



DEVICE DETAILS

NAME OF DEVICE	LIFESENSE II CAPNOMETER/PULSE OXIMETER (MODEL LS1) AND RESPESENSE II CAPNOMETER (MODEL LS1R)
ESTABLISHMENT NAME	ACUCARE SYSTEMS (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC8480220-43563
BRAND NAME	NONIN
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>The LS1 Family of capnography monitors include LifeSense II (Model LS1) and RespSense II (Model LS1R). The LifeSense II monitor includes Nonin OEM III Core SpO2 PureSAT technology platform, as the pulse oximetry signal processor. Both monitors are small, tabletop devices that simultaneously measure, display, monitor, and record the applicable parameters. The LifeSense II Capnography/Pulse Oximeter Monitor (Model LS1) simultaneously measures, display, monitors and records functional oxygen saturation of arterial hemoglobin (SpO2), end tidal carbon dioxide (EtCO2), respiration rate and pulse rate of well or poorly perfused adult, pediatric, and infant patients. The monitor displays real-time functional oxygen saturation of arterial hemoglobin (SpO2) and end tidal carbon dioxide (EtCO2) trend lines and numeric data. It is a battery-backed, mains-powered device equipped with audio and visual alarm indicators. The RespSense II Capnography Monitor (Model LS1R) simultaneously measures, displays, monitors and records functional end tidal carbon dioxide (EtCOs) and respiration rate of adult, pediatric, and infant patients. The monitor displays real-time end tidal carbon dioxide (EtCO2) trend lines and numeric data. It is a battery-backed, mains-powered device equipped with audio and visual alarm indicators.</p>
DEVICE INTENDED PURPOSE	<p>The LifeSense II, Model LS1, capnography/pulse oximetry monitor is indicated for use in simultaneously measuring, displaying, monitoring and recording functional oxygen saturation of arterial hemoglobin (SpO2), end tidal carbon dioxide (EtCO2), respiration, and pulse rate of well or poorly perfused adult, pediatric and infant patients. The RespSense II, Model LS1R, capnography monitor is indicated for use in simultaneously measuring, displaying, monitoring and recording end tidal carbon dioxide (EtCO2) and respiration rate of adult, pediatric, and infant patients. Both models are intended for use in environments where patients require continuous, non-invasive monitoring of these parameters by a healthcare professional, including hospitals, long-term care, medical facilities, sleep laboratories, home healthcare, subacute environments, and Emergency Medical Services (EMS), including patient transport.</p>
VALIDITY DATE OF REGISTRATION	01/06/2020 - 31/05/2025

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	RespSense II Model LS1R Capnography Monitor	LS1R
2	LifeSense II Model LS1 Capnography /Pulse Oximeter Monitor	LS1
3	Power Supply	GPP18-006
4	PSG DAC	PSG DAC
5	Capno RTC (Real Time Cable)	Capno RTC
6	USB Flash Drive	10629-001
7	Capno Report Converter	Capno SW
8	Monitor Mounting Bracket	Sens Mount
9	Adjustable Mounting Clamp	Sense PMC
10	Carrying Case	Capno CC
11	Nasal CO2 Cannula, Infant	4200-7-25
12	Nasal CO2 Cannula, Pediatric	4100-7-25
13	Nasal CO2 Cannula, Adult	4000-7-25
14	CO2 Sample Line	4500-7-25
15	Oxygen Delivery CO2 Nasal Cannula, Infant	4700-7-7-25
16	Oxygen Delivery CO2 Nasal Cannula, Pediatric	4703-7-7-25
17	Oxygen Delivery CO2 Nasal Cannula, Adult	4707-7-7-25
18	Straight T-Connector	Sens TC
19	Nafion Tubing	Sens Nafion
20	Moisture Trap with Filter	Sens TF-1-10
21	Filters	8517-001, 8518-001
22	Finger Clip Sensor, Adult	8000AA
23	Finger Clip Sensor, Adult	8000AA-2
24	Finger Clip Sensor, Adult	8000AA-3
25	Finger Clip Sensor, Pediatric	8000AP
26	Finger Clip Sensor, Pediatric	8000AP-3M



NO	NAME OF DEVICE	IDENTIFIER
27	Soft Sensor, Small	8000SS
28	Soft Sensor, Small	8000SS(3M)
29	Soft Sensor, Medium	8000SM
30	Soft Sensor, Medium	8000SM (3M)
31	Soft Sensor, Large	8000SL
32	Soft Sensor, Large	8000SL (3M)
33	Reflectance Sensor	8000R
34	Reflectance Sensor Holder	8000H
35	Flex Sensor, Adult	8000J
36	Flex Sensor, Adult	8000J-3
37	Flex Sensor, Infant	8008J
38	Adult FlexiWrap	8000JFW
39	Infant FlexiWrap	8008JKW
40	6000C Cloth Series, Single-Use	6000CA
41	6000C Cloth Series sensor	6000CP
42	6000C Cloth Series sensor	6000CI
43	7000 Flexi-Form III Series sensor	7000A
44	7000 Flexi-Form III Series sensor	7000P
45	7000 Flexi-Form III Series sensor	7000I
46	Ear Clip Pulse Oximeter Sensor	8000Q2
47	Durafoam Series Sensor	6500MA
48	Durafoam Series Sensor	6500SA
49	RespSense II Model LS1R Capnometer	LS1R
50	LifeSense II Model LS1 Capnometer /Pulse Oximeter Monitor	LS1
51	Power Supply	GPP18-006
52	PSG DAC	PSG DAC



NO	NAME OF DEVICE	IDENTIFIER
53	Capno RTC (Real Time Cable)	Capno RTC
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66	Straight T-Connector	Sens TC
67	Nafion Tubing	Sens Nafion
68	Moisture Trap with Filter	Sens TF-1-10
69	Filters	8517-001, 8518-001
70	Finger Clip Sensor, Adult	8000AA
71	Finger Clip Sensor, Adult	8000AA-2
72	Finger Clip Sensor, Adult	8000AA-3
73	Finger Clip Sensor, Pediatric	8000AP
74	Finger Clip Sensor, Pediatric	8000AP-3M
75	Soft Sensor, Small	8000SS
76	Soft Sensor, Small	8000SS(3M)
77	Soft Sensor, Medium	8000SM
78	Soft Sensor, Medium	8000SM (3M)



NO	NAME OF DEVICE	IDENTIFIER
79	Soft Sensor, Large	8000SL
80	Soft Sensor, Large	8000SL (3M)
81	Reflectance Sensor	8000R
82	Reflectance Sensor Holder	8000H
83	Flex Sensor, Adult	8000J
84	Flex Sensor, Adult	8000J-3
85	Flex Sensor, Infant	8008J
86	Adult FlexiWrap	8000JFW
87	Infant FlexiWrap	8008JKW
88	6000C Cloth Series, Single-Use	6000CA
89	6000C Cloth Series sensor	6000CP
90	6000C Cloth Series sensor	6000CI
91	7000 Flexi-Form III Series sensor	7000A
92	7000 Flexi-Form III Series sensor	7000P
93	7000 Flexi-Form III Series sensor	7000I
94	Ear Clip Pulse Oximeter Sensor	8000Q2
95	Durafoam Series Sensor	6500MA
96	Durafoam Series Sensor	6500SA

