Medtronic

Envision™ Recorder

User Guide

ZH

BP

AR

HE

Introduction

The Envision™ recorder is a component of the Envision™ Pro Continuous Glucose Monitoring (CGM) system. It is a retrospective CGM system, therefore data is not available to patients in real time. The recorder is compatible with the Envision™ sensor (MMT-7080). The recorder connects to the sensor, and receives and sends data to the Envision™ Pro application (app) through a Bluetooth™* wireless connection. For detailed information on system components consult the Envision™ Pro Continuous Glucose Monitoring System User Guide for Healthcare Professionals.

Indications

The recorder is intended for single-patient, single-use in patients with diabetes mellitus. The recorder is a component of the Envision™ Pro CGM system.

Contraindications

None known.

Warnings

- Always refer to the Envision™ sensor (MMT-7080) user guide for all contraindications, warnings, precautions, and instructions relating to the sensor. Not referring to the sensor user guide can result in serious injury to the patient or damage to the sensor.
- No modification of this equipment is allowed.
- This product contains small parts and may pose a choking hazard for young children.
- Attempting to send data from the recorder when the recorder is near other medical devices that emit radio frequency should be avoided due to possible interference. If you have communication issues, try moving away from such devices.
- Do not expose your recorder to x-ray, ultrasound, or diathermy devices as the performance of the recorder has not been evaluated under those conditions and may be unsafe. If your recorder is exposed to any of these, discontinue use and contact your local country representative for further assistance.
- Do not expose your recorder to MRI equipment or other devices that generate strong magnetic fields as the performance of the recorder has not been evaluated under those conditions and may be unsafe.

If your recorder is inadvertently exposed to a strong magnetic field or ionizing radiation, discontinue use and contact your local country representative for further assistance.

- Do not expose your recorder to temperatures exceeding those listed in the specifications table for Storage Conditions as this may deplete the battery and result in a non-functional recorder.

Precautions

Do not reuse recorders. The recorder is designed to be used for one patient, and one evaluation only. Once the recorder is activated for a patient, it cannot be used for another evaluation or patient. The recorder will not function and no data will be gathered.

Assistance

Please contact your local country representative using the Medtronic Diabetes International Contacts list in this user guide.

IEC60601-1-2; Special EMC Precautions for Medical Electrical Equipment

1. 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. 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.

Installing the Envision™ Pro app

For information on installing the Envision™ Pro app, consult your Envision™ Pro System User Guide for Healthcare Professionals.

Inserting the Envision™ sensor (MMT-7080) and connecting the Envision™ recorder

For information about inserting the sensor and connecting the recorder,

consult your Sensor User Guide.

For information on pairing the recorder with the app, use the Envision™ Pro app and follow the instructions on your screen.

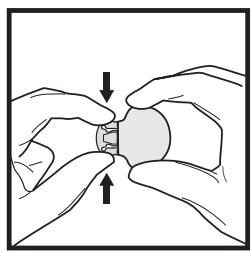
Note: *The graphical image, a type of barcode, on the back of the recorder is for manufacturing purposes only.*

Ending the evaluation and uploading data

End the evaluation and upload the data according to the Envision™ Pro System User Guide for Healthcare Professionals. The patient or HCP can upload data either before or after removing the recorder and sensor from the patient. Be sure to upload data before recorder disposal.

Removing the sensor and the recorder

1. Put on gloves.
2. Peel the sensor and recorder off of the body as one unit.
3. Separate the sensor and the recorder.
4. Dispose of the sensor in a sharps container. Dispose of the recorder according to local regulations for battery disposal (non-incineration).



Note: *Do not discard the recorder in a medical waste container or receptacle in which it would be exposed to extreme heat, above 55 °C (131 °F).*

Bathing and swimming

After the recorder and sensor are connected, they form a waterproof seal to a depth of 2.4 meters (8 feet) for up to 30 minutes. Your patient can shower and swim without removing them. No additional tape is required.

Help

The Envision™ Pro app provides the best source of information for help with the recorder. To access the Help screen, tap **Help**. The app will walk you through the various Help topics.

Storing and transporting the devices

Store the recorder in a clean and dry location at room temperature

between 15 °C (59 °F) and 30 °C (86 °F). Do not transport the recorder at temperatures above 55 °C (131 °F) or below -30 °c (-22 °F). Temperatures outside this range can damage components

Recorder use life

The recorder has a maximum life of 170 hours of glucose recording, plus an additional five days of battery life immediately following the glucose recording to allow for data upload. The life span of the recorder begins when it is connected to the sensor. After 170 hours the recorder will stop recording and no further data will be gathered. When the battery dies, any data not uploaded from the recorder will be lost.

Specifications

Biocompatibility	Recorder: Complies with EN ISO 10993-1
Applied parts	Envision™ Sensor (MMT-7080)
Operating conditions	Temperature: 5 °C to 45 °C (41 °F to 113 °F) Relative humidity: 10% to 95% with no condensation Pressure: 57.6 kPa to 106.0 kPa (8.4 psi to 15.4 psi)
Shipping conditions	Temperature: -30 °C to 55 °C (-22 °F to 131 °F) Relative humidity: 10% to 95% with no condensation Pressure: 57.6 kPa to 106.0 kPa (8.4 psi to 15.4 psi)
Storage conditions	Temperature: 15 °C to 30 °C (59 °F to 86 °F)
Recorder communication frequency	Bluetooth™* version 4.0 (2.4 GHz band)
Modulation	G1D
Maximum output power	-11.5 dBm effective radiated power (ERP)
Operating range	Up to 2.4 meters (8 feet)

Recorder wireless communication

Quality of service

The recorder and mobile app connect via Bluetooth™* Low Energy (BLE). The recorder sends data and related alerts to the app. The recorder and the app verify the integrity of received data after wireless transmission. Quality of the connection is in accordance with the Bluetooth™* Specification v4.0.

Data security

The recorder is designed to only accept BLE communications from recognized and linked devices. You must program the app to accept information from a specific recorder. Transmitted sensitive data is encrypted to prevent unauthorized receipt or communication.

Guidance and Manufacturer's declaration

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the recorder should make sure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The recorder must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The recorder is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the recorder should make sure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±8 kV, ±15 kV Air ±2 kV, ±4 kV, ±6 kV, ±8 kV Contact	±2 kV, ±4 kV, ±8 kV, ±15 kVAir ±2 kV, ±4 kV, ±6 kV, ±8 kV Contact	For use in a typical domestic, commercial, or hospital environment.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable	Requirement does not apply to this battery powered device.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable	Requirement does not apply to this battery powered device.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	Not applicable	Requirement does not apply to this battery powered device.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial, or hospital environment.
Note: *U_T is the a.c. mains voltage prior to application of the test level.*			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the recorder should make sure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 V/m 150 kHz to 80 MHz	Not applicable	Not applicable
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 6 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the recorder, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the recorder. Refer to the recommended separation distance table for more information. $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.70\sqrt{P}$ 800 MHz to 6 GHz Where P is the maximum output power rating of the recorder in watts (W) according to the recorder manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF recorders, as determined by an electromagnetic site survey[3], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the recorder should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance

Note: *At 80 MHz and 800 MHz, the higher frequency range applies.*
Note: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.*
[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF recorders, an electromagnetic site survey should be considered. If the measured field strength in the location in which the recorder is used exceeds the applicable RF compliance level above, the recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the recorder.
[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the recorder

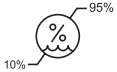
The recorder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. If you have communication issues when attempting to send data from the recorder, try maintaining a separation distance between the recorder and portable or mobile communications equipment as per the following table:

Rated maximum output power of recorder (W)	Separation distance according to the frequency of recorder (m)		
	150 kHz to 80 MHz Not applicable	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 6.0 GHz $d = 0.70\sqrt{P}$
0.01	Not applicable	0.035	0.07
0.1	Not applicable	0.11	0.22
1	Not applicable	0.35	0.7
10	Not applicable	1.1	2.2
100	Not applicable	3.5	7

For recorders rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the recorder, where *p* is the maximum output power rating of the recorder in watts (W) according to the recorder manufacturer.

Recommended separation distances between portable and mobile RF communications equipment and the recorder			
The recorder is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. If you have communication issues when attempting to send data from the recorder, try maintaining a separation distance between the recorder and portable or mobile communications equipment as per the following table:			
Rated maximum output power of recorder (W)	**Separation distance according to the frequency of recorder (m)**		
	150 kHz to 80 MHz Not applicable	**80 MHz to 800 MHz** $d = 0.35\sqrt{P}$	**800 MHz to 6.0 GHz** $d = 0.70\sqrt{P}$
Note: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.* **Note:** *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*			

Icon Table	
SN	Serial number
REF	Catalogue or model number
(1x)	One recorder per container/package
(5x)	Five recorders per container/package
	Manufacturer
	Refer to instruction manual before every use (appears blue on label)
	Manufactured in
	Non-ionizing electromagnetic radiation (RF communication)
CONF	Configuration or unique version identifier
	Degree of protection against electric shock: Type BF applied part
IP48	Recorder: 4 is the level of protection against solid objects with a diameter above 1 mm. 8 is the level of protection against the effects of continuous immersion in water 2.4 meters (8 feet) immersion for 30 minutes

Icon Table	
	Humidity limitation
	This product conforms to Australia Radio Requirements
CE0459	Signifies European technical conformity
EC REP	Authorized representative in the European community
	Do not reuse
	Fragile, handle with care
	Keep dry
	Recycle cardboard, paper, plastic packaging supplies and unwanted written material
	WEEE Initiative: DO NOT THROW IN TRASH. Recycle device according to local disposal requirements
	Magnetic Resonance (MR) unsafe: keep away from magnetic resonance imaging (MRI) equipment
IC	Complies with Industry Canada Radio Communication requirements
	Use by Date
	Storage temperature
	Transit Temperature

Africa:
Medtronic Africa (Pty) Ltd.
Tel: +27 (0) 11 677 4800

Albania:
Net Electronics Albania
Tel: +355 697070121

Argentina:
Corpomedica S.A.
Tel: +(11) 4 814 1333
Medtronic Directo 24/7:+0800 333 0752

Armenia:
Exiol LLC
Tel: +374 98 92 00 11 or +374 94 38 38 52

Australia:
Medtronic Australasia Pty. Ltd.
Tel: 1800 668 670

Azerbaijan:
Isomed
Tel: +994 (12) 464 11 30

Bangladesh:
Sonargaon Healthcare Pvt Ltd.
Mobile: (+91)-9903995417
or (+880)-1714217131

Belarus:
Zarga Medica
Tel: +375 29 625 07 77 or:
+375 44 733 30 99
Helpline: +74995830400

België/Belgique:
N.V. Medtronic Belgium S.A.
Tel: 0800-90805

Bosnia and Herzegovina:
Novopharm d.o.o. Sarajevo
Tel: +387 33 476 444
Helpline: 0800 222 33

Epsilon Research Intern. d.o.o.
Tel: +387 51 251 037
Helpline: 0800 222 33

Brasil:
Medtronic Comercial Ltda.
Tel: +(11) 2182-9200
Medtronic Directo 24/7:
+0800 773 9200

Bulgaria:
RSR EOOD
Tel: +359 888993083
Helpline: +359 884504344

Canada:
Medtronic of Canada Ltd.
Tel: 1-800-284-4416 (toll free/sans frais)

Chile:
Medtronic Chile
Tel: +(9) 66 29 7126
Medtronic Directo 24/7: +1 230 020 9750
Medtronic Directo 24/7 (From Santiago):
+(2) 595 2942

China:
Medtronic (Shanghai) Ltd.
24 Hour Help (Cell): +86 400-820-1981
24 Hour Help (Land): +86 800-820-1981

Colombia:
Medtronic Latin America Inc. Sucursal
Colombia
Tel: +(1) 742 7300
Medtronic Directo 24/7 (Landline):
+01 800 710 2170
Medtronic Directo 24/7
(Cellular): +1 381 4902

Croatia:
Mediligo d.o.o.
Tel: +385 1 6454 295
Helpline: +385 1 4881144

Medtronic Adriatic d.o.o.
Helpline: +385 1 4881120

Česká republika:
Medtronic Czechia s.r.o.
Tel: +420 233 059 111
Non-Stop Helpline (24/7): +420 233 059 059
Zákaznický servis (8:00 - 17:00):
+420 233 059 950

Danmark:
Medtronic Danmark A/S
Tel: +45 32 48 18 00

Deutschland:
Medtronic GmbH
Geschäftsbereich Diabetes
Telefon: +49 2159 8149-370
24-Stdn-Hotline: 0800 6464633

Eire:
Accu-Science Ltd.
Tel: +353 45 433000

España:
Medtronic Ibérica S.A.
Tel: +34 91 625 05 42
24 horas: +34 900 120 330

Estonia:
AB Medical Group Eesti OU
Tel: +372 6552310
Helpline: +372 5140694

Europe:
Medtronic Europe S.A. Europe, Middle East and Africa HQ
Tel: +41 (0) 21-802-7000

France:
Medtronic France S.A.S.
Tel: +33 (0) 1 55 38 17 00

Hellas:
Medtronic Hellas S.A.
Tel: +30 210677-9099

Hong Kong:
Medtronic International Ltd.
Tel: +852 2919-1300
To order supplies: +852 2919-1322
24-hour helpline: +852 2919-6441

India:
India Medtronic Pvt. Ltd.
Tel: (+91)-80-22112245 / 32972359
Mobile: (+91)-9611633007
Patient Care Helpline: 1800 209 6777

Indonesia:
Medtronic International Ltd.
Tel: +65 6436 5090 or +65 6436 5000

Israel:
Medtronic
Tel (orders): +9729972440, option 3 + option 1
Tel (product support): +9729972440, option 2
Helpline: (17:00 – 08:00 daily/weekends – Israel time): 1-800-611-888

Italia:
Medtronic Italia S.p.A.
Tel: +39 02 24137 261
Servizio assistenza tecnica:
N° verde: 800 60 11 22

Japan:
Medtronic Japan Co. Ltd.
Tel: +81-3-6776-0019
24 Hr. Support Line: 0120-56-32-56

Kazakhstan:
Medtronic BV in Kazakhstan
Tel: +7 727 311 05 80 (Almaty)
+7 717 224 48 11 (Astana)
Круглосуточная линия поддержки:
8 800 080 5001

Kosovo:
Yess Pharma
Tel: +377 44 999 900
Helpline: +37745888388

Latin America:
Medtronic, Inc.
Tel: 1(305) 500-9328

Latvija:
RAL SIA
Tel: +371 67316372
Helpline (9am to 6pm): +371 29611419

Lithuania:
Monameda UAB
Tel: +370 68405322
Helpline: +370 68494254

Macedonia:
Alkaloid Kons Dooel
Tel: +389 23204438

Magyarország:
Medtronic Hungária Kft.
Tel: +36 1 889 0688

Malaysia:
Medtronic International Ltd.
Tel: +603 7946 9000

México:
Medtronic Servicios S. de R. L. de C.V.
Tel (México DF): +(11) 029 058
Tel (Interior): +01 800 000 7867
Medtronic Directo 24/7 (from México DF):
+(55) 36 869 787
Medtronic Directo 24/7:
+01 800 681 1845

Middle East and North Africa:
Regional Office
Tel: +961-1-370 670

Montenegro:
Glosarij d.o.o.
Tel: +382 20642495

Nederland, Luxembourg:
Medtronic B.V.
Tel: +31 (0) 45-566-8291
Gratis: 0800-3422338

New Zealand:
Medica Pacifica
Phone: 64 9 414 0318
Free Phone: 0800 106 100

Norge:
Medtronic Norge A/S
Tel: +47 67 10 32 00

Philippines:
Medtronic International Ltd.
Tel: +65 6436 5090 or +65 6436 5000

Россия:
ООО «Медтроник»
Tel: +7 495 580 73 77
Круглосуточная линия поддержки:
8 800 200 76 36

Polska:
Medtronic Poland Sp. z o.o.
Tel: +48 22 465 6934

Portugal:
Medtronic Portugal Lda
Tel: +351 21 7245100

Puerto Rico:
Medtronic Puerto Rico
Tel: 787-753-5270

Republic of Korea:
Medtronic Korea, Co., Ltd.
Tel: +82.2.3404.3600

Romania:
Medtronic Romania S.R.L
Tel: +40372188017
Helpline: +40 726677171

Schweiz:
Medtronic (Schweiz) AG
Tel: + 41 (0) 31 868 0160
24-Stunden-Hotline: 0800 633333

Serbia:
Epsilon Research International d.o.o.
Tel: +381 113115554

Medtronic Serbia D.o.o.
Helpline: +381 112095900

Singapore:
Medtronic International Ltd.
Tel: +65 6436 5090 or +65 6436 5000

Slovenija:
Zaloker & Zaloker d.o.o.
Tel.: +386 1 542 51 11
24-urna tehnična pomoč:
+386 51316560

Slovenská republika:
Medtronic Slovakia, s.r.o.
Tel: +421 26820 6942
HelpLine: +421 26820 6986

Sri Lanka:
Swiss Biogenics Ltd.
Mobile: (+91)-9003077499
or (+94)-777256760

Suomi:
Medtronic Finland Oy
Tel: +358 20 7281 200
Help line: +358 400 100 313

Sverige:
Medtronic AB
Tel: +46 8 568 585 20

Taiwan:
Medtronic (Taiwan) Ltd.
Tel: 02-21836000
Toll Free: +886-800-005285

Thailand:
Medtronic (Thailand) Ltd.
Tel: +662 232 7400

Türkiye:
Medtronic Medikal Teknoloji
Ticaret Ltd. Sirketi.
Tel: +90 216 4694330

Ukraine:
Med Ek Service TOV
Tel: +380 50 3311898
or: +380 50 4344346
Лінія цілодобової підтримки:
0 800 508 300

USA:
Medtronic Diabetes Global
Headquarters
24 Hour HelpLine: +1-800-646-4633
To order supplies: +1-800-843-6687

United Kingdom:
Medtronic Ltd.
Tel: +44 1923-205167

Österreich:
Medtronic Österreich GmbH
Tel: +43 (0) 1 240 44-0
24 – Stunden – Hotline: 0820 820 190

Medtronic

Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325 USA
1 800 646 4633
+1 818 576 5555
www.medtronicdiabetes.com

EC REP
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Sanmina Corporation Mexico
Carretera Guadalajara-Chapala Km 15.5 No. 29
Tlajomulco de Zuniga
Jalisco, Mexico 45640

CE 0459

REF **MMT-7781**

M10542489-021_2