





DEVICE DETAILS

NAME OF DEVICE	NONIN PALMSAT 2500 SERIES HANDHELD PULSE OXIMETER AND ACCESSORIES
ESTABLISHMENT NAME	ACUCARE SYSTEMS (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC4591820-38168
BRAND NAME	NONIN PALMSAT 2500 SERIES HANDHELD PULSE OXIMETER AND ACCESSORIES
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>The PalmSAT 2500/2500A Pulse oximeters are digital handheld devices that display numerical values for functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate. The 2500/2500A Pulse Oximeters will typically operate for 60 continuous hours between alkaline battery replacement or 40 hours with the optional Model 2500B Rechargeable NiMH (Nickel Metal Hydride) battery pack. The devices require no routine calibration or maintenance other than alkaline battery replacement or recharging the optional battery pack. A pulse oximeter determines functional oxygen saturation of the arterial hemoglobin (SpO₂) by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate. The 2500/2500A must be used with Nonin-branded pulse oximeter sensors.</p>
DEVICE INTENDED PURPOSE	<p>The NONIN PalmSAT 2500 Pulse Oximeters are indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adults, pediatric, infant, and neonatal patients. The 2500/2500A pulse oximeters are intended for continuous monitoring and/or spot-checking of patients during both motion and no-motion conditions, and for patients who are well or poorly perfused.</p>
VALIDITY DATE OF REGISTRATION	24/12/2019 - 23/12/2024

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	MODEL 2500 PULSE OXIMETER	2500
2	MODEL 2500A PULSE OXIMETER	2500A
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

NO	NAME OF DEVICE	IDENTIFIER
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
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

NO	NAME OF DEVICE	IDENTIFIER
33	Extension Cable (3ft/1m)	UNI-EXT-1
34	Extension Cable (10ft/3m)	UNI-EXT-3
35	Extension Cable (20ft/6m)	UNI-EXT-6
36	Extension Cable (30ft/9m)	UNI-EXT-9
37	UNI-RA-O (6" ext cable)- Right Angle Connector	UNI-RA-O
38	UNI-RA-O (3m ext cable)- Right Angle Connector	UNI-RA-3
39	2500B Battery Pack NIMH	2500B
40	Power Supply for 2500	8140-002
41	Charging station for 2500	2500C
42	Charger Stand with Power Supply	2500C-UNIV
43	1000MC Serial Cable	1000MC
44	1000RTC Serial cable	1000RTC
45	Carrying Case 	2500CC
46	nVISION Software for Microsoft Windows	nVISION