A7 TouchCare®

Insulin Management System

User Guide

Humalog® is a trademark of Eli Lilly and Company.
NovoLog® is a trademark of Novo Nordisk A/S.
Apidra® is a trademark of Sanofi S.A.

MEDTRUM

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Contents

目录

1 Introduction

1.1 Before you begin

Check with your healthcare provider regarding your individual training needs. Do NOT attempt to use the A7 TouchCare® System before you have been properly trained.

As part of your training, your healthcare provider will work with you to establish diabetes management guidelines and settings that best fit your needs. Your healthcare provider can provide you with the initial settings of your insulin Pump and CGM system. After adequate training and practice, you will find it easy to enter and change the system's settings.

The A7 TouchCare® Pump is designed to use U-100 insulin. The following insulin analogs have been tested and found to be safe for use with the A7 TouchCare® Pump:

Humalog®, NovoLog®, and Apidra®.

Before using different insulin with this Pump, check the insulin label to make sure it can be used with your Pump. Use of any insulin with lesser or greater concentration can result in serious injury or death. Your Pump is not intended to deliver any other substance.

The A7 TouchCare® Continuous Glucose Monitoring (CGM) System incorporates a Glucose Sensor and a Transmitter. The Glucose Sensor measures the glucose level of interstitial fluid. The Transmitter wirelessly transmits your real-time Sensor glucose information to your Personal Diabetes Manager (PDM).

Not all devices or accessories are available in all countries where the A7 TouchCare® System is approved. To order supplies, contact your local representatives.

1.2 Indications

The A7 TouchCare® System is indicated for use in people (ages 2 and older) with diabetes. The system is intended for single patient use and should be used under the guidance of a healthcare provider.

The Patch Pump is indicated for the continuous subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

The CGM System is indicated for continuous monitoring of interstitial fluid glucose levels, and detecting possible low and high glucose episodes. Interpretation of the CGM System results should be based on the glucose trends and several sequential readings.

1.3 Contraindications

The A7 TouchCare® System is not recommended for people who are unwilling or unable to:

- Maintain contact with their healthcare provider.
- Test their blood glucose levels as recommended by their healthcare provider.
- Maintain sufficient diabetes self-care skills.
- Recognize and respond to alerts and alarms. (Sufficient vision and/or hearing are required.)

1.4 User Safety

1.4.1 Warnings and Precautions

General

Make sure that you have read and are familiar with the *User Guide* before using the A7 TouchCare® System. Failure to follow the instructions may result in pain or injury and may also affect the system's performance. If you do not understand something or have questions, ask your healthcare provider, call customer support, or contact your local Medtrum distributor.

The A7 TouchCare® System has many different settings and features. It is best to talk with your healthcare provider to determine which settings and features are right for you. Some features require great knowledge of insulin pumping and advanced self-care skills. Do NOT use the A7 TouchCare® System until you have specific information for your treatment plan and have had specific training on each feature from your healthcare provider or local Medtrum distributor.

No modification of this system is allowed.

Do NOT use the A7 TouchCare® System if you have delicate skin or if you are allergic to acrylic adhesives.

Do NOT use anything other than the accessories specified in this *User Guide*, which could permanently damage your system and voids its warranty.

Do NOT allow young children to hold the Reservoir Patch, Pump Base, Transmitter or Sensor without adult supervision. The Reservoir Patch, Pump Base, Transmitter and Sensor contain small parts and could pose a choking hazard.

Do NOT operate your A7 TouchCare® System in the presence of flammable anesthetics or explosive gases.

The A7 TouchCare® System includes active medical devices. When you dispose of any device in the A7 TouchCare® System, follow the local waste disposal regulations.

We recommend that you have someone around you (family, friends, etc.) who understands diabetes and the A7 TouchCare® System, so that in case of an emergency, they can help you. Make sure they are familiar with any information given by your healthcare provider.

Patch Pump

In case the A7 TouchCare® System is unable to properly deliver insulin you must be prepared to give yourself an injection of insulin. Knowing how to do this will help to avoid the risk of diabetic ketoacidosis (DKA) or very high blood glucose (BG).

Contact your healthcare provider about lifestyle changes such as starting/stopping your exercise program or significant weight loss/gain because this can affect the way that your body uses insulin.

Do NOT stop using your Pump if you are ill unless instructed to do so by your healthcare provider. Even when you are ill, your body still needs insulin.

If failure or damage of your Pump Base is found during usage, please contact customer support or your local Medtrum distributor for replacement.

CGM System

Do NOT ignore symptoms of high or low glucose. If you believe your Sensor glucose readings are inconsistent with how you feel, manually measure your blood glucose with a blood glucose meter. If the problem continues, discard the old Sensor and insert a new one.

The Sensor may create special needs regarding your medical conditions or medications. Please discuss these conditions and medications with your healthcare provider before using the Sensor.

If failure or damage of your Transmitter is found during usage, please contact customer support or your local Medtrum distributor for replacement.

If you suspect your Sensor is broken during usage, do NOT attempt to remove it yourself. Contact your healthcare provider for assistance in removing the Sensor.

Personal Diabetes Manager (PDM)

Check your PDM occasionally to make sure that it emits audible beeps that are easily detectable and that the vibrate feature is working properly.

If you return your PDM for service, a replacement PDM will be sent. Do NOT use the replacement PDM until it has been programmed to fit your specific needs.

If you drop your PDM or if it has been hit against something hard, inspect it to be sure it is still

Check whether the display screen and the touch screen are working properly, whether the PDM can be charged normally. Call customer support or your local Medtrum distributor if you identify or suspect your PDM has been damaged. Your PDM is designed to be charged by matching charger. Use of anything other than a charger that does not match could permanently damage your PDM and voids its warranty.

Operating Temperature Range

Your A7 TouchCare® System is designed to operate between 5°C (41°F) and 40°C (104°F). Do NOT expose the system to temperatures outside that range. Do NOT expose the system to direct sunlight for a long period of time.

Cleaning

Do NOT use household cleaners, chemicals, solvents, bleach, scouring pads or sharp instruments to clean your PDM, Pump Base, or Transmitter. Never put your PDM, Pump Base or Transmitter in the dishwasher or use very hot water to clean it.

Do NOT use a hair dryer, microwave oven, or conventional oven to dry your PDM, Pump Base, or Transmitter. Use a soft towel.

Do NOT clean any part of the system while it is in use.

X-rays, MRIs and CT Scans

The A7 TouchCare® System may be affected by strong radiation or magnetic fields. If you are going to have an X-ray, MRI, CT scan or other type of exposure to radiation, remove your Patch Pump and Glucose Sensing System, and put them outside the treatment area with your PDM. Change the Reservoir Patch and Sensor after the test or procedure is completed.

The A7 TouchCare® System is designed to tolerate common electromagnetic and electrostatic fields, including airport security systems and mobile phones.

1.4.2 Consumables

- **Reservoir Patch**—The Pump Base (MD-JN-012) is only used with the 200-unit Medtrum Reservoir Patch (MD-JN-011). Change your Reservoir Patch every 2-3 days or as directed by your healthcare provider.
- **Glucose Sensor**—The Transmitter (MD-TY-012) is used with the Medtrum Glucose Sensor (MD-JY-006/JY-016). Change your JY-006 Glucose Sensor every seven days or change your JY-016 Glucose Sensor every fourteen days.

Warning: For your protection the Pump Base and Transmitter have undergone

extensive testing to confirm appropriate operation when used with consumables manufactured or distributed by Medtrum. We recommend using Medtrum Reservoir Patches and Glucose Sensors as we cannot guarantee appropriate operation if the system is used with consumables offered by third-parties and therefore we are not responsible for any injury or malfunctioning of the system that may occur in association with such use.

1.4.3 Radio Frequency (RF) Communication

Note: The A7 TouchCare® System can generate, use, and radiate radio frequency energy, and may cause harmful interference to radio communications. There are no guarantees that interference will not occur in a installation. If the A7 TouchCare® System does cause harmful interference to radio or television reception, you are encouraged to try to correct the interference by one of the following measures:

- Move or relocate the A7 TouchCare® System.
- Increase the distance between the A7 TouchCare® System and the other device that is emitting/receiving interference.

Common consumer electronic devices that transmit in the same frequency band used by the A7 TouchCare® System may prevent communication between the PDM and your Patch Pump or Transmitter. This interference, however, does not cause any incorrect data to be sent and does not cause any harm to your device.

RF communication between your Patch Pump and PDM works up to a distance of 4 meters (13 feet). RF communication between your Transmitter and PDM works up to a distance of 10 meters (33 feet).

1.4.4 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 2.0 mL Reservoir Patches
- Extra AAA alkaline batteries
- 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

1.4.5 Water

Both your Patch Pump and Sensor (including the installed Transmitter) are waterproof to a depth of 2.5 meters (8 feet) for up to 60 minutes (IPX8). After exposure to water, rinse the devices with clean water and dry them with a towel.

Warning: Do NOT expose your Patch Pump or Sensor (including the installed Transmitter) to water at depths greater than 2.5 meters (8 feet) or for more than 60 minutes. Check often to make sure the devices are securely attached and in place.

Warning: The PDM is not waterproof. Do NOT spill fluids on it or drop it into fluids.

Warning: The Patch Pump may not be able to deliver normally in water. The Transmitter may not be able to send data normally in water.

Note: Hot water may decrease Sensor life.

1.4.6 Storage

Store the Pump Base and Reservoir Patch at temperatures between -10°C (14°F) and 55°C (131°F), and at humidity levels between 20% and 90% relative humidity. Do NOT store the Pump Base and Reservoir Patch in direct sunlight, extreme temperatures, or in very humid areas.

Store the Sensor at temperatures between 2°C (36°F) and 30°C (86°F), and at humidity levels between 20% and 90% relative humidity for the length of the Sensor's shelf life. For temperatures greater than 30°C (86°F), the Sensor will require cooled storage at temperatures no lower than 2°C (36°F). You may

store the Sensor in the refrigerator if it is within this temperature range. The Sensor should not be stored in the freezer. Wait for the Sensor to warm to room temperature before usage to prevent condensation. Storing the Sensor improperly may cause the Sensor glucose readings to be inaccurate, and you might miss a low or high blood glucose value.

Store the Transmitter at temperatures between -10°C (14°F) and 55°C (131°F), and at humidity levels between 20% and 90% relative humidity. Keep the USB charging cable and the Transmitter separate when in storage.

Store the Personal Diabetes Manager (PDM) at temperatures between -10°C (14°F) and 55°C (131°F), and at humidity levels between 20% and 90% relative humidity.

1.4.7 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.

1.4.8 IC Caution

This device complies with Industry Canada licence-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.

1.5 Warranty Information

Warranty

Personal Diabetes Manager (PDM)

Medtrum Technologies Inc. ("Medtrum") warrants its PDM against defects in materials and workmanship for the period of 4 years from the original date of shipment of the PDM to the original end use purchaser (the "Warranty Period"). During the Warranty Period, Medtrum will, at its discretion, either repair or replace (with a new or recertified PDM, at Medtrum's discretion) any defective PDM, subject to the conditions and exclusions stated herein. This Warranty applies only to new devices and, in the event the PDM is repaired or replaced, the warranty period shall not be extended.

The warranty is valid only if the PDM is used in accordance with Medtrum's instructions and will not apply:

• If damage results from changes or modifications made to the PDM by the user or third persons after the date of manufacture;

• If damage results from service or repairs performed to any part of the PDM by any person or entity other than Medtrum;

• If a charger without matching is used with the PDM

• If damage results from a *Force Majeure* or other event beyond the control of Medtrum; or

• If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the PDM covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the PDM and does not apply to other products or accessories.

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANT CLAIMS. NEITHER MEDTRUM 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.

Warranty

Pump Base

Medtrum Technologies Inc. ("Medtrum") warrants its Pump Base against defects in materials and workmanship for the period of 1 year from the original date of shipment of the Pump Base to the original end use purchaser (the "Warranty Period"). During the Warranty Period, Medtrum will, at its discretion, either repair or replace (with a new or recertified Pump Base, at Medtrum's discretion) any defective Pump Base, subject to the conditions and exclusions stated herein. This Warranty applies only to new devices and, in the event the Pump Base is repaired or replaced, the warranty period shall not be extended

The warranty is valid only if the Pump Base is used in accordance with Medtrum's instructions and will not apply:

• If damage results from changes or modifications made to the Pump Base by the

user or third persons after the date of manufacture;

• If damage results from service or repairs performed to any part of the Pump Base by any person or entity other than Medtrum;

• If a non-Medtrum Reservoir Patch is used with the Pump Base;

• If damage results from a *Force Majeure* or other event beyond the control of Medtrum; or

• If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the Pump Base covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the Pump Base and does not apply to other products or accessories.

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANT CLAIMS. NEITHER MEDTRUM 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.

Warranty

Transmitter

Medtrum Technologies Inc. (“Medtrum”) warrants its Transmitter against defects in materials and workmanship for the period of 1 year from the original date of shipment of the Transmitter to the original end use purchaser (the

"Warranty Period"). During the Warranty Period, Medtrum will, at its discretion, either repair or replace (with a new or recertified Transmitter at Medtrum's discretion) any defective Transmitter, subject to the conditions and exclusions stated herein. This Warranty applies only to new devices and, in the event the Transmitter is repaired or replaced, the warranty period shall not be extended.

The warranty is valid only if the Transmitter is used in accordance with Medtrum's instructions and will not apply:

• If damage results from changes or modifications made to the Transmitter by the user or third persons after the date of manufacture;

• If damage results from service or repairs performed to any part of the Transmitter by any person or entity other than Medtrum;

• If a non-Medtrum Glucose Sensor is used with the Transmitter;

• If damage results from a *Force Majeure* or other event beyond the control of Medtrum; or

• If damage results from negligence or improper use, including but not limited to improper storage or physical abuse such as dropping or otherwise.

This warranty shall be personal to the original end use purchaser. Any sale, rental or other transfer or use of the Transmitter covered by this warranty to or by a user other than the original end use purchaser shall cause this warranty to immediately terminate. This warranty only applies to the Transmitter and does not apply to other products or accessories.

THE REMEDIES PROVIDED FOR IN THIS WARRANTY ARE THE EXCLUSIVE REMEDIES AVAILABLE FOR ANY WARRANT CLAIMS. NEITHER MEDTRUM 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

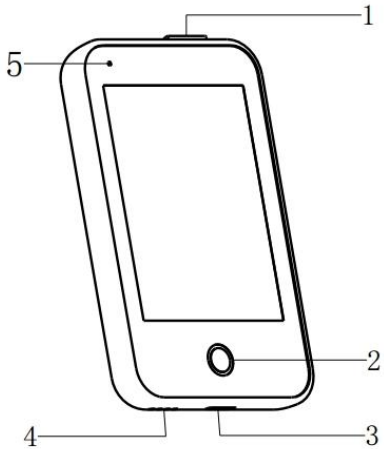
EXCLUDED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

2 Your A7 TouchCare® System

2.1 Personal Diabetes Manager (PDM)

The Personal Diabetes Manager (PDM) monitors and controls your Patch Pump and Continuous Glucose Monitoring System via wireless RF communication. It stores your pump and Sensor data of the last 90 days. Keep the PDM with you at all times so that, when needed, you are able to deliver a bolus, change the basal rate, check your glucose level and so on.

When RF communication is lost or interrupted because of adverse conditions or overlong distance, you will not be able to use your PDM to control or monitor your Patch Pump or Continuous Glucose Monitoring System. Yet the Patch Pump is able to continue delivering basal insulin based on your programmed settings, perform safety checks and automatically stop delivery in case of serious conditions. The Transmitter can continue to record Sensor glucose readings. The PDM is designed to detect and notify you about a disconnection. As soon as the problem is solved, RF communication will be resumed.

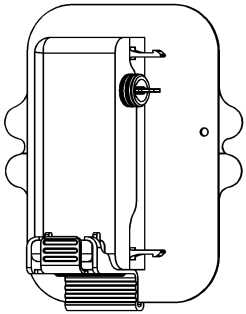


1. Power Key
2. Home Key (Softw Key)
3. Charging Port
4. Sound Hole
5. Charging Indicator

✓ Personal Diabetes Manager (PDM) (MD-FM-008)

2.2 Patch Pump

The Patch Pump is a small, portable, self-adhesive device worn directly on your body to deliver precise, personalized doses of insulin into your body through a needle. The Patch Pump consists of a reusable Pump Base and a disposable Reservoir Patch. The reusable Pump Base holds the electronics and stores all your Pump settings. The disposable 200 Unit Reservoir Patch incorporates a precise dispensing screw, a plunger, a driver, a needle, a buzzer and a battery to power your Pump. The delivery system and enclosure of the Reservoir Patch are applied parts of the Pump.

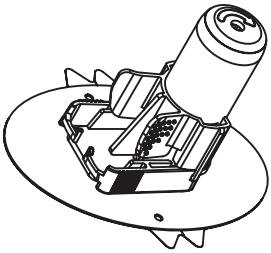


✓ Reservoir Patch (MD-JN-011)(Consumable)

✓ Pump Base (MD-JN-012)

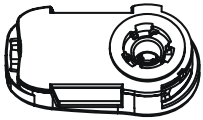
2.3 Glucose Sensing System (Optional)

The Glucose Sensing System is an optional part of the A7 TouchCare® System which consists of a disposable Glucose Sensor and a reusable Transmitter. The Glucose Sensor is inserted under the skin to measure your glucose level in interstitial fluid. The Sensor is the applied part of the Glucose Sensing System. The Transmitter records Sensor data and sends data to a display device via wireless RF communication. The Transmitter's USB charging cable is also included in the package.



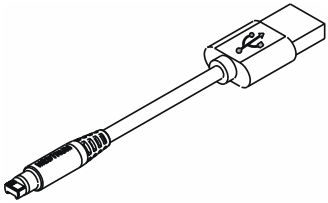
✓ Glucose Sensor

(MD-JY-006 or JY-016)
(Consumable)



✓ Transmitter

(MD-TY-012)



✓ USB charging cable

3 How to Use the PDM

3.1 Basics of the PDM

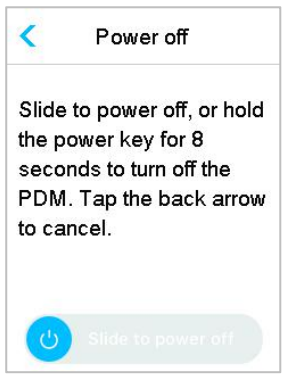
3.1.1 Turn on/off the PDM

1) Turn-on

- When you long-press the power key, then a green light will flash, the screen will light up, the PDM is successfully turned on.
- When you short-press the power key, a yellow light will go on for about 8 seconds but the PDM is not turned on.

1) Turn-off

- When you long-press the power key for about 2 seconds, the shutdown screen appears. Then you can slide to power off, a yellow light will last for about 6 seconds, indicating that the shutdown is completed.



- Or you long-press the power key for about 6 seconds, a yellow light will go on for about 2 seconds, indicating that the shutdown is completed.

3.1.2 Charge the PDM

It is recommended to fully charge the PDM the first time it is used.

As a safety measure, the PDM will give you " **PDM BATTERY LOW** " or " **PDM CHARGE NOW**" alert when you keep the PDM working at a low power level. If you receive a **PDM BATTERY LOW** alert, respond to the alert and continue. Though the PDM will still function normally, the battery life could be decreased.

The PDM requires an AC adapter with an output of DC 5.0V that complies with IEC 60601-1 and IEC 60950 such as UES06WNCPU-050 100SPA, (input: 100-240V, 50/60Hz, 0.2A; output: 5.0V DC, 1.0A). The adapter is designed as a part of the ME system.

Note:

- Do not use other types of chargers. Otherwise the PDM may not work normally.
- You must charge the PDM when the battery is low to keep using the PDM. If the battery is exhausted, the PDM will shut down automatically.
- Even if the PDM is exhausted, or if the PDM is mistaken, the setup information stored in the PDM will not be lost.
- It takes at least 1 hour to fully charge. Usually, the handheld is fully charged, available for handhelds for 1 weeks.
- Blue light flashes when PDM is charging, and the green light is always on indicates full charge.
- Don’t change the battery of the PDM at any time.
- Only person（including patient） with adequate training is permitted to

operate the PDM.

3.1.3 Power Mode

The PDM has two power modes:

1. Sleep Mode

   The PDM enters the Sleep Mode after screen backlight timeout and the screen shuts down. You can turn the PDM into Lock Screen of Awake Mode by short-pressing the Power Key.

a. The activated basal, temporary basal and all bolus functions will not be changed.

b. The screen will be locked after screen backlight timeout.

c. Press Power key, and the screen lights up, the PDM displays the Lock Screen. When PDM is displaying a certain screen before it turns to Lock Screen, PDM will show the previous screen after the screen is unlocked.

2. Awake Mode

   The PDM is in the Awake Mode when the screen backlight stays on.

   a. You can turn Sleep Mode to Awake Mode by pressing Power key.

   b. In the Sleep Mode, all Alert and Alarms regarding the Pump and CGM will immediately wake the screen to enter Lock Screen. The Alerts and Alarms shall be manually cleared after sliding to unlock.

3.1.4 Scroll Bar

If there is excessive text length for the screen, a scroll bar appears on the right side of the screen. You can view any additional text by scrolling up and down.

3.1.5 Beep/Vibrate

The PDM beeps and/or vibrates to notify you of a condition. For more information about Beep/Vibrate.

3.2 Setting up the PDM

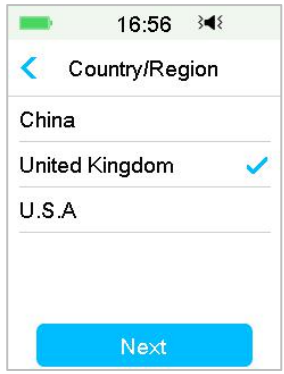
3.2.1 Select a Language

Select your language, then tap Next.

You can change language.

3.2.2 Select country/region

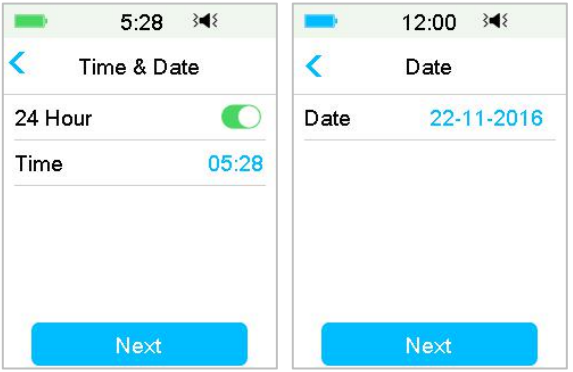
Select your country/region, then tap Next.



3.2.3 Time and Date

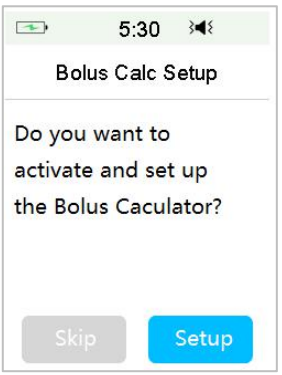
When starting PDM for the first time, you need to set the time and date.

Setting the correct time and date in your PDM is necessary for accurate basal insulin delivery and enables you to keep a correct record of your insulin delivery and Sensor readings. You can select a 12-hour or 24-hour clock format.



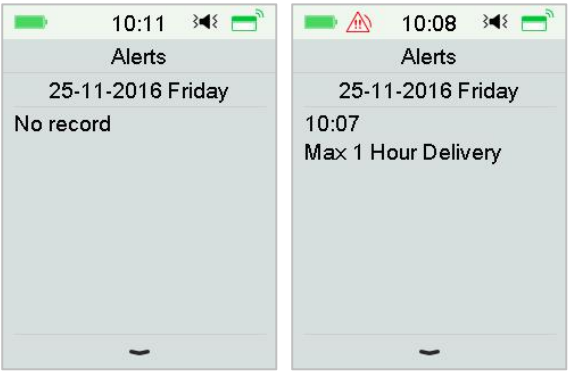
3.2.4 Bolus Calculator

After you finish the settings for date and time, you can choose whether you shall use the Bolus Calculator. Tap “Yes” to enter Bolus Calc Setup. Tap “No” to go directly to Lock Screen.



If you choose “Setup”, the Bolus Calculator function will be forced to turn on;

If you choose “Skip”, the Bolus Calculation function will stay turned-off.



4 Safety System and Alarms

4.1 Safety System

Your A7 TouchCare® System automatically performs a series of safety checks. The PDM sounds an alert or alarm and displays an on-screen message to let you know of an abnormal condition.

If you have more than one notification, you need to clear the first notification to see the next one.

All of your alarm settings and alarm history are stored in the PDM if the battery is removed and will be restored once a new battery is installed. However, only the remaining alarm/alert conditions will be recorded after the new battery is installed.

Note: Do NOT set alarm (time point, limit value etc.) beyond the thresholds or in a way that makes the alarm system useless. Talk with your healthcare provider to see which settings are best for you.

Note: Your PDM consumes battery power when notifying you of alerts, alarms, and reminders. If you do not acknowledge a notification, the PDM battery power drops fast as the notifications repeat and progress. This will result in reduced battery life and the **CHARGE PDM NOW** Alarm screen will appear sooner than expected.

4.2 Safety Checks

A single fault condition will cause the pump to suspend insulin delivery.

Maximum infusion with a single fault condition is 0.05U.

5 Troubleshooting

This chapter contains procedures and information to help you understand and address conditions that might occur with A7 TouchCare System. It will give a simple analysis, and some detailed answers, please look for it in the corresponding sections.

it on.

6 Manufacturer’s Declaration

The A7 TouchCare® System (consisting of the MD-FM-008 PDM, MD-JN-012 Pump Base, MD-JN-011 Reservoir Patch, MD-TY-012 Transmitter and MD-JY-006/JY-016 Glucose Sensor) is intended for use in the electromagnetic environment specified below. The customer or the user of A7 TouchCare® System should make sure that it is used in such an environment.

6.1 Electromagnetic Emissions

Emissions Test	Compliance
RF emissions EN 60601-1-2:2007+AC:2010, IEC 60601-1-2:2007, CISPR 11:2009+A1:2010and IEC 60601-1-2:2014	Group 1
RF emissions EN 60601-1-2:2007+AC:2010, IEC 60601-1-2:2007, CISPR 11:2009+A1:2010and IEC 60601-1-2:2014	Class B

6.2 Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	±2.0 kV, ±4.0 kV, ±6.0kV, ±8.0 kV contact discharge ±2.0 kV, ±4.0 kV, ±8.0 kV, ±15.0 kV air discharge	±2.0 kV, ±4.0 kV, ±6.0 kV, ±8.0 kV contact(56% RH) ±2.0 kV, ±4.0 kV, ±8.0 kV, ±15.0 kV air (56% RH)
RF electromagnetic field immunity test IEC 61000-4-3	10 V/m	10 V/m
Power frequency magnetic fields IEC 61000-4-8	30 A/m	30 A/m

Warning:

1. Medtrum MD-SY-011C system is not designed to be used in an environment with high voltage, high-intensity magnetic field, where the intensity of EM DISTURBANCES is high.

2. Portable RF Communications equipment should be used no closer than 30 cm (12 inches) to any part of the Medtrum products. Otherwise, degradation

of the performance of this equipment could result.

3. It should be avoided to use this equipment adjacent to or stacked with other medical equipment, because it could result in improper operation. If such use is necessary, this equipment and the other medical equipment should be observed to verify that they are operating normally.

7 Appendix I: Symbols and Icons

7.1 Product Label Symbols

Symbol	Meaning	Symbol	Meaning
	Lot number		Do NOT use if package is damaged
	Reference number		Sterilized using ethylene oxide
	Manufacturer		Sterilized using radiation
	Use by: (yyyy-mm-dd)		Follow instructions for use
	Caution: See Instructions for use		Radio communication

Symbol	Meaning	Symbol	Meaning
	Storage temperature	IPX8	Waterproof to 2.5 m for 1 hour
	Do NOT reuse	SN	Device serial number
CE 0197	CE mark by notified body		Type BF equipment (Protection from electrical shock)
	Waste Electrical and Electronic Equipment	EC REP	Authorized representative in the European Community
IP22	Protection Against Insertion of Large Objections and Dripping Water IEC 60529		

7.2 PDM Icons

Icon	Meaning	Icon	Meaning
	High priority alarm		Medium priority alarm
	Alert		Audio off
	Audio temporary off	00:00 am	Time
	Pump RF signal		Battery
	Charging		Charged

8 Appendix II: Technical Information

8.1 Patch Pump Specifications

Model:

Pump Base: MD-JN-012

Reservoir Patch: MD-JN-011

Size: 56.5mm x 33.3mm x 13.3 mm

Weight: 21.5 g (without insulin)

Operating Temperature Range: +5 °C ~ +40 °C

Operating Relative Humidity Range: 20%~90%RH

Operating Atmospheric Pressure: 700~1060 hPa

Storage Temperature Range: -10°C ~ +55°C

Storage Relative Humidity Range: 20%~90%RH

Storage Atmospheric Pressure: 700~1060 hPa

Classification: Internally powered, Type BF applied parts, Continuous operation

Battery: Powered by two button batteries (1.5 V)

Wireless Communication Distance: 4 m

Waterproof Rating: IPX8 (2.5 m, 60 min)

Limited Warranty of Pump Base: 1 year

Shelf Life of Reservoir Patch: 2 years

Sterilization Method of Reservoir Patch: By EO gas

Reservoir Volume: 200 U (2 mL) (1 U=10 μL)

Insulin Type Used: U-100

Basal Rate Range: 0.00~ 10 U/h (increment: 0.05 U/h)

Bolus Range: 0.05 ~ 25 U (increment: 0.05 or 0.1 U)

Bolus Delivery Rate: 0.05 U/2 s

Maximum Infusion Pressure and Occlusion Pressure Threshold: 15 psi

Maximum Time to Occlusion Alarm:

Basal Delivery (0.1 U/h): < 30 h

Basal Delivery (1 U/h): < 3 h

Bolus Delivery (3 U at 1.5 U/min): < 120 s

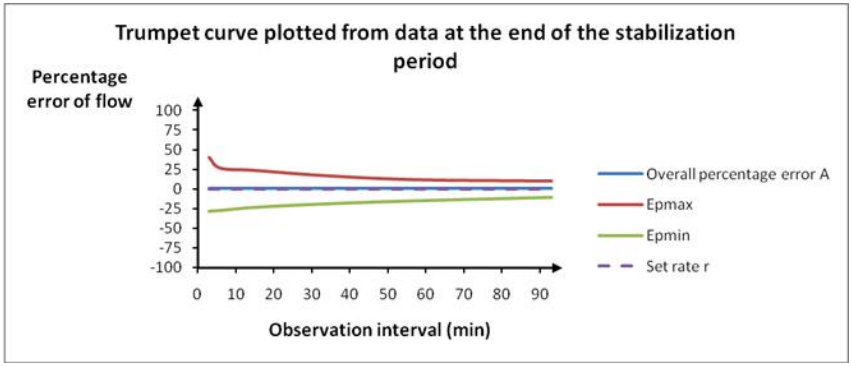
Bolus Volume after Occlusion Release: < 3 U

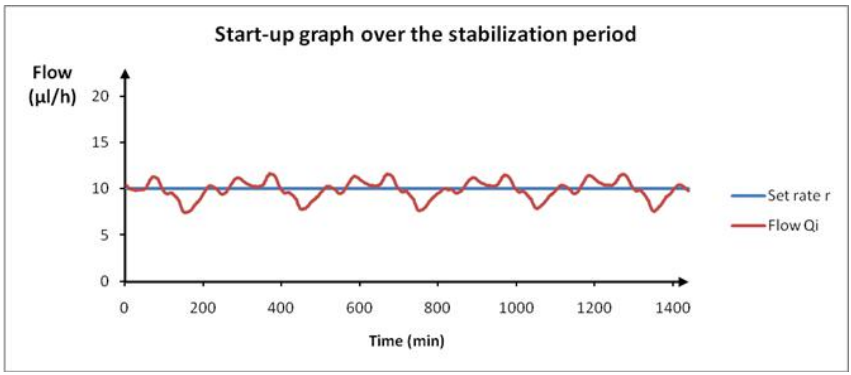
Delivery Accuracy:

Basal: +/- 5% (at rates: 0.1~ 10 U/h)

Bolus: +/- 5% (for all set values: 0.05 ~ 25 U)

Accuracy Test Results (test cycle: 29 H, delivery rate: 1.0 U/H, average error: 0.40%):





Note: The Patch Pump may not be able to achieve the above measurement accuracy under certain circumstances such as vigorous exercise, or abnormal operating conditions.

8.2 PDM Specifications

Model: MD-FM-008

Size: 76.2 x 48.4 x 9.375mm

Weight: 42.4 g

Screen: 2.4 in

Operating Temperature Range: +5°C ~ +40°C

Operating Relative Humidity Range: 20%~ 90%RH

Operating Atmospheric Pressure: 700~1060 hPa

Storage Temperature Range: -10°C ~ +55°C

Storage Relative Humidity Range: 20%~ 90%RH

Storage Atmospheric Pressure: 700~1060 hPa

Classification: Internally powered, Continuous operation

Battery: Built-in 3.8 V polymer lithium ion battery

Power: 5.0VDC, 1.0A

Battery Life: Approximately 1 weeks for fully charged.

Data Storage: Automatically stores the previous 90 days' data

Wireless Communication Distance: 10 m with the Transmitter, 4 m with the insulin pump

Alarm Type: Visual, audible and vibratory

Volume: 52.3 dB(A) measured from 1 m distance

Limited Warranty: 4 years

Dust-proof and Waterproof Rating: IP22

8.3 Transmitter Specifications

Model: MD-TY-012

Size: 36.1 mm x 19.4 mm x 12 mm

Weight: 4.8 g

Operating Temperature Range: +5°C ~+40°C

Operating Relative Humidity Range: 20%~90%RH

Operating Atmospheric Pressure: 700~1060 hPa

Storage Temperature Range: -10°C~+55°C

Storage Relative Humidity Range: 20%~90%RH

Storage Atmospheric Pressure: 700~1060 hPa

Battery: Built-in 3.7 V polymer lithium ion battery

Waterproof Rating: IPX8 (2.5 m, 60 min)

Classification: Type BF equipment, Continuous operation

Data Storage: Automatically stores the previous 14 days' data

Wireless Communication Distance: 10 m

Limited Warranty: 1 year

8.4 Glucose Sensor Specifications

Model: MD-JY-006

Storage Temperature Range: +2°C ~+30°C

Storage Relative Humidity Range: 20%~90%RH

Storage Atmospheric Pressure: 700~1060 hPa

Glucose Range: 2.2~22.2 mmol/L (40~400 mg/dL)

Sterilization Method: By radiation

Sensor Life: Up to 7 days

Model: JY-016

Storage Temperature Range: +2°C~+30°C

Storage Relative Humidity Range: 20%~90%RH

Storage Atmospheric Pressure: 700~1060 hPa

Glucose Range:2.2~22.2mmol/L (40~400mg/dL)

SterilizationMethod: By radiation

Sensor Life: Up to 14 days

8.5 CGM System Accuracy

A multi-center, randomized clinic study is designed to determine the Sensor accuracy in adults with Type 1 or Type 2 diabetes. In-clinic testing consisted of frequent venous blood sample testing (by Yellow Springs Instrument 2300 STAT Plus™ Glucose Analyzer, YSI) on a random day in the 7-day Sensor life. The accuracy is based on the percentage of CGM glucose readings that are within ± 20%, 30% or 40% of YSI values at glucose values at or above (>=) 100 mg/dL (5.6 mmol/L), or within ±20 mg/dL (1.1 mmol/l), 30 mg/dL (1.7 mmol/L) or 40 mg/dL (2.2 mmol/L) of YSI values at glucose values below (<) 100 mg/dL (5.6 mmol/L).

Table. Percentage of CGM Glucose Readings within ±20%/20 mg/dL , ±30%/30 mg/dL, or ±40%/40 mg/dL of the YSI; Calibrating every 12 hours, Abdomen insertion site.

Number of Matched Pairs CGM-YSI	±20%/20 mg/dL	±30%/30 mg/dL	±40%/40 mg/dL
1678	91%	97%	99%

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