



SAMPEN™ SMART INSULIN PEN

INSTRUCTIONS FOR USE

REUSABLE INSULIN DELIVERY PEN

For Single Patient Use Only

1. INTRODUCTION

This instructions for use contain information on how to use the **SAMPEN™** Smart Insulin Pen for subcutaneous injection of insulin.

SAMPEN™ Smart Insulin Pen is a device for giving accurate dose injection. It is designed for ease of use. You can dial from 1 to 60 units in 1-unit increments. The dose knob is a two-way dial, if you have selected a wrong dose, you can turn the dial in either direction without losing any drug solution.

Intended purpose: The intended purpose of the medical device is to administer subcutaneous injections into the human body.

Indication: The pen injector is a reusable pen injector intended for the self-injection of insulin available in 3ml cartridge using disposable pen needle (sold separately).

User profile: The pen injector is intended to be operated by adults and adult caregivers.

Patient Groups:

- This device is suitable for adults
- Age: adults
- Gender: no restrictions
- Weight: no restrictions
- Health: Pen injector are primarily indicated for adult patients with Type I/Type II Diabetes Mellitus.
- Nationality: multiple
- Patient state: Patient is the Operator

Contras: Blind people or those with severe visual problems should not use the pen Injector without help.

USE ENVIRONMENT: The **SAMPEN™** Smart Insulin Pen is intended to be used at home or other non-clinical setting.

Clinical benefits: Shorter learning time, Dose accuracy to meet requirements

Performance Characteristics:

- **Cartridge:** 3ml
- **Increments:** 0.01ml (1 unit)
- **Minimum dose:** 0.01ml (1 unit)



Potential clinical side-effects

1. Hyperglycaemia
2. Suspected influenza/viral respiratory illness
3. Hypoglycaemia
4. Diabetic ketoacidosis

2. IMPORTANT INFORMATION YOU NEED TO KNOW BEFORE USING THE SAMPEN™ SMART INSULIN PEN

- The pen is a device for giving accurate dose injections. The required dose is set by turning the dose knob in a controlled manner and confirmed through the dose window. The dose is then injected by depressing the injection button which via mechanical coupling causes the plunger in the cartridge to move forward thereby expelling the intended dose. The prefilled cartridge and the single use disposable pen needle are not part of the device.
- It is important for you to read and understand the instruction for use before using the pen for injection. This information does not take the place of talking to your healthcare provider about your medical condition.
- DO NOT share your **SAMPEN™** Smart Insulin Pen with other people, even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.
- The pen is not recommended for use by the blind or visually impaired without the assistance of a sighted individual trained to use it.
- Keep your pen and needles out of reach of children.

3. PRECAUTION

- The device is intended to be used with Human insulin 3ml insulin cartridge and single-use disposable pen needle. Consult your healthcare professionals for advice on needle size (gauge).
- DO NOT use your pen if any parts look broken or damaged, DO NOT try to repair your pen or pull it apart.
- DO NOT expose your pen to dust, dirt, or liquid.
- DO NOT wash, soak, or lubricate your pen. If necessary, clean it with a moistened cloth.
- Always carry an extra pen in case yours is lost or damaged.
- Always prime your pen to remove air bubbles before an injection.

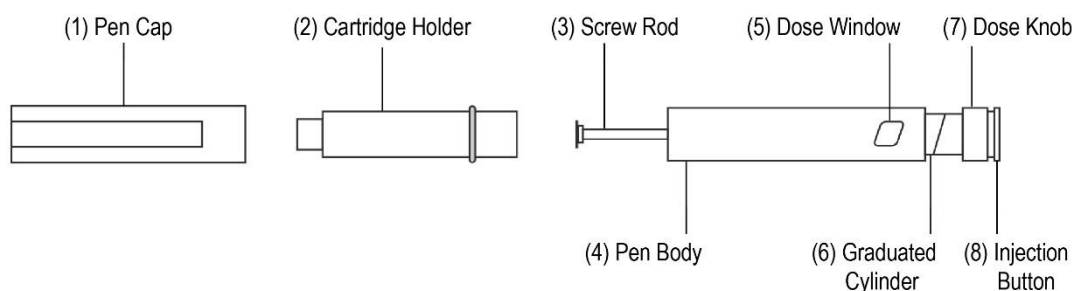
4. SAMPEN™ SMART INSULIN PEN

A. Specification



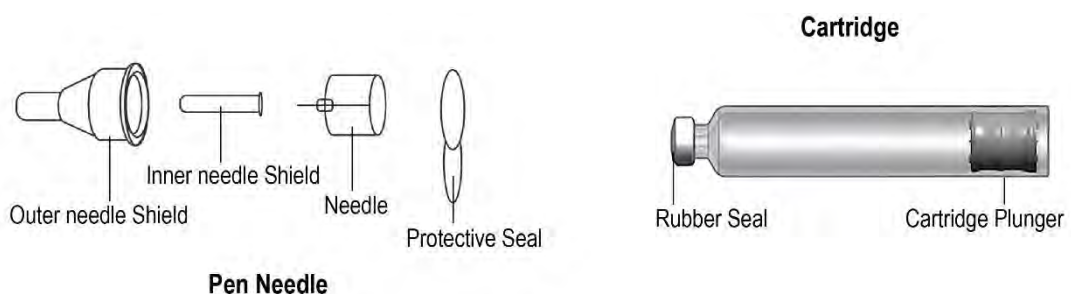
Model	Dose Specification	Compatible with	
		Cartridge	Plunger
KXCF-01B	Min. 0.01mL Max. 0.6mL Increment interval: 0.01mL	3mL Diameter: 11.6±0.15mm Height: 62.3±0.15mm	3mL Diameter: 10mm±0.1mm Height: 11mm±0.3mm

B. Pen Components



C. Needle and Cartridge

The disposable pen is intended to be used with a disposable pen needle and a pre-filled cartridge



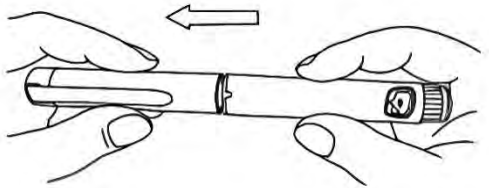
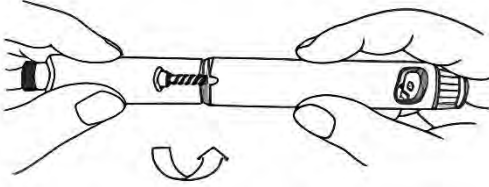
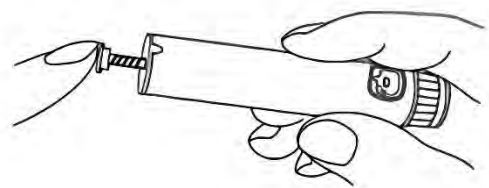
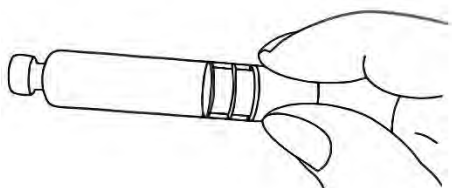
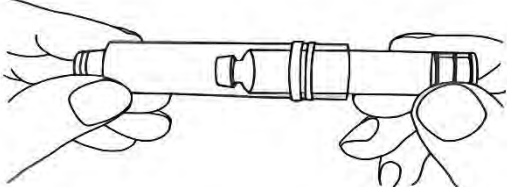
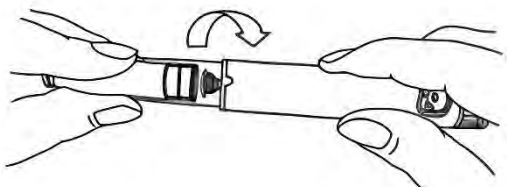
5. PREPARING YOUR INJECTION

- Wash your hand with soap and water
- Check the pen and the cartridge to make sure you are taking the right type of drug solution. The color of the pen does not indicate the type of medicinal product it contains.
- Always use a new needle for each injection to help ensure sterility and prevent blocked needles.
- DO NOT reuse or share your needles with other people. You may give other people a serious infection or get a serious infection from them.

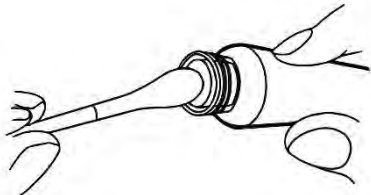
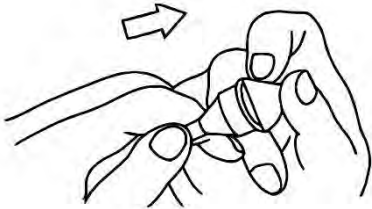
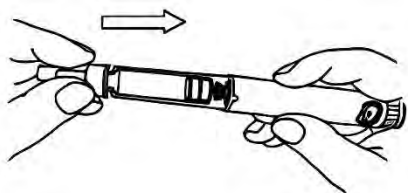
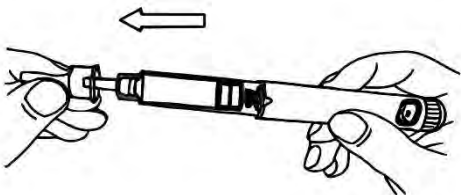
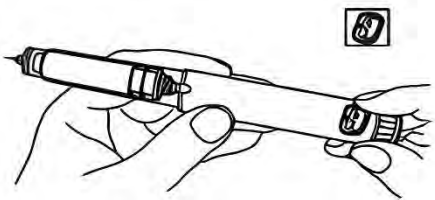
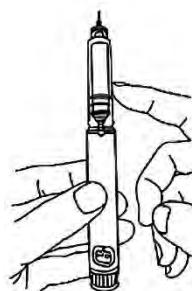
6. OPERATING INSTRUCTIONS

A. Loading a drug Prefilled Cartridge



1. Hold the Pen horizontally and pull the Pen Cap straight off.	
2. Remove Cartridge Holder by twisting cartridge holder in an anticlockwise direction to detach.	
3. Push back the screw rod if needed.	
4. Take a new drug-prefilled cartridge. Check the name, brand and label of the cartridge to make sure it is the right drug solution. Check the expiry date on the pen label. Make sure the cartridge is not cracked or broken.	
5. Insert the drug-prefilled cartridge into the cartridge holder.	
6. Push the cartridge holder straight onto the pen body and twist the cartridge holder in a clockwise direction until is tight. Warning: Make sure that the cartridge holder is installed to the pen appropriately. If the cartridge holder is not installed correctly, the screw rod may not move forward during your injection, and you may get a wrong dose.	
B. Preparing before your injection	

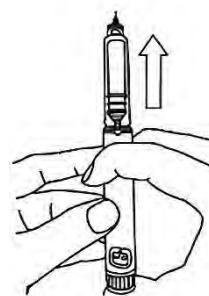


7. Wipe the rubber seal at the end of the cartridge with an alcohol swab.	
8. Take a new needle. Remove Needle protective seal. Warning: Always use a new needle for each injection to help ensure sterility and prevent blocked needles.	
9. Hold the Outer Shield of the needle and push the needle straight onto the cartridge holder. Twist the needle on until it is tight.	
10. Pull off the Outer Needle Shield. DO NOT throw it away. Pull off the Inner Needle Shield and throw it away.	
C. Prime your pen	
Priming your pen means removing the air from the Needle and Cartridge that may collect during normal use and ensures that the Pen is working correctly. Warning: Priming should be done before each injection. If you do not prime before each injection, you may not get the correct dose.	
11. Prime your Pen by turning the Dose Knob until the pointers aligns with the 2-Unit indication mark.	
12. Hold your Pen with the Needle point up. Tap the Cartridge Holder gently to collect air bubbles at the top.	



13. Continue holding your Pen with Needle point up. Push the Dose Knob in until it stops, and “0” is seen in the Dose Window. Hold the Dose Knob in until you see the drug solution at the tip of the Needle. Small bubbles may present even after the priming step. This is normal and will not affect your dose.

Note: If no drop appears, repeat Step 11-13 as shown above up to 4 times. If there is still no drop, change the needle and repeat Step 11-13 as shown above. DO NOT use the pen if a drop still does not appear after using a new needle. Replace with a new pen.



D. Select your dose

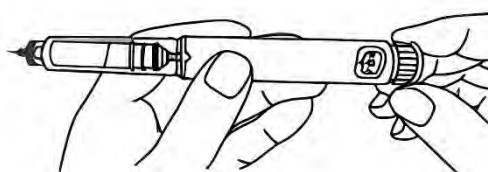
14. Turn the dose Knob to select the number of units you need to inject. The pointer should line up with your intended dose indication line.

Note: Always check the number in the Dose Window to make sure you have dialed the correct dose. If you dial a wrong dose, correct the dose simply by dialing in the opposite direction.

WARNING: DO NOT try to select doses other than the indicated dose. The number in the display must line-up precisely with the pointer to ensure that you get the correct dose.

WARNING: Always follow the prescription given by your healthcare provider, do not change the dose or type of medication arbitrarily.

NOTE: You can give dose from 1 to 60 units in a single injection. If





your dose is more than the maximum deliverable dosage of your pen, you may need to give two or more injections, consult your healthcare provider for assistance and advice on splitting your dose.

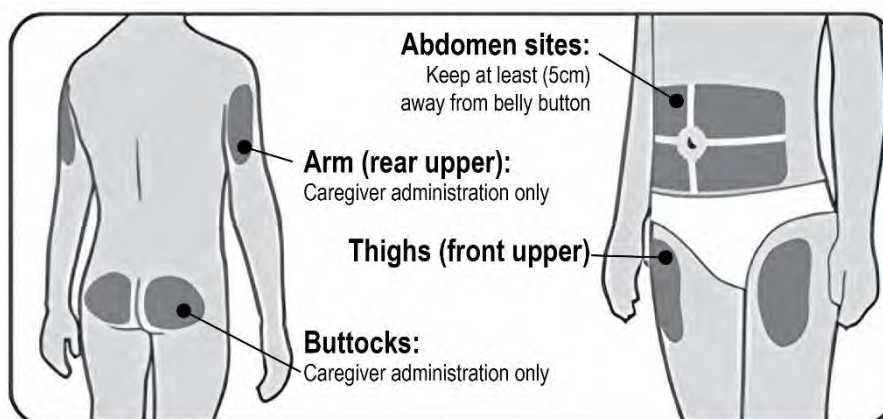
WARNING: The dose selector clicks when you turn it. DO NOT use these clicks to count your dose.

WARNING: DO NOT use the cartridge scale to measure how much drug to inject. It is not accurate enough.

E. Inject your dose

15. Choose your injection site according to your healthcare provider.

The **SAMPEN™** Smart Insulin Pen is intended for subcutaneous injection only. It can be injected under your skin, (subcutaneously) of your stomach area (abdomen) hip, (buttocks), upper legs (thighs), upper arms, or otherwise instructed by your healthcare provider.



WARNING: DO NOT inject into bony areas, areas that are bruised, red, sore, or hard, and areas that have scars or skin conditions.

WARNING: Change the injection site regularly

16. Wipe your skin with an alcohol swab, and let your skin dry before you inject your dose.

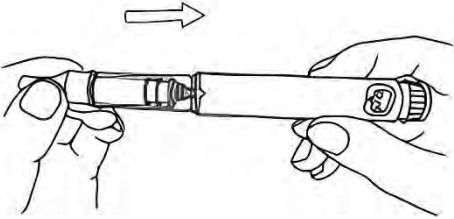
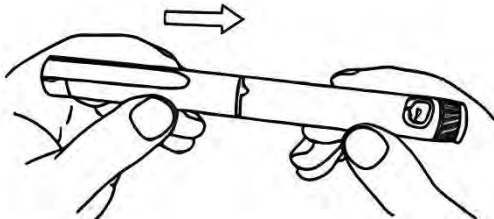
17. Inject your drug dose as your healthcare provider has shown you. Insert the needle into skin, then slowly and firmly push the





injection button down to the button with your thumb. 18. Hold the injection button in for at least 10 seconds before removing the needle from your skin WARNING: DO NOT try to change your dose while injecting. WARNING: Inject your drug solution by pushing the injection button. DO NOT try to inject your drug solution turning the Dose Knob. You will not receive your drug solution by turning the Dose Knob. 19. Pull the Needle out of your skin. A drop of insulin at the Needle tip is normal. It will not affect your dose. 20. Check the number in the Dose Window. make sure "0" is shown on the dose window. NOTE: The SAMPEN™ Smart Insulin Pen allow you to set a dose greater than the remaining deliverable volume. If you do not see "0" in the Dose Window after your injection you did not receive a full dose. Check the cartridge to see if there are enough drug solution, 1) If your cartridge has enough drug solution for your remaining dose, do not redial. Insert the Needle into your skin and finish your injection. 2) If your cartridge dose not have drug solution for your remaining dose. The number in the dose window is the amount you did not receive. To get the rest of your dose, remove the needle, use a new pre-filled cartridge and perform step 2-16 injecting only the dose amount you did not receive.	
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F. After your injection	
21. Cap the needle by carefully replace the Outer Needle Shield 22. Unscrew the capped Needle and throw it away. WARNING: Dispose your used needle according to local requirements.	
23. Replace the pen cap by lining up the cap clip with dose Window and pushing straight on. 24. Store/ Dispose the pen according to the instructions on Storage/ Disposal in this leaflet. WARNING: Always remove the needle from your pen when you store it to reduce the risk of contamination, infection, leakage of drug and blocked needles which may lead to a wrong dose. Caution: Handle the used needle with care to avoid needle sticks.	

7. FREQUENTLY ASKED QUESTIONS

A. PRIMING

1. What is priming and why is it important?

- Priming fills any empty space inside the needle or cartridge with drug solution and checks that the drug solution will flow out when you inject.
- Priming should be done after changing a cartridge and before each injection. If you do not prime until drug solution comes out, you may not get the correct dose.
- You may need to prime the pen for more than one time to get a flow of the drug solution out of the needle.

2. Why doesn't insulin come out when I prime the pen?

- The needle may be clogged; the cartridge holder may not be completely attached; or the push plug of the screw rod may not push against the cartridge plunger.
- Repeat the priming step (step 11-13) until a flow is seen, no more than 4 times.
- If there is still no drug solution flow, hold the pen with the needle facing upwards. Replace the needle and repeat priming step (step 11-13).



- If you are still unable to get drug solution flowing out the needle, do not use the pen. Return the pen to your healthcare professional to obtain a replacement pen.

3. Why are there air bubbles in the Cartridge after priming?

- Hold the pen with the needle facing upwards, gently tap the cartridge holder to collect air bubbles at the top.
- Repeat the priming step (step 11-13).
- Small air bubbles may remain. If you have primed the pen properly, the small air bubbles will not affect your dose.

B. LOADING AND INJECTION

1. What should I do if I can't attach the cartridge holder to the pen dose?

- You may not have inserted the cartridge correctly. Check that a compatible cartridge is correctly inserted into the cartridge holder. Align the cartridge holder with the pen body. Insert straight in and twist to secure.

2. Why does insulin come out when I dial backwards?

- You may have pushed the injection button when dialing backwards, avoid pushing the injection button when dialing backwards, and only push the injection button for injection.

3. Why don't I see "0" in the dose window after my injection?

- You may not have pushed the injection button till the bottom. To get the remaining dose, do not redial. Insert the needle into your skin and finish your injection.
- Your cartridge may not have had enough insulin for your entire dose. The number in the dose window is the amount you did not receive. To get the remaining dose, remove the needle. Use a new pre-filled cartridge and perform step 2-16, injecting only the dose amount you did not receive.

4. Why doesn't the lead screw move forward?

- The cartridge holder is not appropriately attached. Detach the cartridge holder, align the cartridge holder with the pen body, insert straight in and twist to secure.

5. When I try to inject, why is it difficult to push down the injection button?

- You may push the injection button too quick or from the side. Pushing the injection button from the center and slowly will make it easier to inject.



- Your Needle may be blocked. Put on a new Needle and prime the pen. Consult your healthcare professionals for recommendations on needle size (gauge).
- You may have dust, food or liquid inside the pen. Throw the pen away and get a new pen.

8. DISPOSING OF PEN AND NEEDLE

- Always remove the needle from the pen before throwing it away.
- DO NOT throw needle directly into your household trash (unless your local community guidelines allow this).
- Dispose your used injection pen and needle following your local community guidelines.

9. STORAGE

A. General

- Keep dry.
- Protect from heat, light and freezing.
- Keep the pen away from dust, extreme hot or cold temperatures.
- DO NOT freeze your Pen. DO NOT use if it has been frozen.
- Follow storage instruction on drugs to keep/dispose your cartridge.

10. REPLACEMENT

- The **SAMPEN™** Smart Insulin Pen is designed to be used for up to 3 years after production.
- Record the production date from your carton here.
- Contact your healthcare professional to get a new pen when your pen has been used for 3 years.
- The device can bear the assembly of 165 cartridges, 4,958 needles, 4,928 pen cap.



سیم پینTM

اسمارٹ انسولین پین

ہدایات:

صرف ۳ ملی لیٹر انسولین کارٹریدج (۱۰۰ آئی یو / ملی لیٹر یا / اور ۱۰۰ یونٹ / ملی لیٹر) کے لئے۔
یہ پین ایک یونٹ سے لیکر ساٹھ یونٹ تک کے اضافے کے لئے استعمال کیا جاسکتا ہے۔
صرف ایک مریض کے استعمال کے لئے ہے۔
بچوں کی پہنچ سے دور رکھیں۔
گرمی، روشنی اور منجمد ہونے سے محفوظ رکھیں۔
پین کو استعمال نہ کریں اگر اس کا کوئی بھی حصہ ٹوٹا ہوا اور / یا خراب نظر آئے۔

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