



DEVICE DETAILS

NAME OF DEVICE	RAINBOW PULSE OXIMETER
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC430321043618
BRAND NAME	MASIMO
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	THE RADICAL-7 PULSE CO-OXIMETER IS A NONINVASIVE MONITOR THAT MEASURES ARTERIAL OXYGEN SATURATION (SPO2), PULSE RATE (PR), AND PERFUSION INDEX (PI), ALONG WITH OPTIONAL MEASUREMENTS OF HEMOGLOBIN (SPHB)*, CARBOXYHEMOGLOBIN (SPCO)*, TOTAL OXYGEN CONTENT (SPOC), METHEMOGLOBIN (SPMET)*, PLETH VARIABILITY INDEX (PVI), OXYGEN RESERVE INDEX (ORI)*, ACOUSTIC RESPIRATION RATE (RRA)*, AND PLETH RESPIRATION RATE (RRP)*.
DEVICE INTENDED PURPOSE	THE RADICAL-7 PULSE CO-OXIMETER CAN BE USED AS EITHER A HANDHELD OR A STANDALONE MONITOR. THE RADICAL-7 PULSE CO-OXIMETER FEATURES A TOUCHSCREEN THAT CONTINUOUSLY DISPLAYS NUMERIC VALUES FOR ARTERIAL OXYGEN SATURATION (SPO2), PULSE RATE (PR), AND PERFUSION INDEX (PI), ALONG WITH OPTIONAL MEASUREMENTS OF HEMOGLOBIN (SPHB)*, CARBOXYHEMOGLOBIN (SPCO)*, TOTAL OXYGEN CONTENT (SPOC), METHEMOGLOBIN (SPMET)*, PLETH VARIABILITY INDEX (PVI), OXYGEN RESERVE INDEX (ORI)*, ACOUSTIC RESPIRATION RATE (RRA)*, AND PLETH RESPIRATION RATE (RRP)*.
VALIDITY DATE OF REGISTRATION	02/08/2023 - 01/08/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Rad-97	9738
2	Rad-97 NiBP	9797
3	Rad-97 with Nomoline Capnography	9799
4	Radical-7	9500
5	Rad-67	9794
6	Pronto Spot Check Pulse CO-Oximeter	9167
7	Radius-7	9664

NO	NAME OF DEVICE	IDENTIFIER
8	Rad-57 Configurable Pulse CO-Oximeter	9216
9	Masimo RainbowSET IntelliVue Module	3924
10	Root	9515
11	Root NIBPT	9695
12	rainbow RC-12, rainbow Patient Cable, 12 ft	2404
13	rainbow RC-1, rainbow Patient Cable, 1 ft	2405
14	rainbow RC-4, rainbow Patient Cable, 4 ft	2406
15	M-LNC-1, M-LNCS Series Patient Cable, 1 ft	2523
16	M-LNC-4, M-LNCS Series Patient Cable, 4 ft	2524
17	M-LNC-10, M-LNCS Series Patient Cable, 10 ft	2525
18	M-LNC-14, M-LNCS Series Patient Cable, 14 ft	2526
19	M-LNC-10-GE, M-LNCS to GE Patient Cable, 10 ft	2533
20	M-LNC-04-DB9, M-LNCS to DB9 Patient Cable, 4 ft	2534
21	M-LNC-10-DB9, M-LNCS to DB9 Patient Cable, 10 ft	2535
22	M-LNC-14-DB9, M-LNCS to DB9 Patient Cable, 14 ft	2536
23	M-LNC-4-GE, M-LNCS to GE Patient Cable, 4 ft	2655
24	M-LNC-SL-10, M-LNCS to Spacelab Patient Cable, 10 ft	2714
25	M-LNC-MP10, M-LNCS to IVM / MMS, 10 ft	2831
26	RC25-12, rainbow Patient Cable, 12 ft	3342
27	RC25-12RA, rainbow Patient Cable, 12 ft	3343
28	RC25-4RA, rainbow Patient Cable, 4 ft	3375
29	M-LNCS Patient Cable, Red M-LNCv-4	3513
30	M-LNCS Patient Cable, Red M-LNCv-10	3514
31	RC25-4, rainbow Patient Cable, 4 ft	3628
32	M-LNC MP4, M-LNCS to IVM / MMS, 4 ft	3754
33	RC25-1, rainbow Patient Cable, 1ft	3933

NO	NAME OF DEVICE	IDENTIFIER
34	RC25-1RA, Patient Cable, 1ft	3934
35	M-LNC-10-NK, M-LNCS to NK Patient Cable, 10 ft	3985
36	rainbow M20-01, rainbow Patient Cable, 1 ft	4236
37	rainbow M20-04, rainbow Patient Cable, 4 ft	4237
38	rainbow M20-12, raionbow Patient Cable, 12 ft	4238
39	rainbow RC-1 EMS, Patient Cable, 1/box	4480
40	rainbow RC-4 EMS, Patient Cable, 1/box	4481
41	rainbow RC25-1 EMS, Patient Cable, 1/box	4482
42	rainbow RC25-4 EMS, Patient Cable, 1/box	4483
43	rainbow RC25-1RA EMS, Patient Cable, 1/box	4484
44	rainbow RC25-4RA EMS, Patient Cable, 1/box	4485
45	spo2.com NRC-180 Patient Cable	1810
46	spo2.com NRC-395 Patient Cable 	1811
47	spo2.com NRC-P12, Patient Cable	1853
48	spo2.com NRC-GE Patient Cable	1854
49	spo2.com NRC-SL , Spacelabs Replacement Cable	1900
50	spo2.com NRC-P8, Patient Cable, 3M	1949
51	spo2.com NRC-SL2 Spacelabs Replacement Cable	2335
52	LNCS Red Patient Cable, Red LNCTM-04, LNCS 20-pin SpO2 Patient Cable, 4 ft., 1/Box	2055
53	LNCS Red Patient Cable, Red LNCTM-10, LNCS 20-pin SpO2 Patient Cable, 10 ft., 1/Box	2056
54	LNCS Red Patient Cable, Red LNCTM-14, LNCS 20-pin SpO2 Patient Cable, 14 ft., 1/Box	2057
55	LNCTM PATIENT CABLE, LNC-4, 4 FT., 1/BOX	2017
56	LNC PATIENT CABLE, LNC-10, 10 FT., 1/BOX	1814

NO	NAME OF DEVICE	IDENTIFIER
57	RD rainbow SET Patient Cable, MD20-1.5, RD rainbow 20-pin Patient Cable, 1.5 ft., 1/Box	4071
58	RD RAINBOW SET PATIENT CABLE, MD20-05, RD RAINBOW 20-PIN PATIENT CABLE, 5 FT., 1/BOX	4072
59	RD RAINBOW SET PATIENT CABLE, MD20-08, RD RAINBOW 20-PIN PATIENT CABLE, 8 FT., 1/BOX	4109
60	RD RAINBOW SET PATIENT CABLE, MD20-12, RD RAINBOW 20-PIN PATIENT CABLE, 12 FT., 1/BOX	4073
61	RD rainbow SET Patient Cable, 25R-05, RD SET Series, 25-pin Patient Cable, 5 ft., 1/Box 1	4076
62	RD rainbow SET Patient Cable, 25RA-05, RD SET Series, 25-pin Right Angle Patient Cable, 5 ft., 1/Box 1	4077
63	RD rainbow SET Patient Cable, 25R-08, RD SET Series, 25-pin Patient Cable, 8 ft., 1/Box 1	4106
64	RD rainbow SET Patient Cable, 25RA-08, RD SET Series, 25-pin, Right Angle Patient Cable, 8 ft., 1/Box	4107
65	RD RAINBOW SET PATIENT CABLE, 25R-12, RD SET SERIES, 25-PIN PATIENT CABLE, 12 FT., 1/BOX	4078
66	RD rainbow SET Patient Cable, 25RA-12, RD SET Series, 25-pin Right Angle Patient Cable, 12 ft., 1/Box	4079
67	RD SET PATIENT CABLE, MD14-05, 14-PIN RD SET PATIENT CABLE, 5 FT., 1/BOX	4080
68	RD SETTM Patient Cable, MD14-08, 14-pin RD SETTM Patient Cable, 8 ft., 1/box	4108
69	RD SET PATIENT CABLE, MD14-12, 14-PIN RD SET PATIENT CABLE, 12 FT., 1/BOX	4081
70	RD ADAPTER CABLE, RD TO M-LNC ADAPTER CABLE, RD SET SERIES TO M-LNC OR RC PATIENT CABLE, 1.5 FT., 1/BOX	4090
71	RD ADAPTER CABLE, LNCS TO RD ADAPTER CABLE, LNCS SERIES TO RD PATIENT CABLE, 1 FT., 1/BOX	4092
72	RD SET PATIENT CABLE, MD20-1.5, 20-PIN PATIENT CABLE, 1.5 FT., 1/BOX	4102
73	RD SET PATIENT CABLE, MD20-05, 20-PIN PATIENT CABLE, 5 FT., 1/BOX	4103
74	RD SET PATIENT CABLE, MD20-12, 20-PIN PATIENT CABLE, 12 FT., 1/BOX	4104

NO	NAME OF DEVICE	IDENTIFIER
75	RD ADAPTER CABLE, RD TO LNC ADAPTER CABLE, RD SET SERIES TO LNC PATIENT CABLE, 1.5 FT., 1/BOX	4105
76	RD RAINBOW SET PATIENT CABLE, M20-12, RD RAINBOW M20 CONNECTOR PATIENT CABLE, 12 FT., 1/BOX	4257
77	RD rainbow SET Patient Cable, M20-05, RD rainbow M20 Connector Patient Cable, 5 ft., 1/Box	4256
78	RD RAINBOW SET PATIENT CABLE, M20-1.5, RD RAINBOW M20 CONNECTOR PATIENT CABLE, 1.5 FT., 1/BOX	4255
79	RD SEDLINE PATIENT CABLE, 3 FT., 1/BOX	4298
80	LNC PATIENT CABLE, LNC-10-GE, LNCS TO GE PATIENT CABLE, 10 FT., 1/BOX	2016
81	LNCTM Patient Cable, LNC-4-GE, LNCS to GE Patient Cable, 4 ft., 1/Box	2430
82	LNCS DUAL KEY PATIENT CABLE, LNC MP10, LNCS TO INTELLIVUE MASIMO SET OR INTELLIVUE PHILIPS FAST-SPO2, 10 FT., 1/BOX	2281
83	LNC PATIENT CABLE, LNC-04-DB9, LNCS TO DB9 CONNECTOR PATIENT CABLE, 4 FT., 1/BOX	2285
84	RD SETTM Patient Cable, MP-05, RD SETTM to IntelliVue Masimo SET or IntelliVue Philips FAST-SpO2 Dual Key 1 \$190.00 Patient Cable, 5 ft., 1/Box	4082
85	RD SET PATIENT CABLE, MP-12, RD SET TO INTELLIVUE MASIMO SET OR INTELLIVUE PHILIPS FAST-SPO2 DUAL KEY PATIENT CABLE, 12 FT., 1/BOX	4083
86	RD SETTM Patient Cable, GE-05, RD SETTM to GE Patient Cable, 5 ft., 1/Box	4084
87	RD SET PATIENT CABLE, GE-12, RD SET TO GE PATIENT CABLE, 12 FT., 1/BOX	4085
88	RD SET PATIENT CABLE, NK-12, RD SET TO NIHON KOHDEN PATIENT CABLE, 12 FT., 1/BOX	4192
89	RD SETTM Patient Cable, NK-05, RD SETTM to Nihon Kohden Patient Cable, 5 ft., 1/Box	4191
90	rainbow RC-EXT-8, Extension Cable, 8 ft., 1/Box	3659
91	RD rainbow SET RAM Dual Cable MD20-12	4279
92	RD rainbow SET RAM Dual Cable M20-12	4512
93	RD rainbow SET RAM Dual Cable R25-12	4278
94	RAM Dual Cable, LNC-10, 1/Box	3661

NO	NAME OF DEVICE	IDENTIFIER
95	RAM Dual Cable LNC M20-10, 1/Box	4099
96	RAM Dual Cable, Red 25 LNC-10, 1/Box	3906
97	RAM Dual Cable, RC-10, 1/Box	3660
98	RAM Dual Cable M20-10, 1/Box	4100
99	RAM Dual Cable, RC25-10, 1/Box	3503
100	RD SET Patient Cable, RD SET SL-12, RD SET to SpaceLabs Patient Cable, 12 ft., 1/Box	4087
101	RD Extension Cable, RD EXT-4, 4 ft., 1/Box	4095
102	RD Adapter Cable, RD to PC Adapter Cable, RD SET Series to LNOP PC Patient Cable, 1.5 ft., 1/Box	4088
103	RD Adapter Cable, RD to LNC Adapter Cable, RD SET Series to LNC Patient Cable, 3 ft., 1/Box	4089
104	RD Adapter Cable, LNOP to RD Adapter Cable, LNOP Series to RD Patient Cable, 1.5 ft., 1/Box	4091
105	LNCS Red Patient Cable, Red LNC M20-01, LNCS M20 Connector Spot Check Patient Cable, 1 ft., 1/Box	4251
106	LNCS Red Patient Cable, Red LNC M20-04, LNCS M20 Connector Patient Cable, 4 ft., 1/Box	4252
107	LNCS Red Patient Cable, Red LNC M20-10, LNCS M20 Connector Patient Cable, 10 ft., 1/Box	4253
108	LNCS Red Patient Cable, Red LNC M20-14, LNCS M20 Connector Patient Cable, 14 ft., 1/Box	4254
109	LNCS Red Patient Cable, Red LNCTM-01, LNCS 20-pin SpO2 Spot Check Patient Cable, 1 ft., 1/Box	2365
110	LNC Patient Cable, LNC-1, 1 ft., 1/Box	2364
111	LNCS Red Patient Cable, Red 25 LNC-1, LNCS Series 25-pin Patient Cable, 1 ft., 1/Box	3935
112	LNCS Red Patient Cable, Red 25 LNC-4, 25-pin, 4 ft., 1/Box	3630
113	LNCS Red Patient Cable, Red 25 LNC-1RA, LNCS Series 25-pin Right Angle Patient Cable, 1 ft., 1/Box	3936
114	LNCS Red Patient Cable, Red 25 LNC-4RA, 25-pin, 4 ft., 1/Box	3376

NO	NAME OF DEVICE	IDENTIFIER
115	LNCS Red Patient Cable, Red 25 LNC-10, 25-pin, 10 ft., 1/Box	3345
116	LNC Patient Cable, LNC MP4, M-LNCS Dual Key Patient Cable, 4 ft., 1/Box	3755
117	LNC Patient Cable, LNC-10-DB9, LNCS to DB9 Connector Patient Cable, 10 ft., 1/Box	2286
118	LNC Patient Cable, LNC-10-NK, LNCS to Nihon Kohden Patient Cable, 10 ft., 1/Box	3984
119	LNCS Adapter Cable, LNCS Series to LNOP PC Adapter Cable, 18 inch, 1/Box	1816
120	LNCS Adapter Cable, CMS, LNCS Series to Philips 12-pin Instrument Adapter Cable, 3 m, 1/Box	2263
121	LNCS Adapter Cable, MAC-GE, LNCS Series to GE Adapter Cable, 3 m, 1/Box	2264
122	LNCS Adapter Cable, MAC-SL, LNCS Series to Spacelabs Adapter Cable, 3 m, 1/Box	2266
123	LNCS Adapter Cable, MAC-SL2, LNCS Series to Spacelabs Adapter Cable, 3 m, 1/Box	2336
124	LNCS Adapter Cable, MAC-180, LNCS Series to N-180 Adapter Cable, 10 ft., 1/Box	2268
125	LNCS Adapter Cable, MAC-395, LNCS Series to N-395 Adapter Cable, 10 ft., 1/Box	2269
126	Adapter Cable, 14-pin to 20-pin, Connect PXC2 to Masimo SET 20-pin Devices, SpO2 only, 1/Box	2478
127	Mountable Extension Cable, PXC2-16, 16 ft., 1/Box	2371
128	Mountable Extension Cable, PXC2-30, 30 ft., 1/Box	2373
129	Radical Docking Station, RDS-1	9021
130	Radical Docking Station, RDS-3	9023
131	RD rainbow SET R25-1.5	4074
132	RD rainbow SET RA25-1.5	4075
133	RD rainbow SET MD20-1.5, EMS	4791
134	RD rainbow SET MD20-04, EMS	4792
135	RD rainbow SET MD20-12, EMS	4793
136	RD rainbow SET R25-1.5, EMS	4794
137	RD rainbow SET R25-04, EMS	4795

NO	NAME OF DEVICE	IDENTIFIER
138	RD rainbow SET R25-12, EMS	4796
139	RD rainbow SET RA25-1.5, EMS	4797
140	RD rainbow SET RA25-04, EMS	4798
141	RD rainbow SET RA25-12, EMS	4799
142	RD SET MD14-1.5	4675
143	RD SET Rad-G-1.5	4772
144	RD SET Rad-G-5	4773
145	RD SET Rad-G-12	4774

