Public Search

Malaysia Medical Device Register (MMDR)

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	GC9750326-224168
BRAND NAME	NONIN
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The devices within the 7500 Series (i.e., Model 7500 and Model 7500FO) are portable, tabletop devices 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 indicated for spot-checking and / or continuous monitoring of patients during both motion and non-motion conditions, and for patients who are well or poorly perfused. The Model 7500FO has the same measuring and display features as the Model 7500 however it can be used on adult, pediatric, and infant patients in a Magnetic Resonance (MR) environment while operating on battery power alone. The device contains steel screws and steel-wrapped NiMH battery cells. Models 7500 and 7500FO displays use light-emitting diode(LED) components to present patient's SpO2 andpulse rate values, as well as alarm limit and volume settings. Both devices can be powered internally with a 12 VDC 1.5A AC adapter or with an integral sealed 7.2volt rechargeable NiMHbattery pack. Models 7500 and 7500FO include adjustable audible and visual pulse rate, oxygen saturation, and perfusion alarms. They also include a variety of advanced features, including low battery alarms, sensor fault, user defined defaults, real-time data outputs,and patient security mode which prevents accidental changes to critical parameters.Models 7500 and 7500FO can collect and store 70 hours of continuous SpO2 and pulse rate information. Data may be played back with data retrieval software (e.g., nVision® software). The memory in the Model 7500/7500FO functions much like an “endless loop” tape. When the memory is full, the unit begins overwriting the oldest data with new data. Data is written in 4-minute intervals. Each time the devices are turned on, the current time/date information (if the clock is set properly)is stored in memory, starting a new recording session. Only recording sessions greater than one minute in length are stored in memory. Patient SpO2 and pulse rate are sampled every second. Every 4 seconds, the extreme value of the4-second sample period is stored. Oxygen saturation values are stored in 1% increments in therange of 0 to 100%. The stored pulse rate ranges from 18 to 321 pulses per minute. The stored values are in increments of one pulse per minute in the interval from 18 to 200 pulses per minute, and in increments of 2pulses per minute in the interval from 201 to 300 pulses per minute. Patient data is retained even when both external and battery power are lost. Both tabletop pulse oximeter models (7500 and 7500FO) share the same design, functionality, principles of operation, accuracy and performance specifications, and safety profile. The primary variation between the two models is that model 7500FO may be used in MR environments.

DEVICE INTENDED PURPOSE	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.
VALIDITY DATE OF REGISTRATION	27/01/2026 - 26/01/2031

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		

Medical Device AUTHORITY MALAYSIA
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