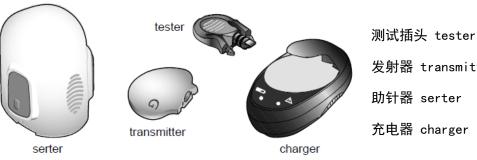
Guardian Link (3) Transmitter

User Guide

Guardian Link (3) 发射器 用户指南

Guardian Link(3)发射器是 MiniMed 670G 胰岛素泵连续血糖监测(CGM)系统的一个 组成部分。发射器仅与 Guardian Sensor(3)血糖探头兼容。发射器从探头收集数据。然后, 发射器将数据无线发送到胰岛素泵。

The Guardian Link (3) transmitter is a component of the continuous glucose monitoring (CGM) system for the MiniMed 670G insulin pump. The transmitter is compatible only with the Guardian Sensor (3) glucose sensor. The transmitter collects data from the sensor. The transmitter then wirelessly sends the data to the insulin pump.



发射器 transmitter 助针器 serter 充电器 charger

Guardian Link (3) 发射器套件组件完整的发射器套件包括以下组件: Guardian Link (3) transmitter kit components A complete transmitter kit includes the following components:

- 发射器 Guardian Link (3) transmitter (MMT-7811)
- 充电器 Charger (MMT-7715)
- 两个测试插头 Two testers (MMT-7736L)
- 探头植入器(助针器) One-press serter (MMT-7512)

Indications for use 使用说明

Guardian Link(3)发射器适用于 MiniMed 670G 系统。The Guardian Link(3) transmitter is intended for use with MiniMed 670G System.

发射器为血糖探头供电,收集并计算探头数据,并将数据无线发送至 MiniMed 670G 泵。该发射器适用于单患者,多用途。The transmitter powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the MiniMed 670G pump. The transmitter is intended for single-patient, multi-use.

Contraindications 禁忌

未知。None known.

Warnings 警告

请勿将发射器与其他电气设备相邻,否则可能会干扰正常的系统操作。这包括移动通信设备,例如手机,GPS 导航系统以及输出发射功率大于 1W 的其他设备。其他可能影响正常系统运行的电气设备是禁忌的。有关更多信息,请参阅第 2 页的"暴露于磁场和辐射"。 Do not use the transmitter adjacent to other electrical equipment which may cause interference with the normal system operation. This includes mobile communication devices such as cell phones, GPS navigation systems, and other devices that have an output transmitter power greater than 1W. Other electrical equipment that may compromise normal system operation has been contraindicated. For more information, see Exposure to magnetic fields and radiation, on page 2.

有关探头的所有注意事项,警告和说明,请务必参阅探头用户指南。不参考探头用户指南可能导致严重伤害或损坏探头。Always refer to the sensor user guide for all precautions, warnings, and instructions relating to the sensor. Not referring to the sensor user guide can result in serious injury or damage to the sensor.

不要让儿童将小部件放入口中。该产品对幼儿造成窒息危险。Do not allow children to put small parts in their mouth. This product poses a choking hazard for young children.

除非 Medtronic Diabetes 明确批准,否则请勿更改或修改设备。修改设备可能会导致严重伤害,干扰您操作设备的能力,并使保修失效。Do not change or modify the device unless expressly approved by Medtronic Diabetes. Modifying the device can cause serious injury, interfere with your ability to operate the device, and void your warranty.

如果与血液接触,请勿使用测试插头。接触血液会导致感染。根据当地医疗废物处理规定处理测试插头,或联系您的医疗保健专业人员获取处理信息。Do not use the tester if it comes in contact with blood. Touching blood can cause infection. Dispose of the tester according to the local regulations for medical waste disposal, or contact your healthcare professional for disposal information.

插入探头后可能会出血。在将发射器连接到探头之前,务必确保现场没有出血。血液可能进入发射器连接器并损坏设备。如果损坏,请丢弃设备。如果发生出血,请在插入部位用无菌纱布或干净布料施加稳定压力,直至出血停止。出血停止后,将发射器连接到探头。Bleeding may occur after inserting the sensor. Always make sure that the site is not bleeding before connecting the transmitter to the sensor. Blood can get into the transmitter connector and damage the device. Discard the device if damaged. If bleeding occurs, apply steady pressure with a sterile gauze or clean cloth at the insertion site until bleeding stops. After bleeding stops, connect the transmitter to the sensor.

如果您遇到与发射器或探头相关的任何不良反应,请联系 24 小时帮助热线。不良反应可能导致严重伤害。Contact the 24 Hour HelpLine if you experience any adverse reactions associated with the transmitter or sensor. Adverse reactions can cause serious injury.

Exposure to magnetic fields and radiation 暴露于磁场和辐射

请勿将发射器暴露于磁共振成像(MRI)设备,透热设备或其他产生强磁场的设备(例如,X 射线,CT 扫描或其他类型的辐射)。暴露在强磁场中尚未进行评估,可能导致设备故障,导致严重伤害或不安全。如果您的发射器暴露在强磁场中,请停止使用并联系 24 小时帮助热线以获得进一步的帮助。Do not expose your transmitter to Magnetic Resonance Imaging (MRI) equipment, diathermy devices, or other devices that generate strong magnetic fields (for example, x-ray, CT scan, or other types of radiation). Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury or be unsafe. If your transmitter is exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.

在进入有 X 射线, MRI, 透热疗法或 CT 扫描设备的房间之前, 请务必取下探头和发射器。 暴露在强磁场中尚未进行评估, 可能导致设备故障, 导致严重伤害或不安全。如果您的探头 或发射器暴露在强磁场中, 请停止使用并联系 24 小时帮助热线以获得进一步的帮助。Always remove your sensor and transmitter before entering a room that has x-ray, MRI, diathermy, or CT scan equipment. Exposure to a strong magnetic field has not been evaluated and can cause the device to malfunction, result in serious injury or be unsafe. If your sensor or transmitter is exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance. 旅行时请随身携带随设备提供的医疗急救卡。医疗应急卡提供有关机场安检系统的重要信息,并在飞机上使用您的发射器,可以帮助您和其他人。不遵循医疗紧急卡的指导可能会导致严重伤害。Always carry the Medical emergency card provided with your device when you are traveling. The Medical emergency card provides critical information about airport security systems, and using your transmitter on an airplane that can help you and others. Not following the guidance on the Medical emergency card could result in serious injury.

Precautions 注意事项

仅将 Guardian 探头(3)(MMT-7020)血糖探头与发射器一起使用。不要使用任何其他探头。其他探头不适用于发射器,会损坏发射器和探头。Only use the Guardian Sensor(3)(MMT-7020)glucose sensor with the transmitter. Do not use any other sensor. Other sensors are not intended for use with the transmitter, and will damage the transmitter and the sensor.

只能将绿色测试插头(MMT-7736L)与发射器一起使用。连接到测试插头时,发射器上的口袋可见。不要使用任何其他测试插头。其他测试插头不适用于发射器,会损坏发射器和测试插头。Only use the green colored tester (MMT-7736L) with the transmitter. Pockets on the transmitter are visible when connected to the tester. Do not use any other test plug. Other test plugs are not intended for use with the transmitter, and will damage the transmitter and the tester.

清洁发射器时务必使用测试插头。不要在发射器上使用任何其他测试插头。使用另一个测试插头可能会让水进入发射器或妨碍正确清洁。水会损坏发射器。Always use the tester when cleaning the transmitter. Do not use any other test plug with the transmitter. Use of another test plug can allow water to get into the transmitter or can prevent proper cleaning. Water can damage the transmitter.

连接到发射器时,请勿扭曲测试插头或探头。扭转测试插头或探头会损坏发射器。Do not twist the tester or sensor while attached to the transmitter. Twisting the tester or sensor will damage the transmitter.

未连接到发射器时,不要让测试插头接触任何液体。湿的测试插头可能会损坏发射器。 Do not allow the tester to come in contact with any liquid when not connected to the transmitter. A wet tester can damage the transmitter.

未连接探头或测试插头时,请勿让发射器接触任何液体。水分会损坏发射器,湿的发射器会损坏探头。Do not allow the transmitter to come in contact with any liquid when not connected to a sensor or to the tester. Moisture will damage the transmitter and a wet transmitter can damage the sensor.

不要用任何物质清洁测试插头上的 0 形圈。清洁 0 形圈会损坏测试插头。Do not clean the o-rings on the tester with any substances. Cleaning the o-rings can damage the tester.

Radio Frequency (RF) communication 射频(RF)通信

本设备符合美国联邦通信委员会(FCC)和电磁兼容性的国际标准。本设备符合 FCC 规则第 15 部分的规定。操作有两个条件:(1)此设备不会产生有害干扰,(2)此设备必须接受任何收到的干扰,包括可能导致意外操作的干扰。This device complies with the United States Federal Communications Commission(FCC) and international standards for electromagnetic compatibility. This device complies with Part 15 of the FCC Rules. Operation is subject to 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.

本设备已经过测试,符合 FCC 规则第 15 部分对 B 类数字设备的限制。这些限制旨在提供合理的保护,防止住宅安装中的有害干扰。该设备会产生,使用并辐射射频能量,如果不按照说明进行安装和使用,可能会对无线电通信造成有害干扰。但是,无法保证在特定安装中不会发生干扰。如果此设备确实对无线电或电视接收造成有害干扰(可通过关闭和打开设备来确定),建议用户尝试通过以下一种或多种措施纠正干扰: This device 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 device 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 device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- 重新调整或摆放接收天线。Reorient or relocate the receiving antenna.
- 增加设备和接收器之间的距离。Increase the separation between the device and the receiver.
- 将发射器和胰岛素泵之间的距离减小到 6 英尺(1.8 米)或更短。Decrease the distance between the transmitter and the insulin pump to 6 feet (1.8 meters) or less.
- 增加发射器与接收或发射干扰的设备之间的距离。Increase the separation between the transmitter and the equipment that is receiving or emitting interference.

注意:FCC 定义的有害干扰如下。任何危及无线电导航服务或其他安全服务功能的辐射,辐射或感应,或严重降低,阻碍或反复中断按照 FCC 规则运行的无线电通信服务。Note: Harmful interference is defined by the FCC as follows. Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.

未经美敦力糖尿病公司明确批准而对本设备进行的更改或修改可能会使用户无权操作 该设备。Changes or modifications made to this equipment not expressly approved by Medtronic Diabetes could void the user's authority to operate the equipment.

Directive 1999/5/EC 指令 1999/5/EC

美敦力声明该产品符合指令 1999/5/EC 关于无线电和电信终端设备的基本要求。 Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment.

有关其他信息,请通过封底上提供的地址或电话号码联系 Medtronic MiniMed。For additional information, contact Medtronic MiniMed at the address or phone number provided on the back cover.

IEC60601-1-2:2007; Special EMC Precautions for Medical

Electrical Equipment 医用电气设备的特殊 EMC 预防措施

1 关于电磁兼容性(EMC)的特殊注意事项:这种人体佩戴的设备应在合理的住宅,家庭,公共或工作环境中运行,其中辐射的"E"(V/m)或"H"场的常见水平(A/m)存在;如手机,WiFi,蓝牙,电动开罐器,微波炉和感应烤箱。该设备会产生,使用并辐射射频能量,如果不按照提供的说明安装和使用,可能会对无线电通信造成有害干扰。Special Precautions regarding Electromagnetic Compatibility(EMC): This body worn device is intended to be operated within a reasonable residential, domestic, public or work environment, where common levels of radiated "E"(V/m)or "H" fields(A/m)exist; such as cellular phones,WiFi,Bluetooth,electric can openers,microwave and induction ovens. This device generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the provided instructions, may cause harmful interference to radio communications.

2 便携式和移动式射频通信设备也会影响医疗电气设备。如果您遇到来自移动或固定 RF 发射器的 RF 干扰,请远离导致干扰的 RF 发射器。Portable and mobile RF communications equipment can affect Medical Electrical Equipment as well. If you encounter RF interference from a mobile or stationary RF transmitter, move away from the RF transmitter that is causing the interference.

Assistance 帮助

Medtronic MiniMed 提供 24 小时帮助热线以获得帮助。致电帮助热线时,请提供您设备的序列号。序列号和 24 小时 HelpLine 电话号码列在设备背面。Medtronic MiniMed provides a 24 Hour HelpLine for assistance. When calling the HelpLine, please have the serial number of your device available. The serial number and the 24 Hour HelpLine phone number are listed on the back of your device.

部门电话号码 Department Telephone number

24 小时帮助热线(美国境内的电话)HelpLine(calls within the United States) 800 646 4633

24 小时帮助热线(美国境外的电话)HelpLine(calls outside the United States) +1 818 576 5555

网址: Website: www.medtronicdiabetes.com

Charger 充电器

发射器包含不可更换的可充电电池,您可以根据需要使用充电器进行充电。充电器具有显示充电状态的绿灯,和可在充电过程中表示问题的红灯。如果看到红灯,请参阅"故障排除"部分。充电器需要一节 AAA 碱性电池。The transmitter contains a non-replaceable, rechargeable battery that you can recharge as needed with the charger. The charger has a green light that shows the charging status and a red light that communicates any problems during charging. If you see a red light, see the Troubleshooting section. The charger needs one AAA alkaline battery.

注意:如果电池安装不正确或电量不足,充电器将无法工作。使用新电池重复电池安装步骤。Note: If the battery is installed incorrectly or is low, the charger will not work. Repeat the battery installation steps using a new battery.

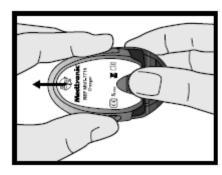
Installing a battery in the charger 在充电器中安装电池

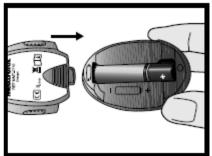
要在充电器中安装电池: To install a battery in the charger:

1推入电池盖并将其滑出(如步骤3中的图像所示)。Push the battery cover in and slide it off (as shown in the image in step 3).

2 插入新的 AAA 碱性电池。确保电池上的+和 - 符号与充电器上显示的相同符号对齐。 Insert a new AAA alkaline battery. Make sure the + and - symbols on the battery align with these same symbols shown on the charger.

3 将盖子向后滑动到充电器上,直至其卡入到位。Slide the cover back on the charger until it clicks into place.





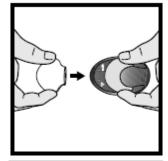
Charging the transmitter 给发射器充电

小心: 在插入探头之前,请务必给发射器充电。没电的发射器不起作用。完全充电的发射器至少工作七天而无需充电。没电的发射器可能需要长达两个小时才能充电。Caution: Always charge the transmitter before inserting your sensor. A depleted transmitter does not function. A fully charged transmitter works at least seven days without recharging. A depleted transmitter can take up to two hours to recharge.

注意:请勿将发射器存放在充电器上超过 60 天。断开并重新连接充电器,以便在使用前重新充电。如果发射器在充电器上放置超过 60 天,电池将永久损坏。Caution: Do not store the transmitter on the charger for more than 60 days. Disconnect and reconnect to the charger to re-charge again before use. If the transmitter is left on the charger for more than 60 days, the battery will be permanently damaged.

为发射器充电: To charge the transmitter:

- 1 将两个组件推到一起,将发射器连接到充电器。Push the two components together to connect the transmitter to the charger.
- 2 连接发射器后 10 秒内, 当充电器开启时, 充电器上的绿灯将闪烁一到两秒钟。在剩余的充电时间内, 充电器上的绿灯将以四次闪烁的模式继续闪烁, 并在四次闪烁之间暂停。Within 10 seconds after the transmitter is connected, a green light on the charger will flash for one to two seconds as the charger powers on. For the rest of the charging time, the green light on the charger will continue to flash in a pattern of four flashes with a pause between the four flashes.
- 3 充电完成后,充电器上的绿灯将保持亮起状态,不会闪烁 15 至 20 秒然后熄灭。When charging is complete, the green light on the charger will stay on, without flashing, for 15 to 20 seconds and then turn off.
- 4 绿色充电器指示灯熄灭后,断开发射器与充电器的连接。 发射器上的绿灯将闪烁 10 次然后熄灭。After the green charger





light turns off, disconnect the transmitter from the charger. The green light on the transmitter will flash 10 times and then turn off.

Pairing your transmitter 配对您的发射器

有关如何将发射器与泵配对的说明,请参阅系统用户指南。Always refer to the system user guide for instructions on how to pair your transmitter to your pump.

Inserting the sensor 插入探头

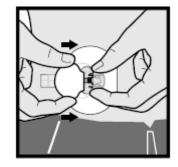
有关如何插入探头的说明,请务必参阅探头用户指南。 Always refer to your sensor user guide for instructions on how to insert the sensor.

Connecting the transmitter to the sensor 将发射器连接到探头

在继续之前,请准备好系统用户指南。 Before proceeding, have your system user guide available.

将发射器连接到探头: To connect the transmitter to the sensor:

- 1 插入探头后,请在连接发射器之前查阅探头用户指南,了解有关应用所需胶纸的详细信息。After the sensor is inserted, consult your sensor user guide for details on applying the required tape before connecting the transmitter.
- 2 握住插入的探头的圆形末端,以防止在连接过程中移动。Hold the rounded end of the inserted sensor to prevent it from moving during connection.
- 3 如图所示握住发射器。将探头的两个槽口与探头的侧臂对齐。发射器的平面应面向皮肤。Hold the transmitter as shown. Line up the two notches on the transmitter with the side arms of the sensor. The flat side of the transmitter should face the skin.
- 4 将发射器滑到探头连接器上,直到探头臂卡入发射器的槽口。如果发射器连接正确,并且探头有足够的时间与组织液进行反应,则发射器上的绿灯将闪烁 6 次。Slide the transmitter



onto the sensor connector until the sensor arms snap into the notches on the transmitter. If the transmitter is properly connected, and if the sensor has had enough time to become hydrated, the green light on the transmitter will flash 6 times.

注意:如果发射器没有闪烁,请参阅第 14 页的故障排除。Note: If the transmitter does not flash, see Troubleshooting, on page 14.

5 连接探头后,如果发射器指示灯呈绿色闪烁,请使用泵启动探头。有关更多说明,请参阅系统用户指南。When the transmitter light flashes green after connecting to the sensor, use your pump to start the sensor. For more instructions, see your system user guide.

6 将探头的粘性片连接到发射器。Attach the adhesive tab of the sensor to the transmitter.

7 有关如何应用第二个胶纸的说明,请参阅探头用户指南。 Refer to the sensor user guide for instructions on how to apply a second tape.

8按照泵屏幕或系统用户指南中的说明进行操作。Follow the instructions that appear on the pump screen or in your system user guide.

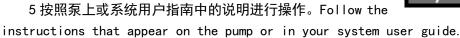


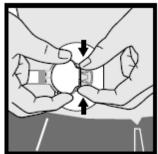
Disconnecting the transmitter from the sensor 断开发射器与探头的连接

在继续之前,请准备好系统用户指南。Before proceeding, have your system user guide available.

要断开发射器与探头的连接: To disconnect the transmitter from the sensor:

- 1 小心地从发射器和探头上取下所有胶纸。Carefully remove any tape from the transmitter and sensor.
 - 2从发射器顶部取下粘性片。Remove the adhesive tab from the top of the transmitter.
- 3 如图所示握住发射器,并将拇指和食指之间的探头的柔性侧臂捏紧。Hold the transmitter as shown, and pinch the flexible side arms of the sensor between your thumb and forefinger.
- 4 轻轻将探头拉离探头。Gently pull the transmitter away from the sensor.





Removing the sensor 卸下探头

有关如何拆卸探头的说明,请务必参阅探头用户指南。Always refer to the sensor user guide for instructions on how to remove the sensor.

Bathing and swimming 沐浴和游泳

连接发射器和探头后,它们形成防水密封,深度为8英尺(2.4米),最长可达30分钟。 你可以淋浴和游泳,而无需移除它们。After the transmitter and sensor are connected, they form a waterproof seal to a depth of 8 feet (2.4 meters) for up to 30 minutes. You can shower and swim without removing them.

Tester 测试插头

测试插头用于测试发射器以确保其正常工作。它还用作清洁发射器所需的组件。将测试插头正确连接到发射器可确保液体不会与发射器内的连接器针脚接触。液体会导致连接器针脚腐蚀并影响发射器的性能。The tester is used to test the transmitter to make sure it is working. It is also used as a required component for cleaning the transmitter. Properly connecting the tester to the transmitter ensures that fluids do not come in contact with the connector pins inside the transmitter. Fluids can cause connector pins to corrode and affect the performance of the transmitter.

连接到发射器时,请勿扭曲测试插头。这会损坏发射器。Do not twist the tester while attached to the transmitter. This will damage the transmitter.

测试插头可以使用一年。如果继续使用测试插头超过一年,发射器内部的连接器针脚可能会损坏,因为测试插头无法继续提供防水密封。有关如何检查连接器引脚的说明,请参阅第 9 页上的"检查发射器连接器引脚"。 The tester can be used for one year. If you continue to use the tester for more than one year, the connector pins inside the transmitter could be damaged, because the tester cannot continue to provide a waterproof seal. For instructions on how to check the connector pins, see Inspecting the transmitter connector pins, on page 9.

注意:只能将绿色测试插头(MMT-7736L)与发射器一起使用。连接到测试插头时,发射器上的插口可见。不要使用任何其他测试插头。其他测试插头不适用于发射器,会损坏发射器和测试插头。Caution: Only use the green colored tester(MMT-7736L)with the transmitter. Pockets on the transmitter are visible when connected to the tester. Do not use any other test plug. Other test plugs are not intended for use with the transmitter, and will damage the transmitter and the tester.

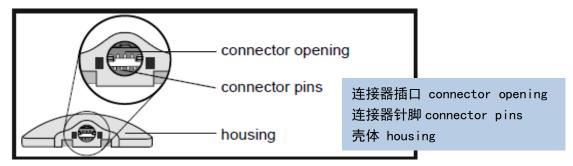


绿色测试插头 green tester

插口 pockets

Inspecting the transmitter connector pins 检查发射器连接器引脚

此图像是连接器引脚应如何显示的示例。This image is an example of how the connector pins should look.



查看发射器的连接器插口内部,确保连接器插针没有损坏或腐蚀。如果连接器引脚损坏或腐蚀,则发射器无法与充电器或泵通信。联系 24 小时帮助热线。可能是时候更换发射器了。Look inside the connector opening of the transmitter to make sure that the connector pins are not damaged or corroded. If the connector pins are damaged or corroded, the transmitter cannot communicate with the charger or pump. Contact the 24 Hour HelpLine. It may be time to replace your transmitter.

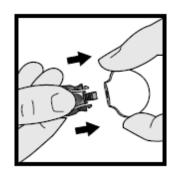
还要在连接器插口内寻找水分。如果看到任何湿气,请让发射器干燥至少一小时。连接器插口内的水分可能导致发射器无法正常工作,并可能导致腐蚀和损坏。Also look for moisture inside the connector opening. If you see any moisture, allow the transmitter to dry for at least one hour. Moisture inside the connector opening could cause the transmitter to not work properly, and could cause corrosion and damage over time.

Connecting the tester for testing or cleaning 连接测试插头进行测试或清洁

在继续之前,请准备好系统用户指南。Before proceeding, have your system user guide available.

连接测试插头: To connect the tester:

- 1 如图所示握住发射器和测试插头。将测试插头的扁平侧与发射器的扁平侧对齐。Hold the transmitter and the tester as shown. Line up the flat side of the tester with the flat side of the transmitter.
- 2 将测试插头推入发射器,直至测试插头的柔性侧臂卡入发射器两侧的槽口。Push the tester into the transmitter until the flexible side arms of the tester click into the notches on both sides of the transmitter.



正确连接后,发射器上的绿灯闪烁 6 次。When properly connected, the green light on the transmitter flashes 6 times.

3 要测试发射器,请检查泵上的探头图标,确保发射器正在发送信号(请参阅系统用户指南)。To test the transmitter, check the sensor icon on the pump to ensure that

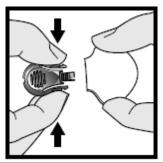
the transmitter is sending a signal (see your system user guide).

- 4 要清洁发射器,请参阅第 10 页的清洁发射器。To clean the transmitter, see Cleaning the transmitter, on page 10.
- 5 测试或清洁后,断开测试插头与发射器的连接。After testing or cleaning, disconnect the tester from the transmitter.

Disconnecting the tester 断开测试插头

要断开测试插头: To disconnect the tester:

- 1 如图所示握住发射器主体并夹住测试插头的侧臂。Hold the transmitter body as shown and pinch the side arms of the tester.
- 2 将测试插头臂夹紧, 轻轻将发射器拉离测试插头。With the tester arms pinched, gently pull the transmitter away from the tester.



注意: 为节省发射器电池寿命,请不要在清洁或测试后连接测试插头。Note: To save transmitter battery life, do NOT leave the tester connected after cleaning or testing.

Cleaning the transmitter 清洁发射器

该发射器是单患者使用的装置,不适合多患者使用。The transmitter is a single-patient use device and not intended for multi-patient use.

警告:请勿丢弃医疗废物容器中的发射器或将其暴露在极热环境中。发射器包含可能会点燃的电池,并导致严重伤害。Warning: Do not discard the transmitter in a medical waste container or expose it to extreme heat. The transmitter contains a battery that may ignite, and result in serious injury.

注意:测试插头是清洁发射器所必需的组件。有关详细信息,请参阅测试插头,第 8 页。 Note: The tester is a required component for cleaning the transmitter. For details, see Tester, on page 8.

每次使用后务必清洁发射器。Always clean the transmitter after each use.

要清洁发射器,您需要以下材料: To clean the transmitter, you need the following materials:

- 温和的液体肥皂(例如,乳白色液体肥皂 <u>PS: 洗手液</u>) mild liquid soap (for example, Ivory liquid soap)
- 软毛小孩牙刷 soft-bristled toddler toothbrush
- 容器 container
- 干净, 不起毛的干布 clean, lint-free dry cloths

您可以在沃尔玛,塔吉特或亚马逊找到这些耗材。You can find these supplies at Walmart, Target, or http://www.amazon.com/.

Use life 使用寿命

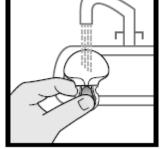
发射器最多可清洗 122 次或一年,以先到者为准。The transmitter can be cleaned up to 122 times or one year, whichever comes first.

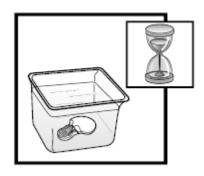
此时丢弃发射器。如果继续使用发射器超过 122 次或一年,清洁过程可能会损坏设备。 联系美敦力订购新的发射器。Discard the transmitter at this point. If you continue to use the transmitter beyond 122 times or one year, the cleaning process may damage the device. Contact Medtronic to order a new transmitter.

警告:如果发现外壳有裂缝,剥落或损坏,请勿使用本设备。外壳开裂,剥落或损坏是恶化的迹象。外壳的劣化会影响正确清洁发射器的能力,并导致严重的伤害。拨打 24 小时帮助热线并根据当地有关电池处理(非焚烧)的规定丢弃设备,或联系您的医疗保健专业人员获取处理信息。Warning: Do not use the device if you see any cracking, flaking, or damage to the housing are signs of deterioration. Deterioration of the housing can affect the ability to properly clean the transmitter, and result in serious injury. Call the 24 Hour HelpLine and discard the device according to local regulations for battery disposal (nonincineration), or contact your healthcare professional for disposal information.

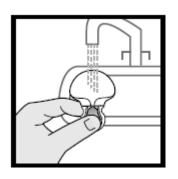
清洁发射器: To clean the transmitter:

- 1 彻底洗净双手。Wash your hands thoroughly.
- 2将测试插头连接到发射器。Attach the tester to the transmitter.
- 3 如果发射器上有粘合剂残留物,请参阅第 13 页的"去除残留物"。If there is adhesive residue on the transmitter, see Removing adhesive residue, on page 13.
- 4 在室温自来水下冲洗发射器至少一分钟,直至明显清洁。确保所有难以触及的区域都完全冲洗干净。 Rinse the transmitter under room temperature tap water for at least one minute, and until visibly clean. Make sure all hard-to-reach areas are rinsed completely.
- 5 每 1 加仑 (3.8 升) 室温自来水使用 1 茶匙 (5 毫升) 温和 液体肥皂制备温和的液体肥皂溶液。Prepare a mild liquid soap solution using 1 teaspoon (5 milliliters) of mild liquid soap per 1 gallon (3.8 liters) of room temperature tap water.
- 6 在测试插头仍然连接的情况下,将发射器浸入温和的液体肥皂溶液中并浸泡一分钟。With the tester still attached, submerge the transmitter in the mild liquid soap solution and soak for one minute.

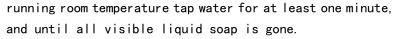




7握住测试插头,使用软毛小孩牙刷刷扫发射器的整个表面。确保刷到所有难以触及的区域,直到看起来干净。Holding the tester, brush the entire surface of the transmitter using a soft-bristled toddler toothbrush. Make sure to brush all hard-to-reach areas until visibly clean.

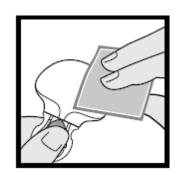


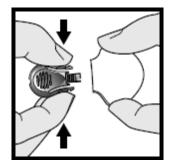
8 在室温自来水下冲洗发射器至 少一分钟, 直至所有可见的液体肥皂 消失。Rinse the transmitter under



9 用干净的干布擦干发射器和 测试插头。Dry the transmitter and tester with a clean, dry cloth.

10 将发射器和测试插头放在干净的干布上, 然后彻底风干。 Place the transmitter and tester on a clean, dry cloth and air dry them completely.





11 轻轻挤压测试插头的臂,将

测试插头与发射器断开。Disconnect the tester from the transmitter by gently squeezing the arms of the tester.

Removing adhesive residue 去除粘合剂残留物

如果发射器上有粘合剂残留物,您可能需要执行此程序。如果目视检查发射器并看到粘合剂残留物,请按照以下说明操作。You may need to perform this procedure if there is adhesive residue present on the transmitter. If you visually inspect the transmitter and see adhesive residue on it, follow the instructions below.

要去除粘合剂残留物,您需要使用 Detachol 医用粘合剂去除剂和棉签。您可以在 http://www.amazon.com/,http://www.medtronicdiabetes.com 或致电 800 646 4633 购买 Detachol。To remove adhesive residue, you need Detachol medical adhesive remover, and cotton swabs. You can buy Detachol at http://www.amazon.com/, http://www.medtronicdiabetes.com, or by calling 800 646 4633.

注意:在测试过程中,Medtronic MiniMed 使用 Detachol 去除发射器上的粘合剂残留物。 Note: During testing, Medtronic MiniMed used Detachol to remove the adhesive residue from the transmitter.

去除粘合剂残留物: To remove adhesive residue:

- 1 确保测试插头已连接到发射器。Make sure the tester is attached to the transmitter.
- 2 握住测试插头,将棉签浸入 Detachol 溶液中,轻轻擦拭 发射器上的粘合剂残留物,直至完全取下。Holding the tester, saturate a cotton swab in the Detachol solution and gently rub the adhesive residue on the transmitter until it is fully removed.
- 3 继续清洁程序。有关详细信息,请参阅第 10 页的清洁发射器。Continue with the cleaning procedure. See Cleaning the transmitter, on page 10 for details.



Cleaning the charger 清洁充电器

根据外貌需要进行一般清洁程序。This procedure is for general cleaning as required, based on physical appearance.

注意: Caution:请勿将充电器浸入水中或任何其他清洁剂中。 充电器不防水。 水可能会损坏充电器,导致设备出现故障。Do not immerse the charger in water or any other cleaning agent. The charger is not waterproof. Water can damage the charger, and cause the device to malfunction.

警告: Warning:请根据当地的电池处理规定处理充电器,或联系您的医疗保健专业人员获取处理信息。 充电器可能会在焚烧时点燃。Dispose the charger according to the local regulations for battery disposal, or contact your healthcare professional for disposal information. The charger may ignite upon incineration.

要清洁充电器: To clean the charger:

- 1 彻底洗净双手。Wash your hands thoroughly.
- 2 使用含有温和清洁溶液的湿布(如餐具洗涤剂)清洁充电器外部的污垢或异物。 切勿使用涂料稀释剂或丙酮等有机溶剂清洁充电器。Use a damp cloth with mild cleaning solution, such as a dishwashing detergent, to clean any dirt or foreign material from the outside of the charger. Never use organic solvents, such as paint thinner or acetone, to clean the charger.
- 3 将充电器放在干净的干布上,风干两到三分钟。Place the charger on a clean, dry cloth and air dry for two to three minutes.

Troubleshooting 故障排除

下表包含发射器,充电器和测试插头的故障排除信息。 有关故障排除的详细信息,请参阅系统用户指南。The following table contains troubleshooting information for the transmitter, charger, and tester. For more information about troubleshooting, see your system user guide.

问题 可能的原因 解析 **Problem** Likely Cause(s) Resolution 发射器连接器针 1 检查发射器连接器针脚是否损坏或腐蚀。有关连接器引 您将发射 器连接到 脚损坏或腐蚀。 脚的更多信息,请参阅第9页的"检查发射器连接器引 充电器,没 脚"。如果引脚已损坏或已损坏,请联系24小时帮助热线。 The transmitter 有灯亮起。 connector pins 可能是时候更换发射器了。Check the transmitter You are damaged or connector pins for damage or corrosion. For more connected corroded. information about your connector pins, see Inspecting the 您的充电器电池 the transmitter connector pins, on page 9. If the pins 没电或没有插入 transmitt are damaged or corroded, contact the 24 Hour HelpLine. 电池。 Your er to the It may be time to replace your transmitter. 2 如果连接器引脚没有损坏,请更换充电器中的电池。有 charger charger battery 关更换充电器电池的说明,请参阅第5页的在充电器中安 and no has no power or 装电池。If there is no damage to the connector pins, lights no battery is inserted. replace the battery in the charger. For instructions came on. on replacing your charger battery, see Installing a battery in the charger, on page 5. 在充电过程中,充电器上闪烁的 您的充电器 更换充电器中的电池。有关更换充电器电 绿灯熄灭。您看到充电器上的红 电池电量不 池的说明,请参阅第5页的"在充电器中 灯闪烁时间更长。During 安装电池"。Replace the battery in the 足。Your charging, the flashing green charger. For instructions on charger battery is light on the charger turns off replacing your charger battery, see and you see a longer flashing low on Installing a battery in the charger, red light on the charger. power. on page 5. 在充电过程中,充电器上闪烁 您的发射器 1 连续为发射器充电一小时。如果闪烁没有 的绿灯熄灭, 您在充电器上看 停止,则进入步骤2。Charge the transmitter 电量不足。 到一系列快速闪烁的红灯, 一 continuously for one hour. If flashing Your 次持续两秒钟。During transmitter does not stop, proceed to step 2. 2 连续为发射器充电 8 小时。如果闪烁没有 charging, the flashing is low on green light on the charger power. 停止, 请拨打 24 小时帮助热线。可能是时候 turns off and you see a 更换发射器了。Charge the transmitter series of quick flashing continuously for eight hours. If

flashing does not stop, call the 24 Hour

HelpLine. It may be time to replace your

transmitter.

red lights on the charger

for two seconds at a time.

问题	可能的原	因 解析			
Problem	Likely Caus	e(s) Resolution			
在充电过程	您的充电器和	1 更换充电器中的电池。有关更换充电器电池的说明,请参			
中,充电器上	发射器电量不	阅第 5 页的在充电器中安装电池。Replace the battery in			
会出现快速和	足。	the charger. For instructions on replacing your charger			
长时间闪烁的	Your charger	battery, see Installing a battery in the charger, on			
红灯混合。	and your	page 5.			
During	transmitter	2 连续为发射器充电一小时。如果快速闪烁的红灯没有停止,			
charging, a	are low on	请继续执行步骤 3。Charge the transmitter continuously			
mix of quick	power.	for one hour. If the quick flashing red lights do not			
and long		stop, proceed to step 3.			
flashing red		3 连续为发射器充电 8 小时。如果闪烁没有停止,请拨打 24			
lights		小时帮助热线。可能是时候更换发射器了。Charge the			
appear on the		transmitter continuously for eight hours. If flashing			
charger.		does not stop, call the 24 Hour HelpLine. It may be time			
		to replace your transmitter.			
将探头连接到	您的发射器未	1 断开发射器与探头的连接。Disconnect the transmitter			
发射器时,发	完全连接。	from the sensor.			
射器上的绿灯	Your	2 等待五秒钟然后重新连接。如果绿灯仍然不闪烁,请继续			
不会闪烁。	transmitter	执行步骤 3。Wait for five seconds and reconnect them.			
The green	is not fully	If the green light still does not flash, proceed to step			
light on the	connected.	3.			
transmitter	您的发射器功	3 将发射器完全充电并将其连接到测试插头。如果绿灯仍然			
does not	率不足。Your	没有闪烁,请参阅故障排除"将发射器连接到测试插头时,			
flash when	transmitter	发射器上的绿灯不闪烁"。如果绿灯闪烁,请继续执行步骤 4。			
you connect	is low on	Fully charge the transmitter and connect it to the			
it to the	power.	tester. If the green light still does not flash, see			
sensor.	您的探头未正	troubleshooting on "The green light on the transmitter			
	确插入您的身	does not flash when you connect it to the tester". If			
	体 。 Your	the green light flashes, proceed to step 4.			
	sensor is not	4 断开发射器与测试插头的连接,至少等待五秒钟,然后将			
	properly	发射器连接到探头。如果绿灯仍然不闪烁,请继续执行步骤			
	inserted into	5. Disconnect the transmitter from the tester, wait at			
	your body.	least five seconds, and connect the transmitter to the			
		sensor. If the green light still does not flash, proceed			
		to step 5.			
		5 探头可能未正确插入您的身体。从身体上取下探头并插入			
		新的探头。The sensor may not be properly inserted into			
		your body. Remove the sensor from your body and insert			
		a new sensor.			

问题	可能的原因	解析			
Problem	Likely Cause	(s) Resolution			
将测试插头连	您的发射器未	1 检查发射器和测试插头之间的连接。如果绿灯仍然不闪			
接到发射器时,	完全连接。	烁,请继续执行步骤 2。Check the connection between the			
发射器上的绿	Your	transmitter and the tester. If the green light still			
灯不会闪烁。	transmitter	does not flash, proceed to step 2.			
The green	is not fully	2 对发射器完全充电。Fully charge the transmitter.			
light on the	connected.	3 再次使用测试插头测试发射器。如果仍然看不到绿灯闪			
transmitter	您的发射器功	烁,请拨打 24 小时帮助热线。可能是时候更换发射器了。			
does not flash	率不足。Your	Test the transmitter with the tester again. If you			
when you	transmitter	still do not see the green light flash, call the 24			
connect it to	is low on	Hour HelpLine. It may be time to replace your			
the tester.	power.	transmitter.			
您的发射器电	将发射器连接	1 在将发射器连接到探头之前对发射器完全充电。如果发射			
池不能持续七	到探头时,发	器电池仍然不能持续七天,请继续执行步骤 2。Fully			
天。	射器未充满	charge the transmitter before connecting it to the			
Your	电 。 Your	sensor. If the transmitter battery still does not last			
transmitter	transmitter	for seven days, proceed to step 2.			
battery does	is not fully	2 远离任何可能导致 RF 干扰的设备。有关 RF 干扰的更多信			
not last for	charged when	息,请参阅第 3 页的射频(RF)通信。Move away from any			
seven days.	you connect	equipment that can cause RF interference. For more			
	it to the	information on RF interference, see Radio Frequency			
	sensor.	(RF) communication, on page 3.			
	发射器和泵经	3 确保您的泵和发射器位于身体的同一侧,以尽量减少射频			
	常失去无线连	干扰。如果完全充电的发射器电池在整整七天之前继续断			
	接 。 The	电,请致电 24 小时帮助热线。可能是时候更换发射器了。			
	transmitter	Make sure your pump and your transmitter are located			
	and pump	on the same side of your body to minimize any RF			
	frequently	interference. If your fully charged transmitter			
	lose wireless	battery continues to lose power before a full seven			
	connection.	days, call the 24 Hour HelpLine. It may be time to			
		replace your transmitter.			

问题	可能的原因	B 解析			
Problem	Likely Cause	e(s) Resolution			
您的发射器已与泵	你的泵超出	1 远离任何可能导致 RF 干扰的设备。 有关 RF 干扰的更			
失去连接。Your	了范围。Your	多信息,请参阅第3页的无线电频率(RF)通信。如果您			
transmitter has	pump is out	的发射器仍未与您的泵通信,请继续执行步骤 2。Move			
lost connection	of range.	away from any equipment that can cause RF			
with your pump.	其他设备存	interference. For more information on RF			
注意: 当您的发射	在射频干扰。	interference, see Radio Frequency (RF)			
器与泵失去连接	There is RF	communication, on page 3. If your transmitter is			
时,会发出警报或	interferenc	still not communicating with your pump, proceed to			
警报并显示消息。	e from other	step 2.			
Note: An alarm or	devices.	2 确保您的泵和发射器位于身体的同一侧, 以尽量减少射			
alert occurs and		频干扰。 如果您的发射器仍未与泵通信, 请致电 24 小时			
a message appears		帮助热线寻求帮助。Make sure your pump and your			
when your		transmitter are located on the same side of your body			
transmitter has		to minimize any RF interference. If your transmitter			
lost connection		is still not communicating with your pump, call the			
with your pump.		24 Hour HelpLine for assistance.			

Storing the devices 存储设备

将发射器,充电器和测试插头存放在室温干净,干燥的地方。 如果不使用发射器,则必须至少每60天对发射器充电一次。虽然不是必需的,但您可以将发射器存放在充电器上。如果您将发射器存放在充电器上,则必须至少每60天断开并重新连接充电器和发射器一次。如果发射器在充电器上放置超过60天,电池将永久损坏。Store the transmitter, charger, and tester in a clean, dry location at room temperature. If the transmitter is not in use, you must charge the transmitter at least once every 60 days. Although not required, you may store the transmitter on the charger. If you are storing the transmitter on the charger, you must disconnect and reconnect the charger and the transmitter at least once every 60 days. If the transmitter is left on the charger for more than 60 days, the battery will be permanently damaged.

Disposal 处置

根据当地有关电池处理的规定丢弃发射器,或联系您的医疗保健专业人员获取处理信息。 Discard the transmitter according to local regulations for battery disposal, or contact your healthcare professional for disposal information.

Specifications 产品规格

Transmitter wireless communication Quality of service

发射器无线通信服务质量

发射器和 Mini Med 670G 胰岛素泵作为 802. 15. 4 网络的一部分,泵作为协调器,发射器作为终端节点。在不利的 RF 环境中,泵将基于能量扫描期间检测到的"噪声"水平来评估通道变化需求。如果在 10 分钟后没有接收到 CGM 发射器信号,则泵将执行能量扫描。如果发生通道更改,泵将在新通道上发送信标。The transmitter and the Mini Med 670G insulin pump are associated as part of an 802. 15. 4 network for which the pump functions as the coordinator and the transmitter as an end node. In an adverse RF environment the pump will assess channel changing needs based on "noise" levels detected during an energy scan. The pump will perform the energy scan if after 10 minutes no CGM transmitter signal has been received. If the channel change occurs the pump will send beacons on the new channel.

当相关信道上的信标检测失败时,发射器将启动信道搜索。搜索将在所有五个频道进行。 当信标被定位时,发射器将重新加入所识别的信道。重新关联后,任何丢失的数据包(最多 10 小时)将从发射器传输到泵。The transmitter will initiate a channel search when beacon detection fails on the associated channel. The search will be conducted across all five channels. When the beacon is located the transmitter will rejoin on the identified channel. Upon re-association any missed packets (up to 10 hours) will be transmitted from the transmitter to the pump.

在正常操作中,发射器将每5分钟发送一个数据包,并在数据损坏或丢失时重新发送数据包。In normal operation the transmitter will transmit a packet every 5 minutes and retransmit the packet if the data is corrupted or missed.

Data security 数据安全

MiniMed 670G 胰岛素泵仅用于接受来自识别和链接设备的射频(RF)通信(您必须对泵进行编程以接受来自特定设备的信息)。The MiniMed 670G insulin pump is designed to only accept radio frequency (RF) communications from recognized and linked devices (you must program your pump to accept information from a specific device).

MiniMed 670G 胰岛素泵和系统组件(仪表和发射器)通过专有方法和数据完整性使用错误检查过程(例如循环冗余校验)确保数据安全。The MiniMed 670G insulin pump and system components (meters and transmitters) ensure data security via proprietary means and data integrity using error checking processes, such as cyclic redundancy checks.

Traveling by air 乘飞机旅行

您的发射器可安全用于商业航空公司。如果航空公司人员询问您使用您的设备,请向他们出示您的医疗急救卡。如果他们要求您关闭系统,则必须遵守。Your transmitter is safe for use on commercial airlines. If questioned by airline personnel about the use of your device, please show them your Medical emergency card. If they request that you turn off your system, you must comply.

Guidance and manufacturer's declaration 指导和制造商的声明

Electromagnetic Emissions 电磁辐射

Electromagnetic Immunity 电磁抗扰度

Recommended separation distances between portable and mobile RF communications equipment and the transmitter 便携式和移动 RF 通信设备与发射器之间的建议间隔距离

PS:这一部分不看了吧。

Warranty 保修

Medtronic MiniMed, Inc。(或在此设备标签上可能被称为制造商的其他法律实体 "Medtronic Minimed")保证 Medtronic 发射器向产品购买者提供一次性材料和工艺缺陷 (1)年份和充电器自购买之日起最多一(1)年。Medtronic MiniMed, Inc. (or such other legal entity as may be referred to as manufacturer on the labeling of this device "Medtronic Minimed") warrants the Medtronic transmitter to the purchaser of the product against defects in material and workmanship for a period of one (1) year and the charger for up to one (1) year from the date of purchase.

在保修期内,Medtronic MiniMed 将根据本文所述的条件和例外情况,自行决定更换或修理任何有缺陷的发射器或充电器。此保修仅适用于新设备。如果更换发射器或充电器,保修期将不会延长到原定的有效期。During the warranty period, Medtronic MiniMed will replace or repair, at its discretion, any defective transmitter or charger, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a transmitter or charger is replaced, the warranty period will not be extended past its original expiration date.

只有在按照制造商的说明使用 Medtronic 发射器或充电器时,此保修才有效。不受限制, 此保修不适用: This warranty is valid only if the Medtronic transmitter or charger is used in accordance with the manufacturer's instructions. Without limitation, this warranty will not apply:

如果损坏是由用户或第三方在购买之日后对发射器或充电器进行的更改或修改造成的; If damage results from changes or modifications made to the transmitter or charger by the user, or third persons, after the date of purchase;

- 如果由制造商以外的任何人或实体进行的维修或修理造成损坏; If damage results from service or repairs performed by any person or entity other than the manufacturer;
- 如果因不可抗力或制造商无法控制的其他事件造成损坏; If damage results from a Force Majeure or other event beyond the control of the manufacturer;
- 如果因疏忽或使用不当造成损坏,包括但不限于:储存不当,浸入水中,身体虐待, (如跌落);If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water, physical abuse, (such as dropping);
- 如果因使用设备而导致的损坏不是根据制造商的产品标签,使用说明或法规通知。 If damage results from use of the device in a manner other than according to the manufacturer's product labeling, instructions for use, or regulatory notifications.

此保修对原始购买者而言应是个人保证。本保修所涵盖的产品的销售,租赁或其他转让或使用,或原始购买者以外的用户,均应立即终止本保修。此保修不适用于葡萄糖探头和其他配件。This warranty shall be personal to the original purchaser. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original purchaser shall cause this warranty to immediately terminate. This warranty does not apply to Glucose Sensors and other accessories.

本保修条款中规定的补救措施是对此违反行为的唯一补救措施。 Medtronic MiniMed 及 其供应商或分销商均不对由于产品缺陷引起的任何性质或类型的任何偶然,后果性或特殊损害承担责任。The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic MiniMed 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.

除强制性法定保证之外的所有其他条件和保证(明示或暗示)均不包括在内,包括适销性和适用于特定用途的保证。All other conditions and warranties, other than mandatory statutory warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

本担保赋予购买者特定的合法权利,购买者还可能拥有根据当地法律不同的其他权利。 此保修不影响购买者的法定权利。This warranty gives the purchaser specific legal rights, and the purchaser may also have other rights that vary under local law. This warranty does not affect the purchaser's statutory rights.

Icon Table 图标示例

PS: 这一部分省略了吧。

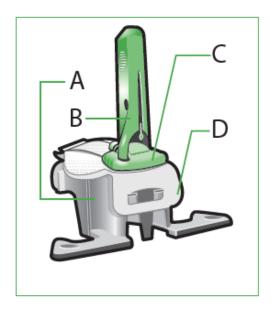
Guardian Sensor (3) glucose sensor

User Guide 三代探头用户指南

Introduction 介绍

Guardian 探头(3)血糖探头是您的连续血糖监测(CGM)系统的一部分。The Guardian Sensor(3)glucose sensor is part of your Continuous Glucose Monitoring(CGM)system.

探头持续将来自皮肤下间质液的微量血糖转化为电子信号。 然后,您的系统使用这些信号来提供探头血糖值。Introduction The sensor continuously converts tiny amounts of glucose from the interstitial fluid under your skin into an electronic signal. Your system then uses these signals to provide sensor glucose values.



A.基座 pedestal

B.针头外壳 needle housing

C.探头 sensor

D.透明衬里 clear liner

Potential risks related to sensor use

与探头使用相关的潜在风险

探头使用的一般风险包括: General risks with sensor use include:

- 皮肤刺激或其他反应 Skin irritation or other reactions
- 瘀血 Bruising
- 不舒服 Discomfort
- 发红 Redness
- 流血的 Bleeding
- 痛 Pain
- 皮疹 Rash
- 感染 Infection
- 凸起隆起 Raised bump
- 插入针头的小雀斑点的外观 Appearance of a small freckle-like dot where needle was inserted
- 过敏反应 Allergic reaction
- 再次出现焦虑或对插针的恐惧而晕倒 Fainting secondary to anxiety or fear of needle insertion
- 酸痛或压痛 Soreness or tenderness
- 插入部位肿胀 Swelling at insertion site
- 探头断裂,破损或损坏 Sensor fracture, breakage or damage
- 与探头针头移除相关的最小血液飞溅 Minimal blood splatter associated with sensor needle removal
- 与粘合剂或胶带或两者相关的残余发红 Residual redness associated with adhesive or tapes or both
- 疤痕 Scarring

Indications for use 使用说明

Guardian 探头(3) 适用于 Medtronic MiniMed 630G, MiniMed 670G 和 Guardian Connect 系统,可持续监测糖尿病患者的血糖水平。 它旨在用于检测 14 岁及以上人群的趋势和跟踪模式。 它也可以被 MiniMed 670G 系统用于自动调节基础胰岛素水平。 它被指示用作辅助装置,以补充而非替代从标准血糖监测装置获得的信息。 探头仅供一次性使用,需要处方。Guardian 探头(3)表示连续使用 7 天。

The Guardian Sensor (3) is intended for use with the Medtronic MiniMed 630G, MiniMed 670G, and Guardian Connect systems to continuously monitor glucose levels in persons with diabetes. It is intended to be used for detecting trends and tracking patterns in persons aged fourteen years and older. It is also intended to be used by the MiniMed 670G system to automatically adjust basal insulin levels. It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for days of continuous use.

Contraindications 禁忌

未知 None known.

Assistance 帮助

部门 Department

24 Hour 帮助热线(美国境内的电话)HelpLine(calls within the United States)

电话号码 Telephone Number 800 646 4633

24 Hour 帮助热线(美国以外的电话)HelpLine(calls outside the United States)

电话号码 Telephone Number +1 818 576 5555

网站 Website www.medtronicdiabetes.com

General warnings 一般警告

在尝试插入探头之前,请阅读整个用户指南。Read this entire user guide before attempting to insert the sensor.

一键式 serter (MMT-7512) 与其他 Medtronic 插入式设备的工作方式不同。如果不遵循指示或使用不同的方法,可能会导致插入不当,疼痛或受伤。The one-press serter (MMT-7512) does not work the same as other Medtronic insertion devices. Failure to follow directions or using a different serter may result in improper insertion, pain, or injury.

Guardian 探头(3)开发,并评估其性能,仅用于经批准的系统。探头不应用作未经批准的系统的一部分,因为它可能提供不准确的探头血糖读数。The Guardian Sensor(3)was developed, and its performance evaluated, for use with the approved system only. The sensor should not be used as part of unapproved systems, as it may provide inaccurate sensor glucose readings.

探头仅适用于经认可的发射器。The sensor is designed to work with approved transmitters only.

它不能与不兼容探头的发射器和记录器互换。将探头连接到未经批准用于探头的发射器或记录仪可能会导致组件损坏或探头血糖值不准确。It is not interchangeable with transmitters and recorders that are not compatible with the sensor. Connecting your sensor to a transmitter or recorder that is not approved for use with the sensor may cause damage to the components or inaccurate sensor glucose values.

不要根据探头血糖值做出治疗决策,因为探头血糖(SG)和血糖(BG)值可能不同。如果您的探头血糖读数低或高,或者您感觉血糖低或高的症状,请在做出治疗决定之前使用手指针刺血液样本确认您的血糖。Do not make therapy decisions based on sensor glucose values because sensor glucose (SG) and blood glucose (BG) values may differ. If your sensor glucose reading is low or high, or if you feel symptoms of low or high glucose, confirm your blood glucose with your meter using a fingerstick blood sample prior to making therapy decisions.

服用含有对乙酰氨基酚的药物,如 Tylenol *, 退烧药或感冒药,同时佩戴探头可能会错误地提高探头血糖读数。不准确程度取决于体内活性对乙酰氨基酚的含量,每个人可能有所不同。始终检查任何药物的标签,以确认对乙酰氨基酚是否为活性成分。 Taking medications with acetaminophen, such as Tylenol *, fever reducers, or cold medicine, while wearing the sensor may falsely raise your sensor glucose readings. The level of inaccuracy depends on the amount of acetaminophen active in your body and may be different for each person. Always check the label of any medications to confirm whether acetaminophen is an active ingredient.

不要将探头暴露在 MRI 设备,透热设备或其他产生强磁场的设备中,因为探头的性能尚未在这些条件下进行评估,并且可能不安全。如果您的探头无意中暴露在强磁场中,请停止使用并联系 24 小时帮助热线以获得进一步的帮助。Do not expose your sensor to MRI equipment, diathermy devices, or other devices that generate strong magnetic fields as the performance of the sensor has not been evaluated under those conditions and may be unsafe. If your sensor is inadvertently exposed to a strong magnetic field, discontinue use and contact the 24 Hour HelpLine for further assistance.

可伸缩针连接到探头,并且可能发生最小的血液飞溅。如果您是医疗保健专业人员或护理人员,请在探头周围包裹无菌纱布,以尽量减少与血液的接触。取下针头时,您和患者之间应保持尽可能远的距离。A retractable needle is attached to the sensor, and minimal blood splatter may occur. If you are a healthcare professional or caregiver, wrap sterile gauze around the sensor to minimize contact with blood. Keep as much distance as possible between you and the patient when removing the needle.

始终将针头外壳保持在视线范围内,以避免意外的针刺或刺穿。Keep the needle housing within sight at all times to avoid an accidental needlestick or puncture.

使用前请务必检查包装是否有损坏。探头是无菌和无热原的,除非包装已被打开或损坏。如果无菌包装已被打开或损坏,请勿使用探头。使用未消毒的探头会导致部位感染。Always inspect the packaging for damage prior to use. Sensors are sterile and non-pyrogenic, unless the package has been opened or damaged. Do not use the sensor if the sterile package has been opened or damaged. Use of an unsterile sensor can cause site infection.

本产品包含小部件,可能对儿童造成窒息危险。This product contains small parts and may pose a choking hazard for children.

注意插入部位(探头下方,周围或顶部)的出血情况。Watch for bleeding at the insertion site (under, around, or on top of the sensor).

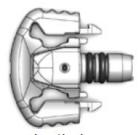
如果发生出血,请执行以下操作: If bleeding occurs, do the following:

- 1. 使用无菌纱布或放置在探头顶部的干净布料施加稳定压力,最多三分钟。使用未消毒的纱布会导致部位感染。Apply steady pressure, using sterile gauze or a clean cloth placed on top of the sensor, for up to three minutes. The use of unsterile gauze can cause site infection.
- 2. 如果出血停止,将发射器连接到探头。If bleeding stops, connect the transmitter to the sensor.

如果没有停止出血,请勿将发射器连接到探头。这可能允许血液进入发射器连接器,并可能损坏设备。If bleeding does not stop, do not connect the transmitter to the sensor. This can allow blood to get into the transmitter connector, and could damage the device.

如果继续出血,导致过度疼痛或不适,或者在探头的塑料底座中明显可见,请执行以下操作: If bleeding continues, causes excessive pain or discomfort, or is significantly visible in the plastic base of the sensor, do the following:

1. 取下探头并继续施加稳定压力直至出血停止。将探头丢弃在 锐器容器中。Remove the sensor and continue to apply steady pressure until the bleeding stops. Discard the sensor in a sharps container.



plastic base plastic base 塑料底座

- 2. 检查部位是否有红肿,出血,刺激,疼痛,压痛或发炎。根据您的医疗保健专业人员的指示治疗。 Check the site for redness, bleeding, irritation, pain, tenderness, or inflammation. Treat based on instructions from your healthcare professional.
 - 3. 将新探头插入其他位置。 Insert a new sensor in a different location.

General precautions 一般预防措施

在插入探头之前,先用肥皂和水洗手,以防止部位感染。Wash your hands with soap and water before inserting the sensor to help prevent site infection.

将探头插入自己以外的人时请戴上手套,以免与患者血液接触。Wear gloves when inserting the sensor into someone other than yourself to avoid contact with patient blood.

请勿通过胶带插入探头。通过胶带插入探头可能会导致探头插入和功能不正确。Do not insert the sensor through tape. Inserting the sensor through tape may cause improper sensor insertion and function.

只能使用酒精来准备插入部位,以确保残留物不会留在皮肤上。Only use alcohol to prepare the insertion site, to ensure that residue is not left on the skin.

轮换探头插入位置,以免部位过度使用。Rotate the sensor insertion site so that sites do not become overused.

每次使用后,将使用过的探头和针头外壳丢弃在锐器容器中,以避免意外的针刺或穿刺。 Discard used sensors and needle housings in a sharps container after each use to avoid accidental needlestick or puncture.

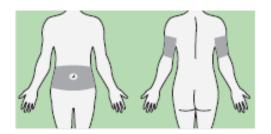
请勿清洁,重新消毒或尝试从针头外壳中拔出针头。可能会发生意外的针刺或穿刺。Do not clean, resterilize, or try to extract the needle from the needle housing. An accidental needlestick or puncture may occur.

不要重复使用探头。重复使用探头可能会损坏探头表面并导致不准确的血糖值,部位刺激或感染。Do not reuse sensors. Reuse of a sensor may cause damage to the sensor surface and lead to inaccurate glucose values, site irritation, or infection.

Where to insert the sensor 在哪里插入探头

注意: 避免肚脐周围 2 英寸(5.0 厘米)的区域,以确保舒适的插入部位,并有助于探头粘连。CAUTION: Avoid the 2 inch (5.0 cm) area around the navel to help ensure a comfortable insertion site and to help with sensor adhesion.

选择具有足够皮下脂肪量的插入部位。这里显示的是探头插入的最佳身体区域(阴影)。 Choose an insertion site that has an adequate amount of subcutaneous fat. Shown here are the best body areas (shaded) for sensor insertion.



注意: 探头插入上臂后部可能需要帮助。一些用户发现难以自身将探头插入其臂中。Note: Assistance may be needed for sensor insertion into the back of the upper arm. Some users found it difficult to insert the sensor into their arm by themselves.

不要将探头插入肌肉或受衣服或配件约束的区域,皮肤坚硬或疤痕组织受损的部位,运动过程中经常移动的部位,或皮带下或腰部的部位,以获得最佳探头性能并避免意外探头去除。Do not insert the sensor in muscle or areas constrained by clothing or accessories, areas with tough skin or scar tissue, sites subjected to rigorous movement during exercise, or in sites under a belt or on the waistline for best sensor performance and to avoid accidental sensor removal.

Removing the sensor 卸下探头

当您准备更换探头时,请按照发射器用户指南中的说明断开发射器与探头的连接。 轻轻地将探头从身体中拉出以将其移除。 将探头放在锐器容器中。When you are ready to change your sensor, disconnect the transmitter from the sensor as described in your transmitter user guide. Gently pull the sensor from your body to remove it. Place the sensor in a sharps container.

Reagents 试剂

该探头含有两种生物试剂:葡萄糖氧化酶和人血清白蛋白(HSA)。葡萄糖氧化酶衍生自黑曲霉(Aspergillus niger)工业纯提取以满足用于诊断,免疫诊断和生物技术应用的酶。探头上使用的 HSA 由 V 级纯化和干燥的白蛋白组成,其来自巴氏杀菌的人血清,通过戊二醛交联。使用大约 3g 的葡萄糖氧化酶和大约 10g 的 HSA 来制造每个探头。 HSA 被批准用于人体静脉输注,其数量远大于探头。The sensor contains two biological reagents: glucose oxidase, and human serum albumin (HSA). Glucose oxidase is derived from Aspergillus niger and manufactured to meet industry requirements for extraction and purification of enzymes for use in diagnostic, immunodiagnostic, and biotechnical applications. The HSA used on the sensor consists of purified and dried albumin fraction V, derived from pasteurized human serum which is cross-linked via glutaraldehyde. Approximately 3 g of glucose oxidase and approximately 10 g of HSA are used to manufacture each sensor. HSA is approved for IV infusion in humans at quantities much larger than in the sensor.

Storage and handling 储存和处理

注意:请勿冷冻探头,或将其存放在阳光直射,极端温度或湿度的环境中。这些情况可能会损坏探头。CAUTION: Do not freeze the sensor, or store it in direct sunlight, extreme temperatures, or humidity. These conditions may damage the sensor.

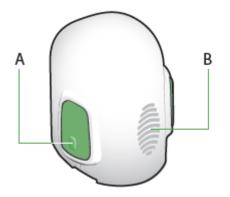
仅在室温下将探头存储在 36° F 至 80° F (2° C 至 27° C) 之间。Only store sensors at room temperature between 36° F to 80° F (2° C to 27° C).

请在标签上标明的"按日期使用"前使用,如果包装已损坏或密封破损,丢弃探头。 Discard sensor after the "Use by date" indicated on the label, if the package is damaged, or the seal is broken.

Sensor life 探头寿命

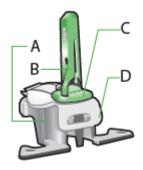
探头可以使用一次,最长寿命为 170 小时(七天)。当探头连接到发射器时,探头的 170 小时寿命开始。The sensor can be used one time, and it has a maximum life of 170 hours (seven days). The 170-hour life span of the sensor begins when the sensor is connected to the transmitter.

Components 组件



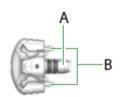
探头植入器(助针器) One-press serter

- A. 两个释放按钮 bump on both buttons
- B. 指纹标记 thumbprint marking



血糖探头组件 Glucose sensor assembly

- A. 基座 pedestal
- B. 针头外壳 needle housing
- C. 探头 sensor
- D. 透明衬里 clear liner

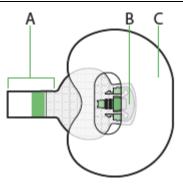


探头基座 Sensor base

- A. 探头连接器 sensor connector
- B. 探头按扣 sensor snaps



发射器 Transmitter



胶带和探头组件 Tape and sensor components

- A. 粘合剂标签 adhesive tab
- B. 探头基础 sensor base
- C. 椭圆形胶带 oval tape

Inserting the sensor 插入探头

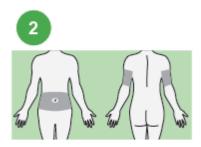
警告:将探头插入非自己的人员时请戴上手套,以免接触患者的血液。可能会出现最小的出血。与患者血液接触可引起感染。WARNING: Wear gloves when inserting the sensor into someone other than yourself to avoid contact with patient blood. Minimal bleeding may occur. Contact with patient blood can cause infection.

1. 洗手。Wash your hands.



2. 选择上臂腹部或背部有足够脂肪的插入部位。Choose an insertion site on the abdomen or back of the upper arm that has an adequate amount of fat.

注意:探头插入上臂后部可能需要帮助。一些用户发现难以将探头插入其自身臂中。Note: Assistance may be needed for sensor insertion into the back of the upper arm. Some users found it difficult to insert the sensor into their arm by themselves.



3. 用酒精清洁插入部位。让该部位风干。Clean the insertion site with alcohol. Let the area air dry.

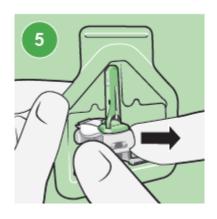


4. 打开探头包装。Open the sensor package.



5. 握住底座,从包装中取出血糖探头组件。将底座放在平坦的表面上。Hold the pedestal and remove the glucose sensor assembly from the package. Place the pedestal on a flat surface.

注意: 基座和血糖探头组件是组件表中已建立的定义。Note: The pedestal and glucose sensor assembly are the established definitions in the component table.



6. 确保探头的粘性标签夹在探头连接器和探头卡扣下方。Make sure that the adhesive tab of the sensor is tucked under the sensor connector and sensor snaps.





7. 正确握住 serter 将拇指放在指纹标记上以保持 serter 而不触摸按钮。 Holding serter correctly Place your thumb on the thumbprint marking to hold the serter without touching the buttons.

不正确地控制 serter 你的手指不应该碰到按钮。Holding serter incorrectly Your fingers should not be touching the buttons.

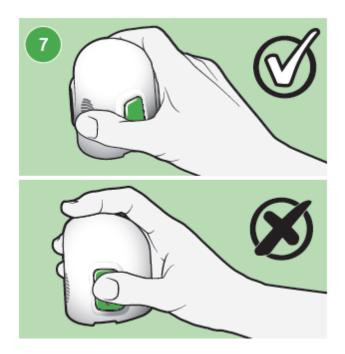
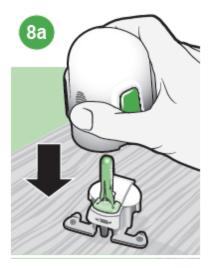
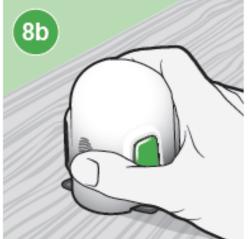


图 8A-8B。抓住 serter,将拇指放在指纹标记上,不要按住按钮。小心地将 serter 向下推到底座上,直到 serter 的底座平放在桌子上并听到咔哒声。8a-8b. Grip the serter, placing your thumb on the thumbprint marking, without holding the buttons. Carefully push the serter down onto the pedestal until the base of the serter sits flat on the table and you hear a click.





9A。要将 serter 从底座上拆下,将一只手的拇指放在指纹标记上并抓住 serter 而不要触碰任何按钮。用另一只手,将两根手指放在基座臂上。9a. To detach the serter from the pedestal, place the thumb of one hand on the thumbprint marking and grip the serter without touching any buttons. With your other hand, place two fingers on the pedestal arms.



9B。在不按住按钮的情况下,将 serter 慢慢向上拉。不要在半空中将底座从 serter 上 拆下,因为这可能会损坏探头。9b. Slowly pull the serter straight up without holding the buttons. Do not detach the pedestal from the serter in midair, as this might damage the sensor.



注意: serter 侧面的箭头与 serter 内部的针对齐。Note: The arrow on the side of the serter aligns with the needle inside the serter.

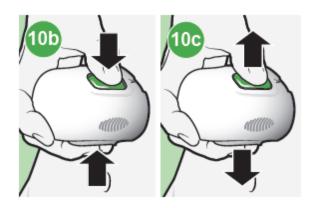


警告: 切勿将装载的 serter 指向任何不需要插入的身体部位。意外按下按钮可能会导致针头将探头注入不需要的位置,造成轻微伤害。WARNING: Never point a loaded serter toward any body part where insertion is not desired. An accidental button-push may cause the needle to inject the sensor in an undesired location, causing minor injury.

10a. 将 serter 稳固地靠在清洁的插入部位, 而不要将 serter 太深地推入皮肤。Hold the serter steady against your cleaned insertion site, without pushing the serter too deeply into your skin.



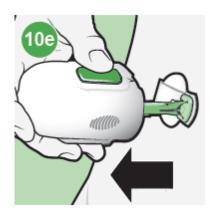
10b-10c. 同时按下并释放两个按钮上的凸起, 同时将 serter 平放在身体上。 Press and release the bump on both buttons at the same time, while holding the serter flat against your body.



10d. 继续将 serter 平放在身体上至少五秒钟, 让粘合剂粘在皮肤上。 Continue holding the serter flat against your body for at least five seconds to let the adhesive stick to your skin.



10e. 慢慢将 serter 抬离身体,确保没有按下按钮。 Slowly lift the serter away from your body, making sure that the buttons are not pressed.



如果您将探头插入自己,请完成步骤 11a。如果您是将探头插入患者的医疗保健专业人员或护理人员,请完成步骤 11b。If you inserted the sensor into yourself, complete step 11a. If you are a healthcare professional or caregiver who inserted the sensor into a patient, complete step 11b.

患者: Patient:

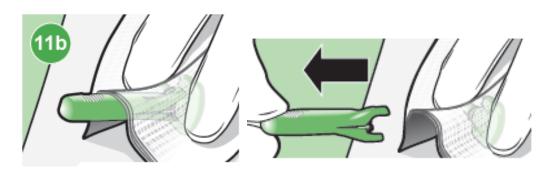
11a. 将探头底座轻轻握住探头连接器和探头底座另一端的皮肤。将针头外壳保持在顶部,然后从探头中缓慢拉出。Gently hold the sensor base against the skin at the sensor connector and the opposite end of sensor base. Hold the needle housing at the top and slowly pull straight out, away from the sensor.





医疗保健专业人员或护理人员: Healthcare professional or caregiver:

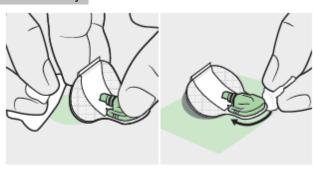
11b. 在探头周围缠上无菌纱布(如图 11b 所示)。将探头底座轻轻握住探头连接器和探头底座另一端的皮肤。将针头外壳保持在顶部,然后从探头中缓慢拉出。Wrap sterile gauze around the sensor (as shown in image 11b). Gently hold the sensor base against the skin at the sensor connector and the opposite end of sensor base. Hold the needle housing at the top and slowly pull straight out, away from the sensor.



警告: 注意插入部位出血。如果在探头下方,周围或顶部出现渗血,请使用无菌纱布或放置在探头顶部的干净布料施加稳定压力最多三分钟。使用未消毒的纱布会导致感染。如果出血没有停止,请取下探头并施加稳定压力直至出血停止。WARNING: Watch for bleeding at the insertion site. If bleeding occurs under, around, or on top of the sensor, apply steady pressure using sterile gauze or a clean cloth placed on top of the sensor for up to three minutes. The use of unsterile gauze can cause an infection. If bleeding does not stop, remove the sensor and apply steady pressure until the bleeding stops.

注意:美敦力粘合剂对压力敏感。将粘合剂压在皮肤上可确保探头在整个使用期间保持粘附在皮肤上。Note: Medtronic adhesives are pressure-sensitive. Pressing the adhesive against the skin ensures that the sensor remains adhered to the skin throughout the wear period.

注意: 插入后,除了胶带外,还可以使用 Skin Tac *等粘合剂产品。如果使用可选的粘合剂产品,则在移除衬垫之前将其涂在粘合垫下面的皮肤上。它也可以应用于粘合垫或探头基座周围的皮肤。让产品干燥。Note: After insertion, use of adhesive products such as Skin Tac * in addition to the tape is optional. If optional adhesive products are used, apply to the skin under the adhesive pad prior to removing the liner. It can also be applied to the adhesive pad or the skin around the sensor base. Allow for product to dry.



12a. 将探头固定到位,然后从粘性垫下方轻轻取下粘合剂衬垫。请勿从矩形粘性标签上取下粘性衬垫。此粘性衬垫将用于在稍后的步骤中保护发射器。 Hold the sensor in place and gently remove the adhesive liner from under the adhesive pad. Do not remove the adhesive liner from the rectangular adhesive tab. This tab will be used to secure the transmitter in a later step.



12b. 将胶垫紧贴皮肤,确保探头仍粘附在皮肤上。 Firmly press the adhesive pad against the skin to make sure that the sensor remains adhered to the skin.



13a. 从连接器下方取下粘合片。 Untuck the adhesive tab from under the connector.

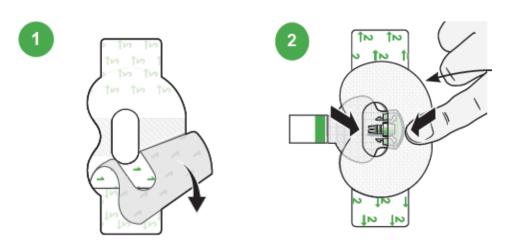


13b. 拉直探头粘接片, 使其平放在皮肤上。 Straighten the sensor adhesive tab so that it lies flat against the skin.



Applying Oval Tape 应用椭圆形胶带

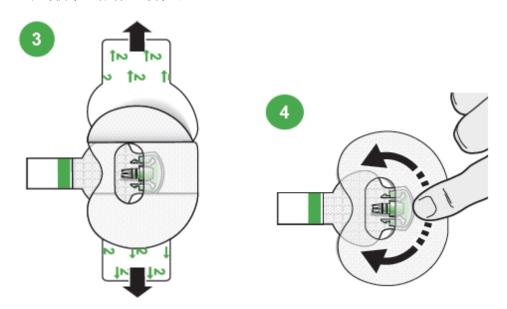
1. 取下标有 1 的衬纸。 Remove the liner marked 1.



2. 如图所示涂抹胶带并将其牢牢按下。Apply the tape as shown and press it down firmly.

胶带的大部分覆盖探头基座的一半。The wide part of the tape covers half of the sensor base.

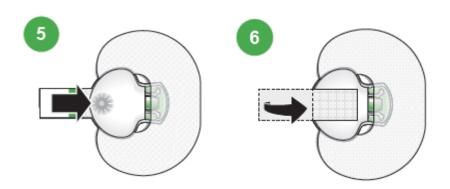
3. 从每侧取下标有 2 的衬纸。 Remove the liner marked 2 from each side.



4. 使胶带平滑。 Smooth the tape.

5. 将发射器连接到探头。 Connect the transmitter to the sensor.

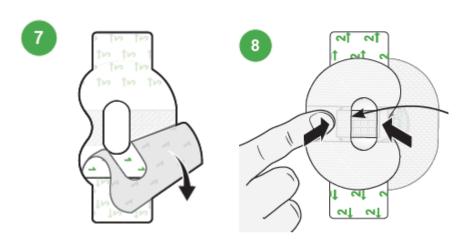
注意: 等待发射器上的绿灯闪烁。如果绿灯不闪烁,请参阅发射器用户指南的"故障排除"部分。Note: Wait for the green light on the transmitter to flash. If the green light does not flash, refer to the Troubleshooting section of your transmitter user guide.



6. 用粘性标签盖住发射器。 Cover the transmitter with the adhesive tab.

注意: 请勿将拉环拉得太紧。Note: Do not pull the tab too tightly.

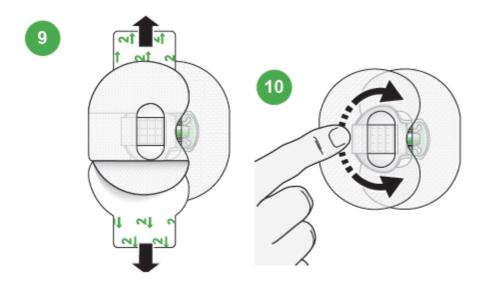
7. 要涂抹第二条胶带,请取下标有 1 的衬纸。 To apply a 2nd tape, remove the liner marked 1.



8. 以与第一盘胶带相反的方向涂抹第二条胶带,并将其放在发射器上。牢牢按下它。 Apply the 2nd tape in the opposite direction to the first tape and place it on the transmitter. Press it down firmly.

胶带的大部分覆盖了发射器的末端以及皮肤。The wide part of the tape covers the end of the transmitter and also the skin.

9. 从每侧取下标记为 2 的衬纸。 Remove the liner marked 2 from each side.



10. 使胶带平滑。 Smooth the tape.

注意:请务必定期检查探头。如果不牢固,请使用额外的现成粘合剂。Note: Be sure to regularly check your sensor site. If the device is not secure, apply an additional off-the-shelf adhesive.

11. 有关如何将探头设置输入泵或移动设备的详细信息,请参阅相应的用户指南。For details on how to enter your sensor settings into your pump or mobile device, refer to the corresponding user guide.



Icon glossary 图标词汇表

有关设备和包装标签上符号的定义, For a definition of the symbols on the device and package labels, 请参阅 see www.medtronicdiabetes.com/symbols-definitions

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