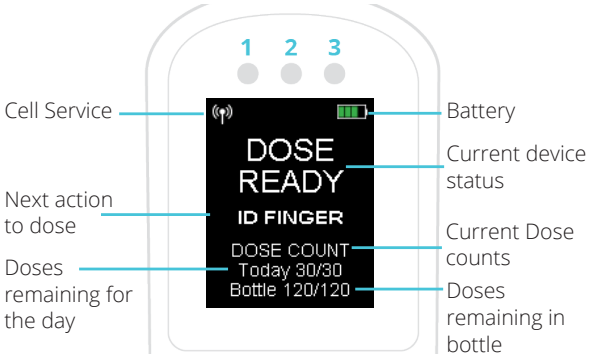
Once COPA is charged (see page 6), turn on device as shown on the left.

The COPA device does not have an OFF button.

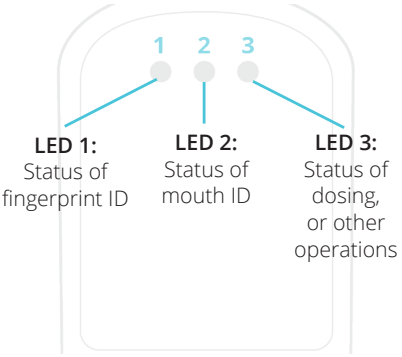
After two minutes of inactivity the device will power off automatically to preserve battery power. See page 6 for charging information.

If at Turn On or any point in use display indicates Device Error, device is no longer operable; contact BBM (214) 389 -1748 to arrange replacement.

Display Screen Details



LED Lights



Many display messages are explained in IFU and full listing on Page 16 and 17.

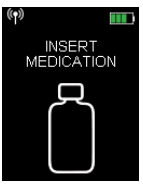
Green Lights indicate Success

Yellow lights indicate Try Again, or Fail.

General Use: Inserting and Removing Bottles

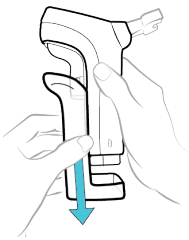
1 COPA device will accept SynCapped bottles registered to the device by authorized dispensers.

If more than one bottle is prepared for a prescription the bottles can be used in any order.
Bottles will be prepared and labeled according to prescriber instructions, for patient use within their registered COPA device.



When prompted, insert medication.

2 Slide clear cover to remove the cover from the device.

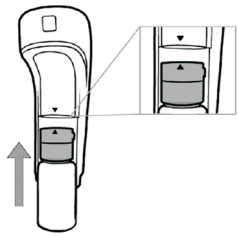


⚠ Do not put fingers in area where the medication bottle is inserted, when no medication bottles are connected. Doing so may cause shock or injury.

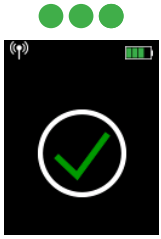
General Use: Inserting and Removing Bottles

3 **Align arrow on SynCap with arrow on device and slide bottle into device until you hear a click.**

The COPA Device will recognize SynCaps that are linked to the prescription set up by the authorized dispenser once the device has received the prescription record.



4 **Once a bottle is properly inserted and the SynCap is recognized the COPA device display and lights will guide use.**



The device display and Lights will indicate if the bottle is recognized.

5 **Slide clear cover back onto device and now its ready for use.**

Once a bottle is inserted, do not remove until COPA displays Insert New Bottle or 30 Day Cleaning is Required.

If bottle is not properly inserted or recognized, the display will provide information for resolution.

Medication is incorrect or expired.
Check bottle label.

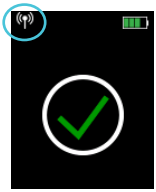
There is not enough medication in bottle for next dispense.
Remove bottle, insert new bottle, and rinse if necessary.

Medication could not be read.
Clean off SynCap with towel and reinsert bottle.

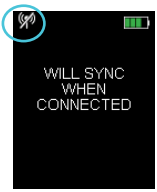
General Use: Syncing / Cellular Connectivity

COPA Device receives prescription information from the COPA management System, as set up by authorized dispensers, through cellular connection. COPA cell service is NOT tied to patient users own personal cell service. Do not attempt to alter COPA device cell service.

General Use: Syncing / Cellular Connectivity



When turned on, the COPA device auto detects if within cell connectivity, and always displays the current status of connectivity.



The COPA device does NOT require cell service for any dose related functions ONCE the initial prescription or future prescriptions are received by the device.

When you observe No Connection please by aware that new or updated prescriptions cannot be received by the COPA. To resolve this issue, change location to an area of better service. If there is a cellular problem with your COPA device, please reach out to Berkshire Biomedical at (214) 389-1748.

This equipment is designed to connect to a cellular network via an internal SIM Card that is not designed to be accessible or configurable by any third party or user. Attempts to connect to any other network type or to reconfigure the network will result in unidentified risks and then Berkshire Biomedical cannot be responsible for controlling these risks. Changes to the IT Network include: configuration of the system; connection of additional devices to the COPA device; disconnecting from the IT network; updating or modifying the equipment without the manufacturer's approval.

General Use: Dose Availability Display

The Pharmacist has set up your COPA device for your prescription.

Once device is sufficiently charged, and a prepared bottle is inserted and recognized, the standard display screen will show user if a dose is ready to be taken at that time. The display will also show how many doses are remaining for the day, and for that bottle.

Current device status

Next action to dose

Current Dose counts

Doses remaining for today and total doses that were prescribed for today

Doses remaining in bottle, and total doses that were contained in the inserted bottle

After you take a dose, the screen will update to show the new dose counts.

Today's Dose Counts Remaining (30) and Total prescribed for Today (3), as well as Bottle Dose Counts Remaining (120) and Total that were contained in the bottle (120).

After 1 dose is taken, Today's Dose Count remaining is reduced by 1 (now 2 are remaining), and Bottle Dose Count remaining is reduced by 1 (now 119 are remaining).

If dose is NOT available, the display screen will indicate the time as prescribed before another dose is available. If no time between doses is specified in prescription, COPA applies a 1 minute minimum wait before next dose available.

COPA resets Daily Counts each night at midnight local time.

Important Information: Dispensing

The device requires confirmation of patient ID prior to dispensing a dose. Make sure COPA is charged; remove from charger prior to dosing.

1 **Wipe with soft cloth and distilled water to remove debris before placing in mouth.**

See page 12 for important information on how to clean and disinfect COPA after every use.

Distilled water does not come with COPA device

⚠ Do not use anything other than distilled water

2 **When battery status is sufficient and medication bottle is inserted, if a dose is available, COPA will display DOSE READY.**

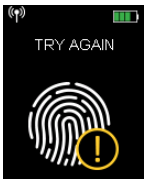
Unplug if device is on charger.

3 **Keep COPA upright during dosing.**

4 **Place fingerprint on fingerprint scanner.**

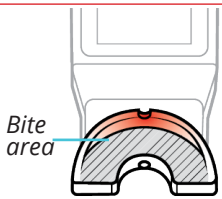
5 **When 1st LED light turns green, the finger ID was successful.**

Fingerprint ID not accepted



Lift finger and reposition it on scanner.

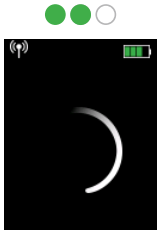
6 **To continue with patient identification, place teeth on mouthpiece and firmly bite down.**



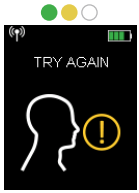
Do not place teeth beyond bite area

Important Information: Dispensing

7 When 2nd LED light turns green, the mouth ID was successful.



Mouth ID not accepted



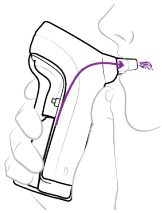
Remove mouth, reposition mouth,
Apply more pressure

For assistance, if dentition profile is significantly changed, contact Berkshire Biomedical at (214) 389-1748 or Copainfo@berkbiomed.com

8 Once both IDs are successful, device will begin to dispense.

Medication will flow into mouth slowly from COPA mouthpiece; COPA dispenses approx. ¼ teaspoon to 2 teaspoons of liquid depending on prescription, in 10 to 60 seconds.

A success chime will indicate a dose has been successfully delivered and it is safe to remove mouth.



Be sure to **keep COPA device upright** and **DO NOT REMOVE MOUTH** until the success chime indicates dispensing is complete. **DO NOT REMOVE BOTTLE** while dispensing.

If you have to remove your mouth prior to this chime, dose will pause, and you will have 60 seconds to return your mouth in order to resume dosing until you hear the success chime.

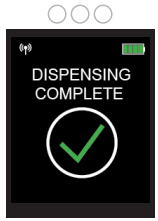
This will show when you have tried the Finger ID or Mouth ID unsuccessfully 5 times. Remove finger or mouth from device, wait 5 seconds, reposition finger or mouth and try again.

The device will allow user to attempt as many times as needed for a successful match. Review the manual for additional instructions on how to use the Finger or Mouth IDs.

9 Listen for success chime as indication it is ok to remove mouth.

You will also see a check-mark on the COPA display, and all 3 LED light will turn off.

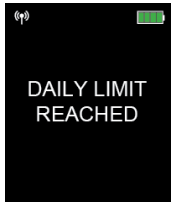
Your dose is complete.



All 3 LED lights will turn off.

Important Information: Dispensing

10 **Once dose at the prescribed time is completed, the screen will indicate when next dose will be available.**



If all doses for the day are complete the display will indicate 'Daily Limit Reached.'

Important Information: Cleaning Device

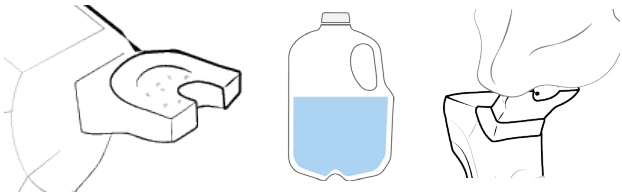
Store device in a dry location free of dust and away from direct sunlight. To clean the plastic housing use a soft dry cloth, slightly dampened with distilled water or isopropyl alcohol.

With proper cleaning, disinfecting, and rinsing, the COPA device will support recurring medication dispensing use for up to 2 years; if you see any signs of excess wear on mouthpiece or device, contact Berkshire Biomedical at (214) 389-1748 or Copainfo@berkbiomed.com

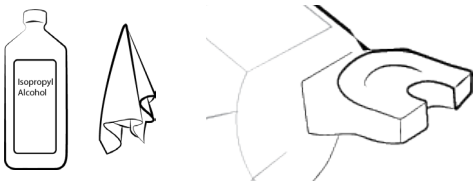
Never submerge in liquid.

- ⚠ Unplug the AC adapter from electrical outlet before cleaning the device.
- ⚠ Do not sterilize COPA device.
- ⚠ Do not place device in the dishwasher.
- ⚠ Clean the Mouthpiece before and after each use with distilled water.
- ⚠ Do not use bleach or other harsh chemicals when cleaning the device.

1 **After taking a dose, throughly wipe mouthpiece with distilled water and a soft cloth for 45 seconds to remove any debris, applying special attention to the exit hole.**



2 **Following the cleaning, disinfect mouthpiece using an isopropyl alcohol wipe for 2 minutes to prepare for next use.**



Important Information: Rinse Cycle

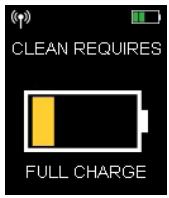
The inside of the COPA device needs to be cleaned and disinfected every 30 days.

For COPA user convenience, as location, timing, or other situations may not accommodate cleaning immediately, the rinse cycle can be done any time within 7 days of the cleaning due message appearing.

Clean and Rinse Bottles

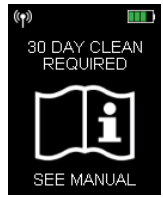
Dish soap, distilled water, isopropyl alcohol and COPA clean and rinse bottles are needed to complete the rinse cycle.

Rinse Cycle



30 days from COPA's last cleaning, device will display "30 Day Cleaning Due". Message will persist for 7 days each time COPA turned unless Rinse Cycle is complete.

Within 7 days of cleaning due notice

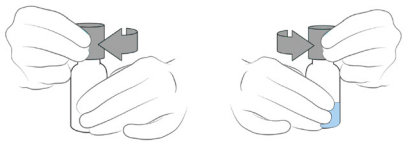


7 days after display initially alerts user, "30 Day Cleaning Required" will be displayed, and DOSING WILL NOT BE ALLOWED until Rinse Cycle in complete.

Recurring Steps

How to remove and place cap on bottle

Twist cap counter-clockwise to remove. Place cap on bottle and twist clockwise to close.

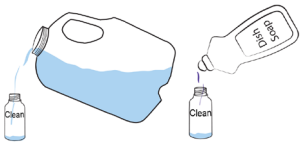


How to fill bottle

Make sure to empty any contents in bottle before filling the bottle for next step.

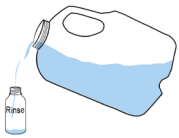
Clean Cycle

Fill clean bottle with distilled water and add one to two drops of dish soap



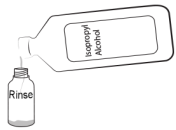
Rinse Cycle 1

Fill rinse bottle with distilled water



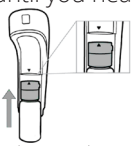
Rinse Cycle 2

Fill rinse bottle with 70% Isopropyl Alcohol
(Common rubbing alcohol)



How to insert bottle

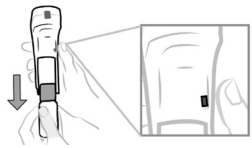
Hold device over sink, align arrow on cap with arrow on COPA device and slide bottle into device until you hear a click.



Each Rinse Cycle step begins about 5 seconds after bottle insert and takes about 5 minutes to complete.

How to remove bottle

Hold the bottle upright, place one hand below the bottle and press the bottle release button on the COPA device.



DO NOT remove bottle until Display indicates

Important Information: Rinse Cycle

Device will not begin Rinse Cycle unless FULLY Charged

1 **Remove medication bottle from COPA device.**
Refer to "How to remove bottle" on Pg 13

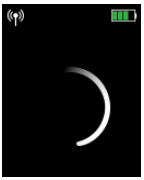
2 **Remove cap from clean bottle. Then fill with distilled water and add one to two drops of dish soap.**
Refer to "How to remove and place cap on bottle" and "How to fill bottle" clean cycle section on Pg 13

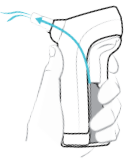
⚠ Do not use anything other than distilled water. Distilled water does not come with COPA device.

3 **Place green cap on clean bottle.**
Refer to "How to remove and place bottle cap " on pg 13

4 **Insert clean bottle into device.**
Refer to "How to insert bottle" on pg 13

5 **Cleaning cycle will start automatically.**
Water will flow through the device and out of mouthpiece.
(Have something to catch water nearby)





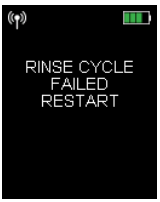
⚠ **Keep Device upright while cleaning.**

⚠ **Do not remove bottle while cleaning is in progress.**

⚠ **Do not put device in mouth while cleaning.**

IMPORTANT: Once bottle is inserted and rinsing begins DO NOT REMOVE BOTTLE until indicated by COPA device.

If bottle is removed, COPA will stop process and allow 5 minutes to resume. If not resumed, Full Rinse Cycle will start over.



6 **When Clean step is done, COPA will display Remove Bottle.**

Refer to "How to remove bottle" on pg 13 to remove clean bottle. Set clean bottle aside for next 30 day cleaning. Once bottle is removed, the device will blow air through the line to push any extra liquid out. COPA will now display Continue Rinse/Disinfect.

Important Information: Rinse Cycle

7 **Remove cap from Rinse bottle and fill contents to prepare for the 1st rinse cycle.**

Refer to "Remove and place bottle cap" and "how to fill bottle" Rinse cycle 1 section on pg 13.

⚠ Do not use anything other than distilled water. Distilled water does not come with COPA device.

8 **Place blue cap on rinse bottle.**

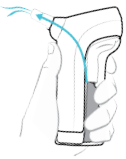
Refer to "How to remove and place bottle cap " on pg 13

9 **Insert rinse bottle into device.**

Refer to "How to insert bottle" on pg 13

10 **Rinse cycle will start automatically.**

Water will flow through the device and out of mouthpiece.
(Have something to catch water nearby)



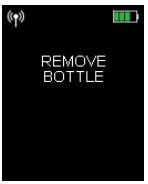
⚠ **Keep Device upright while cleaning.**

⚠ **Do not remove bottle while cleaning is in progress.**

⚠ **Do not put device in mouth while cleaning.**

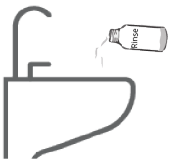
11 **When first Rinse is done running through device, COPA will display Remove Bottle.**

Refer to "How to remove a bottle" on pg 13. Once bottle is removed, COPA will push air through the device and then display Continue Rinse/Disinfect.



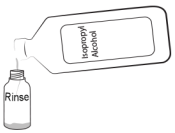
12 **Remove cap from rinse bottle and empty out contents.**

Refer to "How to remove and place bottle cap " on pg 13



13 **Fill rinse bottle with isopropyl alcohol.**

Refer to "How to fill bottle" Rinse cycle 2 section on pg 13



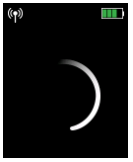
14 **Insert rinse/disinfect bottle into device.**

Refer to "How to insert bottle" on pg 13

Important Information: Rinse Cycle

15 **Disinfect cycle will start automatically.**

Water will flow through the device and out of mouthpiece.
(Have something to catch water nearby)



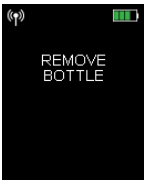
⚠ **Keep Device upright while cleaning.**

⚠ **Do not remove bottle while cleaning is in progress.**

⚠ **Do not put device in mouth while cleaning.**

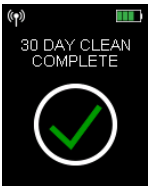
16 **After Disinfect cycle is done running through device, COPA will display Remove Bottle.**

Once bottle is removed, COPA will push air through device, and then display Continue Rinse/Disinfect.



17 **Remove cap from rinse bottle, empty out contents, fill the same rinse bottle with distilled water and insert bottle into device.**

18 **After full rinse cycle is complete, wipe COPA device with soft cloth if any remaining fluid is on exterior of mouthpiece or device.**

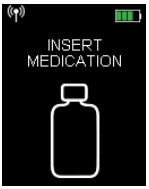


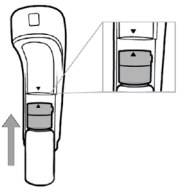
19 **Remove rinse bottle from COPA device.**

Refer to “How to remove bottle” on pg 13

20 **Device will prompt to insert medication.**

Insert medication bottle (for more information, go to page 7) and then slide clear cover onto device.





21 **Device will display dose availability screen. Proceed with regular use.**

Airplane Mode

⚠ **When necessary please put device in airplane mode.**

You can still dispense medication when the device is in airplane mode unless device is above 6561 ft (2000 meters).

If device is on, press the On button to activate airplane mode.

Button is located on back of the device.

If device is in low power mode, press the On button once to turn on the device, and again once display is lit to activate airplane mode.

Screen will confirm that airplane mode is active

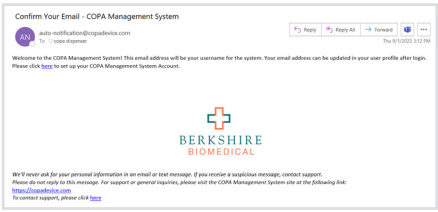
Airplane icon will replace the cell signal in the corner of the display

Press On button to turn off airplane mode

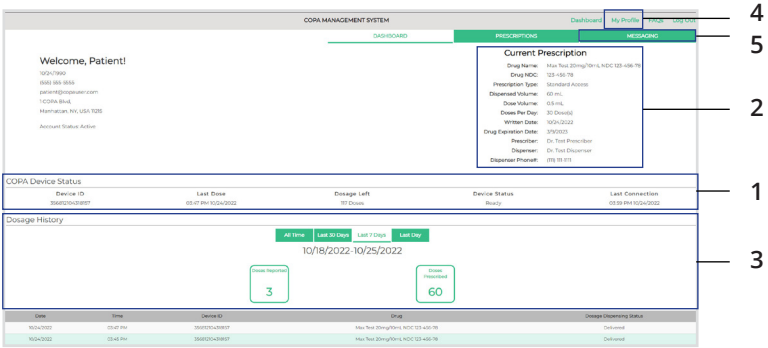
Management System: Patient Dashboard

How to set up

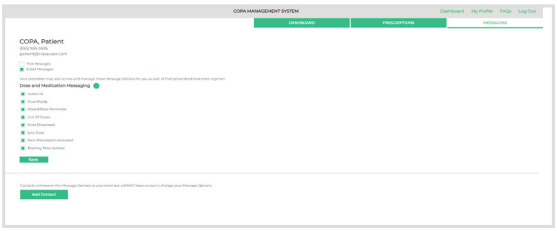
When an authorized Dispenser sets up COPA for use, the patient's email address will be included in the file. **The COPA Management System will send a Welcome Email to the email address used, with a link for the Patient User, like the one below, to set up their password and access the patient dashboard information. Patient Access to the management system is not required for use of COPA for dose dispensing!**

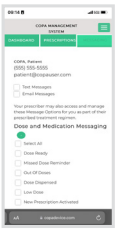


Within the Management System, patient users can **(1) see their own device, (2) prescription, (3) dosing histories, (4) review and edit their own account information** (email address/address), and **(5) select optional messaging and reminders** for email or text delivery to assist them in use of their COPA.

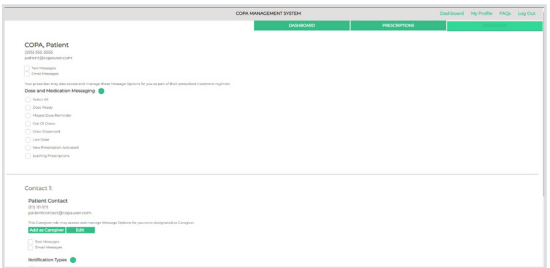


COPA Patient Dashboard can be accessed and viewed via cell phone as well.

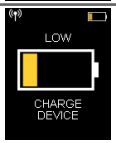
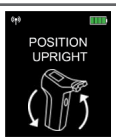
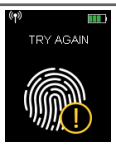
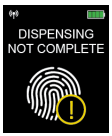
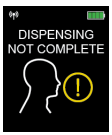




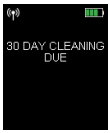
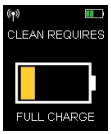
Prescribers, Care Coordinators or others in the patient healthcare network can also be authorized to receive optional messaging; healthcare representatives may assist patient user in initial set up of optional messaging and reminders that most fits the needs for the specific situation.



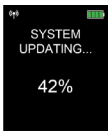
Troubleshooting: Other Messages

Display	Meaning	Suggested Solution
	Medication Bottle was not identified by the COPA device	Clean off SynCap with towel and reinsert bottle. If problem continues, please contact Berkshire Biomedical at (214) 389-1748
	Medication is incorrect or expired	Check medication label and follow the label instructions on medication handling
	Total doses for the bottle has reached 0	Remove bottle and insert new bottle See page 8 of Patient Instructions for Use Device may ask you to rinse See page 13-14 of Patient Instructions for Use
	COPA device battery is too low to dispense	Charge COPA device See Page 6
	COPA device battery is low	Charge COPA device See page 6
	COPA device is tilted too much during dispensing steps	Position COPA device upright to dispense properly
	Dispensing not started due to finger ID not approved in 20 seconds	Try finger ID again
	Dispensing not complete due to finger ID not approved after failure in 20 seconds	Wait for DOSE READY screen reappears and try finger ID again
	Dispensing not completed due to time to resume dose elapsed, or dentition identification fails 5 consecutive times	Wait for medication to return back to bottle and screen to show DOSE READY screen
	Dispensing not started due to mouth ID not approved in 45 seconds	Try mouth ID again

Troubleshooting: Other Messages

Display	Meaning	Suggested Solution
	Dose paused due to removal of mouth from the mouthpiece	Reapply mouth to the mouthpiece within 60 seconds to resume dose
	Dose paused due to charger being connected to the COPA device	Disconnect charger and reapply mouth to the mouthpiece within 60 seconds to resume dose
	COPA Clean per page 13-16 needs to be completed in the next 7 days	Rinse the COPA device using the rinse bottle See page 13 - 16 of Patient Instructions for Use
	COPA Clean requires device being fully charged	Charge COPA device See page 6
	COPA device will not dispense until 30 Day Clean per page 13-16 is complete	Rinse the COPA device using the rinse bottle See page 13 - 16 of Patient Instructions for Use
	COPA device will release air after cleaning and rinsing cycle, once that is done this screen will appear	Fill and insert next bottle. Follow page 13 - 16 of Patient Instructions for Use to see the next step of rinse cycle
	Bottle has been removed during the cleaning or rinsing cycle	Insert bottle again within five minutes of removing the bottle, otherwise rinse cycle will restart
	After clean or rinse cycle is complete, device will indicate to remove bottle	Remove current bottle and follow page 13 - 16 of Patient Instructions for Use to see the next step of rinse cycle
	Reached daily limit of medication	Wait until DOSE READY screen appears to take next dose See Page 9-10 of Patient Instructions for Use
	Poor or no cellular connectivity	Ensure airplane mode is off. Move to an area with better cell service. Device will sync when it auto-detects service.

Troubleshooting: Other Messages

Display	Meaning	Suggested Solution
	Device syncing with management system	Wait until device has completed syncing and DOSE READY screen reappears
	No prescription is available	Dispenser prescription input is incomplete or incorrect. Contact Dispenser.
	System updating	Wait until device has completed updating and DOSE READY screen reappears
	Device is inoperable	Contact Berkshire Biomedical Call (214) 389 -1748
	Low power mode	Device has been inactive for over 1 min. Press On button to turn on

Refills and Disposals

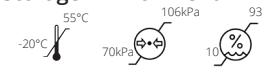
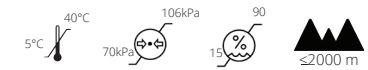
Additional SynCapped bottles will be prepared by the dispenser, as prescribed or authorized for refill, for patient pick-up and use with the existing COPA. For disposal of the medication bottle: check with your local law enforcement officials to find a location near you or with the DEA to find a DEA-authorized collector in your community. You can also check with your pharmacist. Some pharmacies have mail- back programs and disposal kiosks for unused medicines.

Dispose of COPA device per local town electronic waste guidelines

Li-ion

Recycle device at local recycling drop off center that accepts Lithium-ion batteries

COPA Device Specifications

Height	7.50 Inches
Width	2.41 inches
Internal Battery	Rechargeable Lithium ion Battery (Battery will last for 48 Hours before needing to be recharged)
Battery Service Life	Service life of the battery is 3 years
Storage Environment 	Store between -4°F to 131°F (-20 °C to 55°C) Relative Humidity Storage Range: 10% - 93% Atmospheric Pressure: 70 kPa to 106 kPa
Use Environment 	Use the device between 41°F to 104°F (5°C to 40°C) Relative Humidity Operating Range: 15% - 90% Atmospheric Pressure: 70 kPa to 106 kPa Rated to operate to an altitude of 6561 ft (2000 m)
Time Out	The COPA device will automatically time out after 1 minute of no operation.

Dosing Delivery Time	1mL in less than 10 seconds
Warm Up and Cool Down of Device	In minimum storage temperatures, device will take up to 30 minutes to warm up and be ready for use. In maximum storage temperatures, device will take up to 30 minutes to cool down and be ready for use.
Voltage Rating	5VDC
Regulatory	i. Degree of electrical insulation: Type BF (body floating) ii. Protection against water ingress: IP52 iii. Mode of operation: Continuous iv. Power source: Battery v. Protection against electric shock: Class II power supply used vi. Anesthetic Warning: This equipment not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXED WITH AIR or OXYGEN or NITROUS OXIDE. vii. Means of Operator Protection (MOOP) for Power Supply and Means of Protection (MOPP) for COPA device viii. Standards used for COPA device MEDICAL GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH EN 60601-1:2006 + A1:2013 (2013) + A11:2011 + A12:2014. ANSI/AAMI ES60601-1 (2005(R)2012), CAN/CSA-C22.2 No. 60601-1:14 (2014), and IEC 60601-1:2005+A1:2012
IP Rating definition	Classifies and rates the degree of protection provided against intrusion (body parts such as hands and fingers), dust, accidental contact, and water by mechanical casings and electrical enclosures.

COPA Device Specifications

Dosing Delivery Time	1mL in less than 10 seconds
Warm Up and Cool Down of Device	In minimum storage temperatures, device will take up to 30 minutes to warm up and be ready for use. In maximum storage temperatures, device will take up to 30 minutes to cool down and be ready for use.
Voltage Rating	5VDC

Service Life	Service life of this product is 2 years
SynCap Service Life	The SynCap (not packaged with the product) is single use
RinseCap Service Life	The service life of the RinseCap is 1 year
Charging Service Life	The service life of the charging cable is 3 years
Dose Accuracy	+/- 10% of dose volume
Dose Range	COPA device can be used for doses of 0.5mL to 10mL
Charger Model	GTM96180-1807-2.0
Charger Manufacturer	Globtek
COPA device Shelf Life	The shelf life of the COPA device is 1 year

Appendix

Technical Specifications and EMC Tables: The COPA device is intended for use in the electromagnetic environment specified in the following EMC tables. The user of the device should assure that it is such an environment.

Essential Performance of the COPA device: Medical Equipment Performance Criteria - unacceptable operating conditions / responses are: When charging in standby mode the device does not go into operating mode. When in dispensing mode, the COPA device does not stop dispensing. The COPA Device shall deliver the dose with settings as configured by the COPA Management System.

Specification of RF Frequency Bands: Cellular is the only RF Frequency used by the COPA device for transmission and reception. Cellular frequency is 700 MHz

⚠ Do not use near active HF (High-Frequency) surgical equipment and the RF-shielded room of an ME system for Magnetic Resonance Imaging, where the intensity of EM disturbances is high.

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

⚠ Portable radio-frequency communications equipment (including peripherals such as antenna cables and external antennae) should be used no closer than 30 cm (12 inches) to any part of the Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Appendix

Table 1 – Guidance and Manufacture's declaration – Electromagnetic Emissions – For all ME Equipment and ME Systems		
The COPA device is intended for use in the electromagnetic environment specified below. The customer and/or the user of the this device should assure that it is operated in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11 Industrial, scientific, and medical equipment. Radio-frequency disturbance characteristics. Limits and methods of measurement	Group 1, Class B	The COPA device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The COPA device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2 Electromagnetic compatibility (EMC). Part 3-2: Limits. Limits for harmonic current emissions (equipment input current smaller than or equal to 16 A per phase)	Class A	
Voltage fluctuations/flicker Emissions Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low- voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection	Complies	

Table 2: Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The COPA device is intended for use in the electromagnetic environment specified below. The Customer and/or the user of this device should assure that it is operated in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
IEC 61000-4-2 Electromagnetic compatibility (EMC). Part 4-2: Testing and measurement techniques. Electrostatic discharge immunity test	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	The home healthcare environment can be assumed to be uncontrolled with respect to relative humidity and the use of anti-static (or low static) humidity can be quite low in some locations, as low as 5 %.
IEC 61000-4-4 Electromagnetic compatibility (EMC). Part 4-4: Testing and measurement techniques. Electrical fast transient/burst immunity test	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains ±1 kV for input/ output lines	Mains power quality should be that of a typical home healthcare environment.

IEC 61000-4-5 Electromagnetic compatibility (EMC) - Part 4-5 Testing and measurement techniques. Surge immunity test	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical home healthcare environment.
IEC 61000-4-11 Electromagnetic compatibility (EMC). Part 4-11: Testing and measurement techniques. Voltage dips, short interruptions, and voltage variations immunity tests	0 % UT for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle and 70 % UT for 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT for 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT for 1 cycle and 70 % UT for 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical home healthcare environment. If the user of this equipment requires continued operation during power mains interruptions, it is recommended that this equipment be powered from an uninterrupted power supply or a battery.
NOTE: UT is the AC Mains voltage prior to application of the test level.			

IEC 61000-4-8 Electromagnetic compatibility (EMC). Part 4-8: Testing and measurement techniques. Power frequency (50/60 Hz) magnetic field immunity test	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.

Conducted RF IEC 61000-4-6 Electromagnetic compatibility (EMC). Part 4-6: Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields.	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the COPA device, including cables, than the recommended 30 cm separation distance. Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz	6 Vrms Amateur Radio & ISM Bands between 150 kHz and 80 MHz	
Radiated RF IEC 61000-4-3 Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radiofrequency, electromagnetic field immunity test	10 V/m 80 MHz to 2.7 GHz Telecommunication frequencies as specified in clause 8.10 of IEC 60601-1-2:2014	10 V/m	

Appendix

Table 3: Test Specification for Enclosure Port Immunity to RF Wireless Communcations Equipment						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment						
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Modulation (W)**	**Distance (M)**	**Immunity Test Level (V/M)**
385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5 kHz deviation 1kHz sine	2	0.3	28
710 **745** **780**	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
810 **870** **930**	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 **1845** **1970**	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2670	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

SIM Card

SIM CARD

This device uses a Telit SIM card. This SIM card does not have continuous, without interruption or ubiquitous service. It is subject to risks including, but not limited to, lack of coverage, disruption, breakdown, data loss, harm to data integrity, delayed transmission, latency, and other performance limitations, especially as the Service relies on third party networks which AT&T is unable to control and for which it is not responsible (the “Service Limitations”). Telit and AT&T offers no guarantees of specific performance levels of Service nor that calls to emergency serve agencies will be completed. Customer is solely responsible for determining.

Appendix

COPA device and IFU icons	
	ISO 7010-M002 Refer to instruction manual/booklet
	Warning : Indicates a potentially hazardous situation which if not avoided, may result in death or serious injury.
	Caution: Indicates a potentially hazardous situation which if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.
	ISO 7000-2606 Do not use if package is damaged
	MR unsafe, Items should not enter the MRI scanner room.
	IEC 60417 - 6091 Keep out of reach of children
	Device can only be used by the person who is prescribed it.
	This device uses a Lithium ion battery. Recycle device at local recycling drop off center that accepts Lithium-ion batteries
	IEC 60417-6343 Maximum altitude
	ISO 7000-2609 Non-sterile
	IEC 60417-5036 Dangerous voltage
	ISO 7000-0624 Keep away from sunlight
	ISO 7000 - 0626 To indicate that the transport package shall be kept away from rain and in dry conditions
	ISO 7000-2492 Batch code

	Catalog number
	Waste electrical and electronic equipment
	ISO 7000-2621 Humidity limitation
	ISO 7000-0632 Temperature limit
	ISO 7000-2620 Atmospheric pressure limitation
	ISO 60417-5140 Non-ionizing electromagnetic radiation
	IEC 60417-5333 Type BF applied part
	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.
	ISO 7000-3082 Manufacturer
IPxx	IP rating - more information found on page 19
Icons on charging device	
IPxx	IP rating - more information found on page 19
	IEC 60417-5172 Class II equipment
	ISO 7000-0790 Read operator's manual
	IEC 60417-5957 For indoor use only
	ISO 7000-2607 Use by date

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