



DEVICE DETAILS

NAME OF DEVICE	PALMSAT 2500 SERIES HANDHELD PULSE OXIMETER AND ACCESSORIES
ESTABLISHMENT NAME	ACUCARE SYSTEMS (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC7699425-220011
BRAND NAME	NONIN
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. Oxygen saturation and pulse rate values are displayed by light-emitting diode (LED) digital displays. On each detected pulse, the pulse quality LED flashes (blinks). Patient pulse quality signals are graded as good, marginal, or inadequate and are indicated as such by the pulse quality indicator flashing green, yellow or red, respectively. This simple method gives the user a pulse-by-pulse visual indication of waveform signal quality without requiring the user to perform complex waveform analysis.</p>
DEVICE INTENDED PURPOSE	<p>The Nonin® Model 2500 Pulse Oximeter is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate for adult, pediatric, and neonatal patients. The device is 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. The Nonin® Model 2500A PalmSAT® Pulse Oximeter with Alarms is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate for adult, pediatric, and neonatal patients. The device is intended for continuous monitoring and/or spotchecking of patients during both motion and no-motion conditions, and for patients who are well or poorly perfused.</p>
VALIDITY DATE OF REGISTRATION	18/12/2025 - 17/12/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		



MEDICAL DEVICE AUTHORITY