TO BE ROUTED ON DCO FOR APPROVAL AT TWENTY TWENTY

1. Description
   1.1.
2. Appendix A - VS Tracker IFU

VS Tracker

Instructions for Use

Model Number: VS Tracker 100

CAUTION - Investigational device. Limited by United States law to investigational use.

Contents

Instructions for Use

1. Introduction **3**
2. Device Description **3**
3. Intended Use **4**
4. Use Requirements and Restrictions **4**
4.1. Contraindications 4
4.2. Warnings 4
4.3. Precautions 5
5. Technical Description **6**
6. Eye Drop Bottle Compatibility **6**
7. Components and Images **7**
7.1. Component List 7
7.2. Device Images **8**
8. Device Assembly and Usage **9**
8.1. Unpacking the VS Tracker 9
8.2. Charging the battery 9
8.3. Setting up the VS Tracker Smart Dropper mobile phone app 10
8.4. Eye drop bottle setup 18
8.5. Turning the device on 20
8.6. Applying eye drops 21
8.7. After eye drop application is complete 23
9. Cleaning and Maintenance **24**
10. Troubleshooting **24**
11. Environmental Restrictions **26**
12. Liability **26**
13. Disposition **26**
14. Symbols and Standards **27**
14.1. Symbols 27
14.2. Standards 29
15. Contact Information **31**

82.1802-000001

1. Introduction

The Twenty/Twenty Therapeutics **VS Tracker** is a single user handheld medication reminder device for eye drop application. It should be used only by a single user, but that user can use the device multiple times. It may be used at home and work. It works with a variety of commercially available over-the-counter and prescription eye drops. The VS Tracker device works with a companion mobile app, called **VS Tracker** that is available on the Apple App Store and the Google Play Store. The data collected from the device is presented to the user via the app, and the app also provides push notifications to remind the user when it is time to apply eye drops.

2. Device Description

The complete system is comprised of the following items:

- Applicator
- Collar
- Charger (USB-C)
- VS Tracker Mobile Phone App

The VS Tracker assists with managing daily eye drops, providing a reminder when it is time to apply eye drops (via a companion mobile phone app) as well as by assisting with applying eye drops. It is able to communicate with an iOS or Android smartphone via Bluetooth. It includes various sensors and light indicators (LEDs) to assist the user with applying eye drops. It supports a selected range of both over-the-counter and prescription eye drop bottles.

The VS Tracker consists of a ***Collar*** and an ***Applicator***. Multiple Collars are provided to fit a variety of medications (see section 6 for eye drop bottle compatibility). The Collar goes around the neck of an eye drop bottle, and then it magnetically attaches to the Applicator. The Applicator contains the sensors and LEDs that provide guidance to the user in applying eye drops. Once the Collar is attached to the Applicator, the user can turn on the device, tilt their head back, place the VS Tracker over the eye, follow the LED indicators to adjust head position, and squeeze the eye drop bottle to dispense eye drops to the eye.

The companion app is easy to install on compatible smartphones via the Apple App Store or the Google Play Store. After a quick setup process, the app will remind the user when it is time to apply eye drops. It also keeps track of the drops applied by the user and conveniently displays that information to the user in the app's main dashboard.

3. Intended Use

The VS Tracker is intended to be used as a handheld medication reminder device for eye drop application. It sends reminders to the user to apply eye drops (via a mobile application), provides guidance to the user to help them apply their drops successfully, and tracks medication usage over time. The VS Tracker may be used with prescription or over-the-counter medication.

4. Use Requirements and Restrictions

Prior to operating the VS Tracker, carefully read these Instructions For Use. As with all medical devices, the proper function and safe operation of this device depends on the user complying with all safety instructions described in this document.

If you have problems using the VS Tracker, please refer to the Contact Information section near the end of this document.

The VS Tracker is intended for human, personal use only.

Use the VS Tracker only for reminding and assisting the user with eye drops as described in this document. The manufacturer is not liable for any damage arising from improper use, or for the consequences of such use.

Do not use the VS Tracker near flammable substances, including flammable anesthetic agents.

4.1. Contraindications

The VS Tracker must not be used by patients with conditions that would preclude safe use of the device, which includes: adults with balance or coordination problems and patients with neck/shoulder motility difficulties that would preclude them from leaning back.

4.2. Warnings

- Always use the VS Tracker and accessories in accordance with the directions contained in this document.
- Do not use the VS Tracker while standing or walking;
- Ensure you're seated in a stable chair that allows safe reclining without risk of tipping over, or operate the VS tracker while in a supine position.
- VS Tracker is intended for a single user. Sharing the device may result in an ocular infection.
- Keep the VS Tracker and all related components (i.e., Applicator, Charger, Collar) out of reach of children and pets. The VS Tracker contains small parts that may be swallowed.

- The VS Tracker should be inspected prior to each use to ensure that it is free from any foreign material before use, and must not be used if damaged or dropped. If the VS Tracker is damaged or dropped, do not use it. Contact the sponsor, refer to the Contact Information section for details.
- Do not use the VS Tracker if it is damaged or has visible defects. A damaged or cracked device can malfunction or create an electrical safety hazard. Do not use it to deliver eye drops while it is charging.

4.3. Precautions

- Do not expose the VS Tracker to extreme cold or hot temperatures, high humidity, or direct sunlight. Store and use at room temperature.
- Never immerse the VS Tracker in liquid. Do not spray, pour, or spill liquid on the VS Tracker, its button, or enclosure. Do not immerse the VS Tracker in liquids while charging.
- Enable a passcode or biometric security on your smartphone in order to protect data stored in the VS Tracker mobile app.
- Apply iOS and Android operating system updates on your smartphone in a timely manner in order to maintain the security of your data.

5. Technical Description

Product Name	Components
Dimension	Length: 54.2 mm± 5%, Width: 63.3 mm± 5%, Height: 59.6 mm± 5%
Weight	< 90g
Power source	Rechargeable Lithium Battery, 3.7V / 340mAh (min), The battery is in compliance with IEC 62133-2:2017.
External Power : Source	100~240 Vac, 50/60Hz
Power adapter spec.	Brand Name: UNIFIVE TECHNOLOGY CO., LTD Model Name: UM305-0512 Input Spec: 100~240Vac; 50/60Hz, 0.2A Output Spec: 5Vdc, 1.2A
Charging time	3.5 hours
Expected service life	1 year from the date of initial use.

6. Eye Drop Bottle Compatibility

The below list contains the bottles which the VS Tracker currently supports:

- Systane Preservative-Free (PF) formulations, 10 mL bottle
- COSOPT iMulti (Nemera bottle), 10 mL bottle
- TheraTears, 15 mL
- Systane, 15 mL
- COSOPT, 5 mL bottle
- Ganfort, 3mL bottle
- Xalatan, 2.5 mL bottle
- Taflotan (Aptar bottle), 3 mL bottle
- Refresh Relieva PF, 10mL bottle
- OPTASE MGD Advanced Dry Eye Drops, 2.5 mL bottle

7. Components and Images

7.1. Component List

Product Name	Components
VS Tracker	1. Applicator 2. Collars: Detachable collars for various bottles 3. Charger (USB-C) 4. Instructions for Use 5. VS Tracker Mobile Application

7.2. Device Images

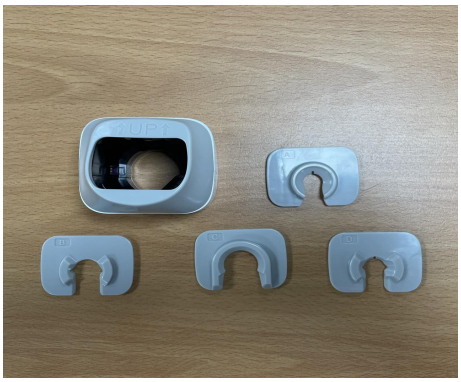
Front view of the VS Tracker Applicator with Collar

Top view

Bottom view (eye drop delivery side)

Charging port (door closed)

Charging port (door open)



Various Collars (for different bottle types)

Charger (included)

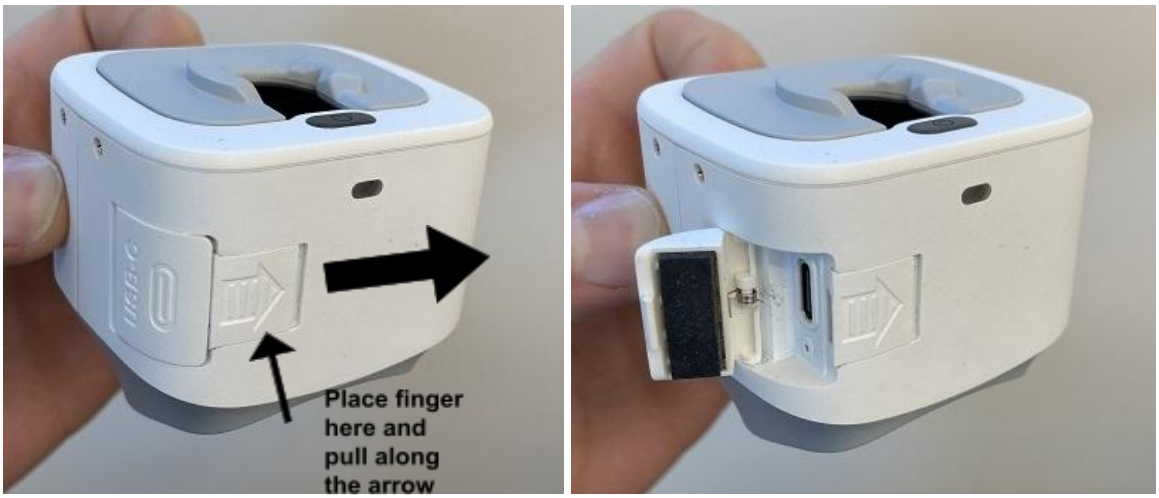
8. Device Assembly and Usage

8.1. Unpacking the VS Tracker

1. Carefully unpack the device.
2. Inspect the device to ensure that the VS Tracker does not appear to be damaged or broken. If there are breaks on the enclosure or other visual defects, DO NOT USE.

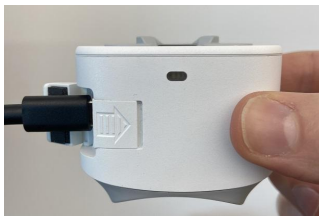
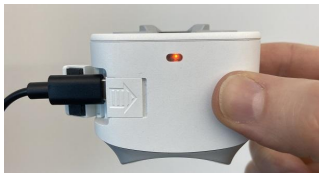
8.2. Charging the battery

1. Open the charging port cover by placing your finger on the arrow in the front, and pulling it in the direction of the arrow.



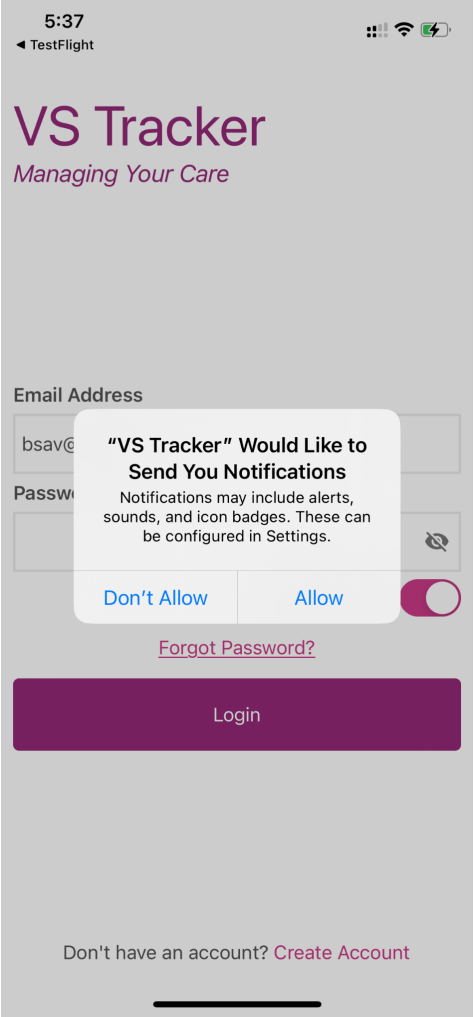
2. Connect the USB-C charger to the charging port on the side of the VS Tracker, and plug into an outlet.

3. The Status LED will turn orange (when charging). When fully charged, the Status LED will be off.
4. Charge the device for at least 3 hours.

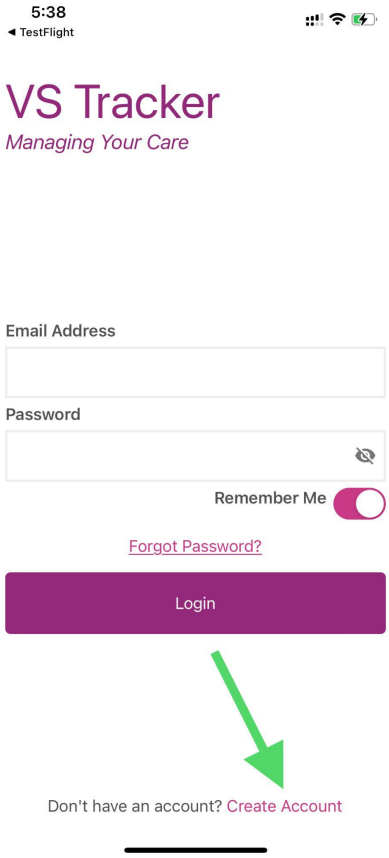
Status LED color while charging	Image	Charge status
LED off		Fully charged
LED Orange		Battery charging

8.3. Setting up the VS Tracker Smart Dropper mobile phone app

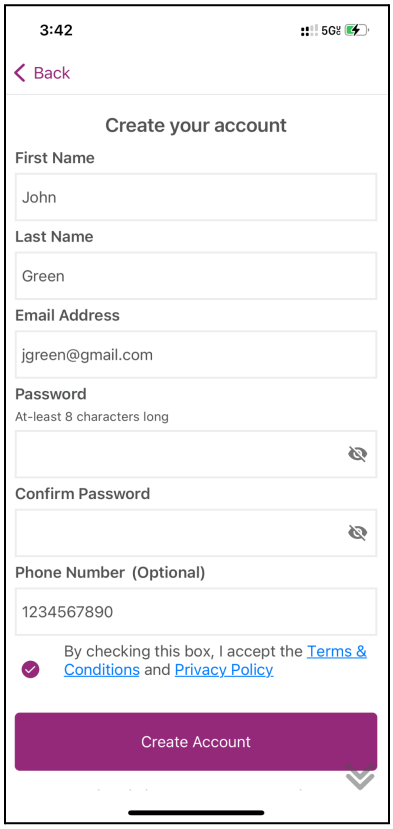
1. Download the VS Tracker application from the Apple App Store or Android Play Store
2. Launch the app.
    a. If a message pops up, click to allow notifications from the app.


5:37
TestFlight
VS Tracker
Managing Your Care
Email Address
bsav@
Passw
"VS Tracker" Would Like to Send You Notifications
Notifications may include alerts, sounds, and icon badges. These can be configured in Settings.
Don't Allow
Allow
Forgot Password?
Login
Don't have an account? Create Account

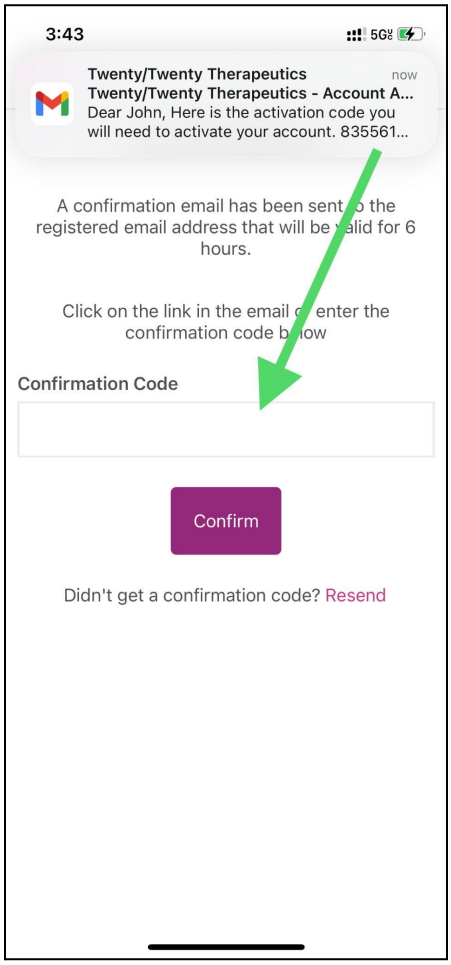
b. Create an account using the Create Account link on the bottom of the screen.



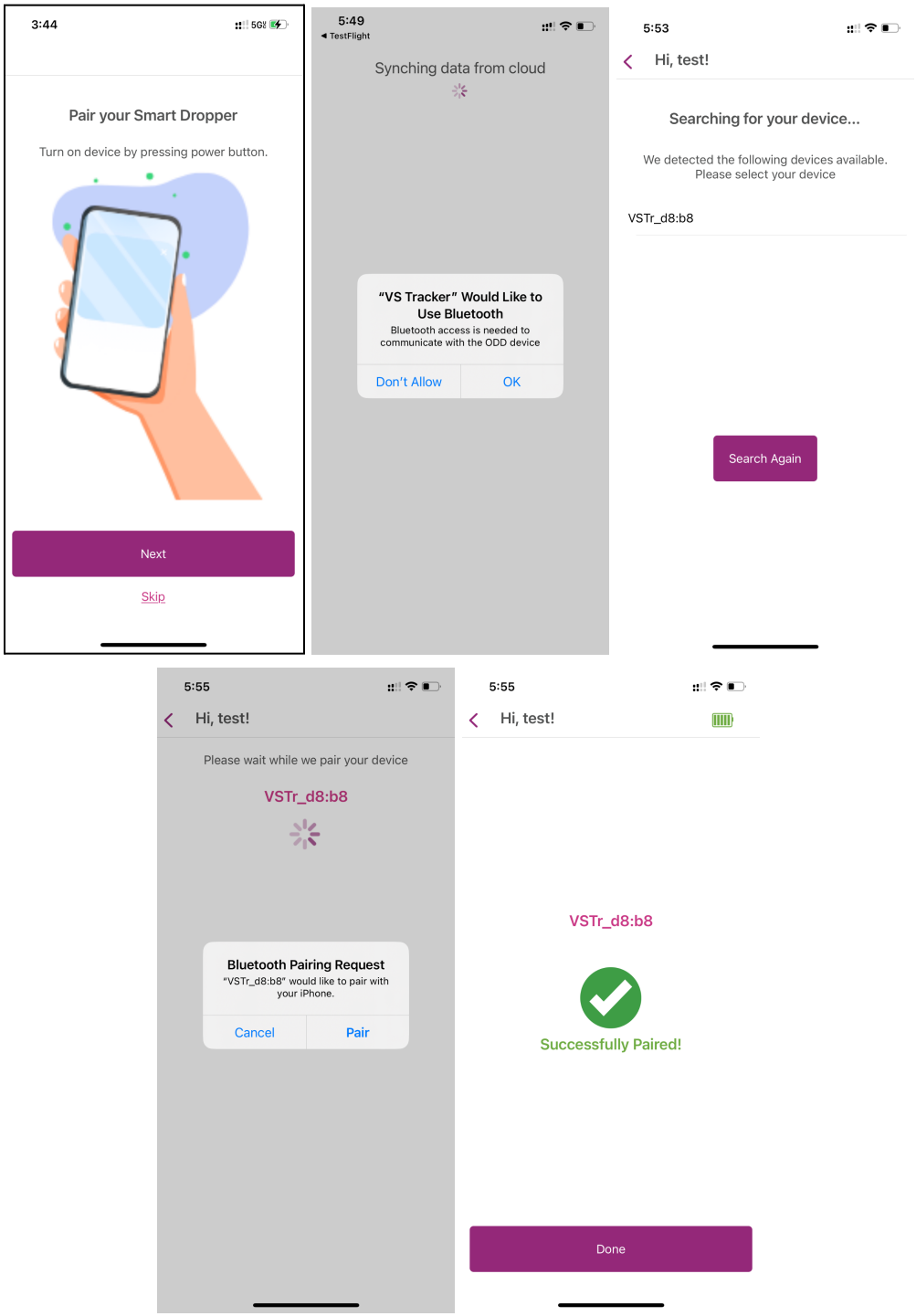
3. Fill in the details in the "Create your account" screen. Click the “Create Account” button.



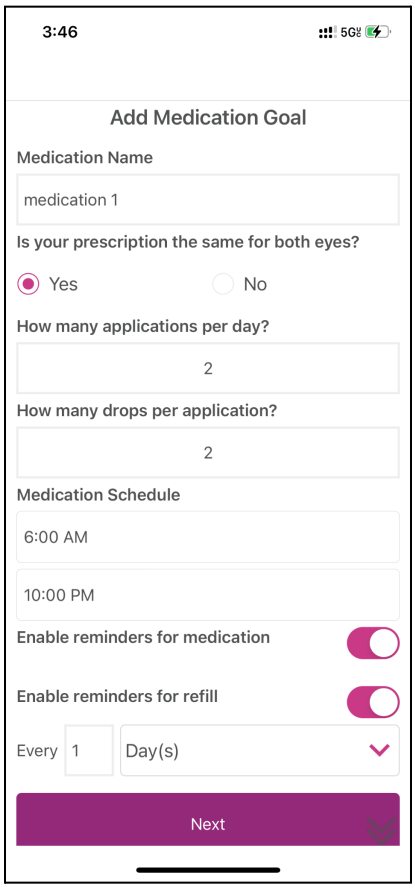
4. You will receive an email with a confirmation code, which you will need to type in the following screen.



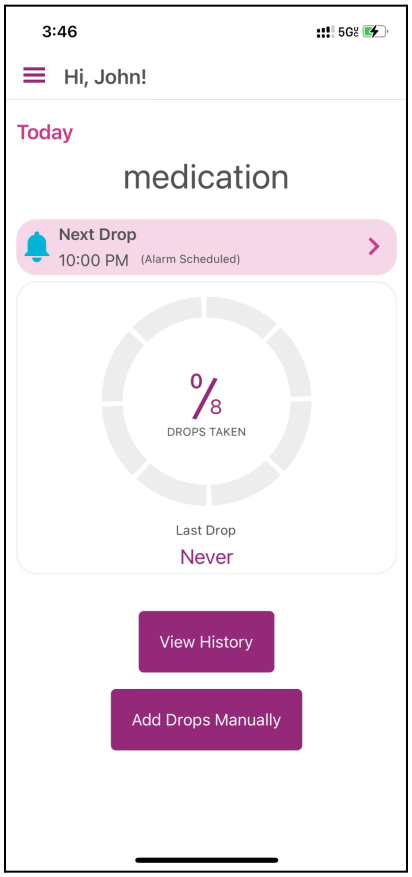
5. Pair your VS Tracker with the app:
    a. Make sure that the VS Tracker is turned on (press the power button on the VS Tracker).
    b. Click “Next” within the “Pair your Smart Dropper” screen.
    c. When a pop-up message appears, select OK to allow Bluetooth usage. Wait a few seconds.
    d. Select the device starting with “VSTr_…” within the “Searching for your device…” screen.
    e. Tap “Pair” within the “Bluetooth Pairing Request” dialog.
    f. Check that the “Successfully Paired” screen is displayed.



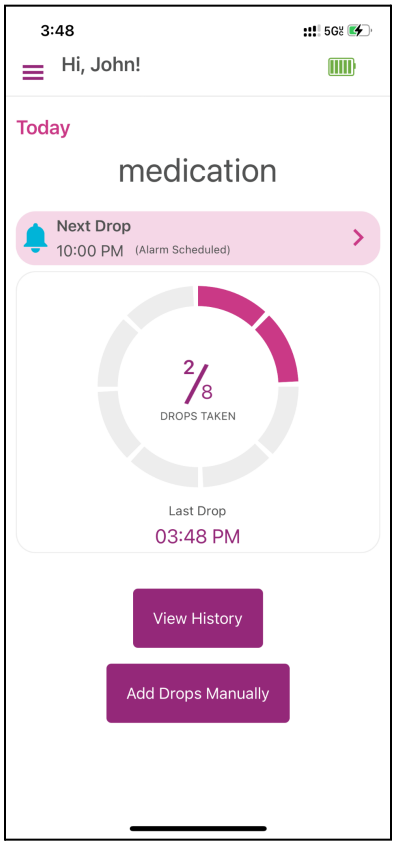
6. To set up medication reminders, fill all required fields within the "Add Medication Goal" screen. Enable reminders for medication and refill in order to receive notifications about your medication.



7. After hitting the “Next” button, the Dashboard screen will show when the next eye drop is scheduled, as well as today's history of eye drop applications.



8. At this point (after pairing the VS Tracker with the phone, and setting up the medication schedule), whenever the VS Tracker is used to apply eye drops, the app will automatically sync and update your daily progress on the dashboard. This will happen as long as the VS Tracker is near your phone (within 3 feet), the app is open and active on your phone, and Bluetooth is enabled on your phone.

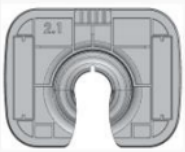
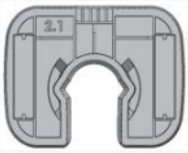
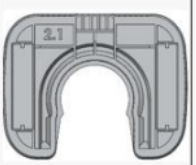
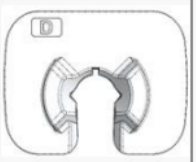
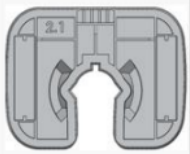


8.4. Eye drop bottle setup

1. Detach the collar from the VS Tracker Applicator:

2. Attach the eye drop bottle to the collar (select the collar that works with the drop bottle), making sure the magnetic strips are pointing up (towards the bottle tip), and the two protrusions are pointing towards the base of the bottle:

Here is a guideline for the compatibility of the collars with some of the commercially available eye drops.

A (Dimple Collar)				Santen dimple bottles Aptar bottle (Taflotan)
B (Neck Collar)				Ganfort bottle TheraTears Systane bottle
C (Wide Collar)			Systane bottles	Nemera bottles (Cosopt) (Systane) Systane bottle
D (Fine neck)			Xalatan, 2.5 mL bottle	Xalatan, 2.5 mL bottle

CAUTION - Investigational device. Limited by United States law to investigational use.

3. Unscrew the bottle top:

4. Attach the magnetic collar, with the bottle, back to the device:

8.5. Turning the device on

1. Activate the device via pressing the gray power button once.
2. The blue light will turn on, meaning the device is being powered up.
3. After a few moments, the green light will turn on, meaning the device is ready to use.

Status LED color (device unplugged)	Device status
●	Device is off

LED off	
LED Blue	Device is booting up, wait a few seconds until it turns green
LED Green	Device is on, ready to be used
LED Green (blinking)	Low battery, please charge device

8.6. Applying eye drops

1. After turning the device on, hold the device such that the green LED is facing you.

2. While sitting (ensure you are sitting on a stable chair or surface) or laying down, tilt your face upwards and align the eyepiece (bottom gray pad) with your eye. The "UP" text on the eyepiece will be pointing towards the top of your head.

3. While looking at the bottle tip, the 4 directional LEDs around it will guide you to align the bottle so that the drop hits your eye. Mode of operation is described below:

a. There are 4 directional LEDs around the bottle tip: left, up, right, down.
b. When a directional LED blinks orange, tilt your head towards that direction.
c. When all 4 directional LEDs are green, it means that the bottle is aligned with the eye, and you may squeeze the bottle.
d. <u>Remember to keep looking at the bottle tip, while following the guidance of the LEDs.</u>

4. When aligned, use your free hand to squeeze the bottle and apply eye drops.
5. If the device is aligned correctly while a drop is released, the device will emit a soft sound, letting you know the device recorded the event.

8.7. After eye drop application is complete

1. The device will turn itself off after 60 seconds of being idle. Alternatively, press and hold the power button for 3 seconds to turn it off.
2. Remove the detachable collar, and take out the bottle.
3. Screw the bottle cap on the medication bottle, and re-attach the collar back to the VS Tracker.

9. Cleaning and Maintenance

- To clean the surface of the VS Tracker, use a cloth, moistened with water or 70% isopropyl alcohol. It is important not to immerse the VS Tracker in water.
- After applying eye drops, remove the eye drop bottle from the collar, and reseal the cap of the bottle.
- Charge the device nightly.

10. Troubleshooting

Scenario	**Action**
Device doesn't turn on after pressing the power button.	Charge the device for at least two hours. If the problem persists, contact the manufacturer or distributor.
Guidance LEDs do not turn on.	Make sure the device is turned on (it turns off after 60 seconds of being idle). If the room is too bright, try finding a darker room to apply the eye drops.
Drop doesn't hit the eye when using the guidance LEDs.	Adjust the bottle angle as needed so that the next drop hits. See section 8.6 Applying eye drops.
The app fails to establish initial handshake (pairing) with the VS Tracker	1) Go to your phone's Bluetooth settings, and remove all devices starting with "VSTr", if any is listed. 2) Turn on the VS Tracker by pressing the power button. Wait until the LED is green. Turn off the device and reset its settings by pressing and holding the power button for at least 15 seconds, and then releasing. 3) Try to pair the device again with the app. See section 8.3
The app fails to synchronize with the VS Tracker, after the device has been used to apply eye drops.	Bring the VS Tracker within 3 feet of the phone, and make sure the app is active on the screen. Also make sure Bluetooth is enabled on your phone.

11. Environmental Restrictions

Operating Environment

- Ambient temperature: 5°C (41°F) to 40°C (86°F)
- Relative humidity: 15% to 90%
- Atmospheric pressure: 700 hPa to 1060 hPa
- Shock (without packing): 10 G, duration 6 ms

Storage Environment

- Ambient temperature: -10°C (14°F) to +55°C (131°F)
- Relative humidity range: 10% to 90%
- Atmospheric pressure: 700 hPa to 1013 hPa

Transportation Environment

- Ambient temperature: -40°C (-40°F) to+70°C (158°F)
- Relative humidity range: 10% to 90%
- Atmospheric pressure: 500 hPa to 1013 hPa
- Vibration, sinusoidal: 10 Hz to 500 Hz: 0.5G
- Shock: 30 G, duration 6 ms
- Bump: 10 G, duration 6 ms

12. Liability

The manufacturer considers itself responsible for the effects on safety, reliability, and performance of the device only if

- Assembly operations, extensions, read adjustments, modifications or repairs are carried out by authorized persons.
- The equipment is used in accordance with these instructions for use.

13. Disposition

Follow the local governing ordinances and recycling plans regarding disposal or recycling of device components, especially when disposing of the lithium ion battery, circuit board, or power cord.

Follow the local governing ordinances and recycling plans when disposing of the circuit board with the lithium battery. Inappropriate disposal may contaminate the environment.

When disposing of packing materials, sort them by material and follow local ordinances and recycling regulations.

14. Symbols and Standards

14.1. Symbols

REF	Catalog Number
GTIN	Global Trade Item Number
SN	Serial Number
	Manufacturer
	Date of manufacture
	Consult instructions for use
IPN_1N_2	IP Classification
	Non-ionizing electromagnetic radiation
	Bluetooth
FC	The identification number assigned by the Federal Communication Commision
	Caution
	Separate Collection

	This way up
	Do not use if package is damaged
	Keep dry
	Fragile
	Temperature limit
	Humidity limitation
	Atmospheric presure limitation

14.2. Standards

Electrical safety	IEC 60601-1:2005+A1:2012+A2:2020 (EN 60601-1:2006+A1:2013+A2:2021)
EMC and regulatory compliance	IEC 60601-1-2: 2014 +A1:2020 (EN 60601-1-2: 2015+A1:2021)
Ophthalmic instruments-Fundamental requirements and test methods Part 2: Light hazard protection	ISO 15004-2:2007
Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments	ISO 15004-1:2020
General radio compliance	Federal Communications Commission (FCC)

Equipment connected to the analog or digital interfaces must be certified according to the representative appropriate national standards (such as EN 60601-1 and IEC 60601-1-2). Furthermore, all configurations shall comply with the system standard IEC 60601-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible for the system complying with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department of your local representative.

Federal Communications Commission (FCC)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the distance between the equipment and the receiver
- Connect the equipment to an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

The correction of interference caused by such unauthorized modification, substitution, or attachment will be the responsibility of the user.

RF Exposure statement: The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

EMC (Electromagnetic Compatibility)

The device complies with the International Electrotechnical Commission standards (IEC 60601-1-2: 2014 +A1:2020) for electromagnetic compatibility as listed in the tables below. Follow the guidance in the tables for use of the device in an electromagnetic environment.

EMC (IEC 60601-1-2: 2014 +A1:2020)

Guidance and manufacturer's declaration electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The 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 device is 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.
Harmonic emissions IEC 61000-3-2	Class A *1	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	*2	

*1 For the regions where the rated voltage is 220 V or greater, this device complies with class A. For the regions where the rated voltage is 127 V or less, this standard is not applicable.
*2 For the regions where the rated voltage is 220 V or greater, this device complies with this standard. For the regions where the rated voltage is 127 V or less, this standard is not applicable.

Guidance and manufacturer's declaration electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ± 2, 4, 8, 15 kV air	±8 kV contact ± 2, 4, 8, 15 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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 commercial or hospital environment.
Surge IEC 61000-4-5	±0.5, 1 kV line(s) to line(s); ±0.5, 1 ,2kV Line to ground	±0.5, 1 kV line(s) to line(s) ; ±0.5, 1, 2kV Line to ground	Mains power quality should be that of a typical commercial or hospital environment.

CAUTION - Investigational device. Limited by United States law to investigational use.

Voltage, dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 cycle (1 phase) 0% UT for 1 cycle 70% UT for 25/30 cycles (50/60 Hz) 0% UT for 250/300 cycles (50/60 Hz)	0% UT for 0.5 cycle (1 phase) 0% UT for 1 cycle 70% UT for 25/30 cycles (50/60 Hz) 0% UT for 250/300 cycles (50/60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 or 60 Hz)	30 A/m at 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration electromagnetic emissions			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3Vrms at 0.15 – 80 MHz & 6V at ISM Frequency	3Vrms (V1=3) at 0.15 – 80 MHz & 6V at ISM Frequency	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=(3.5/V1) $\sqrt{P}$ $\sqrt{P}$ =1.2 $\sqrt{P}$ $\sqrt{P}$ (150 kHz to 80 MHz) d=(3.5/E1) $\sqrt{P}$ $\sqrt{P}$ =1.2 $\sqrt{P}$ $\sqrt{P}$ (80 MHz to 800 MHz d=(7/E1) $\sqrt{P}$ $\sqrt{P}$ =2.3 $\sqrt{P}$ $\sqrt{P}$ (800 MHz to 2.7 GHz) Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as deter- mined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m (E1=3) 80 MHz to 2.7 GHz 80% AM at 1 kHz	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

CAUTION - Investigational device. Limited by United States law to investigational use.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above 3 V/m., the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

15. Contact Information

Distributed by:
Twenty/Twenty Therapeutics, LLC
259 E Grand Ave 94080
South San Francisco, CA 94080 United States

Manufactured by:
Medimaging Integrated Solution Inc.
3F., No.24-2, Industry E. Rd. IV, Hsinchu Science Park, Hsinchu, TAIWAN 30077, R.O.C.

Tel: +886-3-5798860 / 5798865
Fax: +886-3-5798821
Web: http://www.miis.com.tw