MAY 7 1998 K973646

BIRD®

A Thermo Electron Company

# 510(K) SUMMARY

## P/N 15625 Bird Sentry™ Blender

## P/N 15642 Bird Sentry™ "Low-Flow" Blender

## Bird Products Corporation

Neil Battiste
Regulatory Affairs Manager
Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262-6267

760.778.7341 (voice)
760.778.7274 (fax)

September 22, 1997

## General Information

**Device Trade Name:** **Bird Sentry™ Blender**

**Device Common/Classification Name:**

- **868.5330** Mixer, Breathing Gases, Anesthesia Inhalation, 73 BZR

*- **and** -*

- **868.1720** Analyzer, Gas, Oxygen, Gaseous Phase, 73 CCL

**Predicate Device:**

**Bird Sentry Air/Oxygen Microblender**
**FDA 510(k) No: K911962A**

Ceramatec OM25E Oxygen Analyzer
FDA 510(k) No: K911344A

Bird Low Flow Air/Oxygen Blender
FDA 510(k) No: K883038

**Intended Use:**

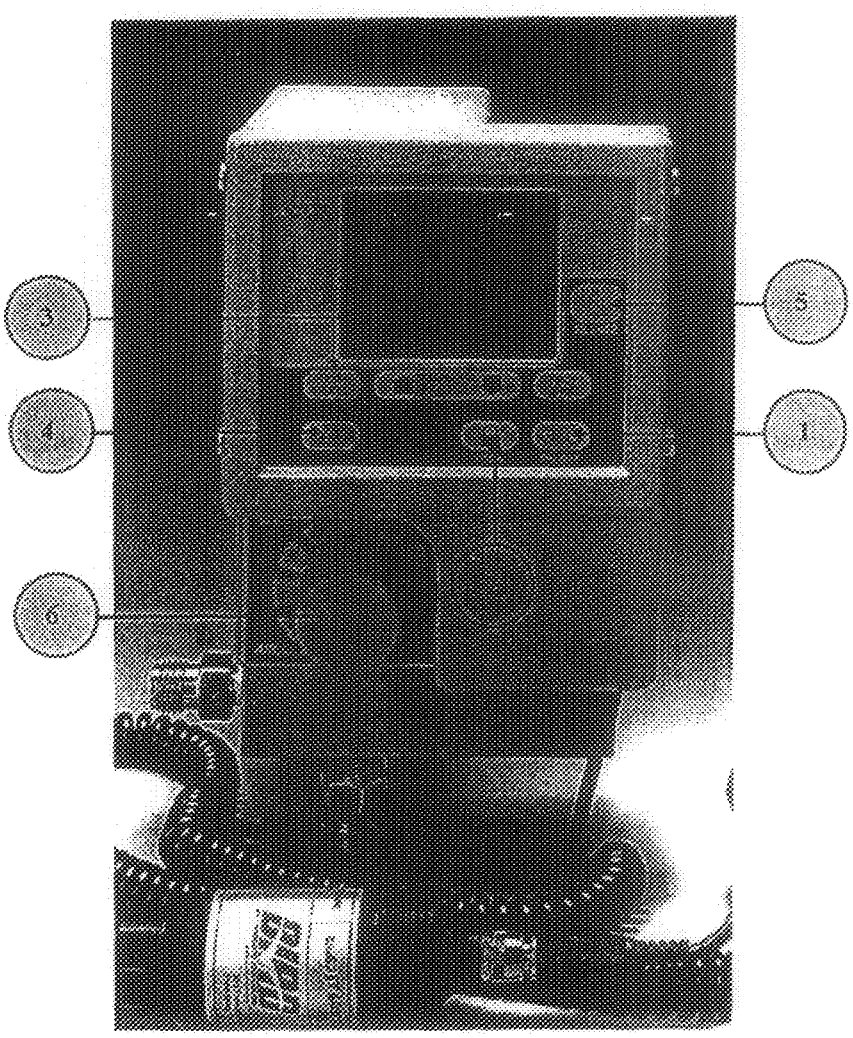
The modified **Bird Sentry™ Blender** is designed to provide a continuous air/oxygen gas mixture to infant, pediatric, and adult patients. It is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician in institutional environments where delivery and monitoring of air/oxygen mixtures is required.

## Device Description

The modified **Bird Sentry™ Blender**, is a compact air/oxygen mixing device which incorporates the use of a battery powered oxygen analyzer/monitor. The gas mixing device (blender) provides for precise mixing of medical grade air and oxygen, and the analyzer measures the selected oxygen concentrations from the blender's gas flow and samples and displays the measured concentrations on a digital display.

Front panel switches allow the operator to perform the following functions:

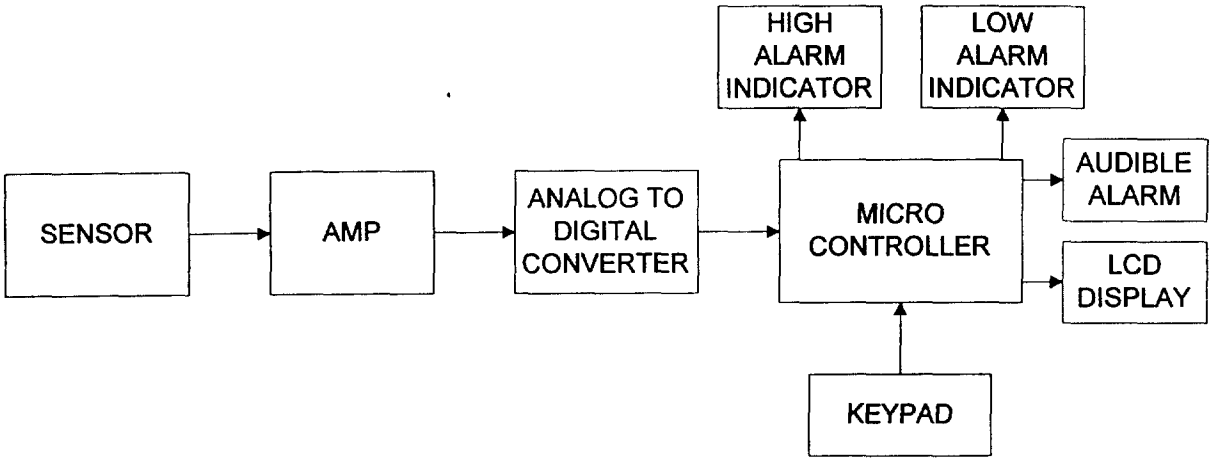
1. Turn the analyzer/display power (batteries) on or off.
2. Lock or unlock the switch controls.
3. Adjust the "low set" and "high set" alarm limits.
4. Calibrate the Sentry.
5. Silence the alarm (120 seconds maximum).
6. Select the percent oxygen concentration (from 21% to 100%).



Oxygen Analyzer

The oxygen analyzer used is the sensor and circuit board from the Ceramatec OM25 Oxygen analyzer, marketed under 510(k) K911344. This oxygen analyzer is controlled from the front panel (#1 through #5 above).

The oxygen sensor is a galvanic, partial pressure sensor that is specific to oxygen. It consists of two electrodes (a cathode and an anode), a teflon membrane and an electrolyte. Oxygen diffuses through the teflon membrane and immediately reacts at a gold cathode. Oxygen ions are transported in the unique electrolyte solution to a lead anode where oxidation occurs, generating an electrical current. Since the sensor is specific to oxygen, the current generated is proportional to the amount of oxygen present in the sample gas.




This current is tracked by the circuit board, which amplifies this signal and converts it to a digital input. The microcontroller converts this input to an equivalent oxygen concentration which is displayed on the LCD. This value is also compared to the high alarm and low alarm settings for oxygen concentration entered by the user to determine if an audible alarm should be generated.

Air/Oxygen Mixer

Two different air/oxygen mixers (blenders) are used in this device;

Model series 15625 incorporates the blender currently used in the existing Sentry (510(k) K911962). This blender can provide 2 to 100 liters per minute (LPM) flow of gas at oxygen concentrations between 21% and 100%.

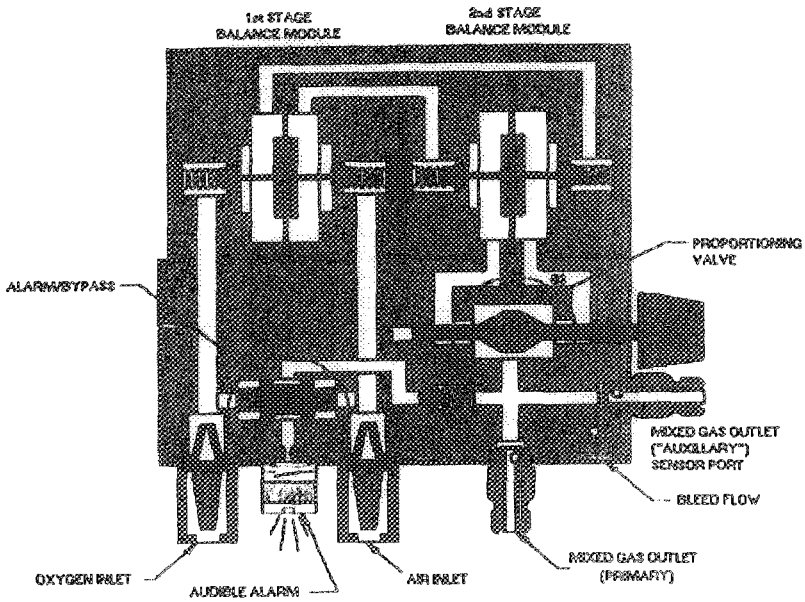
Model series 15642 incorporates a blender which can provide 0 to 30 liters per minute (LPM) flow of gas at oxygen concentrations between 21% and 100%. This blender provides accurate oxygen concentrations at very low flows and incorporates a lower bleed flow. This blender is marketed separately as the Bird Low Flow Microblender (510(k) K883038).

Both Model 15625 and Model 15642 are able to provide oxygen concentrations by means of a single control and is also capable of analyzing and monitoring these concentrations. The Bird Sentry mixes medical grade compressed air and oxygen to provide a mixed gas source from 21% to 100% oxygen.

Gas Inlet

The Bird Sentry is designed to use two (2) 50 PSIG (3.4 BAR) gas sources. The two (2) gas sources enter through the diameter-indexed air and oxygen inlet connectors located on the bottom of the Bird Sentry.

Each inlet connector incorporates a 30 micron particulate filter. Once through the filters, each gas passes through a duckbill check valve which prevents possible reverse gas flow from either the air or the oxygen supply systems.




The two (2) gases then pass through a two-stage balance regulator. The purpose of this regulator is to equalize the operating pressures of the air and oxygen gas sources.

Once these pressures have been balanced, the gases are proportioned according to the oxygen concentration selected on the oxygen concentration selection knob. The oxygen concentration knob allows the clinician to select a desired oxygen concentration from 21% to 100% 02. From this point, the mixed gas flows to the outlet port.

Gas Outlet

There are two (2) gas outlets on the Bird Sentry: one on the bottom of the unit and one on the left side. These outlet ports are fitted with an automatic shut off valve. The flow of gas from either outlet port is automatically initiated by attaching a pneumatic device (such as a flowmeter) to the outlet port. Regardless of whether or the outlet has any device connected to it, a minimal gas bleed flows from the sensor port at the right side of the Bird Sentry.

Alarm/Bypass Function

The Bird Sentry includes a pressure differential alarm which provides an audible alarm if gas source pressures differ by 20 PSI (1.3 BAR) (nominal) or more, or if there is a gas supply failure of one of the source gases. This alarm is generated by a reed alarm located in a cap on the bottom of the Bird Sentry. The primary purpose of the alarm is to audibly warn the operator of an excessive pressure drop or depletion of either source gas pressure. The alarm will also activate when there is an elevation of either source gas pressure resulting in a differential of 20 PSI (1.3 BAR)(nominal) or more. Should both gas pressures increase or decrease simultaneously, an alarm will not activate. If either source gas pressure drops, the outlet pressure will also drop as the mixed gas is always balanced to the lower gas source.

The gas bypass function operates in unison with the alarm. Once the pressure alarm is activated, the bypass function is actuated and the gas with the higher pressure flows directly to the outlet port, bypassing the mixing function of the Bird Sentry. The oxygen concentration flowing out of the Bird Sentry will be that of the gas with the higher pressure. The Bird Sentry in the pressure alarm/bypass mode will deliver oxygen (100% $O_2$) or air (21% $O_2$) until pressures have been restored to a differential of 6 PSI (.4 BAR).

If the Bird Sentry is set to deliver 21% $O_2$ and the OXYGEN source pressure is reduced enough to produce a 20 PSI (1.3 BAR) differential, the unit may not alarm because it will continue to deliver 21% concentration according to the setting. If the setting is moved slightly from 21%, the pressure differential alarm will sound. Similarly, if the Bird Sentry is set to deliver 100% $O_2$ and the AIR source pressure is reduced or lost, the unit may not alarm because it will continue to deliver 100% concentration..

## Comparison to Predicate Device

The modified Bird Sentry Blender is a compact air/oxygen mixing device which incorporates the use of a battery powered oxygen analyzer/monitor. The gas mixing device (blender) provides for precise mixing of medical grade air and oxygen, and the analyzer measures the resulting oxygen concentration from the blender's gas flow and samples and displays the measured concentrations on a digital display.

This Bird Sentry™ is not significantly different from the predicate device Bird Sentry™. Both devices utilize a combination of Microblender and oxygen analyzer to blend and monitor medical air and oxygen used in respiratory care environments. In both devices, Bird has chosen to package an existing oxygen analyzer produced by a recognized manufacturer.

The development of the modified Bird Sentry involves three changes to the currently marketed Bird Sentry:

1. Replacement of the oxygen analyzer circuit board and oxygen sensor.
2. Replacement of the User Interface.
3. Replacement of the Air/Oxygen Mixer.

First Modification: Oxygen Analyzer Circuit Board and Oxygen Sensor

The first modification involves replacement of the oxygen analyzer circuit board and oxygen sensor. This component is currently marketed as the Ceramatec OM25E Oxygen Analyzer (510(k) K911344A).

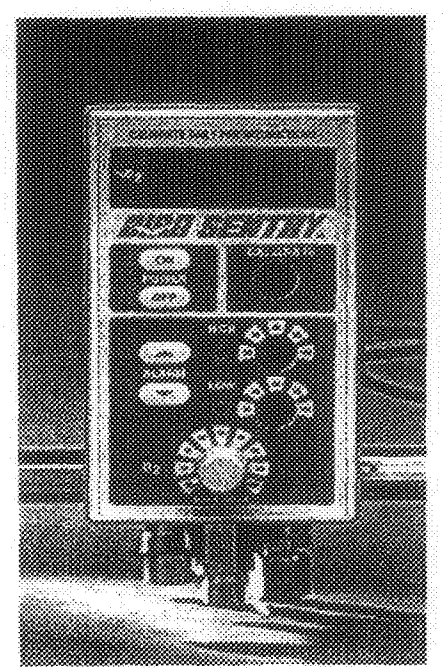
The predicate device utilized Uniox circuitry developed by Vascular Technologies, and the modified device will utilize $MAXO_2$ circuitry developed by Ceramatec Technologies. Differences in design are the result of efforts to update the analyzer circuit board to conform with the EMC directive requirements of IEC 601-1-2. The Vascular Technologies circuitry did not comply with electromagnetic interference requirements and required major redesign; the newer design of the Ceramatec circuitry was already in compliance with EMC requirements. The Ceramatec circuitry was then tested at double the current IEC requirements to ensure continued compliance.

Additional improvements with the Ceramatec design was an improved oxygen sensor which offered a longer life galvanic cell. This change improved life from 438,000 oxygen hours for the Vascular Technologies to over 750,000 oxygen hours with the Ceramatec model.

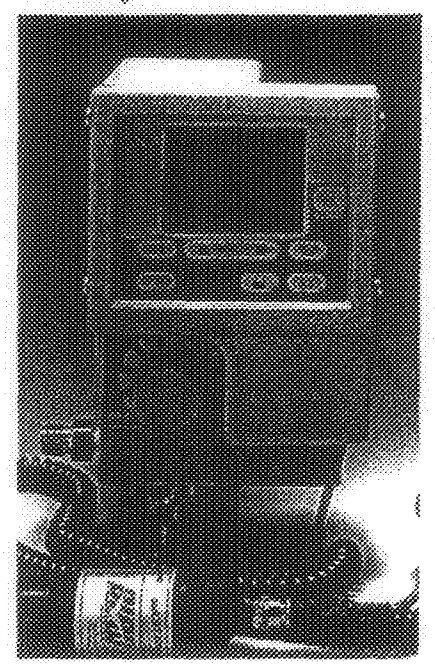
The specification for the oxygen analyzer circuit board is located in Attachment F, page F14. The oxygen sensor specification is in Attachment F, page F19.

Second Modification: Replacement of the User Interface

The second modification is the replacement of the front panel pictured at left below with the front panel pictured at right below. This replacement results in a user interface that is different from the currently marketed Sentry.



User controls remain similar; On/Off, Calibrate, alarm, and blender control functions remain. Additional controls not found on the predicate device are a lock feature which prevents inadvertent changes to settings and a two minute alarm silence which facilitates momentary changes to delivered gas mixtures.



Third Modification: Replacement of the Air/Oxygen Mixer

The second change is replacement of the 2-to-100 LPM Microblender in the current Sentry with a 0-to-30 LPM Low Flow Microblender. This blender provides accurate oxygen concentrations and flows in low-flow conditions and incorporates a smaller bleed flow, which results in less gas usage over time. The Low Flow Microblender is currently marketed as a stand-alone device (510(k) K883038).

Note that Bird Products Corporation intends to market a both a high flow version of the modified Sentry as P/N 15625 and a low flow version of the modified sentry as P/N 15642. The high flow version will incorporate the first and second modifications, and the low flow version will incorporate the first, second and third modifications.

## Summary of Performance Testing

Performance testing was conducted in the laboratory to confirm flow and pressure input and output requirements and accurate delivery and monitoring of oxygen concentrations. Production line tests were also performed. Testing to Environmental, EMI/RFI and Electrical Safety Standards were performed by certified test facilities.

The following table specifies all system level functions and shows the test results for each specification:

| Parameter | Specification | Pass / Fail |
|---|---|---|
| PHYSICAL CHARACTERISTICS | | |
| Dimensional Envelope | 7.75"HighX 4.88"Wide X 4.75"Deep | Pass |
| Weight | Approximately 4.5 lb | Pass |
| Interface | As described on page 3 above | Pass |
| GAS SUPPLY | | |
| Nominal Supply Pressure | 50 ± 10 PSI | Pass |
| Normal Operating Pressure | 30 PSI to 70 PSI | Pass |
| ENVIRONMENTAL WITHSTAND | | |
| Temperature | 59°F to 104°F | Pass |
| Humidity | 0% to 100% non-condensing | Pass |
| Media | Air and Oxygen | Pass |
| Impact | IEC 68-2-27 | Pass |
| Cleaning and Sterilization | Detergent, isopropyl alcohol | Pass |
| AIR / OXYGEN MIXER | | |
| $\%O_2$ Control | 21% -100%, stability ±1%, accuracy ±3% | Pass |
| Flow Characteristics | P/N 15625: 2-100 LPM; P/N 15625: 0-30 LPM | Pass |
| Pressure Drop | ≤ 6 PSI with 50 PSI inlets & 40 LPM flow | Pass |
| Blender Safety Features | Alarm at $\Delta P \geq 20$ PSI | Pass |

| Parameter | Specification | Pass / Fail |
|---|---|---|
| OXYGEN ANALYZER MONITOR | | |
| Monitor Display | 0-100%, resolution 0.1%, accuracy 0.2% | **Pass** |
| Monitor Controls | confirmed to function per list on page 3 | **Pass** |
| Alarm / Alert Conditions | ±1% above/below high limit/low limit | **Pass** |
| Monitor Power Source | 2 AA alkaline batteries | **Pass** |
| Oxygen Sensor | 335 to 722 µV per %O2 | **Pass** |
| OXYGEN BLENDER PERFORMANCE | 0-100%, accuracy ± 3% | **Pass** |
| MONITOR/ANALYZER PERFORMANCE | | |
| Display, Controls, Alarms | ½% increments, controls, alarms function | **Pass** |
| System Accuracy | 0-100%, accuracy ± 2%, 1% increments | **Pass** |
| EMI/RFI PERFORMANCE | IEC 601-1-2 | **Pass** |
| ELECTRICAL SAFETY | IEC 601-1 | **Pass** |
| ENVIRONMENTAL TESTING | IEC 68-2-6, 27, 34, 37 | **Pass** |

Performance testing verified that the P/N 15625 Bird Sentry Air/Oxygen Blender and the P/N 15642 Bird Sentry Low Flow Air/Oxygen Blender meet all of their performance requirements and that these devices are substantially equivalent to medical devices currently legally marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 7 1998

Mr. Neil Battiste
Bird Products Corporation
1100 Bird Center Drive
Palm Springs, CA 92262-8099

Re: K973646
Bird Sentry™ Blender Model 15625 and Model 15642
Regulatory Class: II (two)
Product Code: 73 BZR
Dated: February 6, 1998
Received: February 9, 1998

Dear Mr. Battiste:

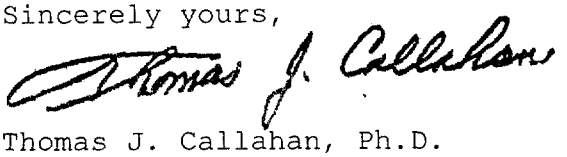
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Statement of Indications for Use
# 510(k) K973646

The modified Bird Sentry™ Blender is designed to provide a continuous air/oxygen gas mixture to infant, pediatric, and adult patients. It is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician in institutional environments where delivery and monitoring of air/oxygen mixtures is required.

PRESCRIPTION USE ✓

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____