



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Medtronic Minimed, Inc. Recalls Guardian 4 Glucose Sensor For Problem With Thin Glucose Oxidase Layer

Recall Date	Product Description	Recalling Firm	Recall Reason
2/14/2024	Guardian 4 Glucose Sensor REF: MMT-7040A, MMT-7040C1, MMT-7040C2, MMT-7040C3, MMT-7040D1, MMT-7040D2, MMT-7040MA, MMT-7040QC1, MMT-7040QC2, MMT-7040QC3	MEDTRONIC MINIMED, INC. Northridge, California	Some sensors may have a glucose oxidase (GOX) layer thickness outside of specification (5.5 to 9.2 μ m). A non-conforming GOX layer thickness could impact sensor function (sensor glucose value) or loss of sensor function due to the sensor layer being too thin. The potential impact resulting from this issue ranges from user inconvenience to over/under delivery of insulin, possibly resulting in hyperglycemia or hypoglycemia, if the sensor glucose values are affected. The issue was identified by the manufacturing team during the execution of Filmetrics Measurement for a Guardian Sensor lot.

Recall Class	Product Identification	Distribution	Affected Dates
II	<p>Guardian 4 Glucose Sensor REF/UDI-DI/Lot: MMT-7040A/20763000413389/HG72B2C, HG72CQQ, HG73VB7, HG73VC8, HG73VFT, HG73WFR, HG7441E, HG745F9, HG7486X, HG74AJ1, HG74SUR, HG74T9Q, HG74U36, HG78LMS, HG79Y9U; MMT-7040C1/00763000555276, 00763000413392, 20763000413396, 20763000555270, 20763000712475, 00763000712471/F1323, F1923, G0323, G1723, G2023, G2623, G2923, HG6RV7S, HG6TGNU, HG6TJ2Y, HG6TW97, HG6TWVU, HG6UNF2, HG6V8NN, HG6VB8S, HG6VNX3, HG6WNE1, HG6XFPR, HG6XH54, HG6XQCG, HG6XZJX, HG6Y0W1, HG6Y3QN, HG6YEK6, HG6YFAF, HG6YFHL, HG6YJAR, HG6YJBD, HG6YNGD, HG6Z7N5, HG6ZARN, HG7038Y, HG70CW5, HG70DAM, HG70JSU, HG70LRC, HG70QWA, HG71VMZ, HG72DB5, HG72G9C, HG72NV9, HG72R1P, HG72RBD, HG72SE3, HG72TPT, HG72TRV, HG72V3J, HG72ZFP, HG7340A, HG73EJX, HG73RNR, HG745SV, HG747E3, HG7480Q, HG749N6, HG74F93, HG75TSX, HG75XA1, HG76HFH, HG76RYY; MMT-7040C2/20763000555287/HG6RC39, HG6RXB5, HG6T4T7, HG6T8RV, HG6TJ2Y, HG6WKZU, HG6WLKS, HG6XFPR, HG6XH54, HG6XLSD, HG6XNH3, HG6Y5C6, HG6Z1X5,</p>	25 Units in California	November, 2023 and prior

	<p>HG713AK, HG73EGX, HG73EJX, HG73FJP, HG73Q24, HG73QPM, HG73RNR, HG7619X, HG764J9, HG76CWC, HG77FMK; MMT- 7040C3/20763000555294/HG6 XNH3, HG73RNR; MMT- 7040D1/00763000413484/HG6 THY1, HG6V7VV; MMT- 7040D2/00763000413491/HG6 TL44; MMT- 7040MA/20763000519692/HG7 4460; MMT- 7040QC1/00763000555313, 20763000555317/HG6WT9A, HG6WUGE, HG73PH3; MMT- 7040QC2/20763000555324, 763000555320/HG6WT9A; MMT- 7040QC3/20763000555331/HG 6WT9A</p>		
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