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Class 2 Device Recall MicroFuel Cell Oxygen Sensor, Class RI5



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Class 2 Recall MicroFuel Cell Oxygen Sensor, Class RI5



21

Date Posted	August 11, 2011
Recall Status¹	Terminated on August 22, 2011
Recall Number	Z-3001-2011
Recall Event ID	58322 ²²
Premarket Notification 510(K) Number	K001095 ²³
Product	Micro-Fuel Cell Oxygen Sensor, Class RI5 Sensor Part Number: C41131-R15 Teledyne Instruments - Analytical Instruments Disposable oxygen sensors with limited useful life. These sensors are accessories to other oxygen diagnostic devices, and are not in themselves suitable for therapeutic use.
Code Information	Sensor Part Number: C41131-R15. Serial Numbers: 593875 to 593894 (20), 599156 to 599254(99), 611100 to 611599 (500), 617125 to 617674(550), 642023 to 642472 (450), 642474 to 642475 (2), 642485 to 643022 (538), 666158 to 666657 (500), 668499 to 668647 (149), and 668652 to 668656 (5).
Recalling Firm/ Manufacturer	Teledyne Instruments - Analytical Instruments 16830 Chestnut St City Of Industry, California 91748-1017

Manufacturer Reason for Recall	The recall was initiated because during a test on a batch of sensors on the company shipping dock, Teledyne Instruments discovered electrolyte loss from the sealing cylinder on a few sensors. This test was done pursuant to a complaint from one customer of label discoloration caused because of the electrolyte loss. The risk of a leak from the oxygen sensor while in use is the disruption of therapy.
FDA Determined Cause 2	DESIGN: Process Design
Action	Teledyne Instruments sent emails and "Urgent--Device Field Corrections/Removal" letters in December 2010 to all affected customers. The letter includes description of device and problem. Customers are advised to check them before use for any signs of electrolyte loss and if discoloration is noted to discontinue its use, and provides recommendation. Teledyne-Instruments to generate a product field corrections/removal log that lists names/addresses of the consignees, quantity of sensors shipped, sensor serial numbers and the date of shipment. For additional information or questions contact Teledyne Instruments at (626) 934-1504.
Quantity in Commerce	2813
Distribution	Worldwide Distribution: Nationwide (US) distribution including the states of CA, TN and WI; and the countries of , Canada, Brazil, Chile, Saudi Arabia, and the U.K.

1 For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)²⁴

2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
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5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
9. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
10. </scripts/cdrh/cfdocs/cfRES/res.cfm>
11. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>

12. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
13. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
14. </scripts/cdrh/cfdocs/cfTPLC/inspect.cfm>
15. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
18. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
19. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
20. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm>
21. <http://www.fda.gov/safety/recalls/enforcementreports/default.htm>
22. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=58322
23. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K001095>
24. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55>

Page Last Updated: 03/26/2014

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6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
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10. </scripts/cdrh/cfdocs/cfRES/res.cfm>
11. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>

12. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
13. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
14. </scripts/cdrh/cfdocs/cfTPLC/inspect.cfm>
15. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
18. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
19. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
20. </scripts/cdrh/cfdocs/cfTPLC/tplc.cfm>
21. <http://www.fda.gov/safety/recalls/enforcementreports/default.htm>
22. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=58322
23. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K001095>
24. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55>