# El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con una Alerta asociada a:

| | |
|---|---|
| **NOMBRE DEL DISPOSITIVO MÉDICO** | Sistema de ventilación invasivo y no invasivo |
| **NO. IDENTIFICACIÓN RISARH** | A1506-258 |
| **REFERENCIAS DEL DISPOSITIVO MEDICO** | Astral 100 y 150. |
| **REGISTRO SANITARIO** | 2011DM-0007955 |
| **INDICACIONES Y USO ESTABLECIDOS** | El sistema de ventilación stellar está diseñado para proporcionar ventilación a pacientes adultos y pediátricos no dependientes (de 13 kg/30 lb o más), que respiran espontáneamente y que padecen insuficiencia respiratoria parcial o total, con o sin apnea obstructiva del sueño. El dispositivo es para uso no invasivo, o para uso invasivo con un tubo de traqueotomía sin manguito o con manguito. Para uso en el hospital o en casa. |
| **NOMBRE DEL FABRICANTE** | Resmed Inc. |
| **DESCRIPCION DEL PROBLEMA** | El fabricante afirma que los ventiladores anteriores permiten a los médicos desactivar todas las alarmas, incluyendo las que detectan la desconexión del circuito, es posible que una desconexión del circuito que se produzca y pase desapercibido pueda llegar a conducir a una ventilación insuficiente y daño al paciente, lo que puede conllevar a que se presenten potencialmente eventos adversos serios sobre el paciente. |
| **FUENTE** | Anexo 1 |
| **FECHA DE NOTIFICACION** | 22 de Junio de 2015 |

**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

# ANEXO 1



## [High Priority ] - A24411 01 : ResMed—Astral Ventilators: Inappropriate Disabling of Alarms May Cause Circuit Disconnection to Go Undetected, Potentially Leading to Insufficient Ventilation

**Medical Device Ongoing Action**

**Published:** Wednesday, June 17, 2015

**UMDNS Terms:**

- Ventilators, Portable/Home Care [17423]

**Product Identifier:**

| Astral Ventilators: | Model Nos.: |
|---|---|
| 100 | 27001 |
| 150 | 27003 |

*[Capital Equipment]*
Serial Nos.: 22141256746, 22141256747, 22141256749, 22141256750, 22141256752, 22141256753, 22141256754, 22141256755, 22141256756, 22141256757, 22141256758, 22141256759, 22141256760, 22141256761, 22141256762, 22141256763, 22141256764, 22141256765, 22141256766, 22141256767, 22141256768, 22141256770, 22141256771, 22141256773, 22141256774, 22141256776, 22141256777, 22141256778, 22141256780, 22141256781, 22141256782, 22141256783, 22141256784, 22141256785, 22141256786, 22141256787, 22141256788, 22141256789, 22141256790, 22141256792, 22141256793, 22141256795, 22141256796, 22141256797, 22141256798, 22141256800, 22141256802, 22141256803, 22141256804, 22141256805, 22141256808, 22141256809, 22141256810, 22141256811, 22141256812, 22141256813, 22141269796, 22141269797, 22141269798, 22141269800, 22141269801, 22141269802, 22141269803, 22141269804, 22141269805, 22141269806, 22141269807, 22141269808, 22141269809, 22141269810, 22141269811, 22141269812, 22141269813, 22141269814, 22141269815, 22141269817, 22141269818, 22141269819, 22141269820, 22141269821, 22141269822, 22141269823, 22141269824, 22141269825, 22141269826, 22141269827, 22141269828, 22141269829, 22141269830, 22141269831, 22141269832, 22141269833, 22141269834, 22141269835, 22141269836, 22141269837, 22141269838, 22141269841, 22141269842, 22141269843, 22141269844, 22141269846, 22141269847, 22141269848, 22141269849, 22141269850, 22141269851, 22141269852, 22141269853, 22141269856, 22141269858, 22141269859, 22141269860, 22141269861, 22141269862, 22141269865, 22141269866, 22141269867, 22141269868, 22141269869, 22141269870, 22141269872, 22141269873, 22141269874, 22141269875, 22141269877, 22141269878, 22141269879, 22141269881, 22141269882, 22141269883, 22141269887, 22141269888, 22141269889, 22141269890, 22141269891, 22141269893, 22141269894, 22141269895, 22141269897, 22141269898, 22141269899, 22141269900, 22141269902, 22141269904, 22141269906, 22141269908, 22141269911, 22141269915, 22141297617, 22141297619, 22141297620, 22141297621, 22141297623, 22141297629, 22141297633, 22141297635, 22141297637, 22141297638, 22141297639, 22141297641, 22141297643, 22141297646, 22141297647, 22141297650, 22141297651, 22141297652, 22141297653, 22141297654, 22141297655, 22141297658, 22141297659, 22141297660, 22141297663, 22141297666, 22141297667, 22141297678, 22141297680, 22141297682, 22141297685, 22141297686, 22141297687, 22141297688, 22141297690, 22141297699, 22141297700, 22141297703, 22141297706, 22141308801, 22141308803, 22141308804, 22141308805, 22141308806, 22141308807, 22141308808, 22141308809, 22141308810, 22141308811, 22141308812, 22141308813, 22141308814, 22141308815, 22141308817, 22141308818, 22141308819, 22141308820, 22141308821, 22141308822, 22141308823, 22141308824, 22141308825, 22141308826, 22141308828, 22141308829, 22141308830, 22141308831, 22141308832, 22141308833, 22141308834, 22141308835, 22141308836, 22141308837, 22141308838, 22141308839, 22141308840, 22141308841, 22141308842, 22141308843, 22141308844, 22141308845, 22141308846, 22141308847, 22141308848, 22141308850, 22141308851, 22141308853, 22141308854, 22141308855, 22141308857, 22141308860, 22141308861, 22141308862, 22141308863, 22141308864, 22141308867, 22141308869, 22141308870, 22141308871, 22141308872, 22141308873, 22141308874, 22141308876, 22141308877, 22141308878, 22141308879, 22141308880, 22141308882, 22141308885, 22141308886, 22141308889, 22141311836, 22141311837, 22141311838, 22141311839, 22141311840, 22141311841, 22141311842, 22141311843, 22141311844, 22141311845, 22141311846, 22141311847, 22141311848, 22141311849, 22141311850, 22141311851, 22141311852, 22141311853, 22141311854, 22141311855, 22141311857, 22141311858, 22141311859, 22141311862, 22141311863, 22141311864, 22141311865, 22141311866, 22141311867, 22141311868, 22141311869, 22141311870, 22141311871, 22141311872, 22141311873, 22141311874, 22141311875, 22141311876, 22141311877, 22141311878, 22141311881, 22141311882, 22141311884, 22141311885, 22141311886, 22141311887, 22141311888, 22141311890, 22141311891, 22141311892, 22141311893, 22141311894, 22141311895, 22141311896, 22141311897, 22141311898, 22141311900, 22141311902, 22141311903, 22141311904, 22141311906, 22141311907, 22141311908, 22141311909, 22141311910, 22141311912, 22141311913, 22141311914, 22141322489, 22141322490, 22141322491, 22141322492, 22141322493, 22141322494, 22141322495, 22141322496, 22141322497, 22141322498, 22141322501, 22141322502, 22141322503, 22141322505, 22141322506, 22141322507, 22141322508, 22141322509, 22141322510, 22141322511, 22141322512, 22141322514, 22141322515, 22141322516, 22141322517, 22141322518, 22141322519, 22141322520, 22141322521, 22141322522, 22141322524, 22141322525, 22141322526, 22141322527, 22141322528, 22141322529, 22141322530, 22141322531, 22141322532, 22141322533, 22141322534, 22141322535, 22141322536, 22141322538, 22141322539, 22141322540, 22141322541, 22141322543, 22141322544, 22141322545, 22141322546, 22141322547, 22141322552, 22141322553, 22141322562, 22141322563, 22141322564, 22141322571, 22141322573, 22141322575, 22141322579, 22141322580, 22141322581, 22141322582, 22141322593, 22141322595, 22141322597, 22141322598, 22141322602, 22141322603, 22141322610, 22141322611, 22141322612, 22141322613, 22141322614, 22141322616, 22141322618, 22141322620, 22141322621, 22141322622, 22141322623, 22141322624, 22141322627, 22141322628, 22141322632, 22141322633, 22141322634, 22141322636, 22141322638, 22141322639, 22141322642, 22141322643, 22141322644, 22141322645, 22141322647, 22141322648, 22141322650, 22141322651, 22141322658, 22141322659, 22141322660, 22141322661, 22141322662, 22141322663, 22141322665, 22141322666, 22141322668, 22141336182, 22141336196, 22141336204, 22141336216, 22141336223, 22141336225, 22141336226, 22141336234, 22141336235, 22141336242, 22141336245, 22141336247, 22141336257, 22141336258, 22141336261, 22141336262, 22141336263, 22141336264, 22141336266, 22141336267, 22141336268, 22141336276, 22141336277, 22141336279, 22141336284, 22141336285, 22141336306, 22141336328, 22141336340, 22141336345, 22141336346, 22141336347, 22141336355, 22141336357, 22141336362, 22141336364, 22141336365, 22141336367, 22141336369, 22141336371, 22141336372, 22141336374, 22141336378, 22141336379, 22141336385, 22141336390, 22141360503, 22141360512, 22141360516, 22141360518, 22141360527, 22141360531, 22141360534, 22141360535, 22141360536, 22141360537, 22141360538, 22141360539, 22141360540, 22141360541, 22141360542, 22141360544, 22141381289, 22141381291, 22141381293, 22141381295, 22141381296, 22141381297, 22141381298, 22141381299, 22141381300, 22141381301, 22141381302, 22141381304, 22141381305, 22141381306, 22141381307, 22141381308, 22141381309, 22141381310, 22141381311, 22141381312, 22141381313, 22141381314, 22141381315, 22141381316, 22141381317, 22141381318, 22141381319, 22141381320, 22141381321, 22141381322, 22141381323, 22141381324, 22141381325, 22141381326, 22141381327, 22141381328, 22141381329, 22141381330, 22141381331, 22141381332, 22141381333, 22141381335, 22141381336, 22141381337, 22141381338, 22141381339, 22141381340, 22141381341, 22141381342, 22141381343, 22141381344, 22141381345, 22141381346, 22141381347, 22141381348, 22141381356, 22141381363, 22141381367, 22141381371, 22141381372, 22141381378, 22141381380, 22141381381, 22141381385, 22141381386, 22141381387, 22141381388, 22141381392, 22141381424, 22141381457, 22141381463, 22141381465, 22141381468, 22141381469, 22141381474, 22141381487, 22141381493, 22141381494, 22141381503, 22141381508, 22141393595, 22141393596, 22141393597, 22141393599, 22141393600, 22141393602, 22141393603, 22141393604, 22141393606, 22141393607, 22141393608, 22141393609, 22141393610, 22141393611, 22141393612, 22141393613, 22141393614, 22141393615, 22141393616, 22141393617, 22141393618, 22141393619, 22141393621, 22141393622, 22141393623, 22141393625, 22141393627, 22141393628, 22141393629, 22141393630, 22141393631, 22141393632,

22141393633, 22141393634, 22141393635, 22141393636, 22141393637, 22141393638, 22141393639, 22141393641, 22141393642, 22141393643, 22141393644, 22141393646, 22141393648, 22141393649, 22141393650, 22141393652, 22141393653, 22141393654, 22141393725, 22141393726, 22141393728, 22141393731, 22141393732, 22141393733, 22141393734, 22141393735, 22141420614, 22141420615, 22141420617, 22141420620, 22141420622, 22141420624, 22141420625, 22141420627, 22141420628, 22141420629, 22141420630, 22141420631, 22141420634, 22141420659, 22141420671, 22141420679, 22141420681, 22141420682, 22141420683, 22141420684, 22141420685, 22141420686, 22141420687, 22141420688, 22141420689, 22141420690, 22141420691, 22141420693, 22141420696, 22141420698, 22141420699, 22141420701, 22141420702, 22141420705, 22141420706, 22141420707, 22141420708, 22141420709, 22141420710, 22141420713, 22141420714, 22141420717, 22141420719, 22141420720, 22141420722, 22141420723, 22141420731, 22141420734, 22141420735, 22141435726, 22141435732, 22141435736, 22141435745, 22141435751, 22141435754, 22141435767, 22141435770, 22141435773, 22141435775, 22141442608, 22141442609, 22141442619, 22141442621, 22141442623, 22141442626, 22141442629, 22141442630, 22141442631, 22141442636, 22141442637, 22141442641, 22141442642, 22141446568, 22141446569, 22141446570, 22141446571, 22141446572, 22141446574, 22141446577, 22141446578, 22141446580, 22141446581, 22141446582, 22141446584, 22141446585, 22141446586, 22141446588, 22141446589, 22141446590, 22141446591, 22141446592, 22141446594, 22141446595, 22141446597, 22141446598, 22141446599, 22141446600, 22141446602, 22141446603, 22141446607, 22141446609, 22141446611, 22141446613, 22141446614, 22141446615, 22141446619, 22141446621, 22141446622, 22141446623, 22141446624, 22141446625, 22141446626, 22141446627, 22141446652, 22141458004, 22141458005, 22141458006, 22141458008, 22141458010, 22141458011, 22141458012, 22141458015, 22141458018, 22141458020, 22141458023, 22141620631, 22141620632, 22141620633, 22141620634, 22141620635, 22141620636, 22141620637, 22141620638, 22141620639, 22141620640, 22141620641, 22141620642, 22141620643, 22141620644, 22141620645, 22141620646, 22141620647, 22141620648, 22141620649, 22141620650, 22141620651, 22141620652, 22141620653, 22141620654, 22141620655, 22141620657, 22141620658, 22141620659, 22141620660, 22141620661, 22141620662, 22141620663, 22141620665, 22141620666, 22141620667, 22141620668, 22141620669, 22141620671, 22141620672, 22141620673, 22141620674, 22141620676, 22141620678, 22141620679, 22141620681, 22141620682, 22141620683, 22141620684, 22141620685, 22141620686, 22141620688, 22141644689, 22141644691, 22141644692, 22141644693, 22141644695, 22141644697, 22141644698, 22141644699, 22141644700, 22141644701, 22141644703, 22141644704, 22141644706, 22141644708, 22141644709, 22141644710, 22141644711, 22141644713, 22141644714, 22141644715, 22141644716, 22141644762, 22141644764, 22141644765, 22141644766, 22141644767, 22141644768, 22141644769, 22141644770, 22141644771, 22141644772, 22141644773, 22141644775, 22141647447, 22141647448, 22141647449, 22141647450, 22141647451, 22141647452, 22141647453, 22141647454, 22141647455, 22141647456, 22141647457, 22141647458, 22141647459, 22141647460, 22141647461, 22141647462, 22141647463, 22141647464, 22141647465, 22141647466, 22141647467, 22141647468, 22141647469, 22141647470, 22141647471, 22141647472, 22141647473, 22141647474, 22141647475, 22141647476, 22141647477, 22141647478, 22141647479, 22141647481, 22141647482, 22141647483, 22141647484, 22141668168, 22141668169, 22141668174, 22141668177, 22141668178, 22141668179, 22141668180, 22141668182, 22141679576, 22141679577, 22141679578, 22141679579, 22141679580, 22141679581, 22141679582, 22141679583, 22141679585, 22141679586, 22141679587, 22141679588, 22141679589, 22141679590, 22141679591, 22141679592, 22141679593, 22141679594, 22141679595, 22141679596, 22141679598, 22141679599, 22141679600, 22141679602, 22141679604, 22141679605, 22141679606, 22141679607, 22141679608, 22141679609, 22141679610, 22141679611, 22141679612, 22141679613, 22141679614, 22151008930, 22151008931, 22151008932, 22151008934, 22151008935, 22151008937, 22151008938, 22151008939, 22151008940, 22151008941, 22151008942, 22151008943, 22151008944, 22151008945, 22151008947, 22151008948, 22151008949, 22151008950, 22151008951, 22151008953, 22151008954, 22151008955, 22151008956, 22151008957, 22151008958, 22151009030, 22151009031, 22151009033, 22151009034, 22151009035, 22151009036, 22151009037, 22151009039, 22151009040, 22151009041, 22151009045, 22151009046, 22151009047, 22151009048, 22151009049, 22151009050, 22151009051, 22151009052, 22151009053, 22151009055, 22151009056, 22151009057, 22151009058, 22151009059, 22151009060, 22151009061, 22151009062, 22151009063, 22151009065, 22151009066, 22151009067, 22151009068, 22151009069, 22151022554, 22151022555, 22151022556, 22151022557, 22151022558, 22151022560, 22151022561, 22151022563, 22151022564, 22151022565, 22151022566, 22151022567, 22151022568, 22151022569, 22151022570, 22151022573, 22151022574, 22151022576, 22151022578, 22151022579, 22151022581, 22151022583, 22151022614, 22151022615, 22151022617, 22151022618, 22151022619, 22151022620, 22151022621, 22151022623, 22151022624, 22151022625, 22151022626, 22151022627, 22151022629, 22151022630, 22151022632, 22151022633, 22151022635, 22151022636, 22151022637, 22151022638, 22151022639, 22151022641, 22151022643, 22151022644, 22151022645, 22151022647, 22151022650, 22151022652, 22151022653, 22151031712, 22151031713, 22151031714, 22151031716, 22151031718, 22151031721, 22151031722, 22151031723, 22151031725, 22151031726, 22151031727, 22151031728, 22151031729, 22151031731, 22151031732, 22151031733, 22151031734, 22151031735, 22151031736, 22151031737, 22151031738, 22151031740, 22151031743, 22151031746, 22151031747, 22151031748, 22151031749, 22151073623, 22151073624, 22151073625, 22151073626, 22151073627, 22151073628, 22151073629, 22151073631, 22151073632, 22151073633, 22151073638, 22151073639, 22151073640, 22151073641, 22151134248, 22151134249, 22151134251, 22151134254, 22151134256, 22151134257, 22151134258, 22151134259, 22151134260, 22151134261, 22151134262, 22151134263, 22151134265, 22151134266, 22151134267, 22151134268, 22151134269, 22151134271, 22151134272, 22151134273, 22151134274, 22151134277, 22151134279, 22151134280, 22151134283, 22151134284, 22151134285, 22151134288, 22151134289, 22151134291, 22151134293, 22151134294, 22151134295, 22151134296, 22151134297, 22151134298, 22151134299, 22151134300, 22151134301, 22151134302, 22151134303, 22151134304, 22151134305, 22151135048, 22151135049, 22151135050, 22151135056, 22151135057, 22151135058, 22151135060, 22151135061, 22151135063, 22151135064, 22151135065, 22151135067, 22151135069, 22151135070, 22151135071, 22151135072, 22151135073, 22151135074, 22151135076, 22151135077, 22151135078, 22151135079, 22151135080, 22151135081, 22151135082, 22151135083, 22151135084, 22151135086, 22151135088, 22151135089, 22151135090, 22151135091, 22151135093, 22151135094, 22151135095, 22151135096, 22151135097, 22151135100, 22151135101, 22151135102, 22151150407, 22151161870, 22151161871, 22151161872, 22151161873, 22151161874, 22151161875, 22151161876, 22151161877, 22151161878, 22151161880, 22151161881, 22151161882, 22151161883, 22151161885, 22151161886, 22151161887, 22151161888, 22151161889, 22151161890, 22151161891, 22151161893, 22151161895, 22151161898, 22151161899, 22151161900, 22151162664, 22151162665, 22151162666, 22151162668, 22151162669, 22151162670, 22151162672, 22151162673, 22151162674, 22151162677, 22151162680, 22151162682, 22151162683, 22151162684, 22151162685, 22151162687, 22151163252, 22151163253, 22151163254, 22151163255, 22151163256, 22151163257, 22151163260, 22151163261, 22151163262, 22151163296, 22151163297, 22151163298, 22151163299, 22151163300, 22151163301, 22151163302, 22151163303, 22151163304, 22151163305, 22151163306, 22151163308, 22151163312, 22151163313, 22151163315, 22151163317, 22151163319, 22151163320, 22151163321, 22151163322, 22151163323, 22151163324, 22151163325, 22151163326, 22151163327, 22151163328, 22151163330, 22151163331, 22151163332, 22151163333, 22151163334, 22151163335, 22151163336, 22151163337, 22151163338, 22151163339, 22151163340, 22151163341, 22151163342, 22151165344, 22151165345, 22151165348, 22151165349, 22151165352, 22151165353, 22151165356, 22151165357, 22151165358, 22151165359, 22151165360, 22151165361, 22151165364, 22151165365, 22151165366, 22151165367, 22151165368, 22151165369, 22151165370, 22151165371, 22151165373, 22151165374, 22151165376, 22151165377, 22151165378, 22151165379, 22151165380, 22151165381, 22151165382, 22151165383, 22151165384, 22151165385, 22151165387, 22151165389, 22151165390, 22151165391, 22151165393, 22151165394, 22151165395, 22151165396, 22151165399, 22151165400, 22151165401, 22151165402, 22151165403, 22151165404, 22151165406, 22151165407, 22151165408, 22151165409, 22151165411, 22151165412, 22151165413, 22151165414, 22151165415, 22151165416, 22151165417, 22151165418, 22151165420, 22151165421, 22151165422, 22151165423, 22151165424, 22151165425, 22151165426, 22151165427, 22151165428, 22151165429, 22151165430, 22151165431, 22151165433, 22151165434, 22151165435, 22151165438, 22151165440, 22151165441, 22151165442, 22151165443, 22151165444, 22151165445, 22151165446, 22151165447, 22151165448, 22151165449, 22151165451, 22151165452, 22151165453, 22151165455, 22151165456, 22151165457, 22151165458, 22151165461, 22151165463, 22151165464, 22151165467, 22151165469, 22151165470, 22151165471, 22151165472, 22151165473, 22151165474, 22151165476, 22151165477, 22151165478, 22151165479, 22151165480, 22151165482, 22151165483, 22151165484, 22151165486, 22151165487, 22151165490, 22151165491, 22151165492, 22151165493, 22151165494, 22151165495, 22151165496, 22151165497, 22151165498, 22151165499, 22151165501, 22151165502, 22151165503, 22151165504, 22151165505, 22151165506, 22151165507, 22151165508, 22151165510, 22151165511, 22151165512, 22151165515, 22151165516, 22151165518, 22151165519, 22151165520, 22151165521, 22151165523, 22151165524, 22151165525, 22151165526, 22151165527, 22151165528, 22151165529, 22151165530, 22151165533, 22151165534, 22151165536, 22151165538, 22151165539, 22151224469, 22151224470, 22151224471, 22151224472, 22151224473, 22151224474, 22151224475, 22151224476, 22151224477, 22151224478, 22151224479, 22151224480, 22151224481, 22151224482, 22151224483, 22151224484, 22151224485, 22151224486, 22151224487, 22151224488, 22151224489,

22151224490, 22151224491, 22151224492, 22151224493, 22151224494, 22151224495, 22151224496, 22151224497, 22151224498, 22151224499, 22151224500, 22151224501, 22151224502, 22151224503, 22151224504, 22151224505, 22151224506, 22151224507, 22151224508, 22151224509, 22151224510, 22151224511, 22151224512, 22151224513, 22151224514, 22151224515, 22151224516, 22151224517, 22151224518, 22151237186, 22151237187, 22151237189, 22151237190, 22151237191, 22151237192, 22151237193, 22151237194, 22151237195, 22151237196, 22151237197, 22151237198, 22151237199, 22151237200, 22151237201, 22151237202, 22151237203, 22151237204, 22151237205, 22151237208, 22151237209, 22151237210, 22151237211, 22151237212, 22151237214, 22151237215, 22151237216, 22151237217, 22151237218, 22151237219, 22151237220, 22151237221, 22151237222, 22151237223, 22151237224, 22151237225, 22151237226, 22151237227, 22151237228, 22151237229, 22151237230, 22151237231, 22151237232, 22151237233, 22151237234, 22151237235, 22151237236, 22151237237, 22151237238, 22151237239, 22151237240, 22151249705, 22151249706, 22151249707, 22151249710, 22151249711, 22151249713, 22151249714, 22151249715, 22151249716, 22151249717, 22151249718, 22151249719, 22151249720, 22151249721, 22151249722, 22151249723, 22151249724, 22151249725, 22151249726, 22151249727, 22151249728, 22151298921, 22151298922, 22151298924, 22151298925, 22151298926, 22151298927, 22151298930, 22151298937, 22151298947, 22151298948, 22151298950, 22151298954, 22151310712, 22151310713, 22151311311, 22151311312, 22151311313, 22151311314, 22151311315, 22151311316, 22151311317, 22151311318, 22151311319, 22151311320, 22151311321, 22151311322, 22151311323, 22151311324, 22151311326, 22151311327, 22151311328, 22151311330, 22151311331, 22151311332, 22151311333, 22151311334, 22151311335, 22151311336, 22151311337, 22151311339, 22151311341, 22151311342, 22151311343, 22151311344, 22151311345, 22151311346, 22151311347, 22151311348, 22151311349, 22151311351, 22151311353, 22151311354, 22151311355, 22151311357, 22151311359, 22151311360, 22151311361, 22151311362, 22151311363, 22151311365, 22151311366, 22151311367, 22151311368, 22151311370
1,519 units distributed

**Geographic Regions:** (Impact in additional regions has not been identified or ruled out at the time of this posting), Canada, Latin America, U.S.

**Manufacturer(s):** ResMed Ltd 1 Elizabeth Macarthur Drive, Bella Vista 2153, Australia

**Suggested Distribution:** Anesthesia, Clinical/Biomedical Engineering, Critical Care, Nursing, OR/Surgery, Pediatrics, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Information Technology, Home Care, Sleep Laboratory

**Summary:**
This Alert provides information based on manufacturer correspondence and FDA Center for Devices and Radiological Health (CDRH) source material for customers in Canada, Latin America, and the U.S. regarding the above ventilators. For information from the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) for customers in Europe, see Alert Accession No. A24411 . The manufacturer states that it issued customer notification letters to remind clinicians to appropriately configure alarms for ventilator dependent patients. Field safety notifications were issued globally in accordance with the appropriate regional use case and in alignment with regional regulatory agency requirements.

**Problem:**
ResMed states that because the above ventilators allow clinicians to disable all alarms, including those that detect circuit disconnection, it is possible for a circuit disconnection to occur and go undetected, potentially leading to insufficient ventilation and harm to the patient. ResMed also states that it has received 1 report involving circuit disconnection of a patient in the hospital in which the device alarms did not operate because all alarms had been disengaged by the physician. ResMed further states that the risk posed by this problem is remote. FDA's CDRH states that the manufacturer notified customers by Customer Notification letter dated May 5, 2015.

**Action Needed:**
Identify any affected product in your inventory. If you have affected product, verify that you have received the letter from ResMed. Notify all relevant personnel at your facility of the information in the letter. Ensure that alarms are appropriately set up for ventilator-dependent patients. ResMed states that because no single alarm can reliably detect a disconnection event, the Astral ventilator is provided with a range of alarms that can be configured to enable detection of disconnection, including low pressure and volume, apnea, leak, and SpO2 alarms. Advice on appropriate configuration of these alarms is available in the Clinical Guide section titled "Detecting Circuit Disconnection and De-Cannulation." ResMed states that it will release an updated version of Astral software in which the circuit disconnection alarm for all ventilation modes for dependent patients cannot be deactivated and that a dedicated mouthpiece mode will be developed that will allow the disconnection alarm to be deactivated only in this mode.

**For Further Information:**
Larissa D'Andrea, ResMed
Tel.: (858) 836-6837
E-mail: larissa.d'andrea@resmed.com
Website: Click here

**References:**


- United States. Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Astral 100 & Astral 150 [online]. 2015 Jun 10 [cited 2015 Jun 12]. Available from Internet: Click here .


**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):**

- 2015 Jun 12. FDA CDRH Database. Class II. Z-1750-2015 Download
- 2015 Jun 12. MHRA FSN. 2015/005/013/291/003 Download
- 2015 Jun 12. MHRA FSN. May 4, 2015, ResMed letter posted by MHRA: FSN1504001 Download