

EVERA MRI™ S VR SURESCAN® DVMC3D4

MR Conditional with PhysioCurve® Design, SmartShock® Technology 2.0, and Complete Capture Management™

Specifications – DF4



Physical characteristics

Physical characteristics

Volume ^a	33 cm ³
Mass	77 g
H x W x D	64 mm x 51 mm x 13 mm
Surface area of device can	57 cm ²
Radiopaque ID ^b	PFZ
Materials in contact with human tissue ^c	Titanium, polyurethane, silicone rubber
Battery	Hybrid CFx lithium/silver vanadium oxide

^a Volume with connector ports unplugged.

^b The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.

^c These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Replacement indicators

Recommended Replacement Time (RRT)	≤ 2.73 V on 3 consecutive daily automatic measurements
End of Service (EOS)	3 months after RRT

Maximum energy levels and typical full energy charge times

Maximum programmed energy	35 J
Maximum delivered energy ^{a,b}	36 J
Maximum stored energy ^c	42 J
Typical charge time at Beginning of Service (BOS) ^d	8.4 s
Typical charge time at Recommended Replacement Time (RRT) ^d	12.5 s

^a Energy delivered at connector block into a 50 Ω load.

^b For 35 J programmed energy, delivered energy exceeds 35 J.

^c Energy stored at charge end on capacitor.

^d Charge time during a nonwireless telemetry session may be slightly higher.

Device parameters

Tachyarrhythmia detection parameters

Parameter	Programmable values
VF Detection	On \diamond ; Off
VF Interval (Rate) ^a	240; 250 ... 320 \diamond ... 400 ms
VF Initial Beats to Detect	12/16; 18/24; 24/32; 30/40 \diamond ; 45/60; 60/80; 75/100; 90/120; 105/140; 120/160
VF Beats to Redetect	6/8; 9/12; 12/16 \diamond ; 18/24; 21/28; 24/32; 27/36; 30/40
FVT Detection	Off \diamond ; via VF; via VT
FVT Interval (Rate) ^a	200; 210 ... 240 \diamond ... 600 ms
VT Detection	On; Off \diamond
VT Interval (Rate) ^a	280; 290 ... 360 \diamond ... 650 ms
VT Initial Beats to Detect	12; 16 \diamond ... 52; 76; 100
VT Beats to Redetect	8; 12 \diamond ... 52
VT Monitor	Monitor \diamond ; Off
VT Monitor Interval (Rate) ^a	280; 290 ... 450 \diamond ... 650 ms
Monitored VT Beats to Detect	16; 20; 24; 28; 32 \diamond ... 56; 80; 110; 130

Wavelet

Wavelet ^b	On \diamond ; Off; Monitor
Template	[date]
Match Threshold	40; 43; 46 ... 70 \diamond ... 97%
Auto Collection	On \diamond ; Off
SVT V. Limit ^a	240; 250; 260 \diamond ... 650 ms

Tachyarrhythmia detection parameters, continued

Parameter	Programmable values
Other enhancements	
Stability ^a	Off ; 30; 40 ... 100 ms
Onset	Off ; On; Monitor
Onset Percent	72; 75; 78; 81 ; 84; 88; 91; 94; 97%
High Rate Timeout	
VF Zone Only	Off; 0.25; 0.5; 0.75 ; 1; 1.25; 1.5; 1.75; 2; 2.5; 3; 3.5; 4; 4.5; 5 min
All Zones	Off ; 0.5; 1; 1.5 ... 5; 6; 7 ... 20; 22; 24; 26; 28; 30 min
T-Wave	On ; Off
RV Lead Noise	On; On+Timeout ; Off
Timeout	0.25; 0.5; 0.75 ... 2 min
Sensitivity	
RV Sensitivity ^{c,d}	0.15; 0.30 ; 0.45; 0.60; 0.90; 1.20 mV

^a The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

^b The Wavelet feature is automatically set to On when VF Detection is set to On.

^c This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

^d Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity threshold to its minimum (most sensitive) setting of 0.15 mV. When susceptibility to modulated interference is tested under the conditions specified in CENELEC standard EN 45502-2-2:2008, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the minimum value of 0.15 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 0.3 mV or higher.

Ventricular tachyarrhythmia therapy parameters

Parameter	Programmable values
VF Therapy parameters	
VF Therapy Status	On ; Off
Energy	Rx1-Rx2: 0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J Rx3-Rx6: 10; 11 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Pathway ^a	AX>B; B>AX Rx1-Rx4: B>AX ; Rx5-Rx6: AX>B
ATP	During Charging ; Before Charging; Off
Deliver ATP if last 8 R-R \geq	200; 210 ... 240 ... 300 ms
Therapy Type	Burst ; Ramp; Ramp+
ChargeSaver [®]	On ; Off
Switch when number of consecutive ATP successes equals	1 ; 2; 3; 4; 6; 8; 10
Smart Mode	On ; Off
VT/FVT Therapy parameters	
VT Therapy Status	On; Off
FVT Therapy Status	On; Off
Therapy Type	CV; Burst; Ramp; Ramp+ Rx1: Burst ; Rx2-Rx6: CV
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J VT Rx1-Rx2: 20 J VT Rx3-Rx6: 35 J; FVT Rx1-Rx6: 35 J

Pathway ^a	AX>B; B>AX Rx1-Rx4: B>AX ; Rx5-Rx6: AX>B
Burst therapy parameters	
Initial # Pulses	1; 2 ... 8 ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88 ; 91; 94; 97%
Interval Dec	0; 10 ... 40 ms
# Sequences	1; 2 ... 10 VT Therapies: 3 ; FVT Therapies: 1
Smart Mode ^b	On; Off
Ramp therapy parameters	
Initial # Pulses	1; 2 ... 8 ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88; 91 ; 94; 97%
Interval Dec	0; 10 ... 40 ms
# Sequences	1; 2 ... 10 VT Therapies: 3 ; FVT Therapies: 1
Smart Mode ^b	On; Off
Ramp+ therapy parameters	
Initial # Pulses	1; 2; 3 ... 15
R-S1 Interval = (%RR)	50; 53; 56; 59; 63; 66 ... 75 ... 84; 88; 91; 94; 97%
S1S2 (Ramp+) = (%RR)	50; 53; 56; 59; 63; 66; 69 ... 84; 88; 91; 94; 97%
S2SN (Ramp+) = (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88; 91; 94; 97%
# Sequences	1; 2 ... 10 VT Therapies: 3 ; FVT Therapies: 1
Smart Mode ^b	On; Off
Shared Settings	
V-V Minimum ATP Interval	150; 160 ... 200 ... 400 ms
V. Amplitude	1; 2 ... 6; 8 V
V. Pulse Width	0.1; 0.2 ... 1.5 ms
V. Pace Blanking	150; 160 ... 240 ... 450 ms
Active Can [®] /SVC Coil ^c	Can+SVC On ; Can Off; SVC Off
Progressive Episode Therapies	On; Off
Confirmation+	On ; Off

^a If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

^b Smart Mode is available only for Rx1-Rx4.

^c The Active Can/SVC Coil parameter applies to all automatic, manual, and emergency high-voltage therapies. It also applies to T-Shock inductions.

Pacing parameters

Modes, rates, and intervals

Parameter	Programmable values
Mode	VVI ; VVIR; VOO; OVO
Lower Rate ^a	30; 35 ... 40 ; 45 ... 150 min ⁻¹ (± 2 min ⁻¹)

^a The corresponding Lower Rate Interval can be calculated as follows:
Lower Rate Interval (ms) = 60,000/Lower Rate.

RV parameters

Parameter	Programmable values
RV Amplitude	0.5; 0.75 ... 3.5 ⚡ ... 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 ⚡ ... 1.5 ms
RV Sensitivity ^a	0.15 mV (± 75%); 0.3 ⚡ ; 0.45; 0.6 mV (± 50%); 0.9; 1.2 mV (± 30%)
RV Pace Polarity	Bipolar; Tip to Coil
RV Sense Polarity	Bipolar; Tip to Coil

^a This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

RV Capture Management[®] parameters

Parameter	Programmable values
RV Capture Management	Adaptive ⚡; Monitor; Off
RV Amplitude Safety Margin	1.5x; 2.0x ⚡; 2.5x; 3.0x
RV Minimum Adapted Amplitude	1.0; 1.5; 2.0 ⚡; 2.5; 3.0; 3.5 V
RV Acute Phase Remaining	Off; 30; 60; 90; 120 ⚡; 150 days

Blanking periods

Parameter	Programmable values
V. Blank Post VP	150; 160 ... 200 ⚡ ... 450 ms
V. Blank Post VS	120 ⚡; 130 ... 170 ms

Rate response pacing parameters

Parameter	Programmable values
Upper Sensor Rate	80; 85 ... 120 ⚡ ... 175 min ⁻¹ (± 2 min ⁻¹)
ADL Rate	60; 65 ... 95 ⚡ ... 170 min ⁻¹ (± 2 min ⁻¹)
Rate Profile Optimisation	On ⚡; Off
ADL Response	1; 2; 3 ⚡; 4; 5
Exertion Response	1; 2; 3 ⚡; 4; 5
Activity Threshold	Low; Medium Low ⚡; Medium High; High
Activity Acceleration	15; 30 ⚡; 60 s
Activity Deceleration	Exercise ⚡; 2.5; 5; 10 min
ADL Setpoint	5; 6 ... 40; 42 ... 80
UR Setpoint	15; 16 ... 40; 42 ... 80; 85 ... 180

Conducted AF response parameters

Parameter	Programmable values
Conducted AF Response	On; Off ⚡
Response Level	Low; Medium ⚡; High
Maximum Rate	80; 85 ... 110 ⚡ ... 130 min ⁻¹

Ventricular rate stabilisation parameters

Parameter	Programmable values
V. Rate Stabilisation	On; Off ⚡
Maximum Rate	80; 85 ... 100 ⚡ ... 120 min ⁻¹
Interval Increment	100; 110 ... 150 ⚡ ... 400 ms

Post VT/VF shock pacing parameters

Parameter	Programmable values
Post VT/VF Shock Pacing	On; Off ⚡
Overdrive Rate	70; 75; 80 ⚡ ... 120 min ⁻¹
Overdrive Duration	0.5 ⚡; 1; 2; 3; 5; 10; 20; 30; 60; 90; 120 min

Post shock pacing parameters

Parameter	Programmable values
Post Shock V. Amplitude	1; 2 ... 6 ⚡; 8 V
Post Shock V. Pulse Width	0.1; 0.2 ... 1.5 ⚡ ms

Sleep parameters

Parameter	Programmable values
Sleep	On; Off ⚡
Sleep Rate	30; 35 ... 50 ⚡; 55; 60; 70; 75 ... 100 min ⁻¹
Bed Time	00:00; 00:10 ... 22:00 ⚡ ... 23:50
Wake Time	00:00; 00:10 ... 07:00 ⚡ ... 23:50

MRI SureScan parameters

Parameter	Programmable values
MRI SureScan	On; Off
MRI Pacing Mode	VOO (Asynchronous); OVO (Off)
MRI Pacing Rate	60; 70; 75 ... 120 min ⁻¹

Additional pacing features

Parameter	Programmable values
Rate Hysteresis	Off ⚡; 30; 40 ... 80 min ⁻¹

Medtronic CareAlert[®] parameters

Clinical management alerts

Parameter	Programmable values
Number of Shocks Delivered in an Episode^a	
Device Tone	
Alert Enable – Urgency	Off ⚡; On-Low; On-High
Patient Home Monitor	
Alert Enable ^b	Off ⚡; On
Shared (Device Tone and Patient Home Monitor)	
Number of Shocks Threshold ^c	1 ⚡; 2; 3; 4; 5; 6

All Therapies in a Zone Exhausted for an Episode

Device Tone	
Alert Enable – Urgency	Off ⚡; On-Low; On-High
Patient Home Monitor	
Alert Enable ^b	Off ⚡; On

^a Note that VF, VT, and FVT therapies could be delivered during a single episode (from initial detection until episode termination).

^b Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

^c This parameter is displayed only if an associated alert has been enabled.

Lead/Device integrity alerts

Parameter	Programmable values
RV Lead	
Device Tone	
Alert Urgency ^a	Low; High \diamond
RV Lead Integrity Enable	On \diamond ; Off
RV Lead Noise Enable	On \diamond ; Off
Patient Home Monitor	
RV Lead Integrity Enable ^c	On \diamond ; Off
RV Lead Noise Enable ^c	On \diamond ; Off
Lead Impedance Out of Range	
Device Tone	
Alert Urgency ^a	Low; High \diamond
RV Pacing Impedance Enable	On \diamond ; Off (Observation only)
RV Defibrillation Impedance Enable	On \diamond ; Off (Observation only)
SVC Defibrillation Impedance Enable ^b	On \diamond ; Off (Observation only)
Patient Home Monitor	
RV Pacing Impedance Enable ^c	Off; On \diamond
RV Defibrillation Impedance Enable ^c	Off; On \diamond
SVC Defibrillation Impedance Enable ^{bc}	Off; On \diamond
Shared (Device Tone and Patient Home Monitor)	
RV Pacing Impedance Less than	200 \diamond ; 300; 400; 500 Ω
RV Pacing Impedance Greater than	1,000; 1,500; 2,000; 3,000 \diamond Ω
RV Defibrillation Impedance Less than	20 \diamond ; 30; 40; 50 Ω
RV Defibrillation Impedance Greater than	100; 130; 160; 200 \diamond Ω
SVC Defibrillation Impedance Less than	20 \diamond ; 30; 40; 50 Ω
SVC Defibrillation Impedance Greater than	100; 130; 160; 200 \diamond Ω
Low Battery Voltage RRT	
Device Tone	
Alert Enable – Urgency	Off; On-Low; On-High \diamond
Patient Home Monitor	
Alert Enable ^c	Off; On \diamond
Excessive Charge Time EOS	
Device Tone	
Alert Enable – Urgency	Off; On-Low; On-High \diamond
Patient Home Monitor	
Alert Enable ^c	Off; On \diamond
VF Detection Off, 3+ VF or 3+ FVT Rx Off	
Device Tone	
Alert Enable	Off; On-High \diamond
Patient Home Monitor	
Alert Enable ^c	Off; On \diamond

^a This parameter is displayed only if an associated alert has been enabled.

^b If an SVC lead is not implanted, the alert will not sound.

^c Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

Shared parameters

Parameter	Programmable values
Patient Home Monitor	Yes; No \diamond
Alert Time ^a	00:00; 00:10 ... 08:00 \diamond ... 23:50

^a This parameter is displayed only if an associated alert has been enabled.

Data collection parameters

Data collection parameters

Parameter	Programmable values
LECG Source (Leadless ECG) ^a	Can to SVC ^b
LECG Range (Leadless ECG)	± 1 ; ± 2 \diamond ; ± 4 ; ± 8 ; ± 12 ; ± 16 ; ± 32 mV
EGM 1 Source	RVtip to RVcoil; RVtip to RVring \diamond
EGM 1 Range	± 1 ; ± 2 ; ± 4 ; ± 8 \diamond ; ± 12 ; ± 16 ; ± 32 mV
EGM 2 (Wavelet) Source	Can to RVcoil \diamond ; Can to RVring; RVtip to RVcoil; RVtip to RVring; Can to SVC ^{bc} ; RVcoil to SVC ^b
EGM 2 (Wavelet) Range	± 1 ; ± 2 ; ± 4 ; ± 8 ; ± 12 \diamond ; ± 16 ; ± 32 mV
EGM 3 Source	RVtip to RVcoil \diamond ; RVtip to RVring
EGM 3 Range	± 1 ; ± 2 ; ± 4 ; ± 8 \diamond ; ± 12 ; ± 16 ; ± 32 mV
Monitored	EGM1 and EGM2 \diamond ; EGM1 and EGM3; EGM1 and LECG; EGM2 and EGM3; EGM2 and LECG; EGM3 and LECG
Pre-arrhythmia EGM	Off \diamond ; On – 1 month; On – 3 months; On Continuous
Device Date/Time ^d	(enter time and date)
Holter Telemetry	Off \diamond ; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr

^a This EGM channel displays far-field signals.

^b An SVC electrode must be present for this configuration.

^c If Can to SVC is selected, the EGM Range is automatically set to ± 2 mV. The EGM Range is automatically set to ± 8 mV for all other EGM Source options.

^d The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

System test parameters

System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Test Type	Amplitude; Pulse Width
Decrement after	2; 3 ... 15 pulses
RV Pace Polarity	Bipolar; Tip to Coil
Mode ^a	VVI; VOO
Lower Rate	30; 35 ... 60; 70; 75 ... 150 min ⁻¹
RV Amplitude	0.25; 0.5 ... 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
V. Pace Blanking	150; 160 ... 450 ms
Sensing Test parameters	
Mode ^a	VVI; OVO
Lower Rate	30; 35 ... 60; 70; 75 ... 120 min ⁻¹
Wavelet Test parameters	
Match Threshold	40; 43 ... 70 \diamond ... 97
Mode ^a	VVI; OVO
Lower Rate	30; 35 ... 60; 70; 75 ... 120 min ⁻¹

^a The selectable values for this parameter depend on the programmed pacing mode.

EP study parameters

T-Shock induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled ; Disabled
Enable	Enabled; Disabled
#S1	2; 3; 4; 5 ; 6; 7; 8
S1S1	300; 310 ... 400 ... 2,000 ms
Delay	20; 30 ... 300 ... 600 ms
Energy	0.4; 0.6; 0.8; 1.0 ... 1.8; 2; 3; 4 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Waveform	Monophasic ; Biphasic
Pathway ^a	AX>B; B>AX

^a If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

50 Hz Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled ; Disabled
Amplitude	1; 2; 3; 4 ; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ... 1.50 ms

Fixed Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled ; Disabled
Interval	100; 110 ... 600 ms
Amplitude	1; 2; 3; 4 ; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ... 1.50 ms

PES induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled ; Disabled
#S1	1; 2 ... 8 ... 15
S1S1	100; 110 ... 600 ... 2,000 ms
S1S2	Off; 100; 110 ... 400 ... 600 ms
S2S3	Off ; 100; 110 ... 400; 410 ... 600 ms ^a
S3S4	Off ; 100; 110 ... 400; 410 ... 600 ms ^a
Amplitude	1; 2; 3; 4 ; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ... 1.50 ms

^a Default value when parameter is On is 400 ms.

Manual defibrillation parameters

Parameter	Selectable values
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Pathway ^a	AX>B; B>AX

^a If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Manual cardioversion parameters

Parameter	Selectable values
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Pathway ^a	AX>B; B>AX

^a If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Shared manual ATP therapy parameters

Parameter	Selectable values
Minimum Interval	150; 160 ... 200 ... 400 ms
Amplitude	1; 2 ... 6 ; 8 V
Pulse Width	0.10; 0.20 ... 1.50 ms

Manual Ramp therapy parameters

Parameter	Selectable values
# Pulses	1; 2 ... 6 ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88; 91; 94; 97 %
Dec/Pulse	0; 10 ; 20; 30; 40 ms

Manual Burst therapy parameters

Parameter	Selectable values
# Pulses	1; 2 ... 8 ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88 ; 91; 94; 97%

Manual Ramp+ therapy parameters

Parameter	Selectable values
# Pulses	1; 2; 3 ... 15
R-S1 (%RR)	50; 53; 56; 59; 63; 66 ... 75 ... 84; 88; 91; 94; 97%
S1-S2 (%RR)	50; 53; 56; 59; 63; 66; 69 ... 84; 88; 91; 94; 97%
S2-SN (%RR)	50; 53; 56; 59; 63; 66 ... 84; 88; 91; 94; 97%

Longevity

Projected service life in years

Pacing Mode, Percent pacing	Pacing Amplitude	Projected service life in years	
		500 Ω pacing impedance	600 Ω pacing impedance
VVI, 0%	2.5 V	11.0	11.0
	3.5 V	11.0	11.0
VVI, 15%	2.5 V	10.7	10.8
	3.5 V	10.4	10.5
VVI, 50%	2.5 V	10.1	10.2
	3.5 V	9.2	9.5
VVI, 100%	2.5 V	9.3	9.6
	3.5 V	7.9	8.3

The service life projections are based on the following assumptions:

- Semi-annual maximum energy charging frequency
- Pre-arrhythmia EGM storage programmed to On for a 6-month period (two 3-month follow-up intervals), over the entire life of the device
- 3 hours of wireless telemetry during implant
- A quarterly schedule of Medtronic CareLink Monitor remote transmissions
- 1 hour of in-office wireless telemetry annually
- Typical shelf storage time before implant

Projected service life estimates are based on accelerated battery discharge data and device modeling as specified.

Do not interpret these values as precise numbers.

Reference:

Evera™ S VR Manual.

Brief Statement

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events.

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