

# User Guide

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InPen™ Reusable Pen Injector



Companion  
Medical

## Symbols in This User Guide

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

	Non-ionizing Radiation
	Consult Instructions For Use
	Caution
	Do Not use if Package is Damaged
	Temperature Limitation
	Humidity Limitation
	Pressure Limitation
	Keep Dry
<b>IP22</b>	Protection Against Insertion of Large Objects and Dripping Water
	Type BF Applied Part
<b>CE</b>	Device Meets European Council Directive 93/42/EEC
	Manufacturer
<b>EC REP</b>	Authorized Representative in the European Community
	Activate By Date
	European Union WEEE Directive 2012/19/EU
	National Recognized Test Laboratory

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## 1 Introduction

Thank you for choosing InPen, the insulin pen designed to help make your insulin treatment easier. This manual will tell you how to use and handle your InPen. Read it carefully before you use your InPen.

InPen is easy to use. It delivers doses from 0.5 ( $\frac{1}{2}$ ) to 30 units of insulin. You can dial your dose one half ( $\frac{1}{2}$ ) unit at a time. If you dial too many units, you can correct the dose without wasting any insulin.

InPen is designed to be used with 3 mL (U-100) insulin cartridges, and compatible disposable needles.



You should read this manual before use – even if you have used the InPen before. Failure to follow the instructions may result in too much or too little insulin being delivered.

**DO NOT SHARE YOUR INPEN OR NEEDLES AS INFECTION OR DISEASE CAN BE SPREAD FROM ONE PERSON TO ANOTHER.**

If any of the parts of your InPen appear broken or damaged, DO NOT USE. Contact your healthcare provider for a replacement.

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

insulin delivery device in case your InPen is lost or damaged.

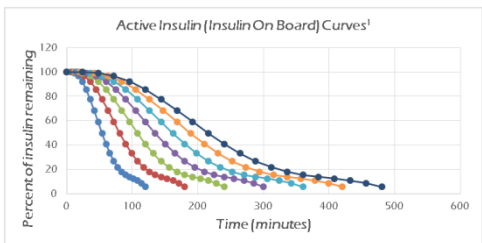
InPen connects to an optional mobile device application - the InPen App - via Bluetooth®. The InPen transmits dose information so that the application ("app") can help you remember the number of units you received from your last injection, when the injection was taken, and other helpful information.

Download the InPen App from the Apple Store (iOS) or Google Play (Android). Refer to the Mobile App User Guide for instructions of how to pair your InPen and use the app.

The insulin dose calculations provided by the app are meant for patients undergoing subcutaneous multiple daily injection (MDI) therapy. Dose calculators have been shown to assist in the optimization of glycemic control in MDI patients under the supervision of healthcare professionals experienced in managing insulin-treated patients. Dose calculators have also been shown to reduce patient fear of hypoglycemia and improve patient confidence in diabetes management.

Dose calculators also track residual bolus insulin to mitigate stacking.

The dose calculator utilizes the current blood glucose measurement, carbohydrate consumption, and active insulin to calculate the estimated dose.



<sup>1</sup>Adapted from Mudaliar et al, Diabetes Care, Volume 22, Number 9, Sept. 1999, page 1501.

## 2 Indications For Use

The InPen is a home-use reusable pen injector for single-patient use by people with diabetes age 12 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Lilly Humalog® U-100 3.0 mL cartridges of insulin and single-use detachable and disposable pen needles (not included). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

The InPen is a home-use reusable pen injector for single-patient use by people with diabetes age 12 and older for the self-injection of a desired dose of insulin. The pen injector is compatible with Novo Nordisk Novolog® U-100 3.0 mL cartridges of insulin and single-use detachable and disposable pen needles (not included). The pen injector allows the user to dial the desired dose from 0.5 to 30 units in one-half (1/2) unit increments.

The InPen dose calculator, a component of the InPen app, is indicated for the management of diabetes by people with diabetes age 12 and older by calculating an insulin dose or carbohydrate intake based on user entered data. Prior to use, a healthcare professional must provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the software.

### **3 Contraindications:**

**The InPen System is not intended for anyone unable or unwilling to:**

- Test blood glucose (BG) levels as recommended by a healthcare provider,
- Demonstrate adequate carbohydrate-counting skills,
- Maintain sufficient diabetes self-care skills, or
- Visit a healthcare provider regularly.

**Caution: US law restricts the sale of the InPen System to sale by or on the order of a physician.**

## 4 Compatible Insulin and Needles

InPen is compatible with 3 mL (U-100) insulin cartridges and disposable needles (supplied separately). Refer to the table below to determine compatible insulin and needles for use with your InPen:

InPen Model	Compatible U-100 3 mL Cartridges	Compatible Needles
INPEN-100EL-XX	Lilly Humalog®	BD Ultra-Fine™ and Novo Nordisk NovoFine®
INPEN-100NN-XX	Novo Nordisk Novolog®	

## 5 Getting Ready

Wash your hands and make sure you have the following items available before beginning:

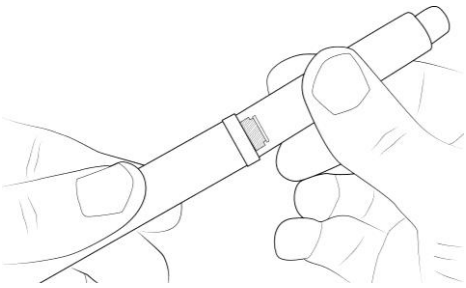
- InPen
- 3 mL U-100 Insulin Cartridge
- New Pen Needle

## 6 Preparing your InPen

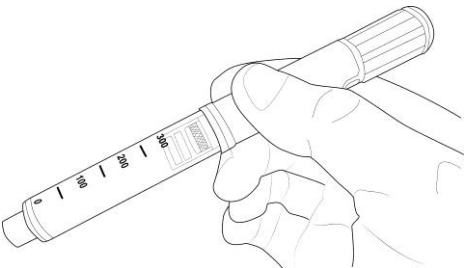
### 6.1 Steps

1. Pull Off Cap
2. Unscrew and Remove the Cartridge Holder.





3. Before inserting the Insulin Cartridge, be sure to inspect your Insulin Cartridge per the manufacturer's instructions. Do not use the cartridge if it has:
  - Expired
  - Unusual visual appearance
  - Cracks, breaks, or other damage
4. Insert the small end of the Insulin Cartridge into the Cartridge Holder.
5. Attach the Cartridge Holder by pushing the Cartridge Holder and InPen Body straight together. Screw the InPen Body onto the Cartridge Holder until it clicks and is secure.



**Caution: If the Cartridge Holder is not securely attached, the cartridge may be misaligned and you may not get your full dose.**

## 6.2 Important Notes

- Your healthcare provider has prescribed the type of insulin best for you. Any changes in insulin should be made only under medical supervision.
- InPen is for use only with 3 mL U-100 Insulin Cartridges.
- Only use Insulin Cartridges compatible with your InPen.
- Read and follow the instructions provided in your Insulin Cartridge Patient Information.
- Before each injection, read the Cartridge Label and be sure the InPen contains the correct Insulin Cartridge.
- The color of the InPen is not intended to indicate insulin type.
- The numbers on the Cartridge Holder give an estimate of the amount of insulin remaining in the Cartridge. Do not use these numbers for measuring an insulin dose.
- For more information on InPen and insulin, please refer

to the Patient Information provided with your Insulin Cartridge or contact your healthcare provider.

### **6.3 Frequently Asked Questions about Preparing your InPen**

#### **1. What should I do if I can't attach the Cartridge Holder to the InPen body?**

Check that the Insulin Cartridge is fully inserted into the Cartridge Holder and the Screw is screwed all the way back inside the InPen. Then carefully line up the Cartridge Holder with the InPen Body and screw together until secure.

#### **2. Why do I pull the InPen apart when I try to remove the InPen cap?**

Twisting the InPen Cap may have unscrewed the Cartridge Holder.

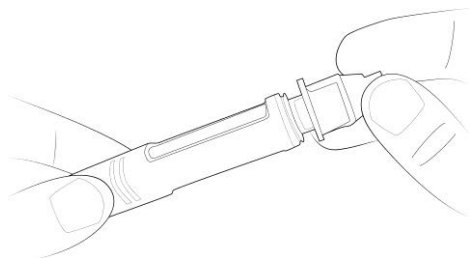
- Remove the cartridge holder and Insulin cartridge from the InPen cap.
- Place the Insulin cartridge into the Cartridge Holder and screw it back onto the InPen assembly.
- Be sure to prime the InPen again before the next use.

## 7 Prime your InPen (Before Every Injection)

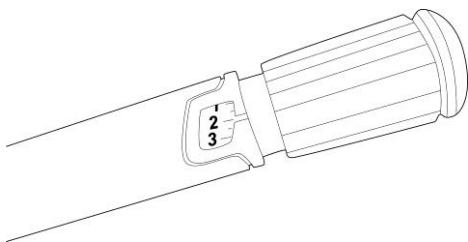
### 7.1 Steps

**Caution: If you do NOT prime, you may receive too much or too little insulin.**

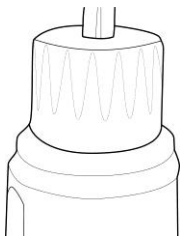
1. Remove Paper Tab from the Needle
2. Attach the Needle by screwing the Needle straight onto the Cartridge Holder as shown.



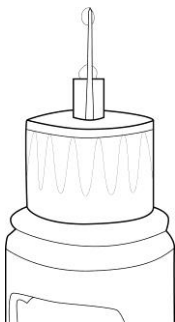
3. Pull off the Outer Cap and the Inner Cap.
  - Discard the Outer Cap.
  - Keep the Inner Cap to remove the Needle after your injection.
4. Turn the Dose Knob to select amount to prime:
  - Dial 2 units as shown.



5. Hold the InPen so the needle is pointing up and tap Cartridge to collect any air at the top.



6. Prime the InPen by pushing the Injection Button with your thumb and holding for eight (8) seconds. You should see a few drops of insulin.



7. If no stream is seen, repeat priming according to steps 4 through 6. A

new Cartridge may need to be primed several times.

**Caution: If no insulin flows after several attempts, attach a new Needle, as the one on your InPen may be clogged.**

## 7.2 Important Notes

- Only use Needles compatible with your InPen.
- The directions regarding Needle handling are not intended to replace local, healthcare provider, or institutional policies.
- Use a new Needle for each injection. This will help ensure sterility. It will also help prevent leakage of insulin, keep out air bubbles, and reduce Needle clogs.

## 7.3 Frequently Asked Questions about Priming Your InPen

### 1. Why is it important to prime before every injection?

If you do NOT prime, you may get too much or too little insulin. Priming helps to ensure that the InPen and Needle are working properly. Once the InPen is properly primed, insulin will flow from the Needle. You may need to prime several times before you see insulin.

**2. Why can it take several attempts to prime when a new Cartridge is inserted?**

There may be a gap between the Screw and the Cartridge Plunger. Repeating the priming steps will move the Screw out to touch the Cartridge Plunger. Once touching, insulin will flow from the Needle when priming.

- Repeat the priming steps until insulin is seen.
- If you are still unable to see insulin flow from the Needle, go to Question 3.

**3. Why can't I see insulin flow from the Needle tip?**

Priming moves the Screw into contact with the Cartridge Plunger and gets the air out of the Cartridge. When you are priming the InPen:

- You may see no flow at all. This may be because the Screw is moving forward to close a gap between the Screw and the Cartridge Plunger.
- If there is air in the Cartridge, the insulin may sputter or drip until all the air is removed.
- Insulin will flow as a stream only when the InPen is properly primed.

- If the Injection Button is hard to push, the Needle may be clogged. Attach a new Needle. Repeat the priming steps until a stream of insulin is seen.

If you are still unable to see a stream of insulin out of the Needle, do NOT use the InPen. Contact your healthcare provider for assistance or to obtain a replacement.

#### **4. What should I do if I have an air bubble in the Cartridge?**

Priming your InPen will remove air. Hold the InPen so that the Needle is pointing up, and tap the Cartridge gently with your finger so any air bubbles can collect near the top. Repeat the priming steps until insulin is seen. A small air bubble may remain in the Cartridge after completion of the priming steps. If you have properly primed the InPen, this small air bubble will not affect your insulin dose.

#### **5. Why does no drop of insulin appear at the needle tip when I check the insulin flow?**

The needle may be blocked.

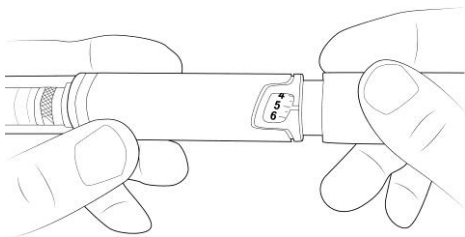
- Screw on a new needle
- Check the insulin flow until insulin appears at the needle tip



## 8 Selecting Your Dose

### 8.1 Steps

1. Select your dose by turning the Dose Knob until the desired dose is lined up with the Dose Indicator. Half units are shown as lines between the numbers.



If you select a wrong dose, simply change it by turning the dose button in either direction. If you change your mind and do not want to inject a dose, you may adjust the knob back to the 0 set point. No insulin will be dispensed until you press the button.

### 8.2 Important Notes:

You cannot select a dose larger than 30 units. If you need more than 30 units, you must divide your dose into two injections.

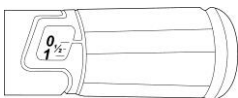
### 8.3 Frequently Asked Questions about Selecting Your Dose

#### 1. How do I read the dose indicator?

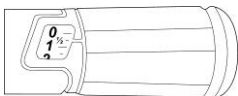
The InPen can be adjusted in steps (increments) of 0.5 ( $\frac{1}{2}$ ) units. Read the numbers shown in the indicator window to see the

current dose setting. If the indicator is between numbers, this means that it is set at a  $\frac{1}{2}$  unit step between the numbers. See below for more examples.

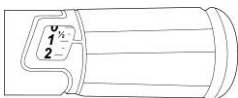
Set to **0 units**. The indicator line is aligned with the "0" mark, which means nothing will happen if the button is pressed. Store the InPen this way.



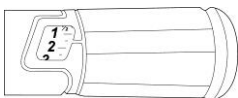
Set to  **$\frac{1}{2}$  unit**. This is the smallest dose setting possible.



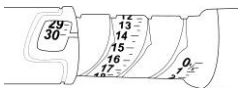
Set to **1 unit**. The indicator line is lined up with the number "1".



Set to **1.5 units**. The indicator line is on the mark between the "1" and "2".



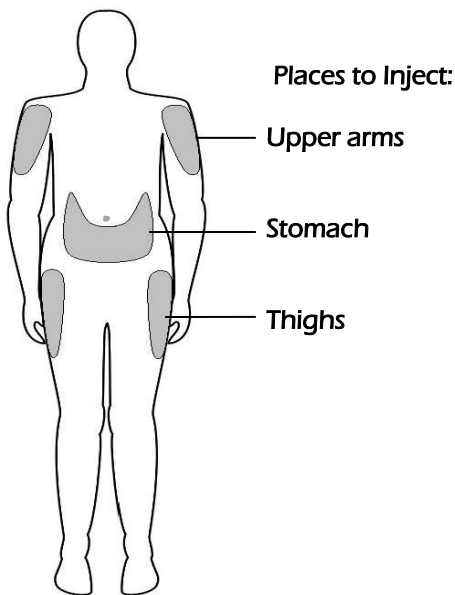
Set to **30 units**. This is the maximum dose setting possible.



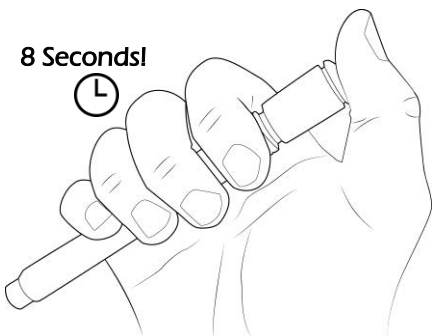
## 9 Injecting the Dose

### 9.1 Steps

1. Choose a place on your body to inject. Make sure your skin is clean and dry.
- 2.



3. Insert the needle into your skin as your healthcare provider has instructed you.
4. To inject your insulin, place your thumb on the Injection Button, then slowly and firmly push the button until it stops moving.



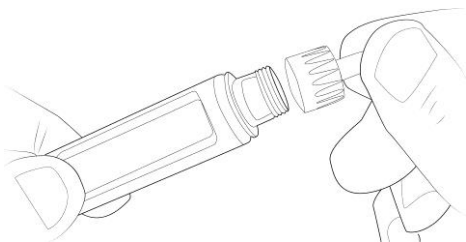
5. Continue to hold the button for 8 seconds and then remove the Needle from your skin. Check to make sure you see a 0 in the Dose Window to confirm you received the complete dose.

**Note: It is possible to set a dose larger than the amount of insulin left in the Cartridge. At the end of an injection, the number in the Dose Window should be 0. If it is not, this number is the amount of insulin you did NOT receive. Remember this number, because you will need to install a new cartridge and inject this much insulin to complete your full dose.**

6. After you remove the needle from the skin a drop of insulin may appear at the needle tip. This is normal and has no effect on the delivered dose.

**Note: To prevent air from entering the Cartridge, do not store the InPen with a Needle attached.**

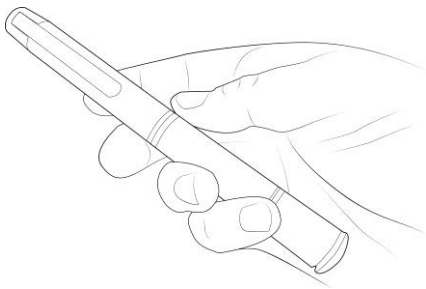
7. Place the cap back onto the Needle, and remove the capped Needle by twisting it off.



8. Put the used Needle in a sharps container or a hard plastic container with a secure lid. Do not throw needles directly into your household trash.
9. Do not recycle the container of used needles. The full container must be disposed of according to your state and local laws.

**Note: For information on how to dispose of the container properly, ask your healthcare provider about options available in your area or go to the FDA website at: [www.fda.gov/safesharpsdisposal](http://www.fda.gov/safesharpsdisposal)**

10. Replace the cap on your InPen.



## 9.2 Important Notes

- You must PUSH the Injection Button straight down for the dose to be delivered.
- You will NOT receive your insulin by turning the Dose Knob.
- Do not attempt to change the dose while injecting.
- Always remove the used needle after each injection and store the InPen without a needle attached. This prevents contamination, infection, and leakage of insulin and will ensure accurate dosing.
- Always put the InPen cap back on after every use.
- Caregivers should be most careful when handling used needles to avoid hurting themselves.

## 9.3 Frequently Asked Questions about Injecting the Dose

### 1. Why does the InPen not deliver any insulin when I turn the dose button to inject?

Turning the dose button will not deliver insulin. You have to press the dose button to inject.

### 2. Why is it difficult to push the Injection Button when I try to inject?

Your Needle may be clogged. Try attaching a new Needle, and then prime the InPen.

Pushing the Injection Button down quickly may make the Button harder to push. Pushing the Button more slowly may make it easier.

Using a larger diameter Needle will make it easier to push the Injection Button during injection. Ask your healthcare provider which Needle is best for you.

If none of the above steps resolves the problem, your InPen may need to be replaced.

Your Injection Button may become harder to push if the inside of your InPen gets dirty with insulin, food, drink or other materials. Following the HANDLING AND STORAGE instructions below should prevent this.

### **3. Why doesn't the Dose Knob go to zero when I inject my dose?**

This can happen if the Insulin Cartridge does not have enough insulin left in it for your entire dose, or if the needle has become clogged. To get the rest of your dose:

- The number in the Dose Window is the amount you did NOT receive. Remember this number, because you still

need to inject this much to complete your dose.

- Adjust the knob back to the "0" setting.
- Remove the Needle from the InPen.
- If the cartridge is empty, replace it with a new cartridge. If it is not empty, it is likely the needle was clogged.
- Install a new Needle.
- Prime the InPen until insulin is observed.

Complete your dose by dialing the amount that you did NOT receive and inject this amount.

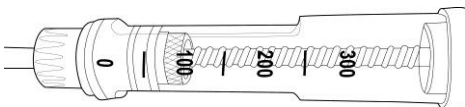
If you are not sure whether you have received your full dose, you should check your blood glucose level more frequently.

## 10 How Much Insulin is Left in Your InPen?

The cartridge scale shows an approximate number of units left in the Cartridge.



**FULL CARTRIDGE**



**EMPTY CARTRIDGE**

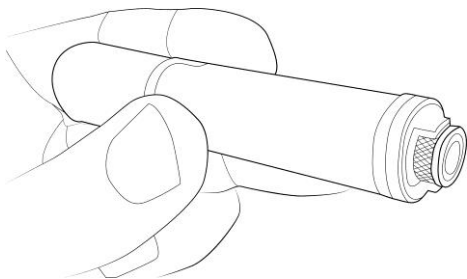


It is ok to set a dose greater than the amount of remaining insulin. The InPen will deliver as much insulin as is left in the cartridge and then you can complete the dose with a new cartridge. Refer to the INJECTING THE DOSE section above.

## 11 Replacing a Used Insulin Cartridge

**Note: Be sure the needle has been removed and disposed of properly.**

- 11.1 The Screw will be extended once you have used the entire insulin cartridge.
- 11.2 Hold the InPen body and turn the Screw counterclockwise into the InPen Body until it stops.



- 11.3 Follow the instructions in PREPARING YOUR INSULIN INPEN section above. Dispose of the used cartridge before installing a new one.

## 12 Handling and Storage of Your InPen

When an Insulin Cartridge is installed in your InPen, store your InPen at room temperature. Refer to your insulin manufacturer or literature that came with your insulin for information from on how to store the cartridges and how long to keep them.

Remove the Needle after every use. Do not store your InPen with the Needle attached.

Do not store the InPen in a refrigerator.

## 13 Cleaning of Your InPen

Cleaning removes dirt from the surface of the device. It does not kill bacteria or viruses. The InPen should be cleaned whenever it is visibly dirty.

Clean your InPen as needed only with a soft cloth moistened with water, being careful not to get water inside. Never submerge the InPen. You may also use an isopropyl alcohol wipe. If you get insulin on your InPen, clean it off right away.

### 13.1 Important Notes

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

- Only use your InPen 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 InPen as this may damage it.
- Keep it away from direct sunlight, water, dust, and dirt.
- Do not expose your InPen (without cartridge) to temperatures below -5 °C (-23°F).
- Do not try to repair a broken InPen

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

## **Frequently asked Questions about Caring for your InPen**

1. What should I do if my InPen has been dropped or knocked against a hard surface, or if I am not sure that it is working properly?
  - If you suspect that your InPen has been damaged or may not be working properly, discontinue using it immediately, and contact your healthcare provider.
  - If you choose to continue using your InPen, check that the Insulin cartridge is not

damaged (see the information provided with the Insulin cartridge) and install a new needle.

- Some disposable needles are supplied with a cap that may be filled to verify the correct volume of insulin is being dispensed. This may be used for added confirmation that the InPen is functioning properly. Refer to the Patient Information provided with the Needle for information on this feature.

## 14 Replacement

Your InPen will last for at least 1 year after first use. Record the date your InPen was first used here: \_\_\_\_/\_\_\_\_/\_\_\_\_. Contact your healthcare provider to obtain a prescription for a new InPen.

## 15 Disposal

Your InPen 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 cartridge, and throw them away as your doctor or nurse has instructed you.

- Throw your InPen away as specified by your local authorities.

## **16 Supplemental Information**

### **16.1 Essential Performance**

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

### **16.2 Dose Accuracy**

InPen fulfils the functional requirements and specification limits for dose accuracy according to ISO 11608-1 Pen-Injectors for Medical use, Part 1: Requirements and test methods.

### **16.3 Applied Parts**

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

### **16.4 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).

### **16.5 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.

## 17 Warranty

Companion Medical warrants the InPen System 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 InPen 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 cartridges or needles.
- 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 InPen system is subject at all times to the Companion Medical Inc. Terms of Service and Privacy Policy (<https://www.companionmedical.com/terms-privacy/>).

## 18 Product Specifications

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

<b>Operating Conditions</b>	5 °C (41 °F) to 40 °C (104 °F) 15 % to 93 % RH (non condensing)
<b>Operating Altitude</b>	-381 m (-1253 ft) to 3010 m (9878 ft)
<b>Operating Pressure</b>	80 kPa – 105 kPa
<b>Storage Conditions</b>	-5 °C (23 °F) to 40 °C (104 °F) 10 % to 98 % RH (non condensing)
<b>Dimensions</b>	16.5 cm (6.5") x ø1.9 cm (0.8")
<b>Weight</b>	35 g
<b>Power Supply</b>	Li-Mn battery (not replaceable)
<b>Lifetime</b>	1 year from activation
<b>Accuracy</b>	±0.5U below 10U and ±5% at 10U and above
<b>Moisture Protection</b>	IP22: Protection against insertion of large objects and dripping water
<b>Protection against Electrical Shock</b>	Type BF applied part

For information contact:



Companion Medical, Inc.  
11011 Via Frontera, Suite D  
San Diego, CA 92127 USA  
[www.companionmedical.com](http://www.companionmedical.com)



Cormedics Medizintechnik GmbH  
Bahnhofstrasse 32  
82041 Deisenhofen Germany

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