



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	BIOMETRIXS MEDITRONIXS GLOBAL
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC5843323-144456
BRAND NAME	ACCURO
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>A Pulse oximeter (ACCURO) is detecting and measurement as below parameters to provide and help doctors for making figure out the patient's vital condition: - Exact and stable oxygen saturation of arterial blood SpO₂ (continuous measurement) The SpO₂ function is indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of patients. The device works by applying a sensor to a pulsating arteriolar vascular bed. The SpO₂ can be measured non-invasively on patient's finger or earlobe. An LED in a sensor serves as a light source to emit red and infrared (IR) light alternately. The blood in capillary absorbs these lights, and the transmitted light is detected with a photodiode on the other side. The device is composed of finger probe and SpO₂ module. SpO₂ module drives currents into RED and IR LEDs in the SpO₂ probe. Then the LEDS emit RED and IR light into the finger nail which is just below the LEDs. The sensor of the finger probe below the finger receives the RED and IR light and intensity of each light is translated into voltage. Voltages for RED and IR light signal are transformed to digital data using A/D converters in SpO₂ module. After the conversion, the CPU in the SpO₂ module calculates the RED to IR intensity ratio to obtain the corresponding SpO₂ value. It also calculates the heart rate from the pulsating feature of input signal. To eliminate the influence of noise and patient's motion, digital signal processing algorithms are adopted in calculating SpO₂ and pulse rate values.</p>
DEVICE INTENDED PURPOSE	<p>The intended use of Pulse oximeter ACCURO is detecting and measurement as below parameters to provide and help doctors for making figure out the patient's vital condition. • Exact and stable Oxygen saturation of arterial blood • Accurate Pulse Rate Especially, Pulse oximeter ACCURO has AGC (Auto Gain Controller) function for weak pulsatile patients. The device is to detect and control its gain automatically in accordance with patient's pulse rate strength.</p>
VALIDITY DATE OF REGISTRATION	11/08/2023 - 10/08/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	ACCURO™ Bedside & portable type pulse oximeter, FDA approved	100200
2	ACCURO™ Bedside & portable type pulse oximeter, FDA approved with Built in Handle	100201
3	C30 plus™ Multi-View Handheld type pulse oximeter with Alkaline battery	100130
4	C30 plus™ Multi-View Handheld type pulse oximeter with Li-ion battery	100131
5	AC-DC adapter 12V 2.5A and power cord for CX100, PRIZM3	DC1-100
6	AC-DC adapter 9V 3.34A and power cord for CX130	DC2-100
7	AC-DC adapter 12V 3.4A and power cord for PRIZM 5/7	DC3-100
8	Power cord CEE 7/16	PCI-100
9	Disposable SpO2 sensor(probe) for all ages	DS1-100
10	Reusable SpO2 sensor(probe) for adults for CX100, CX120, CX130 & ACCURO, 3m	S01-300
11	Reusable SpO2 sensor(probe) for children for CX100, CX120, CX130 & ACCURO, 3m	S02-300
12	Reusable SpO2 sensor(probe) for neonates(infants) for CX100, CX120, CX130 & ACCURO, Y-type, 3m	S03-300
13	Reusable SpO2 sensor(probe) for neonates(infants) for CX100, CX120, CX130 & ACCURO, wrapping type, 3m	S10-300
14	Reusable SpO2 sensor(probe) animals(VET) for CX100, CX120, CX130 & ACCURO, wrapping type, 3m	S03-3V0
15	Reusable SpO2 sensor(probe) for adults for PRIZM Series, 1m	S01-100
16	Reusable SpO2 sensor(probe) for children for PRIZM Series, 1m	S02-100
17	Reusable SpO2 sensor(probe) for neonates(infants) for PRIZM Series, Y-type, 1m	S03-100
18	Reusable SpO2 sensor(probe) for neonates(infants) for PRIZM Series, wrapping type, 1m	S10-100
19	PRIZM SERIES Reusable Y-type (animals),1m	S03-1V0
20	Reusable SpO2 sensor(probe) for adult for ACCURO II, 3M	S04-300
21	Extension cable for SpO2 sensors for CX100, CX120, CX130 & ACCURO, 2.5m	EXT-100
22	Extension cable for SpO2 sensors for ACCURO II	(not set)

NO	NAME OF DEVICE	IDENTIFIER
23	Extension cable for SpO2 sensors for PRIZM Series, 2.2m	EXT-200
24	Front Cover+Slide holder+materials	10020001
25	Keyboard overlay	(not set)
26	Connecter overlay	(not set)
27	LCD window	(not set)
28	Keyboard ASS'Y	10020002
29	Flat Cable	10020003
30	Spo2 Board	10020004
31	POWER B/D ASS'Y	10020005
32	Main Board+LCD	10020006
33	2.4" TFT LCD, resolution: 240x320	10020007
34	4.3" TFT LCD, resolution: 480x272	10020008
35	Rear Cover+materials	10020009
36	Speaker	10020010
37	Rechagaeble battery Li-ion (7.2V, 2200mAh)	10020011
38	HANDLE (for only ACCURO)	10020012
39	Front Cover+materials+cost of printing	10013001
40	LCD Window	(not set)
41	KEY RUBBER	10013003
42	3" TFT LCD	10013004
43	CX130 MAIN B/D ASS'Y	10013005
44	CX130 SPO2 B/D ASS'Y	10013006
45	CX130 KEY B/D ASS'Y	10013007
46	Rear Cover+materials+cost of printing	10020009
47	NI-MH battery (4.8v 2100mAh)	10012010
48	LI-ION Battery (3.7V_2200mAh)	10013009

NO	NAME OF DEVICE	IDENTIFIER
49	IV Pole clamp for general Chamcare products	CMP-100
50	Protective rubber cover for CX130	BTC-100



MEDICAL DEVICE AUTHORITY