ID-Cap Medication Adherence Feedback System

USER MANUAL

TABLE OF CONTENTS

Glossary

Caution

etectRx

Hazard

ID-Cap App

ID-Cap Medication Adherence Feedback System

ID-Cap Reader

ID-Capsule

ID-Tag

Medication Adherence

ID-CAP SYSTEM OVERVIEW

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

User Manual

This User Manual provides important information about the ID-Cap Medication Adherence Feedback System (ID-Cap System) from etectRx. You must read and fully understand the contents of this User Manual before using the System to ensure safe and effective operation of the device.

To support the safe operation of the device, this User Manual categorizes safety instructions into two general types based on potential for harm:

	**ATTENTION** Hazardous situation which can cause material damage or lead to minor or moderate injury

	**WARNING** Hazardous situation which can cause a serious or fatal injury

Device Model Numbers

This User Manual pertains to the following device model numbers:

Model Number for the ID-Cap Reader	ET70002.10
Model Number for the ID-Tag	ET20001.51

Intended Use

The ID-Cap Medication Adherence Feedback System consists of a wearable device for recording of time-stamped ingestion events, including events signaled by the co-incidence with, or co-ingestion with, the ID-Capsule that contains an ingestible sensor. When the ID-Capsule is ingested, the ID-Cap Medication Adherence Feedback System is intended to log, track, and trend intake times. When co-ingested with medication, the tracking and trending of intake times may be used as an aid to measure medication adherence. The ID-Cap Medication Adherence Feedback System enables unattended data collection for clinical and research applications in the home or clinical settings.

The patient is an intended operator of the ID-Cap System.

Device Description

The ID-Cap Medication Adherence Feedback System

Your ID-Cap Medication Adherence Feedback System consists of a wearable ID-Cap Reader, ID-Capsules, and a mobile application. Your ID-Cap Reader is a pendant that is worn around your neck and collects information from the ingested ID-Capsules that are taken with your medication. The ingestible sensor in the ID-Capsule communicates with your ID-Cap Reader after it

reaches your stomach. This allows the system to measure the pattern, regularity, and schedule of your medication taking — your medication adherence. With a simple Bluetooth connection to your mobile device, your ID-Cap Reader sends your ingestion event data to the ID-Cap mobile application to help you keep track of how you are taking your medication. With your permission, this information may be shared with your healthcare providers to help them improve your health outcomes.

ID-Capsule (Ingestible Sensor Capsule)

The ID-Capsule contains an ingestible sensor called the ID-Tag made of ingredients that do not easily react with other chemicals and are found in the food chain. The ingestible sensor communicates with your ID-Cap Reader after it reaches your stomach. It is powered by your stomach fluid.

Key ingredients of the ingestible ID-Tag that are in human contact include magnesium, silver chloride, polyimide, and epoxy. The ID-Tag is delivered in a two-piece gelatin capsule for oral administration. Additional information about ID-Capsules may be requested from the manufacturer.

	WARNING
⚠	DO NOT take an ID-Capsule if you are allergic to any of its ingredients. Please consult with your doctor before using.

ID-Cap Reader

Your battery-operated ID-Cap Reader records the time the ingestible sensor is detected. Information from your ID-Cap Reader will transfer to your mobile phone regularly and automatically as long as the Reader is paired with the mobile phone as indicated by a flashing green light on the Reader.

[ADD PICTURE OF LABELED READER]

The ID-Cap Reader is a pendant that is attached to a grey lanyard provided in the Reader Kit. The lanyard is placed around the neck so the Reader hangs in the center of the chest or just below the sternum. The ID-Cap Reader does not require any adhesives or direct contact with the skin to receive messages from the ID-Tag.

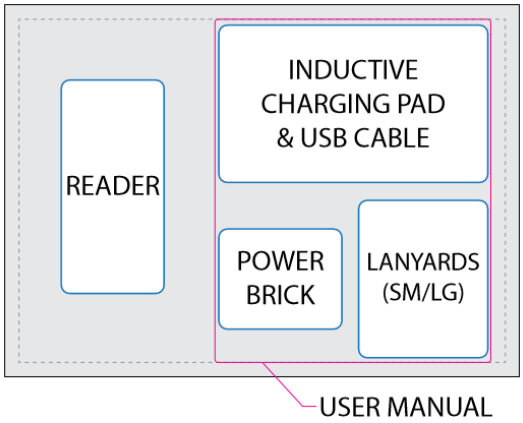
Your ID-Cap Reader may be worn during most activities, including exercise, but should be removed prior to any activities that would expose the Reader to water, including showering, bathing, and swimming.

	ATTENTION
⚠	DO NOT submerge the ID-Cap Reader in or expose it to excessive amounts of water. Your ID-Cap Reader is designed to be weather resistant, but it may not work properly when exposed to water.

ID-Cap Reader Kit

Your ID-Cap Reader Kit contains the device and the following accessories:

- Reader
- Lanyard
- AC Adapter
- USB Charging Cable
- Wireless Charging Pad
- Quick Start Guide
- User Manual



Mobile Phone Application

The ID-Cap Medication Adherence Feedback System may be used with a mobile application that is loaded on a mobile phone. The mobile application reports and displays information about ingestion events and ingestion event

history, sends notifications and messages to the user, and provides updates on the status of the ID-Cap Reader and the System. It also allows the user to manually record an ingestion event that has not been recorded by the ID-Cap System and to report missed or skipped doses.

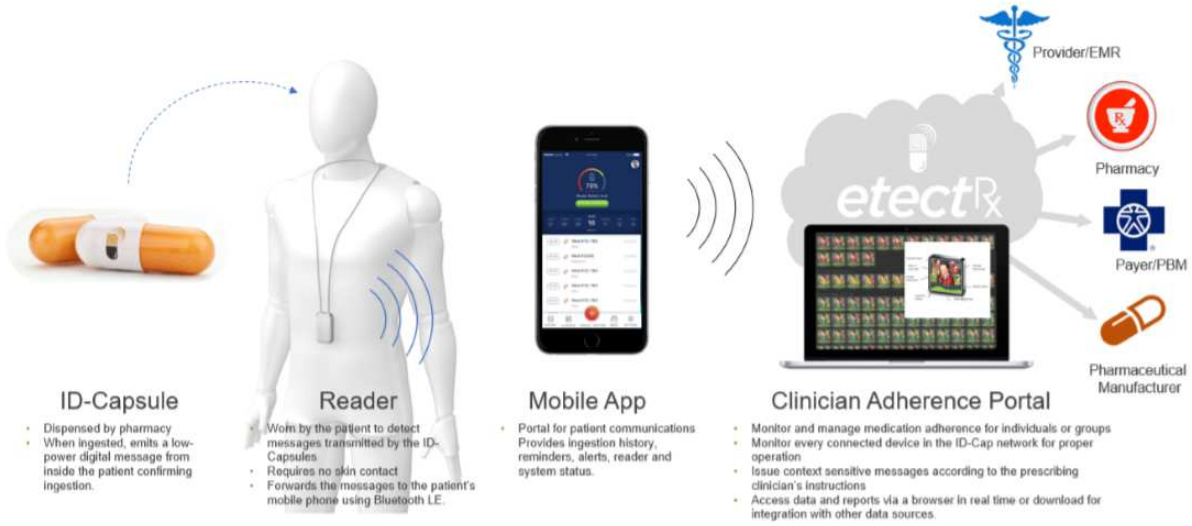
Charging Accessories

Your ID-Cap Reader Kit contains the following accessories for charging the Reader:

- AC Adapter
- USB Charging Cable
- Wireless Charging Pad

This graphic shows the proper set-up of the charging pad in order to effectively charge the device.
[Insert graphic on setup of charging pad]

System Operation Overview



Important Information: Use as An Aid to Measure Medication Adherence

When the ID-Capsule is ingested and the Reader records the time-stamped ingestion event, the ID-Cap System is intended to log, track and trend intake times. When co-ingested with medication, the tracking and trending of intake times may be used as an aid to measure medication adherence.

The ID-Cap System has been designed to provide reliable information that will help you and your physician get the most out of your medication. Proper use by patients and their healthcare providers is essential to the performance and clinical benefit of the ID-Cap System.

Please keep in mind the following while using the ID-Cap System:

• Always take your medication as prescribed by your physician and recommended by your pharmacist regardless of the status and use of the ID-Cap System.

• The ID-Cap System has no effect on your medication.

• With your consent, your doctor or pharmacist may be monitoring your medication use using the ID-Cap System and may contact you regarding the information received.

• As with all wireless communications, an ingestion event message will occasionally not be received by the ID-Cap Reader. Do not be concerned if this happens, and do not change your prescribed medication regimen or alter your medication use. If you are experiencing problems with your ID-Cap System, please refer to the Troubleshooting Section of the User Manual or contact your pharmacist or doctor. With use of the ID-Cap Mobile App, you can manually record ingestion events that were not captured by the ID-Cap System and report missed or skipped doses.

The ID-Cap System should not be used as the sole basis for medication treatment decisions. Detection accuracy is less than 100%. Patients instructed by a doctor to take the ID-Capsule with medication may selectively adhere to one or the other. Therefore, ingestible event data should be interpreted with caution. Patients should discuss medication-taking history with their doctor prior to making medication changes.

Conditions of Use

User Groups

There are two distinct user groups based on their potential use of the ID-Cap System: Patient Users and Clinician Users. Patient Users include individuals for whom a monitored medication is prescribed and who utilize the ID-Cap System to capture ingestion events. The intended user population of patients includes adults 18 years of age and older across a wide range of diverse

demographics and medical conditions who are taking an oral medication that will be monitored.

The user group of Clinician Users include healthcare providers such as pharmacists, nurses, clinical case managers, and physicians, who will be involved in the monitoring of patient adherence to medication regimens and who may facilitate use of the ID-Cap System. Based on their education and experience, Clinician Users have been trained to care for patients, manage medication use, and interpret information regarding adherence to prescribed therapy.

Skills, Training, and Knowledge Required of Patient Users

The patient and/or his or her caregiver must be able to read, understand, and follow the instructions provided in this User Manual. The patient and/or his or her caregiver must be able to understand and follow instructions regarding the taking of oral medications. Use of the ID-Cap System is reserved for users who have the ability to follow medication ingestion instructions while also interacting with the ID-Cap System. This System should not be prescribed to users who might not take their medication as directed due to confusion with the System.

Locations of Use

The ID-Cap System has been designed for use in the home and clinical settings. It is not intended for use on aircraft or in other areas where RF communications are restricted. See Technical Information in Section X of the User Manual for additional restrictions on locations of use due to electromagnetic interference.

The patient may use this device while traveling, but the system should not be used on aircraft or in other locations where RF communications are restricted. The power cable for the charging pad may not be compatible with foreign power sources. If this is the case, the user may need an adapter or a converter to convert to the proper voltage.

Operational Contexts of Use

The ID-Cap System can be utilized with or without use of the optional etectRx mobile application on the patient's smartphone.

If the System is operating in a mode without use of the patient's smartphone, ingestion event data will be recorded and archived by the ID-Cap Reader. In this operational mode, ingestion event data will be uploaded to the monitoring database by the Clinician User after the ID-Cap Reader is

returned by the Patient User either at defined intervals during therapy or at the conclusion of the medication regimen.

If the System is operating in a mode involving use of the etectRx mobile application on the patient's smartphone, ingestion event data will be captured by the ID-Cap Reader, transmitted to the mobile app, and displayed in the monitoring database.

Conditions that Could Affect User Interactions with the Device

The following conditions could affect user interactions with the ID-Cap System:

- Technical issues affecting the Reader (e.g., battery)
- Technical issues affecting the ID-Tag or ID-Capsule or messaging between ID-Tag and Reader
- Technical issues affecting the smartphone and/or mobile app when operating with the mobile app
- Connectivity issues when operating with the mobile app
- Distractions in the user environment that could interrupt the use process

When the Device Should Not Be Used (Contraindications)

	WARNING
⚠	DO NOT use the ID-Cap System in patients or situations in which it is contraindicated.

Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit. The ID-Cap System should not be used in the following situations:

- DO NOT use the ID-Cap System if you are pregnant or breastfeeding. Use in these populations has not been studied.
- The ID-Cap System has not been studied in individuals who are undergoing magnetic resonance imaging (MRI), cautery, or external defibrillation procedures. The ID-Cap System has not been tested or approved for use in the presence of strong magnetic or electrical fields. DO NOT wear the ID-Cap Reader during magnetic resonance imaging (MRI), cautery, and external defibrillation procedures. Damage to the Reader or an unexpected magnetic attraction may result. Please inform

your healthcare professional that the ID-Cap Reader must be removed prior to engaging in one of these procedures.
- DO NOT use the ID-Cap System if you have a cardiac pacemaker or other implanted electronic medical device. The ID-Cap System has not been studied in individuals with implanted electronic medical devices.
- DO NOT use the ID-Cap System or ingest the ID-Capsule if you are unable to take oral medications.
- DO NOT take if you are allergic to any of the ingredients in the ingestible ID-Capsule.
- DO NOT use the ID-Cap Reader if it has been submerged in liquid or exposed to excessive amounts of water.
- DO NOT use if you have a significant medical condition which may affect capsule passage through the gastrointestinal tract.

Risks and Benefits

The ID-Cap System measures and reports the pattern, regularity, and schedule of your medication taking — your medication adherence. With a simple Bluetooth connection to your mobile device, your ID-Cap Reader sends your ingestion event data to the ID-Cap mobile application to help you keep track of how you are taking your medication. With your permission, this information may be shared with your healthcare providers to help them improve your health outcomes.

The ID-Cap System should not be used as the sole basis for medication adherence determinations or treatment decisions. Detection accuracy is less than 100%. Patients instructed by a doctor to take the ID-Capsule with medication may selectively adhere to one or the other. Therefore, ingestible event data should be interpreted with caution. Patients should discuss medication-taking history with their doctor prior to making medication changes.

The risks of the ID-Cap System must be evaluated in light of these benefits and limitations. The safety and tolerability of the ID-Cap System has been evaluated in clinical studies of device performance. The reported adverse effects can be found in Section X of the User Manual.

General Warnings and Precautions

General – ID-Cap System

- Keep components out of reach of children.

- DO NOT use if you are pregnant or breastfeeding.
- Store components as directed in the User Manual.
- DO NOT use as sole basis for medication treatment decisions. Detection accuracy is less than 100%. Patients instructed by a doctor to take the ID-Capsule with medication may selectively adhere to one or the other. Therefore, ingestible event data should be interpreted with caution. Patients should discuss medication-taking history with their doctor prior to making medication changes.
- If you experience clinical worsening or new clinical symptoms, seek medical attention.
- The ID-Cap System has not been studied in individuals who are undergoing magnetic resonance imaging (MRI), cautery, or external defibrillation procedures.
- The ID-Cap System has not been studied in individuals who have implanted electronic medical devices.
- DO NOT use the ID-Cap System while on aircraft or in other locations where RF communications are restricted.
- Talk with your doctor or pharmacist if you have any questions or concerns about the use of the ID-Cap System.

ID-Capsule

- DO NOT ingest if you are unable to take oral medications.
- DO NOT tamper with, open, or expose to any liquid before ingestion.
- DO NOT chew the ID-Capsules.
- DO NOT take more than eight ID-Capsules per day.
- Take with a sufficient amount of water.
- DO NOT take if you are allergic to any of the ingredients in the ingestible ID-Capsule.

ID-Cap Reader

- Keep the Reader charged and ready for use. The Reader may not function properly and may not record ingestion events if it does not have a sufficient charge.
- Do not attempt to replace the battery or open the Reader case. The Reader contains no user-serviceable parts.
- Your ID-Cap Reader is designed to be weather resistant, but DO NOT submerge in or expose to excessive amounts of water.
- Use caution when placing the lanyard near or around the neck area. The lanyard upon which the ID-Cap Reader hangs, as well as the cables for the charging pad, present a risk of strangulation. Use these accessories as instructed. There is a break-away on the lanyard that will open when force is applied to it to help minimize this risk.

- If the ID-Cap Reader or any of the charging accessories becomes damaged during normal use, discontinue use of the Reader and contact your pharmacy for a replacement.

Compliant Use

Ordered by Physician

WARNING

- Federal law (USA) restricts this device to sale or use by, or on the order of a physician.
- Your healthcare professional should evaluate you, as well as the risks and benefits of the device, to ensure that the decision to use the ID-Cap System is appropriate.

Avoiding Unsafe Use Conditions

The ID-Cap System is not intended for use in the diagnosis or treatment of any medical conditions.

The ID-Cap System has not been tested or approved for use in the presence of strong magnetic or electrical fields. DO NOT wear the ID-Cap Reader during magnetic resonance imaging (MRI), cautery, and external defibrillation procedures. Damage to the Reader or an unexpected magnetic attraction may result. Please inform your healthcare professional that the ID-Cap Reader must be removed prior to engaging in one of these procedures.

WARNING

WARNING: No modification of the ID-Cap Reader or the ID-Capsule is allowed. DO NOT tamper with or open the ID-Capsule. Modifying the ID-Cap Reader or the ID-Capsule may cause a safety hazard for the user.

ATTENTION

CAUTION: Your ID-Cap Reader may be worn during most activities, including exercise, but should be removed prior to any activities that would expose the Reader to water, including showering, bathing, and swimming. The ID-Cap Reader is designed to be weather resistant, but DO NOT submerge in liquid or expose to excessive amounts of water or other liquids.

Important Safety Instructions

Electromagnetic Compatibility

The ID-Cap System is compliant with electromagnetic compatibility standards IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

ATTENTION

There are no known significant risks of reciprocal interference posed by the ID-Cap System. When using the ID-Cap System near other medical electrical equipment, consult the manufacturer's instructions for Electromagnetic Compatibility of all devices to ensure potential electromagnetic or other interference is avoided or minimized.

WARNING

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

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.

Electrical Connection

ATTENTION

Use of USB Charging Cable without the Charging Plug decreases charging speed.

Charging

WARNING

Use supplied charger, or the functionality of the Reader may be affected.

Environment

ATTENTION

Do not submerge Reader in water.
Designed to operate between 15°C and 30°C.

Malfunction

The ID-Cap System is designed to have basic user interaction. Refer to Troubleshooting Section. If you continue to experience malfunction, contact your dispensing pharmacy.

WARNING

Contains no user-serviceable parts. Do not attempt to open the Reader case, or injury may result.

INSTRUCTIONS FOR USE

IMPORTANT: DO NOT delay taking prescribed medication if you encounter any difficulty using the ID-Cap System.

Initial Setup

To set up your ID-Cap System, complete the following steps:

1. Turn on the Reader by holding down the power button for two seconds.

2. When turned on for the first time, the Reader LED should be flashing blue indicating it is ready to pair with your mobile device. If the LED is flashing orange, refer to the User Manual for instructions on how to charge the Reader using the wireless charger provided in your Reader box before use.

PROCEED with steps 3 and 4 if you are using your mobile device to receive and communicate ingestion event information.

3. Install the ID-Cap App on your mobile device.
    - Download the ID-Cap App from the iOS App Store or Google Play.
    - Open the App, and follow the prompts to enter your 6-digit Reader ID and 12-digit activation code (both found on the Reader box) and accept the terms of use.

4. Once you have activated the App, pair the ID-Cap Reader to your mobile device.

    - Ensure the Reader and your mobile device are close to each other.
    - Ensure Bluetooth is enabled on your mobile device.
    - If the ID-Cap App is not running, open it.
    - When prompted, enter the pairing code 032669 to complete the pairing.
    - When successfully paired, the LED on the Reader flashes green, and the home screen on the ID-Cap App will indicate that the Reader is paired.

Congratulations! Your ID-Cap System is now ready for use.

Reader LED Indications.

Reader LED	LED Color and Pattern	Reader Status
●	No light	Reader off
●	Flashing green	Ready for ingestion, paired with mobile device
●	Flashing blue	Ready for ingestion, not paired with mobile device

○	Flashing white	Ingestion detected
	Solid orange (on charger) or flashing orange (off charger)	Low battery – charge Reader before using
	Flashing orange/green (paired) or orange/blue (not paired) pattern	Low battery but sufficiently charged for use

Routine Use

1. Ensure the Reader is ready for use as indicated by the LED flashing green.
2. Using the supplied lanyard, wear the Reader around your neck and hanging in front of your chest such that the etectRx logo molded into the Reader case is facing away from your body. The Reader may be worn on the inside or outside of your garments. Do not wear the Reader during any activities that would expose it to water, such as showering, bathing, and swimming.
3. Take an ID-Capsule at the same time as you take each dose of the prescribed medication that is being monitored as directed by your physician or pharmacist.
4. Within a few minutes, the Reader will detect the swallowed ID-Capsule, and the Reader LED will blink white. If the Reader has remained paired to the mobile device running the ID-Cap App, you will receive a confirmation message and the ingestion event will be shown in your Ingestion History on the App.
5. You can take off the Reader as soon as you have received the ingestion confirmation (from the flashing white LED or the confirmation on your mobile device) or 30 minutes after the ID-Capsule is swallowed, whichever occurs sooner.
6. Be sure to keep the Reader charged for next use. You may want to keep the Reader on the charging pad when not in use. Do not turn the Reader off between uses. The Reader will go into a standby mode to conserve power when not in use.

   If you do not receive a confirmation of ingestion, use the App to self-report the ingestion by entering the date and time that the ID-Capsule was taken.

IMPORTANT: If you have taken an ID-Capsule and did not receive a confirmation, DO NOT take additional doses of your prescribed medication or another ID-Capsule until the time your next dose is scheduled.

End-of-Therapy Device Return

After taking the last dose of your ID-Capsule, return the ID-Cap Reader and accessories to etectRx by packaging it in the Reader Kit box and returning it as instructed to etectRx.

Monitoring the Activity of the Device

Device status information is sent to the manufacturer and individuals who have been granted access to your adherence data. This information includes movement of the device as measured by an accelerometer within the device and battery charging status, as well as additional information about the Reader and its operation.

It is important for the user to monitor the activity of the device. LED lights on the top of the Reader and messages communicated through the mobile app are the primary sources of information that should be monitored by the user. For example, it is critical that the Reader remain paired with the mobile phone app as evidenced by the blinking green LED light on the Reader.

As with all wireless communications, an ingestion event message will occasionally not be received by the ID-Cap Reader. Do not be concerned if this happens, and do not change your prescribed medication regimen or alter your medication use. If you are experiencing problems with your ID-Cap System, please refer to the Troubleshooting Section of the User Manual or contact your pharmacist or doctor. With use of the ID-Cap Mobile App, you can manually record ingestion events that were not captured by the ID-Cap System and report missed or skipped doses. See relevant section of instructions for use.

Cleaning the ID-Cap Reader

The ID-Cap Reader should be cleaned periodically as needed. To clean the Reader, DO NOT place under water. Use a clean cloth dampened lightly with water and household soap or a mild detergent to wipe the exterior of the Reader case. Immediately dry it off with a clean, dry cloth.

Maintenance

The ID-Cap Reader contains no user-serviceable parts. For maintenance of the device, please contact the manufacturer. The ID-Cap Reader should be returned to the manufacturer according to the instructions provided after the last ID-Capsule is ingested.

To order replacement parts (e.g., Reader device, lanyard, wireless charging pad, USB charging cable, AC adapter, User Manual, or Quick Start Guide), please visit www.myidcap.com.

Storage and Handling

The ID-Cap System is intended for storage and operation in a room-temperature environment.

ID-Cap Reader

Condition	Temperature	Relative Humidity (non-condensing)	Atmospheric Pressure
Operating	5°C - 40°C	15% - 90%	700 – 1060 hPa
Storage	5°C - 35°C	15% - 90%	700 – 1060 hPa
Transport	5°C - 35°C	15% - 90%	700 – 1060 hPa

If the temperature of the ID-Cap Reader exceeds 56°C, the device automatically shuts down and cannot be used until it cools. When the ambient temperature is 20°C, the time required for the ID-Cap Reader to cool from the maximum storage temperature (35°C) between uses until the ID-Cap Reader is ready for its intended use is [ADD BASED ON TEST RESULTS]. At 20°C, the time required for the ID-Cap Reader to warm from the minimum storage temperature (5°C) between uses until it is ready for intended use is [ADD BASED ON TEST RESULTS].

ID-Capsules

Condition	Temperature	Relative Humidity
Storage	15°C - 30°C (59°F - 86°F)	35% - 65%
Transport	15°C - 30°C (59°F - 86°F)	35% - 65%

Store ID-Capsules in original sealed containers at the recommended temperature and humidity. ID-Capsules may be sensitive to temperature changes. Properly stored and sealed containers will provide optimum performance.

Storing capsules under or near sources of water should be avoided as well.

[Add results of stability testing]

Useful Life and Shelf-Life

The ID-Cap Reader has a shelf-life of 18 months from the date of manufacture. The ID-Cap Reader has a service life of 12 months from initial patient use and must be returned to the manufacturer. The following signs indicate a failing device:

- Failure to mark an ingestion event
- Etc.

The ID-Capsules have a shelf-life of 6 months from the date of manufacture when stored in their original packaging.

Disposal of Waste Products

Do not dispose of your ID-Cap Reader, any Reader accessories, or any ID-Capsules. This medical device may contain substances that could be harmful to the environment or human health if improperly handled at the end of the product's life. In order to avoid release of such substances into the environment and to reduce the use of natural resources, all devices, both used and unused, should not be disposed with household waste. Return all ID-Cap Readers and unused ID-Capsules to the healthcare professional who dispensed the products to you or to the manufacturer.

DEVICE PERFORMANCE

Nonclinical Performance Test Results

[Add results of tests]

Clinical Study Results – Detection Accuracy and Usability

The ID-Cap System was extensively tested in laboratory testing, human body simulation testing, and clinical studies. Overall, TBD volunteers (Age range TBD-TBD, mean: TBD) participated in the clinical studies representing TBD subject-use days and TBD ingestions. The ID-Cap System was highly accurate in detecting ingestions with a positive detection accuracy of greater than 98% in clinical studies. In comparison with direct observation, the ingestible sensor was detected in 98% of ingestions. Only 1 out of every 50 ID-Capsules containing the ingestible sensor may not be detected due to reasons other than non-adherence. No false positives were detected with the use of the system over [TBD] patient-days of use. The ID-Cap System accurately and effectively tracks, trends, and reports confirmed ingestion events and intake times and may be used as an aid to measure adherence.

The ID-Cap System was easy to use and acceptable in usability evaluations conducted among patients and healthcare providers. The human factors validation study demonstrated that the ID-Cap System was used safely and effectively by these target populations in clinical and home use settings.

Clinical Study Results - Adverse Events

The ID-Cap System was safe and well-tolerated in clinical studies across 60 study participants. No serious adverse events and no unanticipated adverse device effects were observed in clinical studies. No study participants experienced skin rashes or skin irritation with use of the device. Adverse events related to the device occurring in ≥ 1% of study participants were minor and included: TBD. In clinical studies, there were no discontinuations due to adverse events that were related to the device.

No retentions reported with the device.

Device Specifications

ID-Cap Reader Specifications

Battery _____Lithium polymer rechargeable battery

Data Recording Time _____Approximately 24-36 hours on a full battery charge; maximum 70-90 days of active use before data upload recommended

Storage Conditions _____Original package under normal room temperature and humidity

Quality Assurance

etectRx has established and follows a quality system to help ensure that our products consistently meet applicable requirements and specifications. ID-Cap Readers and ID-Tags are manufactured and ID-Capsules are assembled in validated production environments. Current good manufacturing practices (CGMPs) are followed throughout the process to assure that our products will meet high quality standards. Consistency, uniformity, and conformance to specifications are maintained at etectRx through process monitoring and control checks that occur throughout production processes. A Certificate of Analysis (COA) will be issued and supplied with each lot of ID-Capsules once the lot is approved by the etectRx Quality Team.

Warranty

etectRx makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the device as instructed. Users of the ingestible sensor and/ or ID-Cap Reader who experience clinical worsening or new clinical symptoms should seek medical attention. Healthcare providers should exercise their clinical judgment in

interpreting and using any data from ingestible sensor and/or ID-Cap Reader for clinical decision-making.

TROUBLESHOOTING

If you experience difficulties in operating this device, refer to the information below or contact your pharmacist or doctor.

To report malfunctioning of the device, mistakes in using the device, quality issues, or injury from the use of the device, contact customer support by phone at 855-TBD-HELP, email at support@myidcapetectrx.com, and our website at www.myidcap.com.

ID-Capsule

Problem	Solution
You experience clinical worsening or new clinical symptoms during use of the ID-Cap™ System.	Seek medical attention.
Problem	**Solution**
You are confused about how or when to take your prescribed medications and/or ID-Capsules.	Talk with your doctor or pharmacist.
Problem	**Solution**
The ID-Capsule gets wet or damaged.	Do not take the wet or damaged ID-Capsule. Swallow a replacement capsule if provided.
Problem	**Solution**
You forgot to take your ID-Capsule, or you intentionally do not take a prescribed dose.	Report a missed dose in the ID-Cap App.

ID-Cap Reader

Problem	Solution

The ID-Cap Reader will not power on.	**Option 1:** Press and hold the power button for two seconds. **Option 2:** Ensure that the device charger is set up and connected correctly, and place the Reader on the charging pad in the correct orientation. After charging, press and hold the power button for two seconds to turn the Reader on. To validate that the charger is connected to a functioning outlet, unplug the charger and then reconnect the power cord. If the charging pad does not very quickly flash blue after reconnecting, either the charger is damaged or the outlet is not functioning. **Option 3:** Contact your physician or pharmacist or etectRx for a replacement device.

Problem	**Solution**
The LED indicator light on the ID-Cap Reader is not working.	Contact your physician or pharmacist or etectRx for a replacement device.

Problem	**Solution**
The ID-Cap Reader is too hot to use and needs to be shut down.	Remove the lanyard from your neck. Press and hold the power button down for ten seconds to shut the Reader off.

Problem	**Solution**
The ID-Cap Reader is shut off or its battery fully discharges.	**Option 1:** If needed, charge the ID-Cap Reader. If your Reader is being used with the ID-Cap App on your Mobile Device, power on the Reader and pair the Reader with the Mobile Device before using. **Option 2:** If needed, charge the ID-Cap Reader. If your ID-Cap Reader is not being used with the ID-Cap App on your Mobile Device, call your physician or pharmacist or contact etectRx.

Mobile Device

Problem	**Solution**
You do not see any new ingestion event data in the ID-Cap App.	**Option 1:** In your home screen on your ID-Cap App, check your ID-Cap Reader battery status for sufficient power and ensure an active connection between the ID-Cap Reader and the Mobile Device. If no connection is indicated, close the application completely and re-start the application.

Option 2: Restart your Mobile Device: press and hold the power button to turn the Mobile Device off, and press and hold the button to turn it back on.

Option 3: If the new ingestion event data does not populate after completing Options 1 and 2, report the ingestion event in the ID-Cap App.

MANUFACTURER CONTACT INFORMATION

etectRx, Inc.
107 SW 140th Terrace, Suite 1, Newberry, FL 32669
Ph: +1-352-443-5713
www.etectrx.com

US Patent No. 9743880 | Made in USA

USER ASSISTANCE

For more information about the ID-Cap System, please visit www.myidcap.com.

If you need assistance with setting up or using the ID-Cap System or to report any problems operating the device, please contact your pharmacist or doctor.

To request technical information or assistance with maintenance of the device, or to report unexpected events or quality issues, please contact the manufacturer, etectRx.

Phone: 855-TBD-HELP
Email: support@myidcapetectrx.com
Website: www.myidcap.com

USER MANUAL INFORMATION

USERMANUAL-001, Rev 1
Date of Issue: 2017-11-20

LEGAL NOTICES

Trademark

All product names appearing in this User Manual are trademarks owned by etectRx unless otherwise noted.

Nothing contained herein shall be construed as conferring by implication, estoppel, or otherwise, any license or right under any patent or trademark of etectRx or any third party.

Copyright

APPENDIX A: TECHNICAL INFORMATION

Device Classification

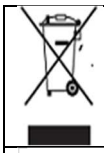
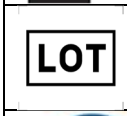
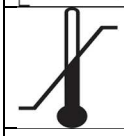
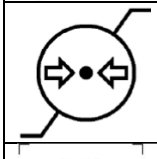
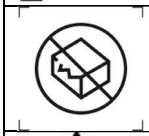
CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

The ID-Cap System is categorized as a Class II medical device by the United States Food and Drug Administration and identified as an ingestible event marker under 21 CFR 880.6305. An ingestible event marker is a prescription device used to record time-stamped, patient-logged ingestion events. The ingestible component links wirelessly through radio frequency communication to an external recorder which records the date and time of ingestion.

The patient is the intended operator of the ID-Cap System.

Symbols Reference Guide

Symbol	*Meaning*
	Caution – Consult Accompanying Documents
	Model Number
	Manufacturer
	Date of Manufacture
	Serial Number
	Class II Equipment
	Keep Dry
	CAUTION: United States federal law restricts this device to sale by or on the order of a physician.

	Not for General Waste
	Lot Number
	Read Instructions Before Use
	Product Does Not Contain Latex
	Independent Lab Tested by F-Squared Labs
	Use by Date
	Temperature Range
	Relative Humidity Range
	Atmospheric Pressure Range
	Do Not Use If Package Is Damaged
	Non-Sterile Product
	Shock Protection Type BF Applied Part
	Single Use Only
	MRI Unsafe – Do Not Wear During Magnetic Resonance Imaging (MRI) Procedures

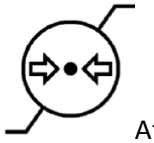
	Emits Radio Waves
IP53	Ingress Protection Rating of IP53 The ID-Cap Reader has an Ingress Protection rating of IP53. This means that the enclosure is protected from limited dust ingress, and it has been rated for protection from water spray less than 60 degrees from vertical.
	Stand-By This symbol identifies the button by means of which the ID-Cap Reader is switched on in order to bring it into the stand-by condition.

Environmental Conditions of Use

The ID-Cap System is intended for home use or use in a clinical setting. The ID-Cap System is intended for storage and operation in a room-temperature environment.

 Temperature

 Relative Humidity

 Atmospheric Pressure

ID-Cap Reader

Condition	Temperature	Relative Humidity	Pressure (Altitude)
Operating	15°C - 30°C	15% - 93%	700 – 1060 hPa
Storage	15°C - 30°C	15% - 93%	700 – 1060 hPa
Transport	2°C - 38°C	15% - 85%	700 – 1060 hPa

When the ambient temperature is 20°C, the time required for the ID-Cap Reader to cool from the maximum storage temperature (30°C) between uses until the ID-Cap Reader is ready for its intended use is [ADD BASED ON TEST RESULTS]. At 20°C, the time required for the ID-Cap Reader to warm from the minimum storage temperature (15°C) between uses until it is ready for intended use is [ADD BASED ON TEST RESULTS].

ID-Capsules

Condition	Temperature	Relative Humidity

Storage	15°C - 30°C (59°F - 86°F)	35% - 65%
Transport	15°C - 30°C (59°F - 86°F)	35% - 65%

Store ID-Capsules in original sealed containers at the recommended temperature and humidity. ID-Capsules may be sensitive to temperature changes. Properly stored and sealed containers will provide optimum performance.

Storing capsules under or near sources of water should be avoided as well.

Biocompatibility

Biocompatibility requirements have been met for the biological evaluation of the ID-Cap System and its component materials that come into contact with the human body. The following tests have been performed under the International Standard ISO-10993 to demonstrate that the ID-Cap Reader and ID-Tag are biocompatible:

- Cytotoxicity, sensitization, and irritation (or intracutaneous reactivity) for both the ingestible ID-Tag and the wearable ID-Cap Reader
- Implantation, acute systemic toxicity, and sub-acute systemic toxicity for the ingestible ID-Tag

Protection Against Ingress of Solids and Liquids

The ID-Cap Reader has an Ingress Protection rating of IP53. This means that the enclosure is protected from limited dust ingress, and it has been rated for protection from water spray less than 60 degrees from vertical.

CAUTION: For continued safety, should the enclosure become damaged, do not use the ID-Cap Reader and contact the manufacturer.

Regulatory Information

Applied Part

The ID-Cap Reader may touch the patient during the normal use of the device and is treated as an Applied Part. The ID-Cap Reader meets all requirements of Applied Parts.

CISPR Interference Statement

Medical Electric Equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this section of the manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The ID-Cap Reader may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.

FCC and Industry Canada Interference Statement

This device complies with part 15 of the FCC Rules and Industry Canada license-exempt RSS Standard(s). Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage; (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This equipment has been tested and found to comply with the limits for

a Class B digital device pursuant to Part 15 of the 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 and, if not installed and used in accordance with the instructions, 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 on and off), the user is encouraged to try to correct the interference by using one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.
- Connect the equipment into 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.

Caution: Changes or modifications not expressly approved by etectRx could void your authority to operate the equipment.

This Class B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Cet appareil numérique de la classe B respecte toutes les exigences du Règlement sur le matériel brouilleur du Canada.

FCC and Canadian Compliance Identifiers

FCC ID for the ID-Cap Reader: 2AL2U-BRCM1078

FCC ID: 2AL2U-ET2000150

IC: 22807-ET2000150

Canadian ID for the ID-Cap Reader: 22807-BRCM1078

Canadian ID for the ID-Tag: 22807-ET2000150

Electromagnetic Compatibility

The ID-Cap Reader has been evaluated and deemed compliant with the requirements in EN60601-1-2 Class B for Electromagnetic Compatibility (EMC). Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this User Manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The ID-Cap Reader should not be used adjacent to or stacked with other

electromagnetic equipment. This may impact the performance of the ID-Cap Reader or the other equipment. If adjacent or stacked use with other electromagnetic equipment is necessary, verify that the ID-Cap Reader operation is normal in the configuration in which it will be used.

Information on the Radio Subsystem

The ID-Cap Reader incorporates a Bluetooth™ radio subsystem which is compliant with the Bluetooth Low Energy standard. The following information is provided to satisfy the requirements of EN/IEC 60601-1-2:

The Bluetooth radio transmits and receives in the 2.4 GHz frequency band on channels which are equally spaced at 2 MHz intervals between 2402 MHz and 2480 MHz.

The effective receive bandwidth is 1 MHz.

The transmit modulation is frequency-hopping using GFSK (Gaussian Frequency Shift Keying) with a bandwidth-bit period product BT-0.5. The Modulation index is between 0.28 and 0.35.

The effective radiated power is 2.5 dBm (P=1.8 mW).

Guidance and manufacturer's declaration - electromagnetic emissions		
The ID-Cap Reader is intended for use in the electromagnetic environment specified below. The customer or the user of ID-Cap Reader should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions - CISPR 11	Group 1	The ID-Cap Reader uses RF energy for its internal functions and BT. Its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The ID-CAP Reader 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	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 6100-3-3	Not Applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

The ID-Cap Reader is intended for use in the electromagnetic environment specified below. The customer or the user of the ID-Cap Reader should assure that it is used in such an environment

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the ID-Cap System, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conduced RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Not Applicable
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz		d = 1,17 √P 80 MHz to 800 MHz d = 2,33 √P 800 MHz to 2,5 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 determined 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: 

Guidance and manufacturer's declaration – electromagnetic immunity

The ID-Cap System is intended for use in the electromagnetic environment specified below. The customer or the user of the ID-Cap system should assure that it is used in such an environment

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8kV contact +/- 15kV air	+/- 8kV contact +/- 15kV air	Floors 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	Not applicable	
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	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.			

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.

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 ID-Cap Reader is used exceeds the applicable RF compliance level above, the ID-Cap Reader should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ID-Cap Reader.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the ID-Cap Reader

The ID-Cap Reader is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ID-Cap Reader can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ID-Cap Reader as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
	$d = 1,2 \sqrt{P}$	$d = 1,2 \sqrt{P}$	$d = 2,3 \sqrt{P}$
0.01	Not applicable	0.1	0.23
0.1	Not applicable	0.4	0.74
1	Not applicable	1.2	2.3
10	Not applicable	3.7	7.4
100	Not applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.

Declaration of Conformity

etectRx, Inc. declares that the ID-Cap Reader is compliant with the following standards:

• Electrical Safety	AAMI/ANSI/ES 60601-1: 2005, 3rd edition
• Home Use Safety	AAMI/IEC 60601-1-11: 2015
• EMC/EMI	AAMI/IEC 60601-1-2: 2014, 4th edition
• RFID Testing	AIM 7351731
• Wireless Coexistence	ANSI C63.27: 2017
• Battery	IEC 62133: 2017