



CooperSurgical®

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June 4, 2021

**URGENT FIELD SAFETY NOTICE**  
COOPERSURGICAL OXYGEN SENSORS

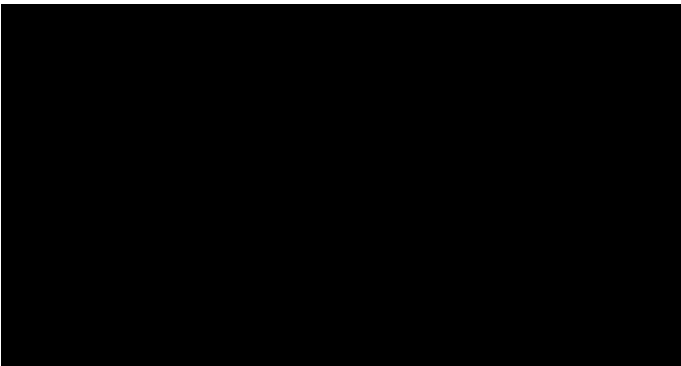
Dear Valued CooperSurgical Customer,

CooperSurgical has issued a Field Safety Notice for 526 lot numbers of its Oxygen Sensors supplied for use in the following incubator and work chamber products; G185 Standard 110V, G185 SensorTech 110V, G185 Standard 230V, G185 SensorTech 230V, G210 InviCell Standard, G210 InviCell Standard US, G210 Invicell Plus Optional pH and External Monitoring, G603 Work Chamber 115V, & G603 Work Chamber 230V. [CooperSurgical part numbers K22400-110, K22200-110, K22400-230, K22200-230, K59500, K59700, K60000, 3.641.831.153, & 3.641.832.153]. The G185 & G210 Incubators provide an environment with controlled temperature at or near body temperature and gas level (CO<sub>2</sub>, O<sub>2</sub> and N<sub>2</sub>), for the development of human gametes and embryos during in vitro fertilization (IVF) treatment. While the G603 is a laboratory device which is intended to be used and operated in IVF laboratories. This appliance is designed for continuous use in within ambient conditions listed in the product manual.

CooperSurgical is issuing this Notice because the Incubator units are displaying output readings that differ from the measurements taken using a Gas Analyzer. When the display is reading a target setting of 5%, an external meter is reading between 3% and 12% and the Incubator does not alarm. The nonconformity was detected during complaint investigations and a corrective action has been initiated to prevent future recurrence. **The oxygen saturation level may be verified with the use of a gas analyzer or external probe to set oxygen levels to 5%, even if the incubator display shows a different value.** No adverse events have been reported to CooperSurgical due to this potential issue.

This Notice affects 526 lot numbers (Table 1) procured from December 1, 2020 to April 26, 2021 and our records indicate that you have purchased the affected product from CooperSurgical. If the affected product at your facility is displaying any of the above characteristics, please complete the attached **Acknowledgement and Receipt Form** to arrange for an onsite field service call at CooperSurgical's expense. Otherwise, this issue will be addressed at your next onsite routine service at no expense for the correction. Please be advised that we are expecting the Oxygen Sensor replacement to be approximately an extra 2.5 hours during this service. If you do not have affected Oxygen Sensors in inventory, please use the same enclosed Form to indicate that and return it to CooperSurgical so that we may document receipt of this Field Safety Notice.

The relevant regulatory authorities have been notified of this field safety notice. We sincerely apologize for any inconvenience caused by this Field Safety Notice. CooperSurgical is committed to high quality, safe and effective products. Please feel free to reach us at +001.203.601.5200 ext. 3300 with any questions regarding this notice.



**COOPERSURGICAL OXYGEN SENSORS WITHIN  
G185 & G210 INCUBATORS & G603 WORK CHAMBERS**

Table 1- Affected Lot Numbers

|        |        |        |        |        |        |        |        |        |        |
|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| 531540 | 531541 | 531542 | 531543 | 531544 | 531545 | 531546 | 531547 | 531548 | 531549 |
| 531550 | 531551 | 531552 | 531553 | 531554 | 531555 | 531556 | 531557 | 531558 | 531559 |
| 531560 | 531561 | 531562 | 531563 | 531564 | 531565 | 531566 | 531567 | 531568 | 531569 |
| 531570 | 531571 | 531572 | 531573 | 531574 | 531575 | 531576 | 531577 | 531578 | 531579 |
| 531580 | 531581 | 531582 | 531583 | 531584 | 531585 | 531586 | 531587 | 531588 | 531589 |
| 531590 | 531591 | 531597 | 531598 | 531599 | 531600 | 531601 | 531602 | 531603 | 531604 |
| 531605 | 531606 | 531607 | 531608 | 531609 | 531610 | 531611 | 531612 | 531613 | 531614 |
| 531615 | 531616 | 531617 | 531618 | 531619 | 531620 | 531621 | 531622 | 531623 | 531624 |
| 531625 | 531626 | 531627 | 531628 | 531629 | 531630 | 531631 | 531632 | 531633 | 531634 |
| 531635 | 531636 | 531637 | 531638 | 531639 | 531640 | 531641 | 531642 | 531643 | 531644 |
| 531645 | 531646 | 531647 | 531648 | 531649 | 531650 | 531651 | 531652 | 531653 | 531654 |
| 531655 | 531656 | 531657 | 531658 | 531659 | 531660 | 531661 | 531662 | 531663 | 531664 |
| 531665 | 531667 | 531668 | 531669 | 531670 | 531671 | 531672 | 531673 | 531674 | 531675 |
| 531676 | 531677 | 531678 | 531679 | 531690 | 531691 | 531692 | 531693 | 531694 | 531695 |
| 531696 | 531697 | 531698 | 531699 | 531700 | 531701 | 531702 | 531703 | 531704 | 531705 |
| 531706 | 531707 | 531708 | 531709 | 531710 | 531711 | 531712 | 531713 | 531714 | 531715 |
| 531716 | 531717 | 531718 | 531719 | 531721 | 531722 | 531723 | 531724 | 531725 | 531726 |
| 531727 | 531728 | 531729 | 531730 | 531731 | 531732 | 531733 | 531734 | 531735 | 531736 |
| 531737 | 531738 | 531739 | 531740 | 531741 | 531742 | 531743 | 531744 | 531745 | 531746 |
| 531747 | 531748 | 531749 | 532001 | 532034 | 532035 | 532036 | 532037 | 532038 | 532039 |
| 532040 | 532041 | 532042 | 532043 | 532044 | 532045 | 532046 | 532047 | 532048 | 532052 |
| 532053 | 532054 | 532070 | 532071 | 532072 | 532073 | 532074 | 532075 | 532076 | 532077 |
| 532079 | 532080 | 532081 | 532082 | 532083 | 532084 | 532085 | 532086 | 532087 | 532088 |
| 532089 | 532090 | 532091 | 532092 | 532103 | 532104 | 532105 | 532106 | 532107 | 532108 |
| 532109 | 532110 | 532111 | 532112 | 532113 | 532114 | 532115 | 532116 | 532117 | 532118 |
| 532119 | 532120 | 532121 | 532122 | 532123 | 532124 | 532125 | 532126 | 532127 | 532128 |
| 532129 | 532130 | 532131 | 532132 | 532134 | 532135 | 532136 | 532137 | 532138 | 532139 |
| 532140 | 532141 | 532142 | 532143 | 532144 | 532145 | 532146 | 532147 | 532148 | 532149 |
| 532150 | 532151 | 532152 | 540659 | 540660 | 540661 | 540662 | 540663 | 540665 | 540666 |
| 540667 | 540668 | 540669 | 540670 | 540671 | 540672 | 540673 | 540674 | 540675 | 540676 |
| 540677 | 540678 | 540679 | 540680 | 540681 | 540682 | 540683 | 540684 | 540685 | 540686 |
| 540687 | 540688 | 540689 | 540691 | 540692 | 540693 | 540694 | 540695 | 540696 | 540697 |
| 540698 | 540699 | 540700 | 540701 | 540702 | 540708 | 540710 | 540711 | 540712 | 540713 |
| 540714 | 540715 | 540716 | 540717 | 540718 | 540719 | 540720 | 540721 | 540723 | 540724 |
| 540725 | 540726 | 540727 | 540730 | 540731 | 540732 | 540733 | 540734 | 540735 | 540736 |
| 540737 | 540738 | 540739 | 540740 | 540741 | 540742 | 540743 | 540744 | 540745 | 540746 |
| 540747 | 560830 | 560831 | 560900 | 560901 | 560930 | 560952 | 560953 | 560954 | 560967 |
| 560968 | 560969 | 560970 | 560971 | 560972 | 560973 | 560974 | 560975 | 560976 | 560977 |
| 560978 | 560979 | 560980 | 560981 | 560983 | 560984 | 560985 | 560986 | 560987 | 560988 |
| 560989 | 560990 | 560991 | 560992 | 560993 | 560994 | 560995 | 560996 | 560997 | 560998 |

|        |        |        |        |        |        |        |        |        |        |
|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| 561000 | 561001 | 561002 | 561003 | 561004 | 561005 | 561006 | 561007 | 561008 | 561009 |
| 561010 | 561011 | 561012 | 561019 | 561025 | 561026 | 561027 | 561028 | 561030 | 561031 |
| 561032 | 561033 | 561034 | 561035 | 561036 | 561040 | 582528 | 582531 | 582533 | 582534 |
| 582535 | 582537 | 582538 | 582539 | 582541 | 582542 | 582543 | 582544 | 582545 | 582547 |
| 582553 | 582554 | 582555 | 582556 | 582557 | 582558 | 582559 | 582560 | 582561 | 582562 |
| 582563 | 582564 | 582566 | 582567 | 582568 | 582569 | 582570 | 582571 | 582572 | 582574 |
| 582576 | 582578 | 582579 | 582580 | 582581 | 582582 | 589268 | 589269 | 589270 | 589272 |
| 589273 | 589274 | 589275 | 589276 | 589277 | 589278 | 589279 | 589280 | 589281 | 589282 |
| 589283 | 589284 | 589285 | 589286 | 589287 | 589288 | 589289 | 589290 | 589291 | 589292 |
| 589293 | 589294 | 589295 | 589296 | 589297 | 589298 | 589299 | 589300 | 589301 | 589302 |
| 589303 | 589304 | 589305 | 589306 | 589307 | 589308 | 589309 | 589310 | 589311 | 589312 |
| 589313 | 589314 | 589315 | 589316 | 589317 | 589318 | 589319 | 589320 | 589321 | 589322 |
| 589323 | 589324 | 589325 | 589326 | 589327 |        |        |        |        |        |

**Acknowledgement and Receipt Form: Response is required**

Please complete this form and return it via email: [recall@coopersurgical.com](mailto:recall@coopersurgical.com) or fax to **+001.203.601.9870** **ATTN: Product Surveillance.**

CooperSurgical will arrange for a product field service at your facility after this form has been received.

Customer Account #: \_\_\_\_\_ Account Name: \_\_\_\_\_

Street Address: \_\_\_\_\_ Town, State, Zip Code: \_\_\_\_\_

Contact Name: \_\_\_\_\_ Phone Number: \_\_\_\_\_

Email address: \_\_\_\_\_

I have read and understand the Notice instructions provided in the June 4, 2021 letter. Yes \_\_\_\_ No \_\_\_\_

Any adverse events associated with product subject to this Notice? Yes \_\_ No \_\_\_\_

If yes, please explain: \_\_\_\_\_

**Please check the appropriate boxes below and complete the table if applicable.**

- We have no inventory within the scope of this Notice.
- We have the following affected product at our facility. We have identified the affected product and will need the following lot numbers serviced onsite.

| Lot Number | Quantity to be Serviced |
|------------|-------------------------|
|            |                         |
|            |                         |
|            |                         |
|            |                         |
|            |                         |
|            |                         |
|            |                         |

If you have additional questions, please contact a CooperSurgical Product Surveillance representative at **+001.203.601.5200 ext. 3300** or email us at [recall@coopersurgical.com](mailto:recall@coopersurgical.com). Adverse reactions or quality problems experienced with the use of this product may be reported to the respective Competent Authority's Adverse Event Reporting program either online, by regular mail or by fax.

**Acknowledgement and Receipt Form: Response is required**

Please complete this form and return it via email: [recall@coopersurgical.com](mailto:recall@coopersurgical.com) or fax to +001.203.601.9870 **ATTN: Product Surveillance.**

**FOR DISTRIBUTORS ONLY:**

Customer Account #: \_\_\_\_\_ Account Name: \_\_\_\_\_

Contact Name/Title: \_\_\_\_\_ Phone Number: \_\_\_\_\_

Email address: \_\_\_\_\_

**Please complete the appropriate information below if applicable.**

I have read and understand the Notice instructions provided in the June 4, 2021 letter. Yes \_\_\_ No\_\_\_

I have checked my stock and have quarantined inventory consisting of \_\_\_\_\_ units

Lot Number shipped to Customer : \_\_\_\_\_ Quantity Shipped: \_\_\_\_\_

I have identified and notified my customers that were shipped or may have been shipped this product by \_\_\_\_\_ (Specify date and method of notification)

**Or**

Please notify the attached is a list of customers who received/may have received this product.

Signature of Receipt: \_\_\_\_\_