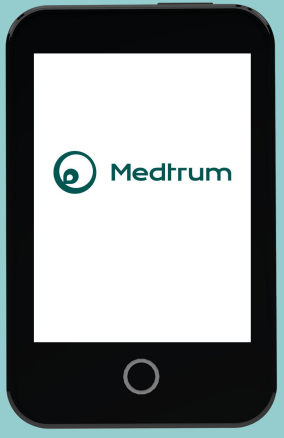
# TouchCare® Insulin Pump System

## Quick Start Guide (mg/dL)

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Simplifying Diabetes

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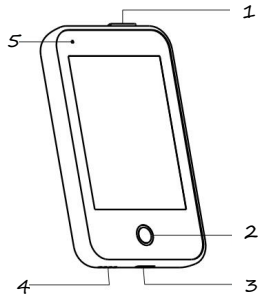
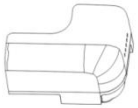
# Insulin Pump System Overview

## The Personal Diabetes Manager (PDM)

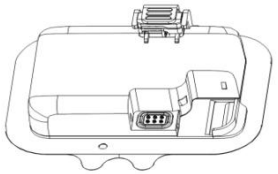



1. Power button
2. Home Key (Software Key)
3. Charging Port
4. Sound Hole
5. Indicator light

## Pump Base



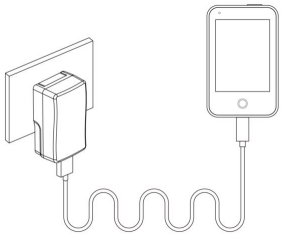
## Reservoir Patch



- Your ultra-thin Patch Pump is composed of a reusable Pump Base (MD0401) and a disposable Reservoir Patch (MD0400) which stores up to 400 U of insulin and lasts for up to 3 days.
- The Pump Base stores delivery settings and sends data to the PDM via Bluetooth Low Energy(communication range 4 meters without blocking).
- The Patch Pump (Base and Patch connected) is waterproof at 8 feet (2.5 meters) for 60 minutes (IP28).
- Store the Pump Base and Reservoir Patch at temperatures between 14°F (-10°C ) and 131°F (55°C).

## Charge PDM

The PDM requires an AC adapter with an output of DC 5.0V



Fully charged
Charging
Not charging
Battery low
Battery empty

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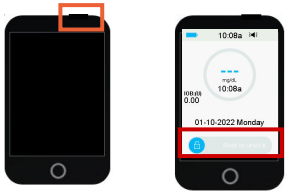
# PDM Settings

## 1. Turn on/off the PDM

- **Turn-on** - Long-press the power button, a green light will flash.
- **Turn-off** - Long-press the power button for about 2 seconds, then slide to power off. Or long-press the power button for about 8 seconds.



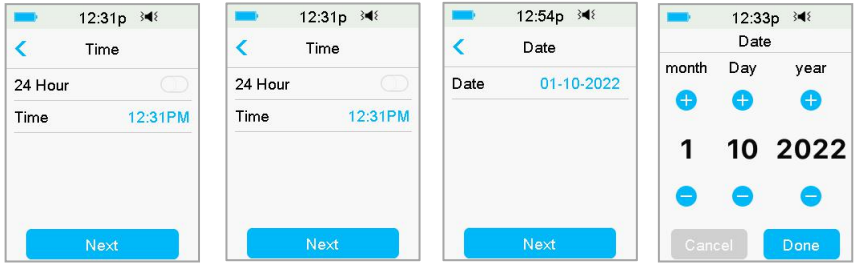

## 2. Wake the PDM

When the screen goes black, press the power button and then slide to unlock

## 3. Select language and country


## 4. Set time and date

**Note:** You can only change the date and time when there is no activated Reservoir Patch.



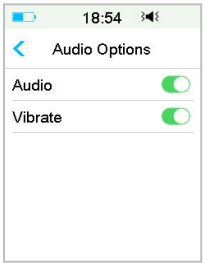

## 5. Bolus Calculator

Refer to Page 5

## 6. Set audio options

**Main Menu ➔ Settings ➔ General ➔ Audio Options**

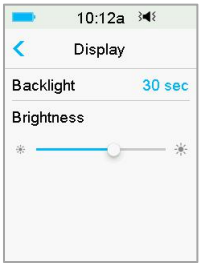
*If you set the audio option to Audio off /Vibrate off, your PDM only vibrates when a serious Alarm occurs.*




## 7. Set display settings

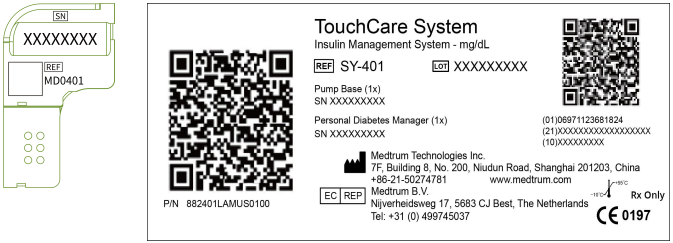
**Main Menu ➔ Settings ➔ General ➔ Display**

*It is recommended for new users to set backlight time as 2 minutes*




## 8. Find Pump Base SN

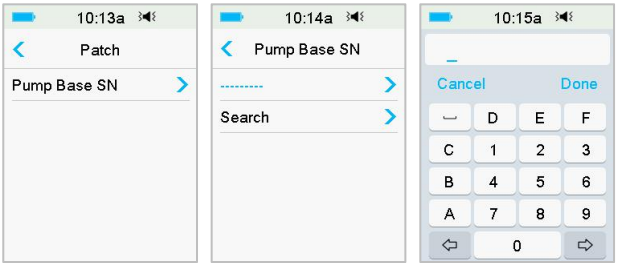
*You can find the Pump Base SN on the product box or on the back of the Pump Base.*




## 9. Enter Pump Base SN

**Main Menu ➔ Patch ➔ Pump Base SN**

*Tap ------ to enter SN manually*



# Basal Settings

**Main Menu ➔ Settings ➔ Insulin Pump ➔ Basal Setup**

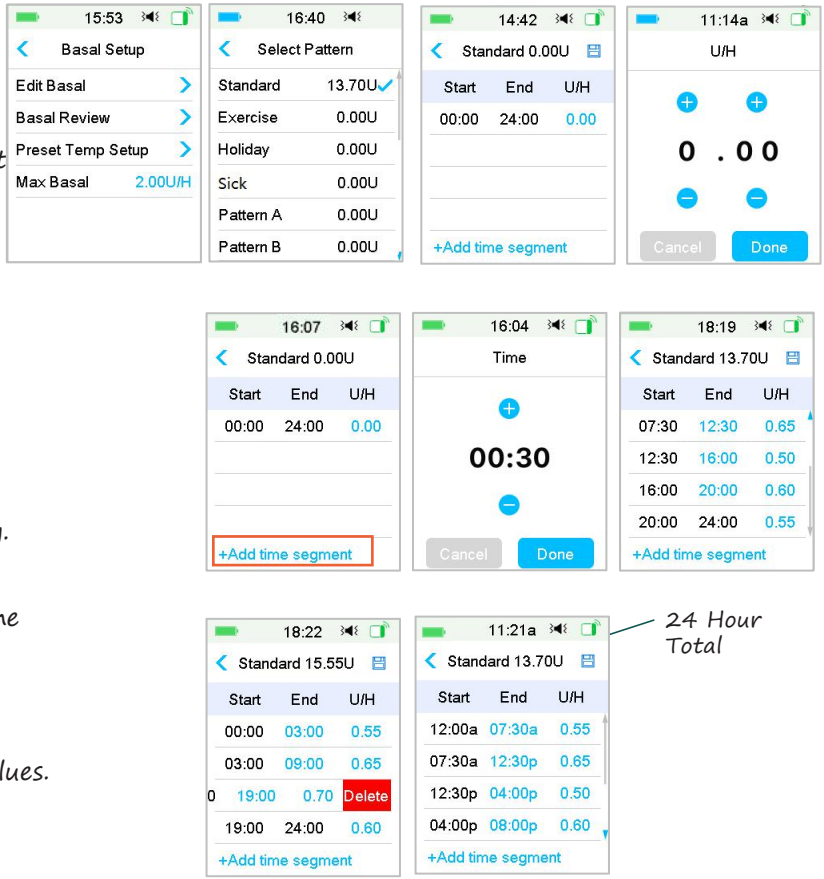
## 1. Max Basal

*Tap the Max Basal rate to edit it*

## 2. Edit Basal Pattern

1. *Tap Edit Basal, then select the Pattern to edit it*
2. *Set basal rate*
   - *Tap blue U/H field to set the Basal rate.*
   - *You can set a basal rate between 0 and the Max Basal Rate with an increment of 0.05 U/H.*
3. *Add Time Segment*
   - *Tap +Add Time Segment to add a new segment.*
   - *You can set up to 48 segments for each day.*
4. *Delete Time Segment*
   - *Slide to left on each segment, tap Delete. The start time of next segment will be adjusted*
   - *Slide on segment back to right to cancel deleting*

   **Note:** *Recheck all the numbers you entered to make sure that they are the intended values.*
5. *Scroll up and down to review all segments*
6. *Tap* 💾 *to save the settings*



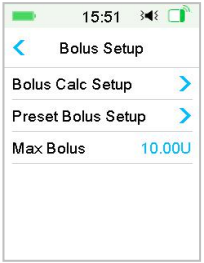

## 3. Select a Basal Pattern

**Main Menu ➔ Basal ➔ Select Pattern**

**Main Menu ➔ Settings➔ Insulin Pump ➔ Bolus Setup**

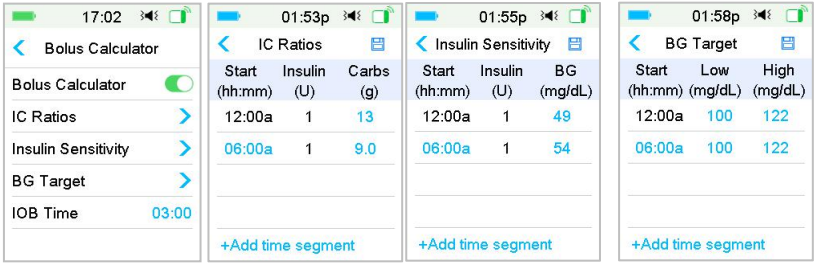
## 1. Max Bolus

*Tap the Max Bolus to edit it*

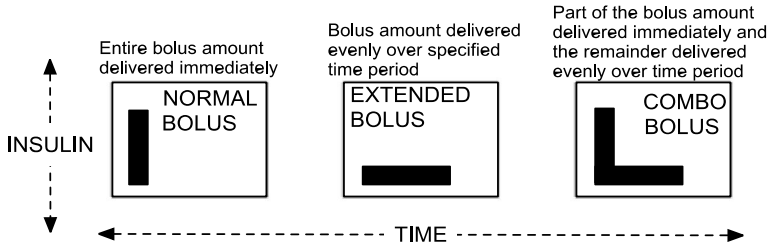



## 2. Set up the Bolus Calculator

- *Turn on/off the Bolus Calculator*
- *Set IC ratios*
- *Set Insulin Sensitivity*
- *Set BG target*
- *Set IOB Time (Active Insulin Time)*



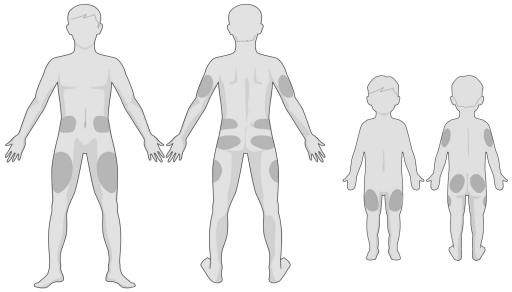

## 3. Normal, Extended and Combo Bolus



# Start a new Patch

## 1 Select the infusion site

- Clean, less hair, no sweat, uncovered, enough fat (at least 0.2 in thick), away from navel.
- A new infusion site should be at least 1 inch (2.5 cm) away from the last site.
- If you choose an infusion site on your abdomen, back or buttocks, apply the Patch horizontally.
- If you choose an infusion site on your upper arm or thigh, apply the Patch vertically.



**Note:** Please pay attention to the location of the Sensor site and Patch site so that there is little communication interruption.

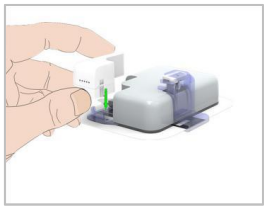
## 2 Prepare the infusion site

- Wash your hands with soap and water.
- Clean the infusion site with an alcohol wipe to enhance adhesion.
- Let the skin air dry completely.

## 3 Connect Pump Base and Reservoir Patch

**Main Menu ➔ Patch ➔ New Patch**

Gently insert the pump base and push down all the way until the pump base is locked in place to the reservoir patch.



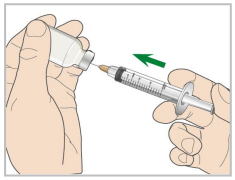
The pump beeps four times

## 4 Fill the New Reservoir Patch

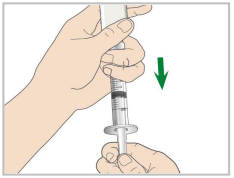
With the help of your healthcare provider, decide on the amount of insulin (70 U - 400 U) you need to insert into the Reservoir Patch.

**Warning:** Do not inject air into the fill port. Doing so may result in unintended or interrupted insulin delivery.

1. Push air into the vial.

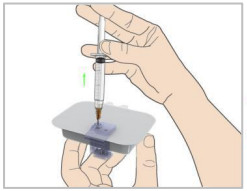


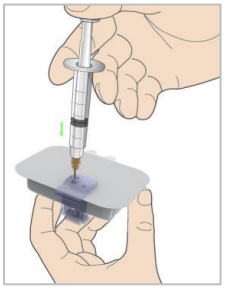
2. Fill the syringe with insulin.



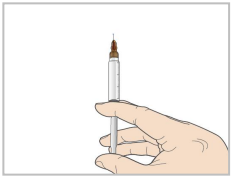
### Remove air

3. Keep the syringe vertical to the Patch Pump, and the needle inside the fill port. Retract the plunger to remove air bubbles.



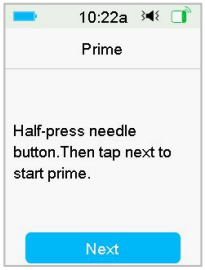


5. Slowly fill the Reservoir with insulin

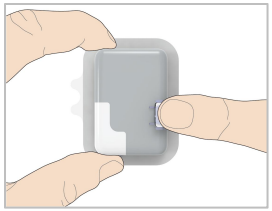


4. Push the plunger until you see a drop of insulin at the tip of the needle

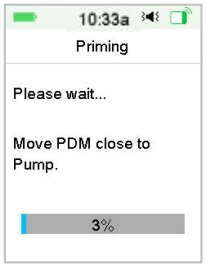
## 5 Prime the Pump



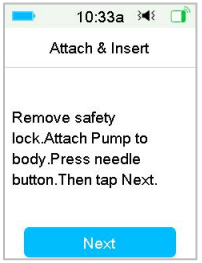

***Press needle button***
Do not start priming before the needle button is pressed.



# Start a new Patch

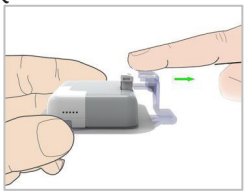



Priming takes about 3 minutes.

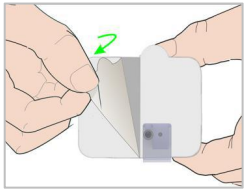



## 6 Place the Patch

1. Remove the safety lock

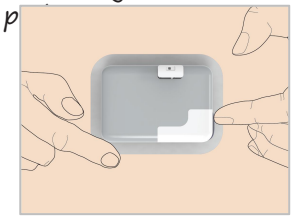


2. Peel off the adhesive liners

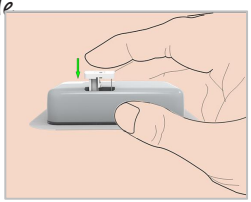


3. Press the Pump against the skin

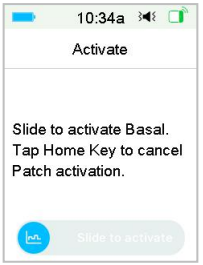
4. Run your finger around the entire edge of the adhesive p

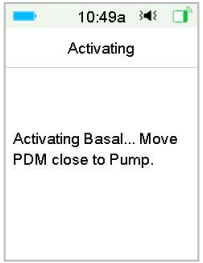


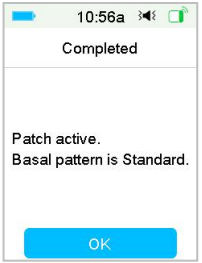
5. Press the needle button with one quick motion to completely insert the needle



## 7 Start Insulin Delivery

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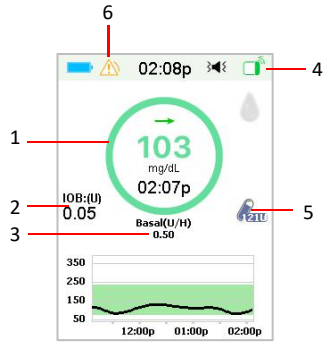
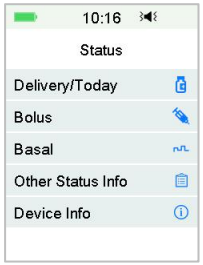
## Home Screen

1. Insulin Delivery Status
2. IOB
3. Delivery details
4. Pump RF Signal
5. Remaining insulin in Reservoir
6. Alarm/Alert



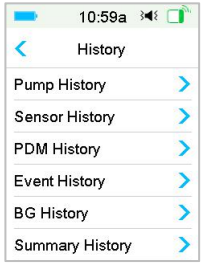




## Pump Status

Slide on the Home Screen from left to right to go to status screen

## Main Menu

Slide on the Home Screen from right to left to go to main menu


## History

**Main Menu ➔ History**

## Delivery Status

| Icon | Shape and Color | Description |
|---|---|---|
| | Grey ring | Grey ring indicates that there is no activated Pump. |
| | Green ring | Green ring represents the basal delivery. |
| | Green and dark green ring | Green ring with dark green part represents Temp Basal, the dark green part indicates the progress of Temp Basal delivery. |
| | Blue and dark blue ring | Blue ring represents the Normal Bolus, the dark blue part indicates the progress of delivery. |
| | Purple and dark purple ring | Purple ring represents the extend Bolus, the deep purple part indicates the progress of delivery. |
| | Red ring | Red ring represents the delivery suspend status. |

# Temp Basal

## Activate a Temp Basal

**Main Menu ➔ Basal ➔ Temp Basal**

*With a Temp Basal you can adjust your Basal rate for a short time*

*Select a Basal type, rate or percent and duration*


## Cancel a Temp Basal

**Main Menu ➔ Basal ➔ Cancel Temp Basal**


## Set Preset Temp Basal

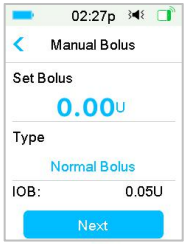
**Main Menu ➔ Settings➔ Insulin Pump ➔ Basal Setup ➔ Preset Temp Setup**

## Activate a Preset Temp Basal

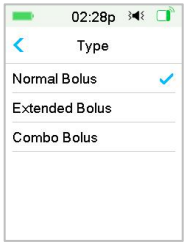
**Main Menu ➔ Basal ➔ Preset Temp Basal**

1 **Main Menu ➔ Bolus ➔ Manual bolus**

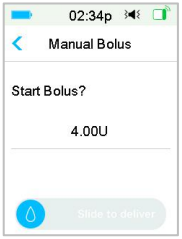

2 **Set Bolus dose**

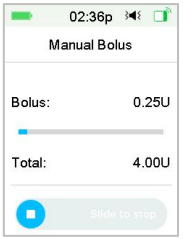



3 **Set Bolus type**



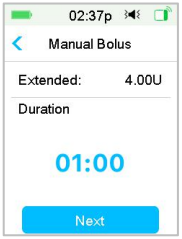

## Normal Bolus

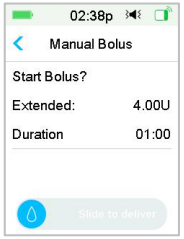



## Extended Bolus

*Set duration*

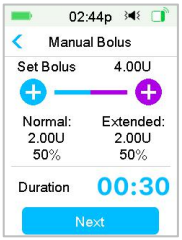


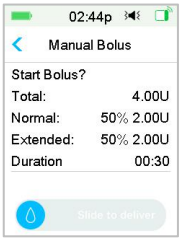




## Combo Bolus

*Tap blue/purple plus sign to set proportion of Normal part and Extended part*

*Set duration*

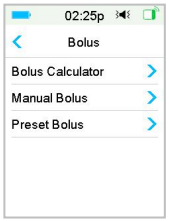


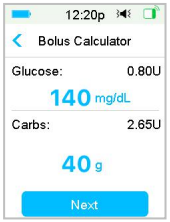

4 **Slide to deliver**

# Food Bolus Calculator

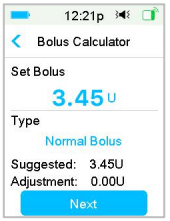
1 **Main Menu ➔ Bolus ➔ Bolus Calculator**



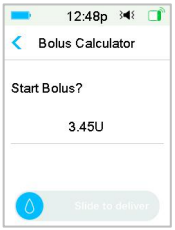

2 **Enter BG or Carb, or both**




3 **Set Bolus dose and Bolus type**

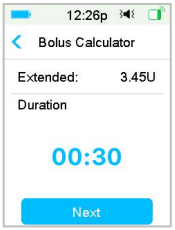



**Normal Bolus**




**Extended Bolus**

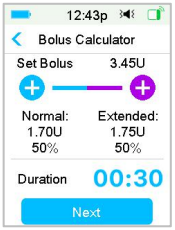
*Set duration*



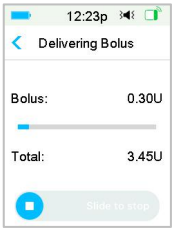

**Combo Bolus**

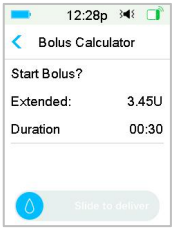
*Tap blue/purple plus sign to set proportion of Normal part and Extended part*

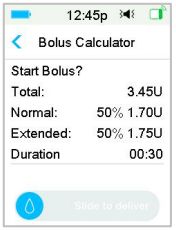
*Set duration*




4 **Slide to deliver**

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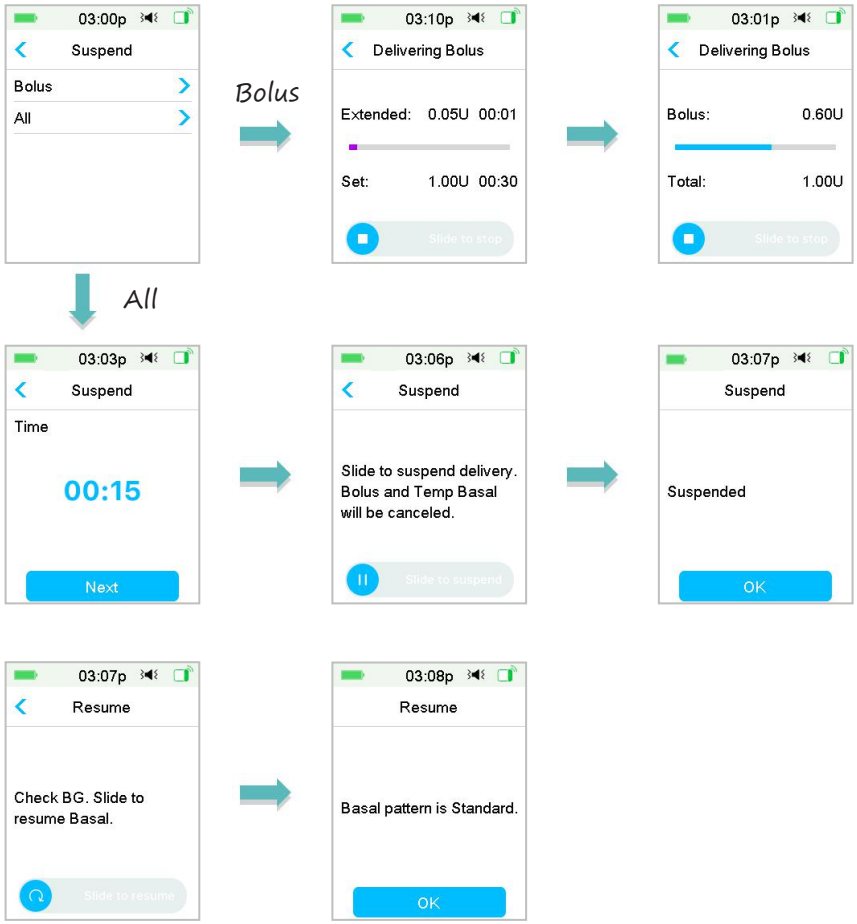
## Suspend

**Main Menu ➔ Suspend**

*A Bolus is being delivered*

*No Bolus is being delivered*




## Resume

**Main Menu ➔ Resume**

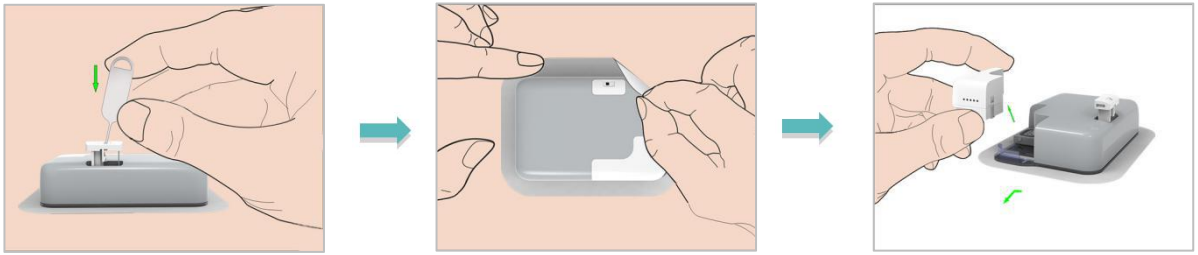
# Deactivate the Patch

## 1 Deactivate the Patch

**Menu➔ Patch➔ Deactivate Patch**


## 2 Remove the Patch

- *After the Reservoir Patch is deactivated, retract the needle with the needle-eject tool.*
- *Gently remove the entire Patch Pump. Use a medical adhesive remover or baby oil if necessary.*
- *Fold and break the tab of Reservoir Patch. Push up the pump base from the bottom and remove it from the old Reservoir Patch.*
- *Discard the old Reservoir Patch according to your local waste disposal regulations. Do NOT discard your Pump Base. It is reusable.*



**Warning:** *Once the Patch is removed from the skin, do not attempt to press the needle button again. Doing so will result in injury.*

## Alert

| PDM Message | Actions to Take |
|---|---|
| END OF SUSPEND | Check BG. Resume basal delivery if necessary. |
| LOW RESERVOIR | Change Patch soon. |
| PATCH EXP IN 1 HOUR | Change Patch soon. |
| PATCH BATTERY LOW | Change Reservoir Patch soon. |

## Alarm (Medium Priority)

| PDM Message | Actions to Take |
|---|---|
| PATCH EXPIRED | Change Patch. Check blood glucose. |
| EMPTY RESERVOIR | Change Patch. Check blood glucose. |
| EXCEEDS MAX TDD | Change Patch. Check blood glucose. Check history. |
| PUMP OUT OF RANGE | Move PDM close to Pump. If failed to recover Pump signal, please change Patch. |
| PUMP RESTARTED | Patch changed? For help call the CC. |

## Alarm (High Priority)

| PDM Message | Actions to Take |
|---|---|
| OCCLUSION DETECTED | Change Patch. Check blood glucose. |
| PATCH ERROR | Change Patch. Check blood glucose. |
| PUMP BASE ERROR | Remove Pump. Contact customer support<br>Check blood glucose. |

## Emergency Kit

Keep an emergency kit with you at all times to make sure you have necessary supplies. Inform a family member, co-worker, and/or friend where this emergency kit is kept.

This kit should include but is not limited to:

- Fast-acting glucose tablets or gel
- BG monitoring supplies
- Urine ketone testing supplies
- Insulin syringe
- Rapid-acting U-100 insulin
- Extra Medtrum 4.0 mL Reservoir Patches
- Power Bank
- Instructions from your healthcare provider about how much insulin to inject if pump delivery is interrupted
- Alcohol wipes
- Glucagon emergency kit
- Emergency contact phone numbers
- If traveling, a copy of a letter from your healthcare provider for airline security

# Your Personal Settings

| Max Basal Rate: _____ U/H |
|---|

| Basal Pattern Name: _____ | | | |
|---|---|---|---|
| Start Time | Rate (U/H) | Start Time | Rate (U/H) |
| : | | : | |
| : | | : | |
| : | | : | |
| : | | : | |
| : | | : | |
| : | | : | |
| : | | : | |

| Basal Pattern Name: _____ | | | |
|---|---|---|---|
| Start Time | Rate (U/H) | Start Time | Rate (U/H) |
| : | | : | |
| : | | : | |
| : | | : | |
| : | | : | |
| : | | : | |
| : | | : | |
| : | | : | |

| Name | Rate | Duration |
|---|---|---|
| Heavy Exercise | _____ % or U/H | : |
| Medium Exercise | _____ % or U/H | : |
| Light Exercise | _____ % or U/H | : |
| Sick | _____ % or U/H | : |
| Temp 1 | _____ % or U/H | : |
| Temp 2 | _____ % or U/H | : |

| I:C Ratio | |
|---|---|
| Start Time | I:C (g Carb) |
| : | 1 U : _____ g |
| : | 1 U : _____ g |
| : | 1 U : _____ g |
| : | 1 U : _____ g |
| : | 1 U : _____ g |
| : | 1 U : _____ g |
| : | 1 U : _____ g |

| Insulin Sensitivity | |
|---|---|
| Start Time | ISF (mg/dL) |
| : | 1 U : _____ mg/dL |
| : | 1 U : _____ mg/dL |
| : | 1 U : _____ mg/dL |
| : | 1 U : _____ mg/dL |
| : | 1 U : _____ mg/dL |
| : | 1 U : _____ mg/dL |
| : | 1 U : _____ mg/dL |

| BG Target (mg/dL) | | |
|---|---|---|
| Start Time | Low Limit | High Limit |
| : | | |
| : | | |
| : | | |
| : | | |
| : | | |
| : | | |
| : | | |

Max Bolus: _____U

Active Insulin Time: _____ : _____

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# FCC Caution

## Labelling requirements

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions : (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

## Information to user

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

**Note:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

## RF warning for portable device

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

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EC REP

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CE 0197

This product complies with Directive 93/42/EEC (MDD) and Directive 2014/53/EU (RED).

SY-401
IM882401US-001
Version:1.00

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