

inpen LBL-00527 Basal smart cap User Guide

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InPen TM Basal
smart cap
User Guide







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Symbols in This User Guide

The following symbols are found on the Cap or the package labels. These symbols tell you about the proper and safe use of the Cap System.

	Non-ionizing Radiation
	Consult Instructions for Use
RX Only	Prescription Use Only
	Caution
	Do Not use if Package is Damaged
	Temperature Limitation
	Humidity Limitation
	Pressure Limitation
	Keep Dry
IP22	Protection Against insertion of Large Objects and Dripping Water

	Type BF Applied Part
	Device Meets European Council Directive 93/42/EEC
	Manufacturer
	Authorized Representative in the European Community
	European Union WEEE Directive 2012/19/EU
	Catalog number
	Use by date
	Batch code

Introduction

This user guide will explain how to use your Cap and related features of the InPen Application (App) to help manage your long-acting insulin doses. Read it carefully before you use your Cap. For information about all other features of the InPen system, refer to the InPen System User Guide.

Important: You should read this manual before use – even if you have used the Cap before. Failure to follow the instructions may result in too much or too little insulin being administered. Do not share your Cap as infection or disease can be spread from one person to another.

The Cap consists of the following:

- InPen Basal smart cap
- InPen Basal smart cap pen adapters (qty. 5)
- Quick Start Guide

If any of the parts of your Cap appear broken or damaged, DO NOT USE. Contact Customer Service by Tapping Settings from the Home screen and selecting Help and Support for a replacement.

Cap is not recommended for the blind or visually impaired without the assistance of a sighted individual trained to use it.

The App is a diabetes management tool that helps track your long-acting insulin doses.

Key Features:

- Dose reminders
- Time since your last long-acting insulin dose
- Intuitive display of your diabetes therapy
- Display of glucose data automatically from supported CGMs and BGMS
- View and share therapy reports with your healthcare provider

Support:

- Setup wizard within the App.
- User Guide links within the App
- Instructional videos within the App.

Indications for Use

The InPen Basal smart cap is a reusable electronic cap for the tracking of long-acting insulin doses for single-patient use by people with diabetes under the supervision of an adult caregiver or by a patient age 7 and older. The Cap is compatible with Levemir®, Tresiba®, Lantus®, Basaglar®, and Toujeo® prefilled pens and communicates with the InPen app. A healthcare professional must provide the patient-specific dose and timing parameters to be programmed into the software prior to use.

Contraindications:

The Cap is not intended for anyone unable or unwilling to:

- Test blood glucose levels as recommended by a healthcare provider
- Maintain sufficient diabetes self-care skills
- Visit a healthcare provider regularly

Caution: US law restricts the sale of the InPen Basal smart cap to sale by or on the order of a prescribing healthcare provider.

Important Pediatric User Information

The following recommendations are meant to help younger patients and their caregivers manage and care for the Cap. Younger children may inadvertently play with the Cap or the App, leading to unintentional blogging of insulin. It is the responsibility of the healthcare provider and the caregiver to determine if the patient is Appropriate for the Cap.

Do not allow small children to chew on or ingest parts, such as the pen cap and adapter components. Small parts could pose a choking hazard. If ingested or swallowed, these component pieces may cause internal injury or infection.

For patients who do not self-manage their disease, the smart device should always be under the supervision of a caregiver. Inadvertent button presses may lead to unintentional dose logging or changes to therapy settings. These changes can potentially lead to hypoglycemic or hyperglycemic events which could result in serious injury or death.

Supported Devices

The App is compatible with:

- iOS 10 or later
- Android 6 or later

Check the Companion Medical website to make sure the App is compatible before updating your smart device. Periodically, the App needs to confirm that it is compatible with your smart device and operating system version. You may see system messages with instructions or warnings. Make sure you have an internet connection (ensure that Wi-Fi or cellular data is enabled) whenever possible.

CAUTION: You must first pair your Cap with the App on a smart device. This will ensure that doses from your Cap are sent wirelessly to the App on your smart device.

WARNING: The Bluetooth® feature of your Cap sends dose information to your smart device. To prevent other people's doses from being sent to the smart device, do not let anyone else use your Cap. The Cap is for single patient use only.

Bluetooth® performance varies due to differences in phone hardware and operating systems. The App is not recommended on Jailbroken or Rooted devices. Your smart device must have enough memory storage or the InPen App will not be able to be installed or log doses. You may need to delete files or Apps from your smart device.

Getting Started

The following steps will get you started using the App:

- a) Download the InPen App from the Apple App Store (iOS) or Google Play Store (Android) and install it on your smart device.
- b) Open the App.
- c) Log in to the App using an existing account or create a new one.
- d) After you log in to the App, follow the steps in the setup wizard.

Setup Wizard

About You

Take a moment to tell us about you.

Therapy Setup

Before the App can be used, you will need your long-acting insulin Therapy Settings from your healthcare provider. Your healthcare provider may have already entered these for you at your visit. If not, you can find these on your prescription.

Optionally you may set up an InPen for your rapid-acting insulin at this time. If you do not have an InPen, tap I do not have my InPen yet.

Long-acting Setup

The App will remind you to take your long-acting insulin. If you either take or manually log a long-acting dose before the reminder time, you will not receive a reminder from the App. If no long-acting dose was logged manually or from Cap then the App will remind you.

Once you have your long-acting insulin settings, tap on each line to set the correct value. Once you have selected the correct value, tap the green check mark to save and the red X to cancel.

IMPORTANT: It is extremely important that Therapy Settings are correct. Proceed only after you are sure that your Therapy Settings are correct from your healthcare provider.

The values that must be set are:

Insulin Type – This is the type of long-acting insulin that you take.

Doses per Day – This is the number of long-acting insulin doses you take per day.

Usual Amount – This is the dose size you have been prescribed by your healthcare provider.

Time – This is the time of day that you are supposed to take your dose.

When you have entered all values and carefully checked that they are correct, tap Next.

Confirm Last Long-acting Dose

The App will ask you to confirm the last long-acting insulin dose that you have taken. The app will then update Cap with your long-acting insulin dose schedule.

IMPORTANT: If the time of the last long-acting dose is incorrect then Cap may indicate that too little or too much time has passed since your last long-acting insulin dose which could lead to hyperglycemia, hypoglycemia, or injury.

Attach Adapter

The App will tell you which number adapter to select for your long-acting insulin. Find the correct adapter in the Cap packaging and make sure the number on the adapter matches the number displayed in the App. Slide the adapter onto the Cap until you hear a “click”. Refer to the video in the App for correct placement of the adapter.

Remove the original cap from your long-acting insulin pen. Place the Cap on your long-acting insulin pen securely. You should hear a “click” and the Cap should feel securely attached to your long-acting insulin pen. If the cap does not “click” and the Cap feels loose, make sure that you have installed the correct adapter. **IMPORTANT:**

Retain the original cap for your long-acting insulin pen.

IMPORTANT: Keep the remaining adapters in a safe place. If your long-acting prescription changes, you may need to change the adapter to fit the new long-acting insulin pen. **Connect InPen Basal Smart Cap**
IMPORTANT: To ensure a secure connection, pair your Cap and smart device in a secure area with limited Bluetooth® devices in range.

CAUTION: Make sure you know which Cap you are pairing with your smart device.

IMPORTANT: Enable the security features of your smart device to prevent unauthorized access to your data and settings.

- Place the smart device and Cap within 3 feet (~1 meter) of each other before you begin. Your Cap will blink red and yellow when unpaired.
- Make sure Bluetooth® is enabled on your smart device.
- Follow the instructions in the App to pair your Cap. The App will ask you to verify a sequence of lights blinking on the Cap.
- The App will display Pairing Successful once successfully paired.

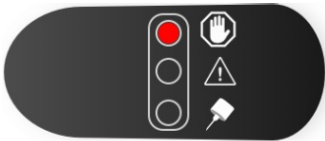


How it Works

- To check if your next dose is due, take the Cap off of your long-acting insulin pen.
- Look for the blinking lights on the Cap.
- Determine if it is time to dose.
- Replace the Cap. You should hear a “click” and the Cap should feel securely attached to your long-acting insulin pen.

Note: When the Cap is removed for more than 8 seconds, an event will be logged within your logbook. Review all logbook events to ensure accuracy of logged doses.

When to Dose

Use the color of the blinking light to determine if it is time to dose. Think like a Stop Light.

Blinking Light	Recommended Action
Red 	STOP. Do not double dose.
Yellow 	CAUTION. Dose is early.
Green 	GO. Okay to dose.

Time Since Last Dose

The color of the blinking light and recommended action is determined by the amount of time that has passed since your last long-acting insulin dose.

Time Since Last Dose		
	Once Daily Dose	Twice Daily Dose
Red	0-12 hours ago	0-6 hours ago
Yellow	12-21 hours ago	6-9 hours ago
Green	Over 21 hours ago	Over 9 hours ago

Note: You can use the logbook within the App to review your recent long-acting insulin doses, as needed.

Automatically Logged Doses

Long-acting insulin doses are automatically logged when the cap is flashing green or yellow and it has been removed for more than 8 seconds. A dose is never automatically logged when the cap is blinking red.

When is a Dose Automatically Logged?		
	Cap off for less than 8 seconds	Cap off for <u>more</u> than 8 seconds
Red	No dose logged.	No dose logged. Do not double dose.
Yellow		Yes, a dose is logged.
Green		

Note: If you take a dose when the light is red, it will not be logged in the App and must be manually entered into the Logbook.

Logging Doses Manually

WARNING: Always log long-acting insulin doses that you take without Cap in the Logbook. The App does not automatically log manual injections that you take without Cap. Failing to log doses in the logbook could lead to double dosing, which could cause hypoglycemia.

For the App to work safely and accurately, it is critical that all long-acting insulin be logged. If you take long-acting insulin from a source other than your Cap, it must be logged manually.

To enter a manual dose, tap Log Dose in the Logbook and select long-acting insulin. To enter the units of long-acting insulin taken, tap Dose Amount and enter the number of units taken from a source other than your Cap.

To enter the time of the dose, tap Dose Time and enter the time when the dose was taken. By default, the time is set to the current time, but it can be adjusted to any time within the last 24 hours to log a dose you previously took.

If you have traveled across a time zone, adjust and enter the dose time as though it was taken in your current time zone.

When you have entered the correct dose, tap Save to save it and return to the Home screen.

To exit without saving a dose, tap Cancel.

Multi-part Injections

If you take a multi-part injection do not replace the Cap until you have taken your complete dose. For example, if you run out of insulin in the middle of your dose, replace the Cap on the new pen after you complete your full

dose.

To view details of your recent long-acting doses, tap Logbook from the Home screen. All doses taken from your Cap will be listed here, along with any doses of long-acting insulin you have manually logged.

Manually logged long-acting doses can be deleted from the logbook by tapping the dose.

Changing Pens

When your long-acting pen is empty or if it needs to be replaced for any reason you can simply replace the cap of the new pen with Cap. Remove Cap and replace on the new pen in less than 8 seconds to prevent logging a dose.

Verify that your recent long-acting doses are logged correctly by tapping Logbook from the Home screen. Manually or incorrectly logged long-acting doses can be deleted from the logbook by tapping the dose.

If your prescription for long-acting insulin changes (ex. from Tresiba® to Basaglar®), you may need to change the adapter to fit your new long-acting insulin pen. Always consult your HCP if you should adjust your dose amount when changing medication types. Tap Settings > My Basal Smart Cap. Tap Remove. Tap Pair New Basal Smart Cap to add your Cap for the new insulin type. Follow the prompts to pair your Cap with the new insulin type. You will be able to change your long-acting insulin settings if needed. Ask your healthcare provider if you are unclear if your settings have changed.

To change the adapter, use a ballpoint pen or other tool to depress the small tab at the base of the adapter and pull the adapter out of the Cap while depressing the tab. Slide the new adapter into Cap and replace the Cap on the new pen. Verify that Cap fits securely on the new pen. If the fit is not secure, confirm you have selected the correct adapter.

Always verify that your recent long-acting doses are logged correctly by tapping Logbook from the Home screen. Manually or incorrectly logged long-acting doses can be deleted from the logbook by tapping the dose.

Smart Device Notes

IMPORTANT: Your smart device must be set up correctly to work properly and safely with the Cap. Your device's internal settings override any App setting. If the settings on your device are incorrect your Cap System may not function properly. IMPORTANT: Enable the security features of your smart device to prevent unauthorized access to your data and settings.

To ensure safety and security, utilize virus/malware scanning software on your smart device.

To receive Alarms or Alerts you must:

- Make sure the notifications are turned on in the settings menu
- Check that the App hasn't been shut down by your smart device
- Make sure to turn on Bluetooth® on your smart device
- Turn off the Do Not Disturb feature on your smart device (if available)
- Start the App after your smart device is restarted
- Set the volume on your smart device at a level you can hear
- Do not kill or force close the App; always run the App in the background
- Unplug your headphones when you are done using them; Alarms and Alerts from the App cannot be heard through your smart device's speakers if headphones are plugged in.

App alerts are not different from other app alerts on your smart device. Medical device apps, like the InPen App, do not have any special priorities over your smart device's features. You cannot determine if an alert is a notification from the App or another App. The only way to know is to look at the screen of your device. The smart device checks and updates the date and time in your Cap. Check the date and time on your device often to be sure it is correct. Check the date and time on your smart device when you travel across time zones.

Always let your smart device manage the date and time automatically. For instructions on setting the date and time on your device, see the user manual for your device.

The App is known to be free of malware.

Troubleshooting

Notification Icons

During use of the App, you may see one or more alert icons on the Home screen. When an icon Appears, it can be tapped for more information or to clear the notification.

Dose Reminder – This icon will appear when the Dose Reminder is enabled and no dose was taken at the reminder time. You can choose to clear or snooze the reminder.

Low Battery – This icon will appear when the Cap is reaching the end of its 1-year life and needs to be replaced. It will appear several times near the end of the lifetime and will remain visible until a new Cap is paired.

Temperature – This icon will appear when the Cap detects a very high or very low temperature. Based on the temperature of the Cap, you may want to consider replacing your long-acting insulin pen.

Common Problems and Solutions

The table below lists some potential issues that may arise during use of the Cap system and solutions to try.

Problem	Solutions to Try
I can't install the App.	Check that your smart device is compatible with the App. See Supported Devices above.
	On your smart device, tap the App Store icon and search for "Companion Medical InPen" and follow the prompts to install the App.
	The App may not be available in all locations.
I paired my Cap but doses are not appearing on the App.	Check that Bluetooth® is enabled on your smart device.
	Move the Cap and your smart device within 3 feet (1 m) of each other.
	Ensure that the Cap is still within its 1-year use life from the date of first use.
	Close and restart the App.
	From your smart device's Bluetooth® Settings screen, if you see a Cap listing, tap it and select "Forget This Device". See Getting Started for instructions to pair if your Cap has been paired before.
	Close and restart the App.
I left my Cap somewhere and I need to take insulin from another source.	You may take long-acting insulin from sources other than your Cap if needed. When you do, be sure to manually log the dose into the App. See Logging Doses

	<p>Manually for instructions on how to manually log a dose.</p> <p>For safety, it is important to log all long-acting insulin taken. Doses taken from a paired Cap are logged automatically and do not need to be manually entered.</p>
I paired my Cap to a new smart device, and now it won't connect with the original one.	<p>Your Cap can only be paired to one smart device at a time. If necessary, follow the instructions in Getting Started to pair it to your original device again.</p> <p>Frequently pairing the Cap to different smart devices may decrease battery life and is not recommended.</p>
I can't hear reminders on my smart device.	See Smart Device Notes for tips on properly setting up your smart device.
The Missed Dose Reminder isn't working.	<p>Tap Long-acting Reminder from Settings > Reminders and ensure that the switch is enabled. Slide it to turn it on.</p> <p>The Long-acting Reminder will only remind you if you have not taken a dose. If you use your Cap normally and take doses at your regular times each day, then the reminder will not appear.</p>

Support

If you have product support questions, do not call your doctor. Help and support is available by phone or email or using the self-service Help Center any time through

Settings > Help and Support > Support.

Check Troubleshooting for explanations of App error messages and a list of other common issues and solutions.

Handling and Storage

Be sure to store your Cap at room temperature when your Cap is installed on a long-acting insulin pen.

Refer to the instructions that came with your insulin pen for information on how to long-acting insulin pens and how long to keep them.

Do not store the Cap in a refrigerator.

Cleaning and Caring

Cleaning removes dirt from the surface of the device.

It does not kill bacteria or viruses. The Cap should be cleaned whenever it is visibly dirty.

Clean your Cap as needed only with a soft cloth moistened with water, being careful not to get water inside. Never submerge the Cap. If you get insulin on your Cap, clean it off right away.

Important Notes

Your Cap is designed to work accurately and safely, but you must still take good care of it.

- Only use your Cap as described in this manual.
- Handle it with care and do not drop it or knock it against hard surfaces.
- Do not try to wash, soak, or lubricate your Cap as this may damage it.
- Keep it away from direct sunlight, water, dust, and dirt.
- Do not expose your Cap to temperatures below -25 °C (-13°F).
- Do not try to repair a broken Cap

When you receive a battery warning or the Cap can no longer communicate with the Application, contact your healthcare provider to obtain a prescription for a new Cap.

If you suspect that your Cap has been damaged or may not be working properly, discontinue using it immediately, and contact Customer Support for assistance or to obtain a replacement.

If you choose to continue using your Cap, check that the long-acting insulin pen is not damaged and refer to the information provided with the long-acting insulin pen.

Disposal

Your Cap contains a lithium battery and electronic parts, so you should not throw it out with your household waste, but do so in a safe and environmentally correct way:

- Remove the needle and pen, and dispose of them as your doctor or nurse has instructed you.
- Dispose of your Cap as specified by your local authorities.

Legal Information

Apple Legal Notice

Apple, iPad, iPhone, iPod, and iPod touch are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

Android Legal Notice

Android is a registered trademark owned by Alphabet Inc.

About Bluetooth®

Bluetooth is a type of wireless (RF) communication. Cell phones use Bluetooth technology as do many other devices. Your Cap uses Bluetooth to pair with your smart device and to send data to the App.

Your Cap is subject to and complies with U.S. federal guidelines, Part 15 of the FCC rules for devices with RF capability. These rules state two conditions specific to the operation of the device. They are:

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

These guidelines help ensure that your Cap will not affect the operation of other nearby electronic devices. With the exception of your smart device, other electronic wireless devices that are in use nearby, such as a cell phone or a wireless network, may prevent or delay the transmission of data from your Cap to the App. Moving away from or turning off these electronic devices may allow communication. The Cap has been tested and found to be appropriate for use at home. In most cases, it should not interfere with other home electronic devices if used as instructed.

However, the Cap gives off RF energy and may interfere with your TV, radio, or other electronic devices that receive or transmit RF signals.

If you experience Cap interference problems, try moving your Cap away from the source of the interference. You can also move the electronic device or its antenna to another location to solve the problem.

If you continue to experience interference, contact Customer Support. The Bluetooth wordmark and logos are owned by the Bluetooth SIG, Inc. and any use of such marks by Companion Medical, Inc. is under license. Other trademarks and trade names are those of their respective owners.

Supplemental Information

Essential Performance

Essential Performance, as defined by IEC 60601-1, is not Applicable to the Cap system.

Operating frequency 2.4 GHz ISM band, GFSK
Effective radiated power (ERP) 0.16 mW (-8.01 dBm)
Effective isotropic radiated power (EIRP) 0.26 mW (-5.86 dBm)

Applied Parts

The Cap is a hand held device and is considered the Applied part as defined by IEC 60601-1.

Declaration of Conformity

Companion Medical declares that this product is in conformity with the essential requirements of Directive 1995/5/EC on Radio and Telecommunications Terminal Equipment and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (M5).

FCC Compliance

This device complies with FCC Part 15 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. Changes or modifications to the equipment could void the user's authority to operate the equipment.

Electromagnetic Emissions and Immunity Declaration and Guidance

Be careful when using the Cap closer than 30 cm (12 in) to portable radio frequency (RF) equipment or electrical equipment. If the Cap must be used next to portable RF equipment or electrical equipment, observe the Cap to verify correct system operation. Degradation of the performance of the Cap could result.


Guidance and manufacturer's declaration – Electromagnetic Emissions		
Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	CISPR 11 Group1, Class B	The Cap uses RF energy only for system communications. Therefore, its RF emissions are very low and are
Harmonic emissions	Not applicable	

Voltage fluctuations/ flicker emissions	Not applicable	not likely to cause any interference in nearby equipment.
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Surge IEC 61000-4-5	Not applicable	The requirement does not apply to ce.
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-4-11	Not applicable	Requirement does not apply to this battery-powered device.
Power frequency (50/60 Hz) electromagnetic field IEC 61000-4-8, IEC 60601-1-2	30 A/m	For use in a typical domestic, com ment.
Proximity fields from RF wireless communication s equipment IEC 61000-4-3	IEC 60601-1-2: 2014, Table 9	For use in a typical domestic, commercial, or hospital environme

Guidance and manufacturer's declaration – Electromagnetic Immunity

Immunity test	DEC 60601-1-22014 Compliance e Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD)	±8 kV contact ±2, 4, 8,kV air	For use in a typical domestic, comm hospital environment.
Conducted disturbances induced by RF fields	Not applicable	Requirement does not apply to this t device.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Requirement does not apply to this t

Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Portable and mobile RF communications e quipment should be used no closer to any part of the Cap, including cables, than the recommended separation distance of 30 c m (12 inches).
		Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.
		Interference may occur in the vicinity of eq uipment marked with the following symbol:
		

Note: UT is the a.c. mains voltage prior to application of the test level.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and

reflection from structures, objects, and people

Warranty

Companion Medical warrants the Cap against defects in materials and workmanship for a period of 1 year from the date of purchase. During the warranty period, Companion Medical will, at its discretion, replace any defective device, subject to the conditions and exclusions stated herein. In the event that a device is replaced, the warranty period will not be extended. This warranty is valid only if the Cap System is used in accordance with the manufacturer's instructions and within the use-by-date. This warranty will not apply:

- If damage results from changes or modifications made to the device.
- If damage results from use of incompatible pen injectors.
- If damage results from a Force Majeure or other event beyond the control of the manufacturer.
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water or physical abuse, such as dropping or otherwise.

This warranty shall apply to the original user. Any sale or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate. The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Companion Medical nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

All other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose. Use of the Cap system is subject at all times to the Companion Medical Inc. Terms of Service

(<https://www.companionmedical.com/terms-of-service>)
(<https://www.companionmedical.com/privacy-notice>).

and

Privacy

Policy

Product Specifications

The Cap is intended for use by patients at home and in healthcare facilities.

Operating Conditions

5 °C (41 °F) to 40 °C (104 °F) 15% to 90% RH (non condensing)

Operating Altitude

-381 m (-1253 ft) to 3010 m (9878 ft)

Operating Pressure

70 kPa – 106 kPa

Storage Conditions

-25 °C (-13 °F) to 70 °C (158 °F)

15% to 90% RH (non condensing)

Dimensions

8.9 cm (3.5") x ø2.5 cm (1.0")

Weight

35 g

Power Supply

Li-Mn battery (not replaceable)

Lifetime

1 year from activation

Moisture Protection

IP22: Protection against insertion of large objects and dripping water

Protection against Electrical Shock

Type BF Applied part



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LBL-00527-AC

01-2021

Documents / Resources

<p>InPen™ Basal smart cap User Guide</p> <p><small>1/2 Only</small></p>	<p>inpen LBL-00527 Basal smart cap [pdf] User Guide INCAP, 2AGUHINCAP, LBL-00527, Basal smart cap</p>
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