




DEVICE DETAILS


NAME OF DEVICE	NONIN MODEL 7500 PULSE OXIMETER AND ACCESSORIES
ESTABLISHMENT NAME	ACUCARE SYSTEMS (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC4547419-36840
BRAND NAME	NONIN MODEL 7500 PULSE OXIMETER AND ACCESSORIES
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>The Nonin Model 7500 Digital Pulse Oximeter is a portable, tabletop device indicated for use in measuring, displaying and recording functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult, pediatric, infant, and neonatal patients. It is indicated for spot-checking and/or continuous monitoring of patients during both motion and no-motion conditions, and for patients who are well or poorly perfused. The Nonin Model 7500FO Digital Pulse Oximeter is a portable, tabletop device indicated for use in simultaneously measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult, pediatric and infant patients in an Magnetic Resonance (MR) environment while operating on battery power alone. Testing was performed in MR conditional environments at 1.5T and 3T. It is intended for spot checking and/or continuous monitoring of patients who are well or poorly perfused.</p>
DEVICE INTENDED PURPOSE	<p>The NONIN Model 7500 Digital Pulse Oximeter is a portable, tabletop device indicated for use in simultaneously measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult, pediatric, infant and neonatal patients. It is intended for spot-checking and/or continuous monitoring of patients during both motion and no-motion conditions, and for patients who are well or poorly perfused. The Nonin Model 7500FO Digital Pulse Oximeter is a portable, tabletop device indicated for use in simultaneously measuring, displaying, and recording functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult, pediatric and infant patients in a Magnetic Resonance (MR) environment while operating on battery power alone. Testing was performed in MR conditional environments at 1.5T and 3T. It is intended for spot checking and/or continuous monitoring of patients who are well or poorly perfused.</p>
VALIDITY DATE OF REGISTRATION	28/11/2019 - 27/11/2024

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Nonin Model 7500 Pulse Oximeter	7500
2	Nonin Model 7500FO Pulse Oximeter	7500FO

NO	NAME OF DEVICE	IDENTIFIER
3	Finger Clip Sensor, Adult	8000AA
4	Finger Clip Sensor, Adult	8000AA-2
5	Finger Clip Sensor, Adult	8000AA-3
6	Finger Clip Sensor, Pediatric	8000AP
7	Finger Clip Sensor, Pediatric	8000AP-3M
8	Soft Sensor, Small	8000SS
9	Soft Sensor, Small	8000SS(3M)
10	Soft Sensor, Medium	8000SM
11	Soft Sensor, Medium	8000SM (3M)
12	Soft Sensor, Large	8000SL
13	Soft Sensor, Large	8000SL (3M)
14	Reflectance Sensor	8000R
15	Reflectance Sensor Holder 	8000H
16	Flex Sensor, Adult	8000J
17	Flex Sensor, Adult	8000J-3
18	Flex Sensor, Neonatal	8001J
19	Neonatal Flexiwrap	8001JFW
20	Flex Sensor, Infant	8008J
21	Adult FlexiWrap	8000JFW
22	Infant FlexiWrap	8008JKW
23	6000C Cloth Series, Single-Use	6000CA
24	6000C Cloth Series sensor	6000CP
25	6000C Cloth Series sensor	6000CI
26	7000 Flexi-Form III Series sensor	7000A
27	7000 Flexi-Form III Series sensor	7000P
28	7000 Flexi-Form III Series sensor	7000I

NO	NAME OF DEVICE	IDENTIFIER
29	7000 Flexi-Form III Series sensor	7000N
30	Ear Clip Pulse Oximeter Sensor	8000Q2
31	Durafoam Series Sensor	6500MA
32	Durafoam Series Sensor	6500SA
33	Adult Fiber Optic Pulse Oximeter Sensor	8000FC
34	Infant/Pediatric Fiber Optic Pulse Oximeter Sensor	8000FI
35	Rechargeable NiMH Battery Pack	Battery Pack
36	Power supply, 30W	MPP30M-004
37	Power cord, United Kingdom	7600PCS-UK
38	Power cord, North America	7600PCS-US
39	Power cord, European Union and South America	7600PCS-EU
40	Power cord, Australia	7600PCS-AU
41	Power cord, Japan 	7600PCS-JP
42	7500 Serial output cable	7500SC
43	Adult Sensor Wrap	8000FW
44	Infant/Pediatric Sensor Wrap	8000TW
45	Avant PC, Pole Mount Clamp	5924-000
46	Avant RD-D Deluxe Rolling Stand	3668-100
47	7500CC-Carrying Case, Black	7500CC
48	7500A Analog Cable	7500A
49	Extension Cable (3ft/1m)	UNI-EXT-1
50	Extension Cable (10ft/3m)	UNI-EXT-3
51	Extension Cable (20ft/6m)	UNI-EXT-6
52	Extension Cable (30ft/9m)	UNI-EXT-9
53	UNI-RA-O (6" exy cable)- Right Angle Connector	UNI-RA-O
54	Nonin Model 7500 Pulse Oximeter	7500

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55	Nonin Model 7500FO Pulse Oximeter	7500FO
56	Finger Clip Sensor, Adult	8000AA
57	Finger Clip Sensor, Adult	8000AA-2
58	Finger Clip Sensor, Adult	8000AA-3
59	Finger Clip Sensor, Pediatric	8000AP
60	Finger Clip Sensor, Pediatric	8000AP-3M
61	Soft Sensor, Small	8000SS
62	Soft Sensor, Small	8000SS(3M)
63	Soft Sensor, Medium	8000SM
64	Soft Sensor, Medium	8000SM (3M)
65	Soft Sensor, Large	8000SL
66	Soft Sensor, Large	8000SL (3M)
67	Reflectance Sensor 	8000R
68	Reflectance Sensor Holder	8000H
69	Flex Sensor, Adult	8000J
70	Flex Sensor, Adult	8000J-3
71	Flex Sensor, Neonatal	8001J
72	Neonatal Flexiwrap	8001JFW
73	Flex Sensor, Infant	8008J
74	Adult FlexiWrap	8000JFW
75	Infant FlexiWrap	8008JKW
76	6000C Cloth Series, Single-Use	6000CA
77	6000C Cloth Series sensor	6000CP
78	6000C Cloth Series sensor	6000CI
79	7000 Flexi-Form III Series sensor	7000A
80	7000 Flexi-Form III Series sensor	7000P

NO	NAME OF DEVICE	IDENTIFIER
81	7000 Flexi-Form III Series sensor	7000I
82	7000 Flexi-Form III Series sensor	7000N
83	Ear Clip Pulse Oximeter Sensor	8000Q2
84	Durafoam Series Sensor	6500MA
85	Durafoam Series Sensor	6500SA
86	Adult Fiber Optic Pulse Oximeter Sensor	8000FC
87	Infant/Pediatric Fiber Optic Pulse Oximeter Sensor	8000FI
88	Rechargeable NiMH Battery Pack	Battery Pack
89	Power supply, 30W	MPP30M-004
90	Power cord, United Kingdom	7600PCS-UK
91	Power cord, North America	7600PCS-US
92	Power cord, European Union and South America	7600PCS-EU
93	Power cord, Australia 	7600PCS-AU
94	Power cord, Japan	7600PCS-JP
95	7500 Serial output cable	7500SC
96	Adult Sensor Wrap	8000FW
97	Infant/Pediatric Sensor Wrap	8000TW
98	Avant PC, Pole Mount Clamp	5924-000
99	Avant RD-D Deluxe Rolling Stand	3668-100
100	7500CC-Carrying Case, Black	7500CC
101	7500A Analog Cable	7500A
102	Extension Cable (3ft/1m)	UNI-EXT-1
103	Extension Cable (10ft/3m)	UNI-EXT-3
104	Extension Cable (20ft/6m)	UNI-EXT-6
105	Extension Cable (30ft/9m)	UNI-EXT-9
106	UNI-RA-O (6" exy cable)- Right Angle Connector	UNI-RA-O

NO	NAME OF DEVICE	IDENTIFIER
107	nVISION Software for Microsoft Windows	nVISION

