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EU REP

CMC Medical Devices & Drugs S.L
C/Horacio Lengo N° 18 CP 29006,
Málaga-Spain

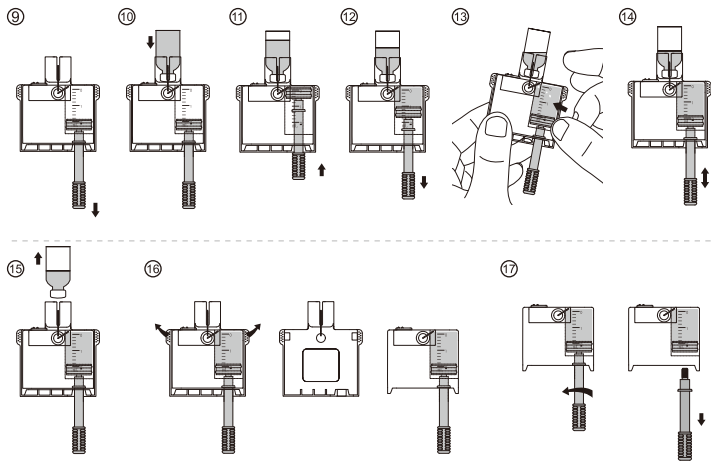
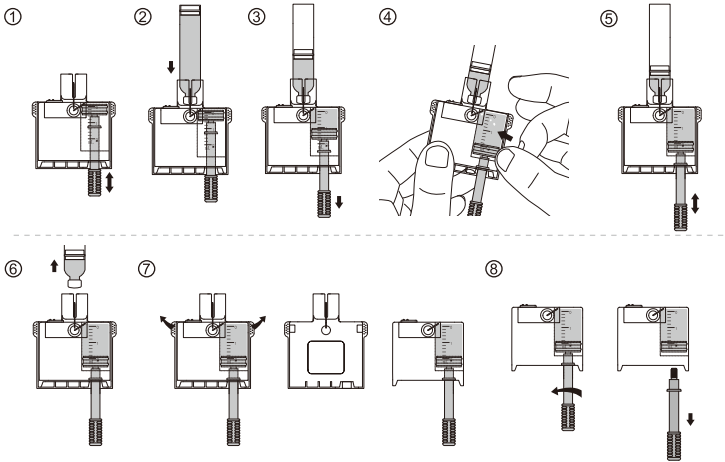
1001-PMTL-428.V02
Effective Date:2025-12-23



CE 0197

Insulin Infusion Pump Reservoir

MTM-3WP # MTM-10WP



English

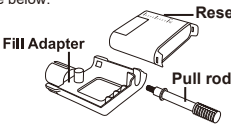
Product Name: Insulin Infusion Pump Reservoir
#MTM-3WP(The fill adapter for 3 mL insulin cartridge)
#MTM-10WP(The fill adapter for 10 mL insulin vial)
Shelf Life: 3 years

1. Intended purpose

The insulin infusion pump reservoir is intended for the subcutaneous delivery of insulin when using with insulin infusion set and ambulatory insulin infusion pump.

2. Components

The Insulin Infusion Pump Reservoir consists of a reservoir, fill adapter and pull rod, as shown in the figure below:



The total capacity of the reservoir is 2.0ml, which is equal to 200 units of U-100 insulin.

3. Intended Patient

Type 1 and Type 2 diabetes patients aged 3 and above requiring insulin pump therapy.

4. Intended user

From device operation perspective, this device is intended to be operated by professional users and lay users with age of 18 and above.

Requirement for professional users:

- Graduate from medical school or graduate with medical related major
- With normal touch, visual and hearing ability
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Requirement for Lay users:

- With elementary school or above education background
- No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
- With basic cognitive ability for using the device

Note

Learning to use your Equil patch insulin pump system and compatible supplies correctly is important for safe and effective use. Different training methods are available to match your learning needs. Your healthcare provider can help you to coordinate and set up appropriate training. For pediatric patients, lay person refers to caregiver, parent, or legal guardian.

5. Indications

- Patients with type 1 diabetes mellitus or type 2 diabetes mellitus who require insulin pump therapy.
- Patients with type 1 diabetes who are motivated to improve glycemic control following a trial of multiple daily insulin injection (MDI) therapy and who can show the level of self-care required for adherence.
- Patients with type 2 diabetes on MDI who can use the device safely (either by them-selves or with a caregiver).

6. Expected use environment

Hospital setting and Home setting.

7. Contraindication

- Diabetic patients unwilling to perform insulin pump treatment.
- Patients who do not want to or do not have access to self-monitoring of blood glucose levels.
- Patients with alcohol addiction, drug abuse, or with severe mental disorders (e.g. depression, schizophrenia).
- Allergies, including insulin allergies and severe skin allergies.
- People who are unconscious or disoriented.
- People who are intellectually impaired and unable

to understand or master the instructions for use.

- People with severe visual or hearing impairments.
- Elderly diabetics living alone.
- Children with diabetes who are too young to take care of themselves.
- The pump system has not been evaluated in:
 - Pregnant woman
 - Children below 3 years
- Diabetic patients who do not require insulin therapy.
- Patients with granulomatous nodules, which are tiny lumps or nodules beneath the skin, should not use this product.
- Patients with any of the following conditions should not use this product:
 - Blood albumin level lower than 90 g/L (may indicate poor nutrition or liver problems);
 - White blood cell count lower than $4.0 \times 10^9/L$ (weakened immunity, higher risk of infection);
 - Platelet count lower than $90 \times 10^9/L$ (reduced clotting ability, higher risk of bleeding).
- Patients in the acute phase of diabetic ketoacidosis or hyperosmolar coma.
- Hyperglycemic patients with severe circulatory disorders.
- Diabetic patients allergic to subcutaneous infusion sets or adhesive tapes.
- Patients and family members lacking relevant knowledge and still unable to use the device correctly after training. Diabetic patients unwilling to perform insulin pump treatment.

8. Application

This Insulin Infusion Pump Reservoir is compatible only with MicroTech Ambulatory Insulin Infusion Pump and Insulin Infusion Set. The compatible devices and models are as follows:

- MTM-3WP and MTM-10WP

Compatible device	
Name	Model
Ambulatory Insulin Infusion Pump	MTM-H1
Insulin Infusion Set	HRN-S-60 software cannula with MTM-4 pump base
	HRN-S-90 software cannula with MTM-4 pump base

9. Usage

The fill adapter for 3 ml insulin cartridge:

- Remove the new reservoir from the packaging.
- Use the pull rod to pull the piston to the full position inside the reservoir, then push it completely to the empty position. Repeat this three times ending with the piston in the empty position (Figure 1).
- Use an alcohol wipe to clean the top of the insulin vial and then attach it to the fill adapter (Figure 2).
- With the insulin vial on top, insert the needle into the vial, slowly pull the pull rod and draw insulin into the reservoir (Figure 3).
- Tap the side of the reservoir to encourage any air bubbles to rise to the top of the reservoir (Figure 4).
- Push the pull rod slowly to eject the bubbles back into the vial, then slowly pull to draw more insulin into the reservoir. Repeat until the reservoir is filled with the required amount of insulin again (Figure 5).
- Remove the insulin vial from the fill adapter (Figure 6).
- Pull the two release tabs away from the reservoir to release the fill adapter (Figure 7).
- Remove the pull rod by unscrewing it counterclockwise (Figure 8).

The fill adapter for 10 ml insulin vial:

- Remove the new reservoir from the packaging.
- Use the pull rod to pull the piston to the full position inside the reservoir (Figure 9).
- Use an alcohol wipe to clean the top of the insulin vial and then attach it to the fill adapter (Figure 10).
- Insert the needle into the vial and inject the air, injecting air makes it easier to withdraw insulin from the vial (Figure 11).
- Slowly pull the pull rod downwards in the direction of the arrow to fill the reservoir with insulin (Figure

12).

- Tap the side of the reservoir to encourage any air bubbles to rise to the top of the reservoir (Figure 13).
- Push the pull rod slowly to eject the bubbles back into the vial, then slowly pull to draw more insulin into the reservoir. Repeat until the reservoir is filled with the required amount of insulin again and there are no any air bubbles (Figure 14).
- Remove the insulin vial from the fill adapter (Figure 15).
- Release the reservoir from the fill adapter (Figure 16).
- Remove the pull rod by unscrewing it counterclockwise (Figure 17).

10. Precautions

- Please be sure to operate in strict accordance with this instruction manual, because failure to follow the instructions may result in unsafe practices. Microtech Medical is not liable for any related legal obligations arising from misuse.
- Use Ambulatory Insulin Infusion Pump, pump battery, and Insulin Infusion Set manufactured by MicroTech or bearing the Equil brand identifier. The use of non-compatible components may compromise product safety, leading to insufficient or excessive insulin delivery and subsequent glycemic risks.
- Regular blood glucose (BG) monitoring is crucial for verifying the effectiveness of insulin delivery.
- The Fill Adapter contains a needle. Handle with care when drawing insulin. Keep the Fill Adapter out of reach of children.
- This product has been sterilized by EO (Ethylene Oxide) and packaged in a sterile barrier. Do not use if the package is damaged.
- This product can only be used to administer U-100 insulin.

11. Warnings

- Use only components that are manufactured by MicroTech Medical, or with the Equil brand name. The use of non-standard components may affect the safety of the device.
- Before proceeding, ensure you are fully familiar with the reservoir operation procedures.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- The insulin reservoir must be replaced every 72 hours after activation.

12. Potential Clinical Benefits

- Improved management of A1C, GMI and TIR for tighter glycemic control.
- Reduction in Hypoglycemia events.
- Reduction in Total Daily Dose of insulin.

13. Potential Risks

- Under delivery or excessive delivery of Insulin leading to severe hypoglycemia or diabetic ketoacidosis
- Infusion site problems
 - Pruritus (Skin redness), Swelling and other skin allergies
- Hyperglycemia or hypoglycaemia
- Hardware defects
 - Adhesion issues, difficulty peeling off the device, cannula deformation, etc.
- Failure to follow the instructions may lead to risks of hyperglycemia or hypoglycemia, and diabetic ketoacidosis (DKA). Both DKA and hypoglycemia can potentially lead to death.

14. Electronic Manual

You can visit our website at any time to browse or download the latest electronic manual of this product: <https://microtechmd.com/support/download/83/148>

15. Notes

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Insulin should be at room temperature before filling the Reservoir.

Use immediately after filling. Do not store insulin in the Reservoir when the Reservoir is not in use.

This product should be used under the guidance of doctors or other healthcare professionals. It can be

used in a home or hospital environment after proper training. If you are a new user, you should prepare your first reservoir with professional help.

Please read this insert carefully before use and follow the directions. Read the Ambulatory Insulin Infusion Pump and Insulin Infusion Set user guides carefully as well.

16. Sterilization Information

Sterilization method: ethylene oxide sterilization

17. Operating Condition

- Temperature range: 5°C to 40°C (41°F to 104°F)
- Relative humidity range: 10% to 93%
- Atmospheric pressure range: 70kPa-106kPa

18. Storage Condition

- Temperature range: -40°C-50°C
- Relative humidity range: 5%-95%
- Atmospheric pressure range: 50kPa-106kPa

19. Symbol list

Do not re-use	
Caution	
Use-by date	
Lot number	
Single sterile barrier system with protective packaging outside using ethylene oxide	
Single sterile barrier system. Sterilized using ethylene oxide	
Sterilized using ethylene oxide	
Consult instructions for use	
Do not use if package is damaged	
Manufacture date	
Manufacturer	
CE Mark	
Authorised Representative in the European Community	
Medical device	
Model number	
Importer	
Unique device identifier	
Operating temperature limitation	
Operating humidity limitation	
Operating atmospheric pressure limitation	
Storage temperature limitation	
Storage humidity limitation	
Storage atmospheric pressure limitation	
Do not resterilize	

[EN] For use with the Equil Ambulatory Insulin Infusion Pump and Equil Insulin Infusion Set.

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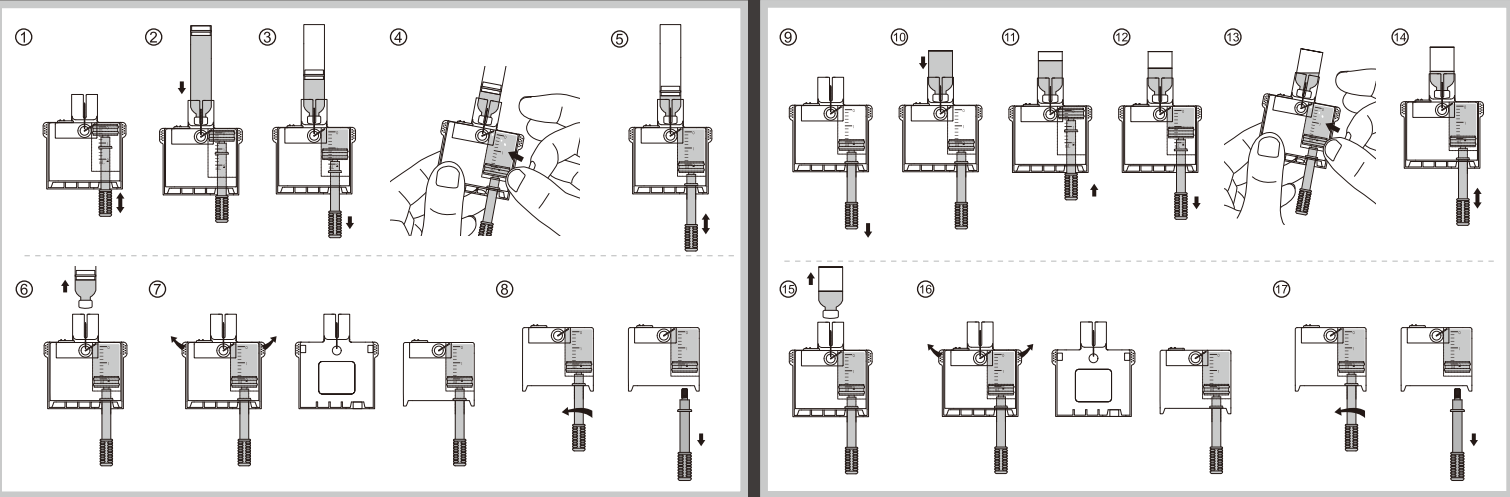
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Insulin Infusion Pump Reservoir

MTM-3WP MTM-10WP



[EN] English

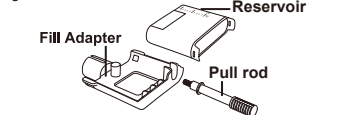
Product Name: Insulin Infusion Pump Reservoir
[E] **MTM-3WP** (The fill adapter for 3 mL insulin cartridge)
[E] **MTM-10WP** (The fill adapter for 10 mL insulin vial)
Shelf Life: 3 years

1. Intended purpose

The insulin infusion pump reservoir is intended for the subcutaneous delivery of insulin when using with insulin infusion set and ambulatory insulin infusion pump.

2. Components

The Insulin Infusion Pump Reservoir consists of a reservoir, fill adapter and pull rod, as shown in the figure below.



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3. Intended Patient

Type 1 and Type 2 diabetes patients aged 3 and above requiring insulin pump therapy.

4. Intended user

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Requirement for professional users:

- Graduate from medical school or graduate with medical related major
 - With normal touch, visual and hearing ability
 - No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
 - With basic cognitive ability for using the device
- Requirement for Lay users:
- With elementary school or above education background
 - No Parkinson's disease, amnesia, or other disorders that impair the psychological health or abilities of the patient
 - With basic cognitive ability for using the device

[CN] Note

Learning to use your Equil patch insulin pump system and compatible supplies correctly is important for safe and effective use. Different training methods are available to match your learning needs. Your healthcare provider can help you to coordinate and set up appropriate training. For pediatric patients, lay person refers to caregiver, parent, or legal guardian.

5. Indications

- ① Patients with type 1 diabetes mellitus or type 2 diabetes mellitus who require insulin pump therapy.
- ② Patients with type 1 diabetes who are motivated to improve glycemic control following a trial of multiple daily insulin injection (MDI) therapy and who can show the level of self-care required for adherence.
- ③ Patients with type 2 diabetes on MDI who can use the device safely (either by them-selves or with a caregiver).

6. Expected use environment

Hospital setting and Home setting.

7. Contraindication

- ① Diabetic patients unwilling to perform insulin pump treatment.
- ② Patients who do not want to or do not have access to self-monitoring of blood glucose levels.
- ③ Patients with alcohol addiction, drug abuse, or with severe mental disorders (e.g. depression, schizophrenia).
- ④ Allergies, including insulin allergies and severe skin allergies.
- ⑤ People who are unconscious or disoriented.
- ⑥ People who are intellectually impaired and unable

to understand or master the instructions for use.

- ⑦ People with severe visual or hearing impairments.
- ⑧ Elderly diabetes living alone.
- ⑨ Children with diabetes who are too young to take care of themselves.
- ⑩ The pump system has not been evaluated in:
 - Pregnant woman
 - Children below 3 years

- ⑪ Diabetic patients who do not require insulin therapy.

- ⑫ Patients with granulomatous nodules, which are tiny lumps or nodules beneath the skin, should not use this product.

- ⑬ Patients with any of the following conditions should not use this product:
 - Blood albumin level lower than 90 g/L (may indicate poor nutrition or liver problems);
 - White blood cell count lower than $4 \times 10^9/L$ (weakened immunity, higher risk of infection);
 - Platelet count lower than $80 \times 10^9/L$ (reduced clotting ability, higher risk of bleeding).

- ⑭ Patients in the acute phase of diabetic ketoacidosis or hyperosmolar coma.

- ⑮ Hyperglycemic patients with severe circulatory disorders.

- ⑯ Diabetic patients allergic to subcutaneous infusion sets or adhesive tapes.

- ⑰ Patients and family members lacking relevant knowledge and still unable to use the device correctly after training. Diabetic patients unwilling to perform insulin pump treatment.

8. Application

This Insulin Infusion Pump Reservoir is compatible only with MicroTech Ambulatory Insulin Infusion Pump and Insulin Infusion Set. The compatible devices and models are as follows:

- MTM-3WP and MTM-10WP

Compatible device

Name	Model
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Ambulatory Insulin Infusion Pump	MTM-H1
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Insulin Infusion Set	HRN-S-90 software cannula with MTM-4 pump base
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	HRN-S-90 software cannula with MTM-4 pump base
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9. Usage

The fill adapter for 3 mL insulin cartridge:

- ① Remove the new reservoir from the packaging.

- ② Use the pull rod to pull the piston to the full position inside the reservoir, then push it completely to the empty position. Repeat this three times ending with the piston in the empty position (Figure 1).

- ③ Use an alcohol wipe to clean the top of the insulin vial and then attach it to the fill adapter (Figure 2).

- ④ With the insulin vial on top, insert the needle into the vial, slowly pull the pull rod and draw insulin into the reservoir (Figure 3).

- ⑤ Tap the side of the reservoir to encourage any air bubbles to rise to the top of the reservoir (Figure 4).

- ⑥ Push the pull rod slowly to elect the bubbles back into the vial, then slowly pull to draw more insulin filled with the required amount of insulin again (Figure 5).

- ⑦ Remove the insulin vial from the fill adapter (Figure 6).

- ⑧ Pull the two release tabs away from the reservoir to release the fill adapter (Figure 7).

- ⑨ Remove the pull rod by unscrewing it counterclockwise (Figure 8).

The fill adapter for 10 mL insulin vial:

- ① Remove the new reservoir from the packaging.

- ② Use the pull rod to pull the piston to the full position inside the reservoir (Figure 9).

- ③ Use an alcohol wipe to clean the top of the insulin vial and then attach it to the fill adapter (Figure 10).

- ④ Insert the needle into the vial and inject the air, injecting air makes it easier to withdraw insulin from the vial (Figure 11).

- ⑤ Slowly pull the pull rod downwards in the direction of the arrow to fill the reservoir with insulin (Figure 12).

- ⑬ Tap the side of the reservoir to encourage any air bubbles to rise to the top of the reservoir (Figure 13).

- ⑭ Push the pull rod slowly to elect the bubbles back into the vial, then slowly pull to draw more insulin into the reservoir. Repeat until the reservoir is filled with the required amount of insulin again and there are no air bubbles (Figure 14).

- ⑮ Remove the insulin vial from the fill adapter (Figure 15).

- ⑯ Release the reservoir from the fill adapter (Figure 16).

- ⑰ Remove the pull rod by unscrewing it counterclockwise (Figure 17).

10. Precautions

- ① Please be sure to operate in strict accordance with this instruction manual, because failure to follow the instructions may result in unsafe practices. MicroTech Medical is not liable for any related legal obligations arising from misuse.

- ② Use Ambulatory Insulin Infusion Pump, pump battery and Insulin Infusion Set manufactured by MicroTech or bearing the Equil brand identifier. The use of non-compatible components may compromise product safety, leading to insufficient or excessive insulin delivery and subsequent glycemic risks.

- ③ Regular blood glucose (BG) monitoring is crucial for verifying the effectiveness of insulin delivery.

- ④ The Fill Adapter contains a needle. Handle with care when drawing insulin. Keep the Fill Adapter out of reach of children.

- ⑤ This product has been sterilized by EO (Ethylene Oxide) and packaged in a sterile barrier. Do not use if the package is damaged.

- ⑥ This product can only be used to administer U-100 insulin.

11. Warnings

- ① Use only components that are manufactured by MicroTech Medical, or with the Equil brand name. The use of non-standard components may affect the safety of the device.

- ② Before proceeding, ensure you are fully familiar with the reservoir operation procedures.

- ③ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

- ④ The insulin reservoir must be replaced every 72 hours after activation.

12. Potential Clinical Benefits

- Improved management of A1C, GMI and TIR for tighter glycemic control
- Reduction in Hypoglycemia events.
- Reduction in Total Daily Dose of insulin.

13. Potential Risks

- ① Under delivery or excessive delivery of insulin leading to severe hypoglycemia or diabetic ketoacidosis

- ② Infusion site problems
 - Pruritis (Skin redness), Swelling and other skin allergies

- ③ Hypoglycemia or hypoglycaemia

- ④ Hardware defects
 - Adhesion issues, difficulty peeling off the device, cannula deformation, etc.

- ⑤ Failure to follow the instructions may lead to risks of hypoglycemia or hypoglycaemia, and diabetic ketoacidosis (DKA). Both DKA and hypoglycaemia can potentially lead to death.

14. Electronic Manual

You can visit our website at any time to browse or download the latest electronic manual of this product: <https://microtechmd.com/support/download/83148>

15. Notes

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Insulin should be at room temperature before filling the Reservoir.

Use immediately after filling. Do not store insulin in the Reservoir when the Reservoir is not in use.

This product should be used under the guidance of doctors or other healthcare professionals. It can be

used in a home or hospital environment after proper training. If you are a new user, you should prepare your first reservoir with professional help.

Please read this insert carefully before use and follow the directions. Read the Ambulatory Insulin Infusion Pump and Insulin Infusion Set user guides carefully as well.

16. Sterilization Information

Sterilization method: ethylene oxide sterilization

17. Operating Condition

- Temperature range: 5°C to 40°C (41°F to 104°F)
- Relative humidity range: 10% to 95%
- Atmospheric pressure range: 70kPa-106kPa

18. Storage Condition

- Temperature range: -40°C-50°C
- Relative humidity range: 5%-95%
- Atmospheric pressure range: 50kPa-106kPa

19. Symbol list

- Do not re-use

- Caution

- Use-by date

- Lot number

- Single sterile barrier system with protective packaging outside using ethylene oxide

- Single sterile barrier system. Sterilized using ethylene oxide

- Sterilized using ethylene oxide

- Consult instructions for use

- Do not use if package is damaged

- Manufacture date

- Manufacturer

- CE Mark

- Authorised Representative in the European Community

- Medical device

- Model number

- Importer

- Unique device identifier

- Operating temperature limitation

- Operating humidity limitation

- Operating atmospheric pressure limitation

- Storage temperature limitation

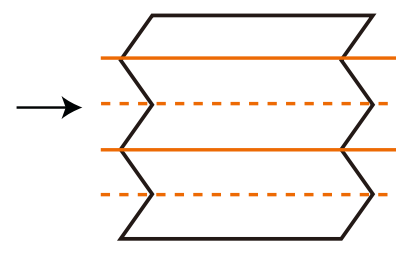
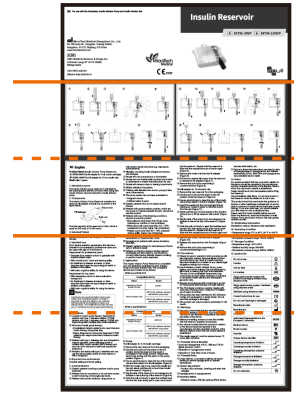
- Storage humidity limitation

- Storage atmospheric pressure limitation

- Do not resterilize

折叠方式

外折线
内折线



纵向5等分

横向2等分



折叠后105*71.2mm
封面朝上



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本图纸应与说明，产品状况，产品结构设计与有关图纸协调使用，发现任何差异请立即通知设计师。

图档中所有尺寸比例为1:1。
公差: L(长)* (宽): +1/-1mm, H(高): ±1mm

项目信息

名称 MTM-3WP&MTM-10WP储药器说明书 (MDR)

图纸号 物料号 1001-PMTL-428

版本号 V02

版本变更描述 更改章节3/4/5内容

发放范围 生产 () 采购 (√) 计划 (√) 其他:

切刀

压线

开槽

半穿

粘合

备注

无印刷

尺寸: 210*356mm

印刷颜色: 黑白

材质: 70g轻涂纸

特种工艺:

备注:

设计审核

设计

审核

批准

生效日期

日期