



DEVICE DETAILS

NAME OF DEVICE	NONIN WRISTOX2 WRIST-WORN PULSE OXIMETER AND ACCESSORIES
ESTABLISHMENT NAME	ACUCARE SYSTEMS (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC9651826-227139
BRAND NAME	NONIN
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>Nonin WristOx2 Model 3150 BLE Pulse Oximeter is a pulse oximeter with memory for patient data collection and Bluetooth® communication capability to transmit oximetry readings to a Bluetooth enabled host. The Model 3150 with the use of an external sensor (with a specific cable connection and optional interface cable for Nonin standard sensors) measures the patient's %SpO2 and pulse rate. The unit is small and light weight allowing it to be worn by the patient (wrist, upper arm, or infant's thigh) or strapped to a bed rail, with the use of an adjustable strap. Readings are obtained from the display located on the face of the Model 3150, without any peripheral equipment required, or they may be transmitted to a data storage system via Bluetooth and/or USB. Model 3150 have approximately 1080 hours of non-volatile memory at 4-second sampling rate. The Store & Forward memory feature of this device allows users to take readings outside their home and transmit the time-stamped data on return. The Model 3150 WristOx2 is powered by 2 1.5-volt AAA disposable alkaline batteries2, for approximately 600 spot checks (and/or 44 hours of battery life). The Model 3150 WristOx2 requires no calibration or maintenance other than battery replacement. Both wrist-worn pulse oximeter models (3150 BLE and 3150 USB) 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 3150 BLE enables the data to be transferred to a device wirelessly, whereas the 3150 USB provides download capability of the data via USB transfer.</p>
DEVICE INTENDED PURPOSE	<p>The Nonin WristOx2 Model 3150 Pulse Oximeter is a small, wrist-worn device indicated for use in measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. It is intended for spot-checking and/or data collection and recording of adult and pediatric patients, during both no motion and motion conditions, and for patients who are well or poorly perfused. The intended use environments are hospitals, medical facilities, ambulatory, subacute, and sleep study environments, and mobile units.</p>
VALIDITY DATE OF REGISTRATION	27/02/2026 - 26/02/2031

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		



MEDICAL DEVICE AUTHORITY