# INFORME DE SEGURIDAD

## DIRECCIÓN DE DISPOSITIVOS MÉDICOS Y OTRAS TECNOLOGÍAS

**El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Informe de Seguridad asociado a:**

| | |
|---|---|
| **NOMBRE DEL DISPOSITIVO MÉDICO** | Capnografos NONIN |
| **NO. IDENTIFICACIÓN RISARH** | I1707-299 |
| **REFERENCIAS DEL DISPOSITIVO MEDICO** | LIFESENSE y REPSENSE |
| **REGISTRO SANITARIO** | 2011EBC-0006893 |
| **INDICACIONES Y USO ESTABLECIDOS** | Mide y visualiza la cantidad de dióxido de carbono en la respiración de pacientes y la frecuencia de respiración en pacientes adultos y pediátricos. |
| **NOMBRE DEL FABRICANTE** | Nonin Medical, Inc |
| **DESCRIPCION DEL PROBLEMA** | El fabricante ha identificado que pueden existir fugas en las trampas de agua y/o en las líneas de muestreo que impedirán realizar una correcta medición de los niveles de $CO_2$ sin disparar las alarmas correspondientes, conllevando a que se presenten posibles eventos adversos sobre los pacientes. |
| **FUENTE** | ANEXO |
| **FECHA DE NOTIFICACION** | 17 de Julio de 2017 |

**RECOMENDACIÓN:**

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

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**ANEXO**



### [High Priority ] - H0388 : Nonin—LifeSense and RespSense EtCO2 Monitors: Sampling Lines May Leak, Potentially Preventing Detection of Respiratory Depression

**Medical Device Hazard Report**

**Published:** Wednesday, July 12, 2017
**Last Updated:** Thursday, July 13, 2017

**UMDNS Terms:**

- Monitors, Physiologic, Respiration, Respiratory Gas, Exhaled Carbon Dioxide, Bedside/Intraoperative [16938]

**Product Identifier:**
EtCO 2 Monitors: (1) LifeSense, (2) RespSense *[Capital Equipment]*

**Geographic Regions:** Worldwide

**Manufacturer(s):** Nonin Medical Inc13700 1st Ave N, Plymouth, MN 55441, United States

**Suggested Distribution:** Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, OR/Surgery, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Home Care, EMS/Transport

**Problem:**

1. Loose connectors of single-use sampling lines for the above monitors can leak, diluting the monitored CO2.
2. If the monitored $CO_2$ is not diluted enough to activate a low CO2 alarm, the monitor will not detect the leak.
3. It is possible to have an undetected leak that dilutes the patient's exhaled CO2 enough to prevent alarm activation for high CO2 levels associated with respiratory depression.

**Manufacturer's Recommendations:**

1. Review operating instructions for the Nonin Medical LifeSense and RespSense monitors for proper attachment of the moisture trap and sampling lines.
2. Watch the Nonin Medical LifeSense and RespSense troubleshooting video, which may be downloaded to the facility's computer system(s) for convenience, from the firm's website .
3. Ensure all clinical personnel tasked with the operation of Nonin Medical LifeSense and RespSense monitors are properly trained in all aspects of the monitors' setup and use. A competency checklist is available on the Nonin Medical website .
4. Contact the Nonin Medical technical service department by e-mail at technicalservice@nonin.com or by telephone at (800) 356-8874 for all questions and concerns regarding the operation of the LifeSense and RespSense monitors.

**ECRI Recommendations:** *Clinicians:*

1. Confirm proper attachment of the moisture trap before attaching the sampling line by occluding the trap until an occlusion alarm is activated.
2. Confirm that all sampling line connections are secure by occluding the sampling line at the patient end until an occlusion alarm is activated.
3. Attach the Nonin Medical Capnography Troubleshooting Supplement Quick Guide to each monitor.

**Background:**

- The monitor has a pump that draws the patient's exhaled CO2 from a nasal/oral cannula sampling line or a sampling line connected to a ventilator breathing circuit.
- If the moisture trap is not securely attached, the monitor will sample room air, which will result in a NO BREATH audible and visual alarm. ECRI Institute's testing confirmed this.
- If any connectors in the sampling line leak, some air can be drawn in and will dilute the CO2 reaching the monitor. The dilution may not be enough to activate the NO BREATH alarms.
- In that case, the respiratory rate alarm may indicate respiratory depression. However, respiratory rate alone is not always sufficient to detect respiratory depression (refer to Implementing Monitoring for Opioid-Induced Respiratory Depression in Medical-Surgical and Other General Care Units ).
- An ECRI Institute member hospital reported incidents of missed high-CO2 values that were attributed to leakage of the monitor's moisture trap when there was no alarm.

**Manufacturer's Perspectives:**

- Instructions on correct placement of the moisture trap are provided in the operator's manuals, and instructions for detecting whether there is a leak are provided in the troubleshooting video and troubleshooting supplement quick guide.
- LifeSense and RespSense monitors are sold worldwide; Nonin Medical has not received a reportable incident related to this problem.

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- Air leaks can occur with any sidestream capnometer if a sampling line connector is not tight.

**References:**

- The following documents can be downloaded here :
  1. Nonin LifeSense LS1-9R Capnograph/Pulse Oximeter Operator's Manual
  2. Nonin RespSense LS1R-9R Capnograph Operator's Manual
  3. Nonin LifeSense/RespSense User Training Video
  4. Nonin LifeSense/RespSense Troubleshooting Video
  5. Nonin Capnography Troubleshooting Supplement Quick Guide

To request the doctuments, contact the Nonin Medical technical service department by e-mail at technicalservice@nonin.com or by telephone at (800) 356-8874.

**Comments:**

- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide .

**Source(s):**

- 2017 Jul 12. ECRI Institute researched member report