ID-Cap System
USER MANUAL

Pendant Reader

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

Device Model Numbers

This User Manual pertains to the following device model numbers:

Model Number for the ID-Cap Reader REF	ET71001.00
Model Number for the ID-Capsule	ET30001.51, ET30001.52

TABLE OF CONTENTS

GLOSSARY

Term	Definition
Authorized User	Patient who has been registered to use the ID-Cap System or a clinician or program administrator who has been granted access to view the ingestion event data
Caution	Important notification or instruction regarding a hazardous situation which can cause material damage or lead to minor or moderate injury  **ATTENTION** Hazardous situation which can cause material damage or lead to minor or moderate injury
etectRx	Manufacturer of the ID-Cap System
ID-Cap App (optional)	Smartphone application for the patient that may be used to report and display ingestion event data, transfer data to the secure server for viewing by others as authorized, send notifications to users, provide updates on the status of the Reader, and manually record an ingestion event that has not been recorded by the ID-Cap System
ID-Cap Reader	Wearable reader which receives the signal from the ID-Tag and confirms the ingestion event
ID-Cap Reader Kit	Kit comprised of the ID-Cap Reader, Reader accessories, and instruction manuals supplied to the patient
ID-Cap System	System comprised of a wearable ID-Cap Reader, ID-Capsules, and a mobile application for the patient
ID-Capsule	Capsule for oral administration which contains the ID-Tag
ID-Tag	Ingestible sensor which transmits a signal once ingested and is subsequently excreted
Warning	Important notification or instruction regarding a hazardous situation which can cause a serious or fatal injury  **WARNING** Hazardous situation which can cause a serious or fatal injury

ID-CAP SYSTEM OVERVIEW

Introduction
The ID-Cap System from etectRx is a medical device that has been cleared by the United States Food and Drug Administration (FDA) for marketing in the United States. The ID-Cap System is classified by the FDA as an ingestible event marker (IEM).

Prescription-Use Only
℞ Only

CAUTION: Federal law restricts this device to sale by or on the order of a licensed practitioner.

Indications for Use
The ID-Cap System consists of a wearable reader for ambulatory recording of events signaled by swallowing the ID-Capsule which contains the ID-Tag, an ingestible sensor. The ID-Cap System is intended to log, track, and trend intake times and enables unattended data collection for clinical applications. The ID-Cap System may be used in any instance where quantifiable analysis of ingestion events, including events signaled by the co-incidence with or co-ingestion with the ID-Capsule, is desirable.

Conditions of Use
The ID-Cap System records an event signaled by swallowing the ID-Capsule. ID-Capsules may be taken on a specific schedule to mark ingestion events. When used to mark events signaled by the co-incidence with or co-ingestion with the ID-Capsule, the ID-Capsule should be taken at the same time as the specific event of interest or at the same time as a dose of medication.

The ID-Cap System should be used with the patient's use of our mobile application. The ID-Cap App collects the ingestion event and Reader status messages from the Reader and forwards them via the mobile network to the ID-Cap secure server, allowing authorized users to view ingestion events as they occur. The ID-Cap App reports and displays information about ingestion events and ingestion event history, sends notifications to the user, and provides updates on the status of the ID-Cap Reader. It can also allow the patient to manually record an ingestion event that has not been recorded by the ID-Cap System when applicable. If the ID-Cap App and phone are not used with the ID-Cap System, the Reader may collect and store information that can be downloaded at a later time.

Device Description- Pendant Reader

The ID-Cap System

Your ID-Cap System consists of a wearable ID-Cap Reader, ID-Capsules, and a mobile application for recording of events signaled by swallowing the ID-Capsule which contains an ingestible sensor. Your ID-Cap Reader is worn like a watch and collects information from the ingested ID-Capsules that are taken as directed by your doctor. Your doctor may instruct you to take the ID-Capsule on a specific schedule, at the same time as a specific event, or with a specific 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 ingestion events. With a simple Bluetooth connection to your mobile device, your ID-Cap Reader sends information to the ID-Cap App to help you keep track of your ingestion events. With your permission, this information will be shared with your healthcare provider to help them improve your health outcomes.

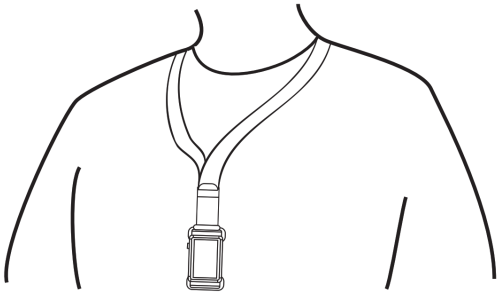
ID-Capsule (Ingestible Sensor Capsule)

ID-Capsules are available by prescription only for use with the ID-Cap Reader. ID-Capsules are taken by mouth. The ID-Capsule is a capsule shell that contains an ingestible sensor called the ID-Tag. The ID-Tag is 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.

The ID-Tag has been designed to be safe for human consumption. Clinical studies have demonstrated the safety of ID-Capsules. Animal tests have demonstrated that the ID-Tag is biocompatible and non-toxic. Key ingredients of the ingestible ID-Tag that are in human contact include magnesium, silver, silver chloride, polyimide, and epoxy. Additional information about ID-Capsules, including the specific ingredients of the capsule shells, may be requested from the manufacturer. The ID-Tag passes through your digestive system intact and is excreted in the feces.

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

ID-Cap Reader



The ID-Cap Reader is available by prescription only for use with ID-Capsules. The ID-Cap Reader is a lanyard-worn reader which you wear around your neck. The ID-Cap Reader detects ingested ID-Capsules. The Reader does not require skin contact to detect the signal and does **not** require an adhesive patch. Animal tests and clinical studies have demonstrated that the Reader is biocompatible and non-irritating.

The Reader must be worn with the display screen facing away from your body.

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
	CAUTION: 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 or other liquids.

The Reader contains a lithium polymer rechargeable battery. It is charged using a charging clip that is supplied in the Reader Kit. The Reader connects with authorized computing devices, such as tablets or smartphones, using Bluetooth technology.

Reader Display

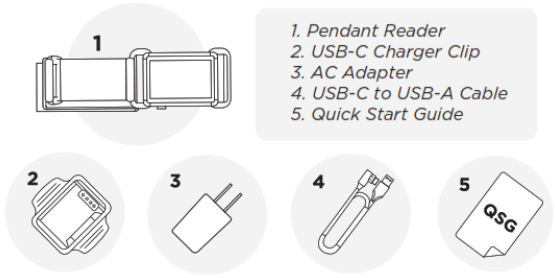
What the Reader Display indicates:

- If the display screen is black, the Reader is powered OFF. Once powered ON, DO NOT turn the Reader off, even when not in use. The Reader conserves power when not in use.
- The reader can be turned on by pressing and holding the button for 3 seconds.
- When the Reader is positioned properly on the supplied charging clip, the Reader display will turn on.
- Please check the battery which will display on your home screen.
- An ingestion can be detected with just one bar of battery.
- The pill icon will display for approximately one hour when a pill is detected, and then revert back to time of day.

ID-Cap Reader Kit

The ID-Cap Reader Kit that is available by prescription-only contains:

- ID-Cap Pendant Reader with pre-attached Lanyard
- USB-C Charger Clip
- AC Adapter
- Quick Start Guide



Mobile Application (ID-Cap App) for Your Smartphone

The ID-Cap System may be used with a mobile application, the ID-Cap App, which can be loaded on your smartphone.

The ID-Cap App:

- Allows the user to view and track ingestion events
- Transfers data to the secure server for viewing by your healthcare provider(s) and others as authorized
- Sends notifications to the user, such as acknowledgements of reported ingestion events, low battery alerts, and reminder notifications
- Provides updates on the status of the Reader and System
- Can allow the user to manually record an ingestion event that has not been recorded by the ID-Cap System or if the ID-Cap System was not used (if applicable).

The ID-Cap App collects the ingestion event and Reader status messages and forwards them via the mobile network to the ID-Cap secure server, allowing authorized users to view ingestion events as they occur. Your healthcare provider may view your ingestion data on a web-based system called the ID-Cap Dashboard. The ID-Cap App on

your phone reports and displays information about your ingestion events, sends notifications to you, and provides updates on the status of your Reader and the System. If you are receiving reminder notifications for use of the ID-Cap System, you have the option to stop or modify them in your phone App settings. The App also allows you to manually record an ingestion event that has not been recorded by the ID-Cap System, if applicable.

Refer to your doctor or study team for information about the functionality of the App, instructions for use, and minimum requirements for your smartphone to run the App.

Patient Users

Federal law restricts this device by prescription only of a licensed practitioner. The ID-Cap System is intended to be used by patients for ambulatory recording of events signaled by swallowing the ID-Capsule.

	ATTENTION
⚠	Your healthcare provider 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.

The patient (or patient's caregiver) must be able to read, understand, and follow the instructions provided in the User Manual and Quick Start Guide. The patient (or patient's caregiver) must be able to set up, charge, and use the ID-Cap Reader and follow instructions regarding how and when to take ID-Capsules to mark ingestion events. Use of the ID-Cap System is reserved for users who can follow ID-Capsule ingestion instructions without interfering with other health behaviors, such as properly taking prescribed medication.

Locations of Use

The ID-Cap System has been designed for ambulatory use, enabling unattended data collection for clinical applications.

	ATTENTION
⚠	**CAUTION:** The ID-Cap System is not intended for use on aircraft.

See Technical Information in Appendix A of this User Manual for additional restrictions on locations of use due to electromagnetic interference. The AC adapter for the charging clip may not be compatible with power sources other than 120V, 60Hz (U.S. Standard). If being used outside of the United States, the user may need an adapter or a converter to convert to the proper voltage.

When the Device Should Not Be Used

Contraindications are conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.

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

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 pregnant or breastfeeding women has not been studied.
- Avoid exposure to known sources of electromagnetic interference (EMI) with medical devices, such as magnetic resonance imaging (MRI) systems, diathermy, lithotripsy, electrocautery, Radio Frequency Identification (RFID) devices, and electromagnetic security systems, such as metal detectors. Note that the presence of RFID devices may not be obvious.
- 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 if you are unable to swallow oral medications.
- DO NOT use the ID-Cap System if you are allergic to any of the ingredients in the ingestible ID-Capsule.
- DO NOT use the ID-Cap System if you have a significant medical condition which may affect capsule passage through your digestive system.

Risks and Benefits

The ID-Cap System records events signaled by swallowing ID-Capsules. The System logs, tracks, and trends intake times for clinical use. This allows the ID-Cap System to measure and report the pattern, regularity, and schedule of your ingestion events. This information may help you or your healthcare provider better understand your health behaviors and improve your health outcomes.

The risks of the ID-Cap System must be evaluated in light of its benefits and limitations. The risks of the ID-Cap System include:

- Risk of incomplete, inaccurate, or misinterpreted ingestion event data that may impact treatment decisions
- Minor, self-limiting adverse events, such as minor digestive problems and the sensation of the capsule in the esophagus
- Risks associated with failure to eliminate the ID-Tag in the feces
- Risk of breach of confidentiality, privacy, or security involving ingestion data
- Risk of allergic reactions (including life-threatening reactions) when taking any ingestible product

Expectations of the Device

When the ID-Capsule is ingested, the capsule will soften and disintegrate. During this process, the ID-Tag will power up and begin sending messages. The ID-Cap Reader detects the messages from the ingested ID-Capsule. The average time for the Reader to detect an ID-Capsule ingestion is about 6.5 minutes after the ingestion. The ID-Tag will continue to send messages repeatedly until it runs out of power in approximately 20-30 minutes. When it is worn as instructed, the Reader will continue to record these messages from the ID-Tag and store this information in its memory. The ID-Tag passes through your digestive system intact and is excreted in the feces.

The ID-Cap System is used effectively with the patient's use of the mobile application. When the Reader is paired with the patient's smartphone using the ID-Cap App, the user may receive a notification of the ingestion event on his or her smartphone about 6.5 minutes on average after taking the ID-Capsule. It can also allow the patient to manually record an ingestion event that has not been recorded by the ID-Cap System if applicable. The ID-Cap App collects the ingestion event and Reader status messages and forwards them via your phone's mobile network to the ID-Cap monitoring database. This enables authorized users, such as your doctor, to view ingestion events as they occur when the phone is paired with the Reader. No personal or protected health information (PHI) is sent from the ID-Tag, ID-Cap Reader, or ID-Cap App

Parameter	Results (mean)
Time to Detection on ID-Cap Reader from ID-Capsule Ingestion	6.4 minutes
Average Duration of ID-Tag Detections by ID-Cap Reader	27.9 minutes
Time to Phone Notification from ID-Capsule Ingestion	6.5 minutes
Time to Server Notification from ID-Capsule Ingestion	6.5 minutes

Data Captured by the ID-Cap System

The following data are collected and reported using the ID-Cap System:

- Date and time of ingestion events detected by the Reader (signaled by swallowing the ID-Capsule while wearing the Reader)
- Date and time of ingestion events manually recorded by the patient using the ID-Cap App
- Reader status messages

The Reader status messages communicate information about whether your Reader is on, its battery level, its operational state (that is, whether or not it is ready for use in detecting ingestions of the ID-Capsule), and its movement. The movement of the device is measured by an accelerometer within the device. No other data is collected by the accelerometer other than a change in the position of the Reader. The Reader status messages also collect some information about your use of the Reader. The information that is captured includes whether the Reader is powered ON or OFF, the Reader battery level, whether the Reader is on or off the charging pad, and Reader movement.

When paired with the phone, the Reader stays in regular communication with the ID-Cap App and secure server by sending Reader status messages. When not paired with the App, these messages are stored on the Reader for future download.

IMPORTANT:
No personal or protected health information (or "PHI") is sent from the ingestible sensor, ID-Cap Reader, or ID-Cap App. There is not a Global Positioning System (GPS) in the Reader, and the Reader does not collect any location information. The ID-Cap App also does not capture or track any location information.

IMPORTANT USE INFORMATION

The ID-Cap System records an event signaled by swallowing the ID-Capsule. ID-Capsules may be taken on a specific schedule to mark ingestion events. When used to mark events signaled by the co-incidence with or co-ingestion with the ID-Capsule, the ID-Capsule should be taken at the same time as the specific event of interest or at the same time as a dose of medication. Your doctor will prescribe an ingestion schedule and provide instructions for taking the ID-Capsules. The ID-Cap System logs, tracks and trends your ID-Capsule ingestion times.

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

- The ID-Cap System simply records and tracks your ingestions of ID-Capsules when you are wearing the ID-Cap Reader.
- Talk with your doctor or pharmacist if you have questions about the ID-Cap System.
- With your consent, your healthcare provider may be monitoring your ingestion events using the ID-Cap System and may contact you regarding the information received.
- The ID-Cap System may occasionally fail to detect or record an ingestion. If this occurs or if you forget to use the Reader, **DO NOT** take an additional ID-Capsule. There is no need to repeat the ingestion. Wait until your next scheduled ingestion. If an ingestion is not detected or not reported in the App, you can manually record the ingestion event in the ID-Cap App, if applicable.

Always take your medication as prescribed regardless of the status and use of the ID-Cap SystGENERAL WARNINGS AND PRECAUTIONS

	WARNINGS and PRECAUTIONS
	Ensure that you read and fully understand the warnings and precautions outlined here. If you have any questions about how to safely and effectively use the ID-Cap System, ask your doctor or pharmacist.

General System

- DO NOT use if you are pregnant or breastfeeding.

- DO NOT use as the sole basis for healthcare decisions or treatment changes related to ingestion events. Detection accuracy is less than 100%. Patients instructed by a doctor to take the ID-Capsule to mark an event signaled by the co-incidence with or co-ingestion with the ID-Capsule may selectively adhere to one or the other. Therefore, ingestion event data should be interpreted with caution. Patients should discuss ingestion events with their doctor prior to making changes in their treatment or health behaviors.
- Avoid exposure to known sources of electromagnetic interference (EMI) with medical devices, such as magnetic resonance imaging (MRI) systems, diathermy, lithotripsy, electrocautery, Radio Frequency Identification (RFID) devices, and electromagnetic security systems, such as metal detectors. Note that the presence of RFID devices may not be obvious.
- The ID-Cap System has not been studied in individuals who have implanted electronic medical devices.
- Keep components out of reach of children.
- DO NOT use the ID-Cap System while on aircraft.

ID-Cap Reader

- Keep the Reader powered ON and charged at all times, so it is 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 turn the Reader off at any time as it may impact the proper functioning of the System.
- Do not attempt to replace the battery or open the Reader case. The Reader contains no user-serviceable parts.
- The ID-Cap Reader is designed to be weather resistant, but DO NOT submerge in or expose to excessive amounts of water or other liquids.
- If the ID-Cap Reader or any of the charging accessories becomes damaged during normal use, discontinue use of the Reader, and contact your healthcare provider for a replacement.

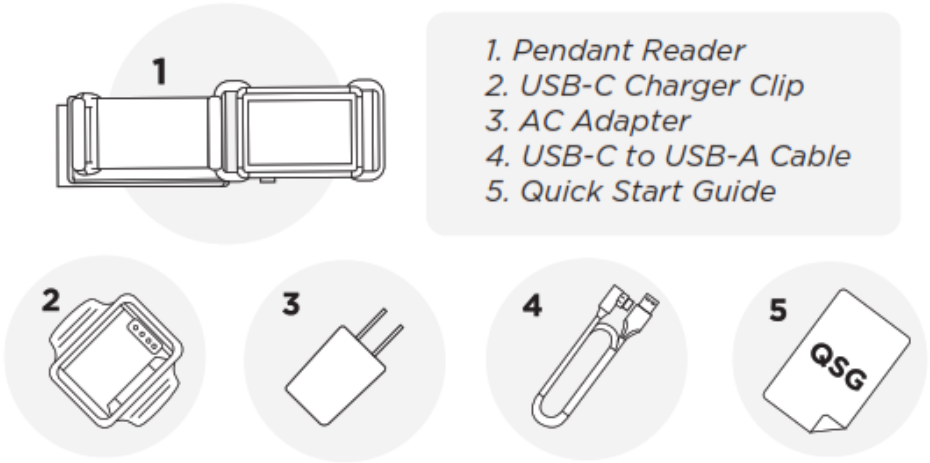
ID-Capsule

- 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 take more than five ID-Capsules per day with a minimum of 90 minutes between ID-Capsule ingestions to ensure that each ID-Tag is appropriately identified, and each ingestion event is detected.
- Take with a sufficient amount of water. DO NOT chew the ID-Capsules.
- DO NOT take if you are allergic to any of the ingredients in the ingestible ID-Capsule.

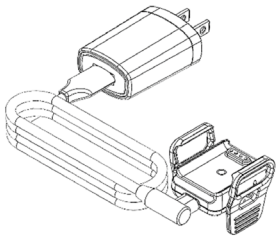
INSTRUCTIONS FOR USE OF THE ID-CAP SYSTEM WITH THE ID-CAP APP

Initial Setup of the ID-Cap Reader and its Charging Clip

1. Begin by removing all contents from the ID-Cap Reader kit. Save the Reader kit packaging.



2. Fully charge your reader with the included charging clip.



Reader Display

- The reader display will show a lightning bolt over the battery icon when charging.

- **IMPORTANT: Always** keep the Reader powered ON. DO NOT turn the Reader OFF. The Reader conserves power when not in use.

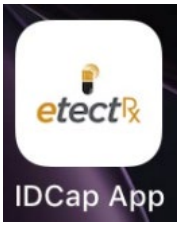
3. Download the "IDCap App" on your smartphone.

Initial Setup of the ID-Cap App

PROCEED with these steps if you are using your smartphone (and the ID-Cap App) to receive and communicate ingestion event information. This will allow authorized users to view and track your ingestion events when they occur and as they are recorded by the ID-Cap Reader.

To download and install "IDCap App" on your smartphone, complete the following steps:

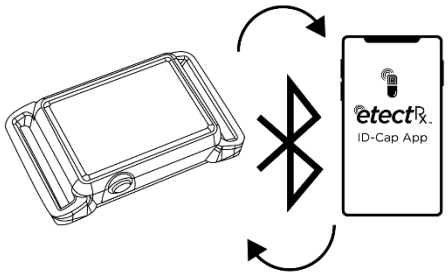
1. Download "IDCap App" from the App Store or Google Play. Search for "IDCap App" without any deviations in spelling or spacing and select the correct app ("IDCap App"**) or scan the QR code below with your smartphone to download the application.**



2. Open the App and follow the prompts to enter your 6-digit Reader ID and 12-digit App activation code. All codes needed to activate the App can be found on the GOLD sticker on the side of the Reader Kit box. The Reader Kit box is the cardboard box in which the Reader and accessories were packaged. The codes found that you will need to enter when prompted include the Reader ID, App activation code, and Bluetooth pairing code (which will be entered after you activate the App).
3. If you cannot locate these codes, contact the individual who dispensed the Reader to you.
4. Accept the terms of use and agreement regarding the privacy policy to proceed.
5. If prompted, you must allow permissions and notifications for App activation.

Pair Your Reader and Phone Before Use

With a simple Bluetooth connection to your phone, your ID-Cap Reader sends information to the ID-Cap App to help you keep track of your ingestion events. With your permission, this information will be shared with your healthcare providers to help them improve your health outcomes.



Before pairing your Reader with your phone, make sure you have completed the setup steps listed on the previous page to power up the Reader and activate the App.

Pair the Reader with your phone by completing the following steps:

1. Ensure the Reader and your phone are within 10 feet of each other.
2. Ensure Bluetooth on your phone is turned ON (i.e., enabled).
3. Ensure Location Services on your phone are turned ON.
4. If the ID-Cap App is not running, open it.
5. When prompted, enter the Bluetooth pairing code (**032669**) in the ID-Cap App to complete the pairing, the Bluetooth icon on the Reader will stop blinking.
6. Your phone will automatically pair with the Reader.
7. When successfully paired the home screen of the ID-Cap App will indicate that the Reader is connected and will display the Reader battery level as shown to the right

The Bluetooth icon on the reader display will blink until it is connected to your smartphone.

Routine Use of the ID-Cap System with the ID-Cap App

Use your Reader <u>every</u> time you ingest an ID-Capsule to record the ingestion event. Before first use, make sure you follow the instructions for setting up your Reader and ID-Cap App.

FOR EACH INGESTION EVENT, complete the six steps outlined below to record the ID-Capsule ingestion on the Reader and the ID-Cap App. Each of these steps is described in more detail in the text below this summary graphic.

1. Confirm Reader is **ON**, **paired**, and has at least **one bar** of battery.

2. Place reader around your neck.

3. Ingest ID-Capsule **as prescribed** by your doctor. Take one ID-Capsule at the scheduled time or at the same time as the ingestion event to be tracked.

4. Look for the pill detection message on the reader indicating a confirmed ingestion. This may take several minutes. Look for the ingestion event record in the App. The pill icon will display for one hour and then revert back to time of day.

5. **You may remove the Reader after** the pill detection message is received or after 30 minutes if no message is received.

6. Place Reader on the supplied charging clip. Leave Reader **powered ON**. Reader will not fully charge unless it is **ON**.

If you forget to put on the Reader before you ingest the ID-Capsule, you may still be able to detect the ingestion. If this occurs, put the Reader on as soon as you remember. The ingestible sensor sends a signal for an average of **nearly 30 minutes** after it is swallowed, so there is still an opportunity for the Reader to detect it.

	WARNING
	If you have taken an ID-Capsule and have not received confirmation of the ingestion on the Reader and/or App, DO NOT take an additional ID-Capsule until the time your next dose is scheduled. There is no need to repeat the ingestion if it was not recorded properly. If an ingestion is not detected or not reported in the App, you may be able to manually record the ingestion event in the ID-Cap App if applicable.

Manually Recording an Ingestion Event in the ID-Cap App (if applicable, your Doctor will inform and train you if this is available to you)

The System may occasionally fail to detect or record an ingestion event. If this occurs or if you forget to wear your

Reader when taking an ID-Capsule, **DO NOT** take an additional ID-Capsule. There is no need to repeat the ingestion. You can manually record the ingestion event in the App if applicable.

To manually record an ingestion event in the ID-Cap App, follow these steps:

1. Select the + sign in the top right corner of the App Home page.
2. Enter the date and time that the ID-Capsule was taken.
3. Remember that the ingestion event **must be recorded within two days of the ingestion** in the ID-Cap App and cannot be deleted or edited once it is manually entered.

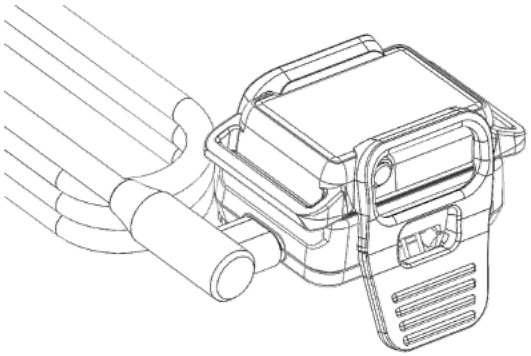
The type of ingestion event recorded in the App can be identified by the icon displayed at the end of each ingestion event listing on the Home, History, and Calendar screens. Manually recorded ingestion events are displayed with the icon of the person and check mark. Reader-detected ingestion events are displayed with the icon of the Reader.

Symbol for manually entered ingestion event

Symbol for Reader-detected ingestion event

Charging the ID-Cap Reader

The Reader contains a rechargeable battery. Keep the Reader charged so it is ready for use. It is recommended to leave the Reader on the Reader charging clip when not in use as shown below.

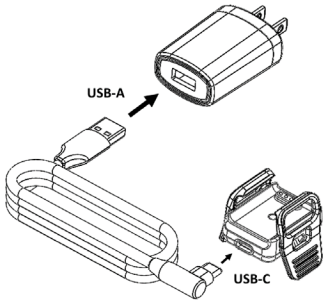


Only use the supplied charging clip, USB cable, and AC adapter to charge the Reader. Using a charger other than the one provided with your Reader may affect the charging of the Reader.

When you are not using the Reader to detect an ingestion, it is recommended to keep it on the charging clip.

The Reader kit contains the following three items for charging the Reader: a charging clip, an AC adapter or wall plug, and a USB cable.

Setting up the charger:



- Connect the charging pad to the wall plug using the supplied USB cable.
- Plug the charging pad into a standard electrical outlet at a convenient location.

To charge the Reader:

- Attach the Reader on the charging clip as shown above.
- After the Reader reaches full charge, the Charging Complete screen will be displayed on the reader screen.

- The Reader battery has a life of **approximately 24 hours on a full charge.** The Reader battery level is displayed on the Home screen of the Wrist reader. The battery level must be at least 1 bar to detect an ingestion.

Do not attempt to replace the battery or open the Reader case. The Reader contains no user-serviceable parts.

If the reader charge level drops below a level where it can detect a pill, the critical battery level screen (see below) will be displayed momentarily when the button is pressed. This screen will be displayed until the reader is charged.

Device Return

After your last ID-Capsule ingestion, return the ID-Cap Reader, charging clip, and accessories to your healthcare provider or to etectRx by packaging it in the Reader Kit box and returning it as instructed.

Monitoring the Activity of the Device

Reader status information and ingestion event data are sent to the manufacturer and authorized users who have been granted access to your ingestion event 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. There is **not** a Global Positioning System (GPS) in the Reader, and the Reader does not collect any location information. The ID-Cap App does not capture or track any location information.

As with all wireless communications, an ingestion event message will occasionally not be received by the ID-Cap Reader. If this occurs more often than just occasionally, contact your healthcare provider or etectRx. If you are experiencing problems with your ID-Cap System, please refer to the Troubleshooting Section of this User Manual or contact your doctor.

Conditions Affecting Device Performance and Use

The following conditions may affect device performance, the integrity of the data collected by the System, and/or user interactions with the ID-Cap System:

- Failure to follow instructions for use
- Technical issues affecting any of the following:
  - ID-Cap Reader (e.g., low battery)
  - ID-Tag, ID-Capsule, or messaging between the ID-Tag and Reader
  - Smartphone and/or ID-Cap App when using the device with the ID-Cap App
- Connectivity between the Reader and smartphone
- Distractions in the user environment that could interrupt use

Maintenance

The ID-Cap Reader contains no user-serviceable parts. For maintenance of the device, please contact the manufacturer, etectRx. ID-Cap Reader should be returned to etectRx for cleaning and recertification before assignment to the next patient.

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.

Storage and Handling

Storage and Operating Requirements

The ID-Cap System is intended for storage and operation in a room-temperature environment. Store ID-Capsules in original sealed containers. ID-Capsules may be sensitive to moisture and humidity.

Please refer to the storage and handling information in Appendix A for environmental conditions required for proper operation, storage, and transport of ID-Cap Readers and ID-Capsules.

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 at the conclusion of the scheduled ingestions. The ID-Cap Reader contains no user-serviceable parts.

The ID-Capsules have a shelf life of three months from the date of manufacture when stored in their original packaging. Refer to the use date on the ID-Capsule container.
The following signs may indicate a failing device:

- Failure to mark ingestion events
- Discoloration or deformity of the ID-Capsule shell
- Discoloration or deformity of the Reader or its materials
- Display screen not showing

Disposal of Waste Products

Do not dispose of the 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. 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.

Compliant Use

Ordered by Doctor or Licensed Practitioner

Federal law (USA) restricts this device to be provided by prescription only on the order of a licensed practitioner.

	ATTENTION
⚠	**CAUTION:** Your healthcare provider 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.

The Reader contains no user-serviceable parts. Do not attempt to replace the battery or open the Reader case.

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.

Important Safety Instructions for Compliant Use

Electromagnetic Compatibility

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

	**ATTENTION**
	CAUTION: Use caution when operating the ID-Cap System near other electrical equipment. Check the instructions or ask your doctor to make sure the devices are compatible.

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

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**
	CAUTION: The charging clip should be plugged into a power outlet using the supplied AC adapter. Plugging the charging pad into the USB port of another electronic device may prevent it from charging the Reader or may increase the time required to charge the Reader.

Charging

	**ATTENTION**
	CAUTION: The reader must be turned **ON** to achieve full charge. If the reader is turned off it will charge only partially until it is powered **ON**.

Environment

	**ATTENTION**
	CAUTION: Do not submerge the Reader in water. The Reader is designed to operate between 41-104 degrees Fahrenheit.

Malfunction

The ID-Cap System is designed to have basic user interaction. Refer to the Troubleshooting Section in this User Manual if you experience a problem. If the device is not working properly, contact your doctor, or the manufacturer.

TROUBLESHOOTING

If you experience difficulties or device malfunction, refer to the information below or contact your doctor.

To report an injury from the use of the device contact your doctor or study team.

ID-Capsule

Problem	Solution
You experience clinical worsening or new clinical symptoms during use of the ID-Cap System.	Seek medical attention.
You are confused about how or when to take your ID-Capsules.	Talk with your doctor
The ID-Capsule gets wet or damaged.	Do not take the wet or damaged ID-Capsule. Swallow a replacement capsule if provided.

ID-Cap Reader

Problem	Solution
The ID-Cap Reader will not power on.	***Option 1:*** Press and hold the power button for three seconds. ***Option 2:*** Ensure that the device charger is set up and connected correctly and place the Reader on the charging clip in the correct orientation. After charging for 30 minutes, press and hold the power button for three seconds to turn the Reader on. ***Option 3:*** Contact your doctor or etectRx for a replacement device if the reader does not turn on.
The display screen on the ID-Cap Reader is not working.	Contact your doctor or etectRx for a replacement device.
The ID-Cap Reader is shut off or its battery fully discharges.	Charge the reader if needed. Attempt to power on the Reader by holding the power button for three seconds. If your Reader is being used with the ID-Cap App on your smartphone, pair the Reader with the smartphone before dosing. ***NOTE:*** Always keep the Reader powered on and sufficiently charged.

Mobile Application

Problem	Solution
An ingestion event appears on the reader but is not displayed 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 smartphone. If no connection is indicated, close the App completely and re-start the App.

	Option 2: Restart your phone: press and hold the power button to turn the phone off and press and hold the button to turn it back on. Re-start the ID-Cap App. ***Option 3:*** If the app home screen indicates that the device is not paired, check that Bluetooth on the phone is turned on. If Bluetooth is off, turn it on. If Bluetooth is on but not connected, shut down app, go to settings and forget the reader device, restart app, and enter pairing code when prompted. ***Option 4:*** If the ingestion event does not populate after completing Options 1-3, report the ingestion event in the ID-Cap App as a manual entry (if applicable)
Problem An ingestion event is not detected by the reader after waiting 30 minutes	**Solution** If the ingestion event does not appear on the reader, please report the ingestion event in the ID-Cap App as a manual ingestion event entry (if applicable)

USER ASSISTANCE

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

Email: support@etectrx.com

MANUFACTURER

etectRx, Inc.
747 SW 2nd Ave, Suite 365T, IMB 24, Gainesville, FL, 32601
Ph: (352) 443-5713
www.etectrx.com
US Patent No. 9743880 | Made in USA

NOTICES

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 the ID-Cap System for clinical decision-making.

Trademark
All ID-Cap System 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

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, ID-Tags, and ID-Capsules are manufactured and 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.

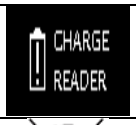
APPENDIX A: TECHNICAL INFORMATION

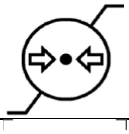
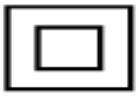
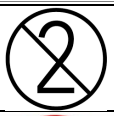
Device Classification

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

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.

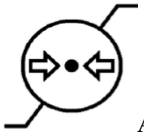
Symbols Reference Guide

Symbol	Meaning
	Caution – Consult Accompanying Documents - Hazardous situation which can cause material damage or lead to minor or moderate injury
	Warning – Consult Accompanying Documents - Hazardous situation which can cause a serious or fatal injury
	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 licensed practitioner.
	Not for General Waste
	Lot Number
	Read Instructions Before Use

Symbol	Meaning
	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
	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 has been designed for ambulatory use, enabling unattended data collection for clinical applications. 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 (non-condensing)	Atmospheric Pressure
Operating	41°F – 104°F	15% – 90%	700 – 1060 hPa
Storage	-13°F – 158°F	15% – 90%	700 – 1060 hPa
Transport	-13°F – 158°F	15% – 90%	700 – 1060 hPa

If the internal temperature of the ID-Cap Reader exceeds 132°F, the device automatically shuts down and cannot be used until it cools. During this time, an overheat message is displayed until the ID-Cap Reader cools to below 113°F.

ID-Capsules

Condition	Temperature	Relative Humidity
Storage	59°F - 86°F	35% – 65%
Transport	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. Avoid storing ID-Capsules under or near sources of water.

Biocompatibility

Biocompatibility and toxicity 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, ID-Capsule, and ID-Tag are biocompatible and non-toxic:

- Cytotoxicity, sensitization, primary buccal irritation, intracutaneous irritation, pyrogenicity, intramuscular implantation, acute systemic toxicity, and subacute systemic toxicity tests for the ingestible ID-Tag
- Cytotoxicity, sensitization, intracutaneous irritation, and pyrogenicity tests for the ingestible ID-Capsule
- Chemical characterization and degradation study of the ID-Capsule and toxicological risk assessment
- Cytotoxicity, sensitization, and primary skin irritation tests for the wearable ID-Cap Reader

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.

	ATTENTION
	**CAUTION:** For continued safety, if the enclosure becomes damaged, do not use the ID-Cap Reader and contact the manufacturer.

Regulatory Information

Declaration of Conformity

etectRx declares that the ID-Cap System is compliant with the following standards:

Product Safety	AAMI/ANSI/ES 60601-1: 2005; (R) 2012 +A1, +A2
Home Use Safety	AAMI/IEC 60601-1-11: 2015
Electromagnetic Compatibility (EMC)/ Electromagnetic Immunity (EMI)	AAMI/IEC 60601-1-2: 2014
Wireless Coexistence	ANSI C63.27: 2017
Battery	IEC 62133: 2012
Biocompatibility/Toxicity	ISO 10993-1: 2009; ISO 10993-5: 2009; ISO 10993-6: 2016; ISO 10993-10: 2010; ISO 10993-11: 2017; ISO 10993-12: 2012; USP 40-NF35: 2017

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 User Manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The ID-Cap System 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 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.

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 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.

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

FCC Compliance Identifiers

FCC ID for the ID-Cap Reader: 2AL2U-020002
FCC ID for the ID-Tag: 2AL2U-ET2000150

ISED Interference Statement

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

FRENCH: 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, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Electromagnetic Compatibility

The ID-Cap System 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. The device will function normally when subject to the immunity testing described below.

Information on the Radio Subsystem

The ID-Tag is a low power transmitter operating in the frequency range of 286 to 320 MHz, with an average RF output power of <1 mW. The modulation is ASK (Amplitude Shift Keying).

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 isotropic radiated power is 1.95 dBm (P=1.55 mW).

<table>
<tr><th colspan="3">Guidance and Manufacturer's Declaration - Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The ID-Cap System 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.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>The ID-Cap Reader uses RF energy for its internal functions and BLE. Its RF emissions are low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The ID-Cap System 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not Applicable</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 6100-3-3</td><td>Not Applicable</td></tr>
</table>

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	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 kV air	The relative humidity should be at least 5%.
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	30 A/m	30 A/m	Power frequency magnetic fields from common appliances in the home are not expected to affect the device. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Keep the ID-Cap System away from sources of high levels of power line magnetic fields (in excess of 30 A/m) to reduce the likelihood of interference.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	The ID-Cap System is suitable for the electromagnetic environment of typical homes and commercial or hospital settings.
NOTE UT is the a.c. mains voltage prior to application of the test level.			