

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 R23 Patient IFU



For Oral Use only

Indications for use: The COPA System functions as a Remote Medication Management System and is intended for use as an aid to medical providers in managing therapeutic regimens for patients in home or clinic. The system provides a means: for the patient's prescribed medications to be stored in a delivery unit; for a medical provider or professional dispenser to remotely schedule the patient's prescribed medications; to provide notification to the patient when the prescribed medications are due to be taken; to release the prescribed medications to a mouthpiece of the delivery unit accessible to the patient on the patient's command; and to provide to the medical provider a history of the event.

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.



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.



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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 Smart Cap appears broken or damaged.

 Device must use bottle with COPA Smart Cap.

 COPA Smart Cap cannot be removed from medication bottle.

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


Rx ONLY 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 6561 ft (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. Potential choking hazard. Use with caution.

Storage and Handling

Clean the Mouthpiece before and after each use with water. Do not use bleach or other harsh chemicals when cleaning the device.

The medication for the device is stored inside the unit; additional medication should be stored in accordance with specified instructions from the drug manufacturer.

Follow the storage conditions for your medication found on the prescription information sheet or bottle label.

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

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



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



Keep device dry.



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



Do not store device in hot or cold areas. 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.

COPA device Kit

The COPA device kit contains the following components:



COPA device



Medication
Bottle



Rinse Bottle



Charging
Cable

COPA device Components



Important Information You Need to know: User Interface

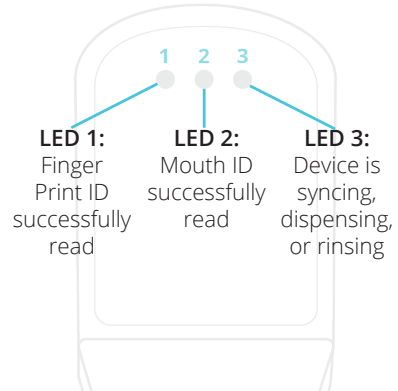
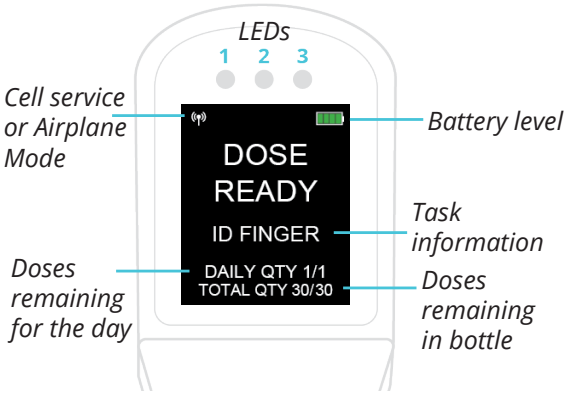
Wake Device Up



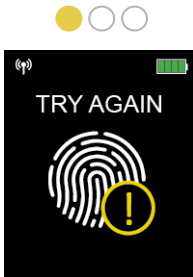
To wake device up press the fingerprint scanner. The screen will go into low power mode after one minute of inactivity.

This device does not have a power off button. If the screen does not turn on after pressing the fingerprint scanner, make sure the device is fully charged. See page 14 for charging information.

Display Screen Details

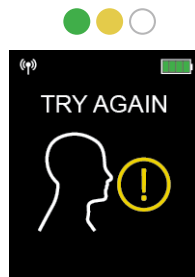


Finger ID not accepted

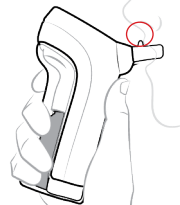
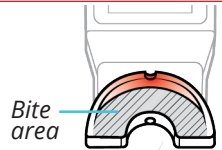


Lift finger and reposition it on scanner

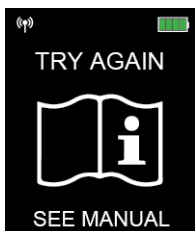
Mouth ID not accepted



Remove mouth, reposition mouth and apply more pressure



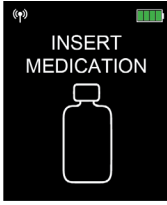
Do not place teeth beyond bite area



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

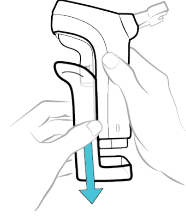
Inserting a New Bottle

- 1 When prompted insert medication



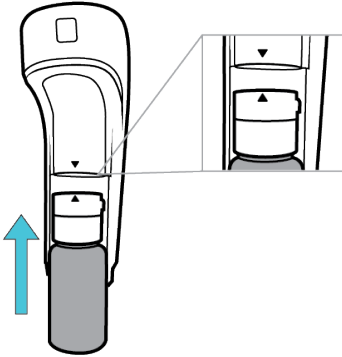
This screen will also show if bottle is not fully inserted

Slide clear cover to remove the cover from the device.

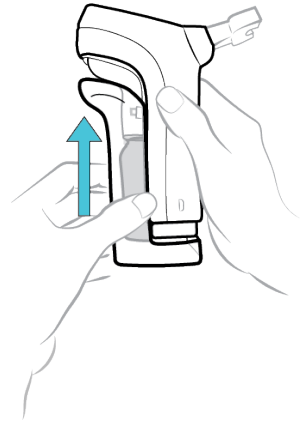


⚠ Do not put fingers in area where the medication bottle is inserted, when no medication bottles are connected. Doing so may cause shock or injury.

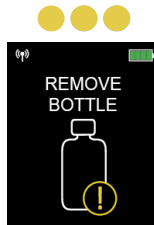
- 2 Align arrow on cap with arrow on device and slide bottle into device until you hear a click and the bottle is secure.



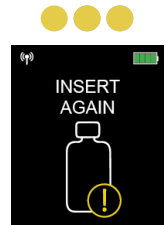
- 3 Slide clear cover onto device



Medication is incorrect or expired. Check bottle label.



There is not enough medication in bottle for next dispense. Remove bottle and rinse system.



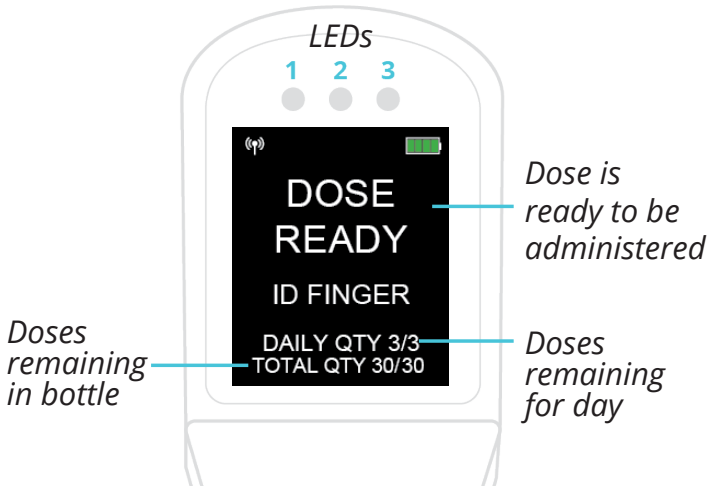
Medication could not be read. Clean off smart cap with towel and reinsert bottle.

Important Information You Need to Know: Dosage

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

This screen will show you if the dose is ready to be taken, how many doses are remaining in time period and the number of doses remaining in bottle.

The system will not dispense medication until Finger ID is confirmed and Mouth ID is sensed.

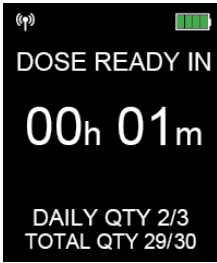


The screen will change after you take a dose to show your updated availability



In the example above, 1 dose has been taken. 2 more doses can be taken today. There are 29 doses left in the bottle.

Dose Availability Information



This screen will indicate the time required until your next dose is available. The minimum amount of time will be 1 min.

Dose per day:

Prescription is 1 or more doses a day with at minimum a 1 minute wait time between dose for safety.

Frequency:

Prescription is multiple doses a day with at minimum a 1 hour wait time between doses.

Daily Planner:

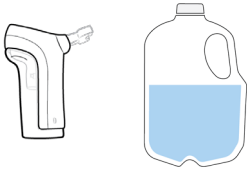
Prescription is multiple doses a day with specific suggested times that dose should be taken at in script. There is at minimum a 1 minute wait time between doses for safety.

Dispensing Steps

The device requires confirmation of patient ID prior to dispensing a dose. Follow these steps for dispensing:

1

Clean the Mouthpiece with distilled water.



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

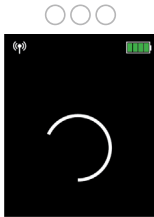
Place finger on fingerprint scanner



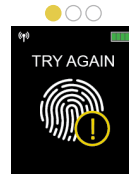
2

When 1st LED light turns green and hear the COPA device prepare to dispense, the finger ID was successful.

COPA device will not dispense until Mouth ID is successful



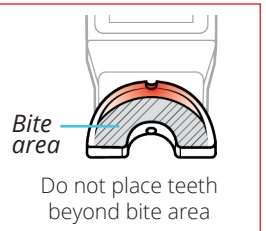
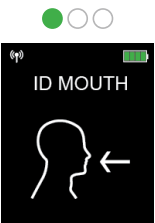
Fingerprint ID not accepted



Lift finger and reposition it on scanner

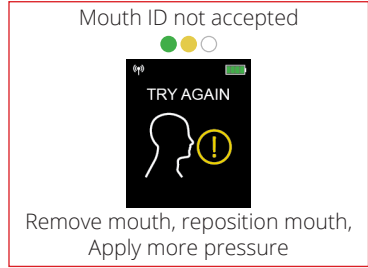
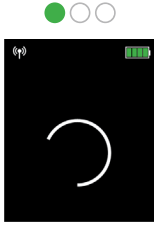
3

To confirm patient identification, place teeth on mouthpiece and firmly bite down



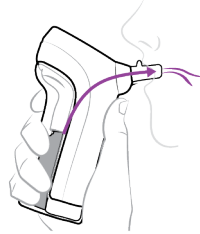
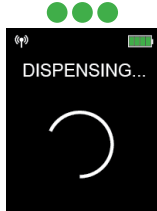
Dispensing Steps

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

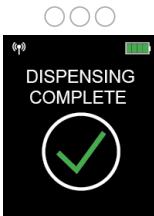


5 When 3rd LED light turns on dispensing is in progress

Do not remove mouth until dispensing is complete

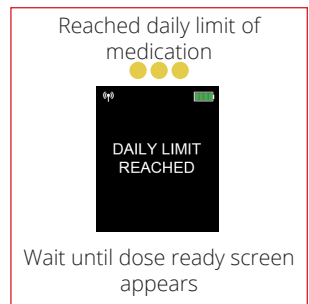
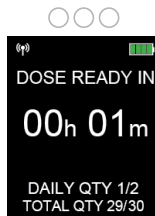


6 Look for check-mark when dispensing is complete.



All 3 LED lights will turn off

7 After dispensing there will be a minimum 1 minute timer until your next dose will be ready.



8 After the prescribed time is completed, the screen will indicate when the next dose will be available. This will vary based on your prescription. See page 8 - 9 for more information.

Maintenance: Rinse Cycle



As configured by your pharmacist, the device will signal when a Rinse is required; generally when an entire prescription has been completed or when changing to another prescription.

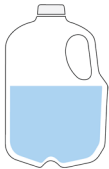
Using the empty rinse bottle which came with your COPA device and distilled water, follow the instructions below to perform a rinse. The rinse bottle will have a blue cap.

1 Remove blue rinse cap from rinse bottle

Turn blue rinse cap counter-clockwise to remove cap



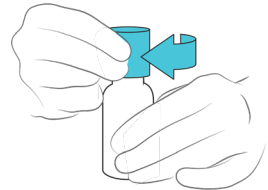
2 Fill bottle with distilled water



Distilled water does not come with COPA device

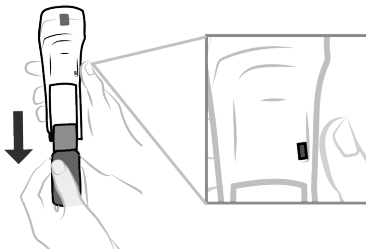
3 Replace blue rinse cap

Turn cap clockwise



4 Remove medication bottle

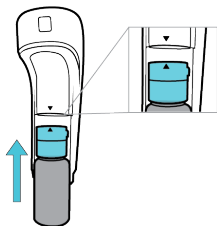
Place one hand below bottle and press bottle release button on device.



Maintenance: Rinse Cycle

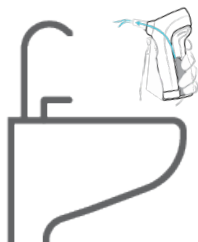
5 Hold device over sink and insert rinse bottle

Align arrow on cap with arrow on device and slide bottle into device until you hear a click and the bottle is secure.



6 Rinse cycle will start automatically

Hold device over sink. Water will flow through device and out mouthpiece.



⚠ Do not remove bottle while rinse is in progress.

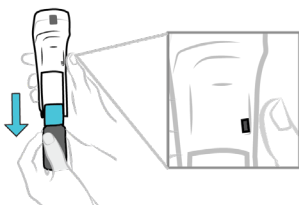
⚠ Do not put device in mouth while rinsing

7 Rinse cycle finished



8 Remove rinse bottle

Press bottle release button on device.



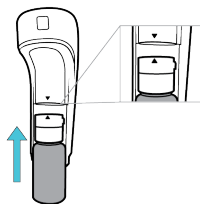
9 Air will automatically flow through the device to remove any liquid remaining inside.

When complete, wipe mouthpiece until it is dry.

10 Pour out any water remaining in rinse bottle. Let sit until it is completely dry.

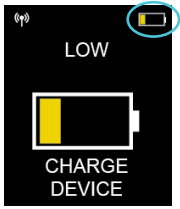


11 Insert new medication bottle.



See page 7 for more information

Maintenance: Charging



When COPA device battery is low, charge device using provided power cable.

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.

⚠ Do not use extension cords. Plug the AC adapter directly into the electrical outlet.

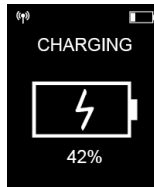
⚠ Do not pull the power cord of AC adapter strongly.

⚠ Do not position the equipment (battery charger) so that it is difficult to disconnect from the electrical outlet.

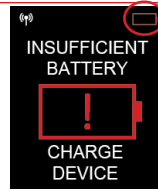
⚠ The supplied USB charger is part of the COPA device equipment and should only be used to charge the COPA device.

1 Using charging cable plug device into outlet

To check for battery status press fingerprint scanner while charging.

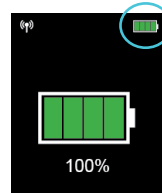
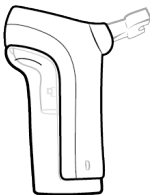


Charging battery status example



If device battery is too low the device will not dispense medication until device is charged.

2 Unplug device once fully charged



Maintenance: Cleaning device

Store device in a dry location free of dust and away from direct sunlight. Use a soft dry cloth to clean the plastic housing or a cloth slightly dampened with distilled water.

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.

Disposal

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.



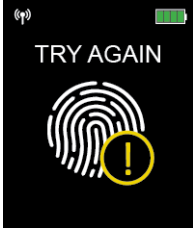
Dispose of COPA device per local town electronic waste guidelines



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

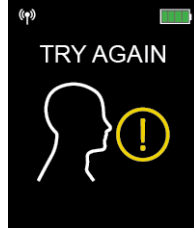
Troubleshooting: ID Errors

Finger ID not accepted

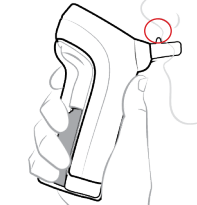
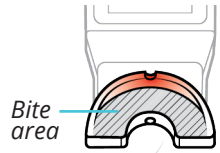


Lift finger and reposition it on scanner

Mouth ID not accepted



Remove mouth, reposition mouth and apply more pressure





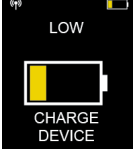

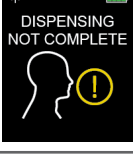
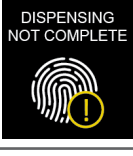



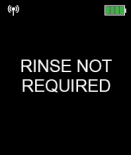



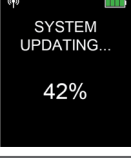


Do not place teeth beyond bite area



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


Troubleshooting: Other Messages

Display	Meaning	Suggested Solution
	<p>Medication Bottle was not identified by the COPA device</p>	<p>Clean off Smart Cap with towel and reinsert bottle. If problem continues, please contact Berkshire Biomedical at (214) 389-1748</p>
	<p>Medication is incorrect or expired.</p>	<p>Check medication label and follow the label instructions on medication handling</p>
	<p>Total quantity for the bottle has reached 0</p>	<p>Remove bottle and insert new bottle See page 7 Device may ask you to rinse See page 12-13</p>
	<p>COPA device battery is too low to dispense</p>	<p>Charge COPA device See Page 14</p>
	<p>COPA device battery is low</p>	<p>Charge COPA device See page 14</p>
	<p>COPA device is tilted too much during dispensing steps</p>	<p>Position COPA device upright to dispense properly</p>
	<p>Dispensing not completed due to removal of mouth from mouthpiece</p>	<p>Wait for medication to return back to bottle and screen to show DOSE READY screen</p>
	<p>Dispensing not complete due to finger ID not approved in 20 seconds</p>	<p>Wait for DOSE READY screen reappears and try finger ID again</p>

Display	Meaning	Suggested Solution
	<p>A different prescribed medication bottle was inserted into the system, the medication last used in the system has expired, the COPA device has been inactive for at least 30 days, or a partial dose occurred.</p>	<p>Rinse the COPA device using the rinse bottle See page 12 - 13</p>
	<p>Rinse bottle was inserted when a rinse was not required</p>	<p>Remove rinse bottle and insert medication bottle</p>
	<p>Reached daily limit of medication</p>	<p>Wait until DOSE READY screen appears to take next dose See Page 8</p>
	<p>Poor or no cellular connectivity</p>	<p>Ensure airplane mode is off. Move to an area with better cell service. Device will sync when it has service.</p>
	<p>Device syncing with management system</p>	<p>Wait until device has completed syncing and DOSE READY screen reappears</p>
	<p>System updating</p>	<p>Wait until device has completed updating and DOSE READY screen reappears</p>
	<p>Device is inoperable</p>	<p>Contact Berkshire Biomedical Call (214) 389 -1748</p>
	<p>Low power mode</p>	<p>Device has been inactive for over 1 min. Touch finger scanner to turn on.</p>

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).

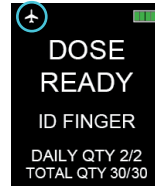
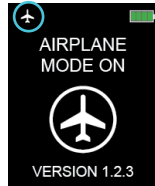
Press airplane mode button to turn on

Button is located on back of the device.

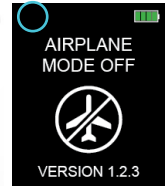


Screen will confirm that airplane mode is active

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



Press airplane mode button to turn off



Management System


Management system is not required for dispensing medication


The connection to the management system is through cellular communication and that connection is required for the device to receive updated prescriptions. If the COPA device is not connected to the Management System, it will be unable to receive updated prescription data and provide usage information to the Management System.

The COPA Management System is designed to send prescription information and software updates to the COPA device. The COPA Management System also allows registered users to review their own dosing records.

The connection from the Management System to the COPA device is via a cellular network.

The transmitted information has no patient specific information.

 If you observe this icon (no cell service icon), please observe that there is no cellular service and that the updated prescriptions cannot be received and that data and software updates cannot be performed.

 Failure to connect to the cellular network will result in the inability to upload dose data and download new prescriptions. To resolve this issue, change location to an area of better service.

For troubleshooting or weak areas of cellular service, we recommend that you go in an area of better cellular 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.

Management System

What is on management system:

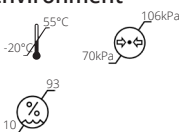
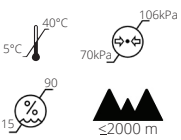
- See dosage history
- See device status
- See current prescription
- See prescription history
- Update profile
- Add caregiver/ give someone access to see information
- FAQs
- Optional notifications by e-mail or text:
 - Dose ready
 - Low dose/empty
 - Completed dose delivery
 - Etc.

How to set up


- An email is sent to patient email with link to set up account
- Log onto <https://www.copadevice.com>

FOR FURTHER USE INFORMATION SEE MANAGEMENT SYSTEM

COPA device Specifications

Height	6.00 Inches
Width	2.00 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.

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
Regulatory	 <ul style="list-style-type: none"> i. Degree of electrical insulation: Type BF (body floating) ii. Protection against water ingress: IP54 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 IP54	5 Dust protected ingress of dust is not entirely prevented, but it must not enter in sufficient quantity to interfere with the satisfactory operation of the equipment; complete protection against contact. 4 protection against water splashes from all directions. Limited ingress permitted
Charger IP42	4 Protection against a solid object greater than 1mm. 2 protection against vertically falling drops of water with enclosure tilted up to 15 degrees from the vertical. Limited ingress permitted
Service Life	Service life of this product is 1 year
Smart Cap Service Life	The Smart Cap (not packaged with the product) is single use
Rinse Cap Service Life	The service life of the rinse cap is 3 years
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 1mL to 5mL
Charger Model	GTM96180-1807-2.0
Charger Manufacturer	Globtek
COPA device Shelf Life	The shelf life of the COPA device is 3 years

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

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.


RF emissions CISPR 11	Group 1, Class B	These components use RF energy only for their internal functions. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	These components are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker Emissions IEC 61000-3-3	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
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 6 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) flooring and material. The relative humidity can be quite low in some locations, as low as 5 %.

Appendix

Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical home healthcare environment.
Surge IEC 61000-4-5	± 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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	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.
Immunity test	IEC 60601 Test level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 6 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) flooring and material. The relative humidity can be quite low in some locations, as low as 5 %.
NOTE: UT is the AC Mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 	3 V 0.15 MHz – 80 MHz 6 V in ISM bands and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of this equipment, including cables, than 30 cm (12 inches) to any part of the COPA device. Otherwise, degradation of the performance could result. Interference may occur in the vicinity of equipment marked with the following symbol:

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
Rx ONLY	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
LOT	ISO 7000-2492 Batch code

CAT	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 20
Icons on charging device	
IPxx	IP rating - more information found on page 20
	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

For any questions please contact : Berkshire Biomedical 5950 Berkshire Ln, ste 450, Dallas, TX 75225



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