



ID-Cap™ Medication Adherence Feedback System

USER MANUAL

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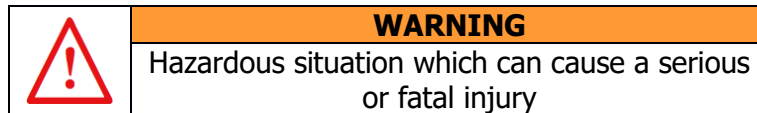
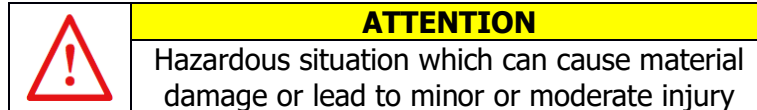
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1. Introduction

This manual is your introduction to the etectRx ID-CAP System. You must read and fully understand this manual before using the system. Use this manual to initially set up the system, and keep it as a reference for day-to-day routines and as a guide to maintenance. If you have any difficulties in setting-up or using the etectRx ID-CAP, contact your dispensing pharmacy.

1.1. Conventions

To avoid physical and material damage, this document identifies safety instructions into 2 danger levels:



2. etectRx Medication Adherence System Overview

2.1. Description

ID-Cap System is an ingestible event monitoring system which can provide near real-time confirmation of an ingestible event and act as an aid to measuring medication adherence and compliance. It utilizes a proprietary in vivo communications technology to emit a very low power digital message from within the patient each time a sensor is ingested.

2.1.1. System Components:

The components of the system include the following which are explained in greater detail in section 2.4.

- ID-Capsule, a capsule which contains the ingestible sensor, the ID-Tag;
- ID-Tag, ingestible sensor which transmits signal and is excreted
- ID-Cap Reader, a wearable Reader, which receives the signal from the ID-Tag, verifies the message as being a valid ingestion event, and forwards the message using Bluetooth LE protocol;
- Optional Display System, includes an App which archives messages received from ID-Cap Reader

2.1.2. System Operation Overview

The ID-Capsule is a standard medication capsule that contains an ID-Tag ingestible sensor. As the capsule dissolves in a patient's stomach, the ID-Tag will power up when in contact with stomach fluid. It then emits a very low power digital radio frequency (RF) message to the patient-worn ID-Cap Reader to indicate an ingestion event has occurred. The ID-Tag subsequently passes through the patient's GI tract and exits the body intact.

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The ID-Cap Reader receives the ingestion signal from the tag, stores the message, and communicates to the patient that the ingestion was detected both via the ID-Cap Reader and the optional phone app. No protected health information (PHI) data is transmitted between the ID-Tag and Reader.

When an ingestion event message is received, the Reader can either securely store the ingestion event for post-event download, or dynamically transmit the ingestion event using a secure, HIPAA-compatible data protocol over BLE to a smartphone, tablet or PC running the etectRx mobile application (App). The Reader also provides device status messages to the App to allow for management of the Reader and system. The App collects the ingestion event and device status messages and forwards them via the mobile network to the etectRx database. The App contains a log of time-stamped ingestion event messages, device status messages, and system management information. The captured events may be used to generate reminder, confirmation or information messages to the subject.

2.2. Intended Use

The intended use of the etectRx ID-CAP System is to measure adherence with medication regimens for prescribed oral medications in ambulatory, unattended clinical and research applications in the home and clinical settings.

2.3. Indications for Use

The ID-Cap System is intended to record time-stamped ingestions with the ingestible sensor, ID-Tag which transmits a signal to the ID-Cap Reader. When co-ingested with medication the tracking and trending of intake times may be used as an aid to measure adherence. The ID-Cap System enables unattended data collection

For use with adult patients taking oral medications in an ambulatory or home-use environment.

2.3.1. Contraindications

- Not for use while on an aircraft or other areas where RF communications are restricted.
- Not for use with patients who may have a significant medical condition which may affect capsule passage through the gastrointestinal tract (including, but not limited to, Crohn's disease, small bowel tumors, intestinal adhesions, ulcerations, and radiation enteritis).
- Not for use with patients who may have a swallowing disorder (dysphagia).
- Not for use with patients who have a cardiac pacemaker or other implanted electro-medical device.
- Not for use with patients subjected to strong electromagnetic fields i.e., MRI.
- Not for use with children under the age of **TBD**.
- Not for use with patients who are pregnant.
- Not for use with patients who have a hypersensitivity to gelatin, Kapton, magnesium, or silver chloride.

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- Not for use with colorblind patients.

2.3.2. Compliant Use



- Federal law (USA) restricts this device to sale or use by, or on the order of a physician.
- A healthcare professional should evaluate each patient to ensure that the decision to use the etectRx ID-CAP System on that particular patient is appropriate.
- Use the ID-Cap System as directed by your healthcare provider.

2.3.3. Precautions



- 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 because of confusion with this system.
- Caregivers should use appropriate judgement when considering the use of the etectRx ID-CAP System on patients at risk of harming themselves or others. The equipment, including the Reader, lanyard, AC Adapter, USB Charging Cable, and Wireless Charging Pad may create a hazard for at-risk patients and their caregivers.
- If the Reader or any of the Charging Components becomes damaged during normal use, discontinue use of the product and contact your pharmacy for a replacement.

2.4. System Components

The components of the system include the following (Reference Figure TBD):

- ID-Capsule, a capsule which contains the ingestible sensor, the ID-Tag: Product Code **TBD**;
- ID-Tag, ingestible sensor which transmits signal and is excreted;
- ID-Cap Reader, a wearable Reader, which receives the signal from the ID-Tag, verifies the message as being a valid ingestion event, and forwards the message using Bluetooth LE protocol: Product Code **TBD**, Software Version **TBD**;
- Optional Display System, includes an App which archives messages received from ID-Cap Reader

2.5. Safety Instructions

2.5.1. Electromagnetic Compatibility

The etectRx 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.

There are no known significant risks of reciprocal interference posed by the etectRx 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.

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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 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.

2.5.2. Electrical Connection



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

2.5.3. Charging



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

2.5.4. Environment



Contains no user-serviceable parts – do not attempt to open Reader case or injury may result.



Do not submerge Reader in water.
Designed to operate between 5°C and 40°C.

2.5.5. Malfunction

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

3. Instructions for Use – Patients Using App

These instructions apply to patients using the ETECTRX ADHERENCE APP with their phone.

Prior to First Use:

3.1. Initial Setup

When the Reader box is opened, ensure the prescription on the side of the box identifies the correct patient. Save this box to store the system when not in use and to return the system at end of therapy.

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Read this manual and the pharmacy prescription instructions before using this product.

The Reader box should contain the following components (see picture TBD) – please contact your dispensing pharmacy if any item is missing:

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

3.1.1. Charger Setup

Note that the Reader in the box only has a partial charge to allow for initial setup, and should be charged before taking any ID-Capsule ingestions.

Connect the AC Adapter, the USB Charger Cable, and the Wireless Charging Pad as shown in Figure TBD. Plug the AC Adapter into a 110V wall outlet. A blue indicator light on the charging pad will briefly flash when it is plugged in and ready for the Reader to be placed.

3.1.2. Reader Charging

Attach the Lanyard to the Reader as shown in Figure TBD.

Note that the Reader LED blinks green whenever it is paired and ready to use, blinks a green/orange pattern when the battery is low, and blinks orange when the battery is too low to be used – See Figure TBD.

To charge the Reader, place the Reader on the Wireless Charger Pad as seen in Figure TBD. The Reader LED will show steady orange while charging and still below enough battery for use, and steady green while charging and ready to be used. Once fully charged the Reader LED will blink green.

The Reader will automatically stop charging once the battery is fully charged.

3.1.3. App Setup

Use of the optional App requires a compatible iPhone or Android phone to pair with the Reader (iPhone v### or later or Android v### or later).

Prior to setting up the App, call the dispensing pharmacy to confirm receipt of the Reader and to obtain a unique ID# that is required to setup the App.

Follow the phone operating instructions to download the etectRx App “ELECTRX ADHERENCE APP” to the phone, and then open the App.

Follow guidance within the App for setup of any preferences and interactions.

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Ensure App remains open at phone at all times to ensure communications received from Reader.

3.1.4. Reader Pairing

Turn the Reader on by pressing the power button for 2 seconds until the Reader LED emits a blinking Blue light. See figure TBD.

Ensure the Reader and Phone are within 10ft of each other.

Open “Settings” on the phone and ensure Bluetooth is turned on. **NOTE:** Bluetooth must be enabled on the phone for proper communications with the etectRx Reader. etectRx recommends leaving Bluetooth enabled for the duration of device use.

Close “Settings” on the phone, and open or re-open the eTectRx Adherence App. The phone will automatically pair with the Reader, and then will require entry of code “032669” to complete pairing. The LED on the Reader will blink Green once successfully paired.

3.2. Ingesting an ID-Capsule

Before ingesting each ID-Capsule:

Remove Reader from the Wireless Charging Pad and check for the blinking Green light signifying the Reader is ready to detect an ingestion. If the Reader shows an Orange light, the battery is too low and should be charged for 30 minutes prior to the ingestion. If the Reader shows a blinking Blue light, the Reader and App are not paired – reference Troubleshooting.

Once you have verified the Reader is paired and has enough battery life to record the ingestion, place the Reader around your neck using the lanyard with the etectRx brand facing away from the body.



DO NOT delay taking prescribed medication if the Reader is not charged or if you encounter any issue with the ID-CAP system.

When ingesting each ID-Capsule:

Proceed to swallow an ID-CAPSULE at the same time as your prescribed medication. After swallowing ID-Capsule, continue wearing the Reader around your neck while going about normal daily activities.

After Ingesting each ID-Capsule:

Within 30 minutes, the Reader will detect the swallowed ID-Capsule and notify by a blinking white LED light on the Reader which displays for **TBD** minutes and a message of “ingestion detected” on the App.

If the confirmation of ingestion is not observed, use the App to self-report an ingestion.

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DO NOT take an additional ingestion if the first one was not reported.

Remove Reader and Charge

Once the ingestion has been detected or 30minutes after ingestion, take off the Reader and place back on the charger to ensure readiness for the next use.

3.3. End of Therapy / Reader Return

4. Instructions for Use – Patients Not Using App

These instructions apply to patients using the etectRx ID-CAP System but not using the optional App with their phone.

Prior to First Use:

4.1. Initial Setup

When the Reader box is opened, ensure the prescription on the side of the box identifies the correct patient. Save this box to store the system when not in use and to return the system at end of therapy.

Read this manual and the pharmacy prescription instructions before using this product.

The Reader box should contain the following components (see picture TBD) – please contact your dispensing pharmacy if any item is missing:

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

4.1.1. Charger Setup

Note that the Reader in the box only has a partial charge to allow for initial setup, and should be charged before taking any ID-Capsule ingestions.

Connect the AC Adapter, the USB Charger Cable, and the Wireless Charging Pad as shown in Figure TBD. Plug the AC Adapter into a 110V wall outlet. A blue indicator light on the charging pad will briefly flash when it is plugged in and ready for the Reader to be placed.

4.1.2. Reader Charging

Attach the Lanyard to the Reader as shown in Figure TBD.

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Note that the Reader LED blinks green whenever it is paired and ready to use, blinks a green/orange pattern when the battery is low, and blinks orange when the battery is too low to be used – See Figure TBD.

To charge the Reader, place the Reader on the Wireless Charger Pad as seen in Figure TBD. The Reader LED will show steady orange while charging and still below enough battery for use, and steady green while charging and ready to be used. Once fully charged the Reader LED will blink green.

The Reader will automatically stop charging once the battery is fully charged.

4.2. Ingesting an ID-CAPSULE

Before ingesting each ID-Capsule:

Remove Reader from the Wireless Charging Pad and check for the blinking Blue light signifying the Reader is ready to detect an ingestion. If the Reader shows an Orange light, the battery is too low and should be charged for 30 minutes prior to the ingestion.

Once you have verified the Reader has enough battery life to record the ingestion, place the Reader around your neck using the lanyard with the etectRx brand facing away from the body.



DO NOT delay taking prescribed medication if the Reader is not charged or if you encounter any issue with the ID-CAP system.

When ingesting each ID-Capsule:

Proceed to swallow an ID-CAPSULE at the same time as your prescribed medication. After swallowing ID-Capsule, continue wearing the Reader around your neck while going about normal daily activities.

After Ingesting each ID-Capsule:

Within 30 minutes, the Reader will detect the swallowed ID-Capsule and notify by a blinking white LED light on the Reader which displays for TBD minutes.



DO NOT take an additional ingestion if the first one was not reported.

Remove Reader and Charge

Once the ingestion has been detected or 30minutes after ingestion, take off the Reader and place back on the charger until the next use.

4.3. Periodic Download

Coordinate with the dispensing pharmacy to bring the Reader in to them for data download.

4.4. End of Therapy / Reader Return

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Once your prescription has completed, call the dispensing pharmacy to initiate a return of the Reader.

5. Cleaning the Reader

The Reader should be cleaned periodically as needed. To clean the Reader, DO NOT put under water. Use a clean cloth dampened with water and household soap or mild detergent to wipe the case. Immediately dry off with a clean, dry cloth.

6. System Maintenance

The Reader contains no user-serviceable parts. For any issues encountered, please contact the manufacturer.

To order replacements for any parts of the system (Reader Device, Lanyard, Wireless Charger Pad, USB Charging Cable, AC Adapter, Instruction Manual, or Quick Start Guide), please contact the dispensing pharmacy.

7. Error Messages, Troubleshooting

7.1. App does not install

Attempt to download App again. If problems persist, call your pharmacy.

7.2. App does not recognize Unique ID

Call your dispensing pharmacy, as they can generate a new Unique ID if needed.

7.3. Unable to pair Reader with Phone

If you encounter issues in pairing the Reader with the App, follow the following steps:

- Confirm BT on phone is on.
- Ensure Reader and Phone are within 10 feet of each other.
- Ensure Reader is turned on (Flashing Blue or Flashing Green light).
- Close and re-open the App.
- As the App will look for a specific Reader, ensure Reader # found in “etectRx Reader” under settings matches the Reader # on the back of the Reader.
- If problems persist, call dispensing pharmacy.

7.4. Unable to power-on charger

Note that the charger indicator will very briefly flash blue when initially plugged in, but will remain off until a Reader needing a charge is placed on the pad. If a fully charged Reader is placed on the Charger Pad, no indicator will be observed.

If the Charger Pad does not appear to be on, check all connections. If problems persist, plug into a different wall outlet.

7.5. Unable to charge Reader

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Note that if Reader battery is fully charged it will not sync with the Charger Pad. If you are using the phone App, you can check battery level of Reader. If Reader is not charging while on Charger Pad first ensure charger is plugged in, then adjust Reader position on pad until pad blue light comes on. If problems persist, call dispensing pharmacy.

7.6. App loses connection with Reader and is unable to reconnect

- Confirm BT on phone is on.
- Ensure Reader and Phone are within 10 feet of each other.
- Ensure Reader is turned on (Flashing Blue or Flashing Green light).
- Go to settings on phone, access BT, and forget device. Ensure BT is on.
- Shutdown and then restart App.
- If still not successful, restart phone and Reader, then start App.
- If still unsuccessful, call dispensing pharmacy.

7.7. Ingestion was not detected

If using the App, follow instructions to add an ingestion manually. If not using the App, do nothing. If issue persists, call your dispensing pharmacy.

7.8. Ingestion detected when ID-Capsule was not taken

Call your dispensing pharmacy.

7.9. Reader light remains Orange

Do NOT ingest an ID-Capsule if the Reader displays an Orange light. Charge your Reader per the instructions until a Green Light is observed. If the light is still Orange after 30 minutes, the Reader can be restarted by holding the power button down for TBD seconds to turn off and then holding the power button down for 2 seconds to turn back on. If the light is still Orange after 8 hours of charging and the reboot does not address, call your dispensing pharmacy.

7.10. Reader Error ###

TBD

7.11. App Error ###

TBD

7.12. Other Messages

8. Warranty, Useful Life, and Shelf-Life

This product has a shelf life of 18 months from date of manufacture and a service life of 12 months from patient initial use.

9. Technical Information

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9.1 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.

9.2 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.

ID-Cap Reader

Condition	Temperature	Humidity	Pressure (Altitude)
Operating	20°C - 28°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

ID-Capsules

Condition	Temperature	Humidity
Storage		
Transport		

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

9.4 Avoiding Unsafe Use Conditions

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

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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: No modification of the ID-Cap Reader 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.

10. Regulatory Information

CISPR Interference Statement

Medical Electric Equipment needs special precautions regarding 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 Interference Statement

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

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 within the limits of 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

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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 Identifier

FCC ID:

Electromagnetic Compatibility (EMC)

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

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

The Bluetooth radio transmits and receives on __ frequency bands which are equally spaced at __ MHz intervals between __ MHz and __ MHz.

The effective receive bandwidth is ____ 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 -15dBm (P=0.032mW).

Tables to be completed:

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














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 assume that it is used in such an environment			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

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.






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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 VP	d = 1,2 VP	d = 2,3 VP

11. Symbols Reference Guide

	Manufacturer
	Date of Manufacture
	Serial Number
	Class II Equipment
	Keep Dry
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Separate Waste Collection for Waste of Electrical and Electronic Equipment (WEE)
	Model Number
	Batch Code – the Manufacturer’s Code
	Refer to Instructions for Use
	Not made with Natural Rubber Latex
	Independent Lab Tested (Put Lab’s Symbol)
	Expiry Date

etectRx Patient Manual – DRAFT NOTE: This is a word doc used to build content only. The User Manual will be laid out using a publishing program, so please do not focus reviews on numbering / indents / etc.

	Storage Temp
	Do not use if packaging damaged
	Product Non-Sterile
	Shock Protection B or BF – IF NEEDED
	Single Use Only
TBD	TBD

12. Legal Notices

13. Declaration of Conformity

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

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

14. Manufacturer Contact Information



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