



DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER
ESTABLISHMENT NAME	KORMED RESOURCES PLT.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC3134223-121051
BRAND NAME	EDAN
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>H100B&H100N are models of H100 series Pulse Oximeter. They display SpO2 value, pulse rate value, plethysmogram, bar graph, temperature (only for H100N), etc. H100B is installed with EDAN SpO2 module inside. H100N is installed with Nellcor SpO2 module and the manufacturer's TEMP module inside. They both integrate parameter module, display and data output functions. They can be powered by four 1.5 V AA batteries or four 1.2 V Rechargeable Ni-MH AA batteries. They can clearly display all the parameter information on LCD. The H100B Pulse oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation (SpO2) and pulse rate of single adult, pediatric or neonate patient in hospitals, intra-hospital transport and hospital type facilities. H100N Pulse Oximeter (hereinafter called oximeter) is one model of H100 series Pulse Oximeter. The oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation (SpO2), pulse rate and for oral, axillary and rectal temperature measurement. It is intended to be used on adult, pediatric or neonatal patient in hospitals, intra-hospital transport and hospital type facilities. The software version of H100B is V2.6, the software version of H100N is V1.6, and they were developed to V2.6 and V1.6 separately to add display electric quantity of battery.</p>
DEVICE INTENDED PURPOSE	<p>The H100B Pulse oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation (SpO2) and pulse rate of single adult, pediatric or neonate patient in hospitals, intra-hospital transport and hospital type facilities. H100N Pulse Oximeter (hereinafter called oximeter) is one model of H100 series Pulse Oximeter. The oximeter is intended for continuous monitoring or spot-checking of functional arterial oxygen saturation (SpO2), pulse rate and for oral, axillary and rectal temperature measurement. It is intended to be used on adult, pediatric or neonatal patient in hospitals, intra-hospital transport and hospital type facilities.</p>
VALIDITY DATE OF REGISTRATION	24/02/2023 - 23/02/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximeter	H100B

NO	NAME OF DEVICE	IDENTIFIER
2	SPO2 Finger Sensor,Adult,1m,reusable (has to work with EDAN SpO2 Extension Cable for patient monitor) [*CFDA+CE+FDA*]	02.01.210120
3	AA Size Battery	01.21.064086
4	Carry Bag	01.56.465634011
5	User Manual	21.54.109000
6	SPO2 Finger Sensor,Adult,1m,reusable (has to work with EDAN SpO2 Extension Cable for patient monitor) [*CFDA+CE+FDA*]	02.01.210120
7	SpO2 Warp Sensor,Neonate,1m,resuable (has to work with EDAN SpO2 Extension Cable for patient monitor)	02.01.210673
8	SpO2 Silicone Soft-tip Sensor,Adult,1m,reusable (has to work with EDAN SpO2 Extension Cable for patient monitor)	02.01.210122
9	SpO2 Silicone Soft-tip Sensor,Pediatric,1m,reusable (has to work with EDAN SpO2 Extension Cable for patient monitor) [*CFDA+CE+FDA*]	02.01.210121
10	SpO2 Sensor,Adult,0.5m,Disposable,with EDAN logo (has to work with EDAN SpO2 Extension Cable for patient monitor) [*CFDA+CE+FDA+CA*]	01.57.471235
11	SpO2 Sensor,Pediatric,0.5m,Disposable,with EDAN logo (has to work with EDAN SpO2 Extension Cable for patient monitor) [*CFDA+CE+FDA+CA*]	01.57.471236
12	SpO2 Sensor,Infant,0.5m,Disposable,with EDAN logo (has to work with EDAN SpO2 Extension Cable for patient monitor) [*CFDA+CE+FDA+CA*]	01.57.471237
13	SpO2 Sensor,Neonate/Adult,0.5m,Disposable,with EDAN logo (has to work with EDAN SpO2 Extension Cable for patient monitor)	01.57.471238
14	SpO2 Sensor,Adult,0.5m,Disposable (has to work with EDAN SpO2 Extension Cable for patient monitor) [*CFDA+CE+FDA+CA*]	01.57.471746
15	SpO2 Sensor,Pediatric,0.5m,Disposable (has to work with EDAN SpO2 Extension Cable for patient monitor) [*CFDA+CE+FDA+CA*]	01.57.471747
16	SpO2 Sensor,Infant,0.5m,Disposable (has to work with EDAN SpO2 Extension Cable for patient monitor) [*CFDA+CE+FDA+CA*]	01.57.471748
17	SpO2 Sensor,Neonate/Adult,0.5m,Disposable (has to work with EDAN SpO2 Extension Cable for patient monitor)	01.57.471749
18	SpO2 Extension cable, 1.5m	01.13.110504
19	Data Management Kit: 1 x PatientCare Viewer (for H100B) Data Management Software and user manual (One CD) 1 x RS-232 Cable for VE-H100B(1m)	83.61.110260

NO	NAME OF DEVICE	IDENTIFIER
20	RS-232 Cable for H100B,VE-H100B(1m)	01.13.109038011
21	RS232 to USB Adapter and Driver CD (HL-340, for H100B,VE-H100B)	01.13.036770
22	Battery Charger Stand kit (Euro),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.112409
23	Battery Charger Stand kit (US),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.113589
24	Battery Charger Stand kit (AR),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.316045
25	Battery Charger Stand kit (AU),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.316050
26	Battery Charger Stand kit (UK),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.316055
27	Battery Charger Stand kit (Euro,EDAN 2),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.316028
28	Battery Charger Stand (Euro),including: 1 x Charger stand with power cord	83.60.261429
29	Battery Charger Stand (US),including: 1 x Charger stand with power cord	83.60.261430
30	Battery Charger Stand (AR),including: 1 x Charger stand with power cord	83.60.261431
31	Battery Charger Stand (AU),including: 1 x Charger stand with power cord	83.60.261433
32	Battery Charger Stand (UK),including: 1 x Charger stand with power cord	83.60.261434
33	Battery Charger Stand (Euro,EDAN 2),including: 1 x Charger stand with power cord	83.60.261435
34	Rechargeable Ni-MH Battery	21.21.064164013
35	Power Cord (UK)	01.13.036693
36	Mounting Kit for H100 Series Pulse Oximeter	02.04.240101
37	Protective Cover (Gray)	01.51.110164
38	Protective Cover (Blue)	01.51.112408
39	Protective Cover (Green)	01.51.112407
40	Carry Bag (with EDAN logo)	01.56.465635
41	Carry Bag(without EDAN logo)	01.56.465634

NO	NAME OF DEVICE	IDENTIFIER
42	AA Size Battery	01.21.064086
43	Service Manual	01.54.109017
44	Pulse Oximeter	H100N
45	Nellcor Reusable Adult SpO2 Sensor (DS-100A OxiMax) [*CE+FDA+CA+BA*]	01.15.30043
46	Carry Bag	01.56.465634011
47	User Manual	21.54.109000
48	AA Size Battery	01.21.064086
49	Nellcor Reusable Adult SpO2 Sensor(DS-100A OxiMax) [*CE+FDA+CA+BA*]	01.15.030043
50	Nellcor Reusable Adult/Neonate SpO2 Sensor(OXI-A/N OxiMax)	01.15.040096
51	Nellcor Reusable SpO2 sensors, Pediatric/Infant 3-40 kg (OXI-P/I)	01.57.040437
52	Nellcor Reusable multisite SpO2 sensors, Multisite >1 kg (D-YS)	01.57.040438
53	Nellcor Forehead SpO2 sensor, Adult/Pediatric >10 kg (MAX-FAST), 1pc, 24pcs/pack	01.57.040436
54	Nellcor Adhesive SpO2 sensor, Adult >30 kg (MAX-A/MAX-AL), 1pc, 24pcs/pack	01.57.040440
55	Nellcor Adhesive SpO2 sensor, Neonatal<3 kg/Adult>40 kg (MAX-N), 1pc, 24pcs/pack	01.57.040441
56	Nellcor Adhesive SpO2 sensor, Infant 3-20 kg (MAX-I), 1pc, 24pcs/pack	01.57.040442
57	Nellcor Adhesive SpO2 sensor, Pediatric 10-50 kg (MAX-P), 1pc, 24pcs/pack	01.57.040445
58	Temperature Probe,skin,adult,3m,reusable	01.15.040188
59	Temperature Probe,rectal/oral,adult,3m,reusable	01.15.040424
60	Data Management Kit: 1 x PatientCare Viewer (for H100N) Data Management Software and user manual (One CD) 1 x DB9 to USB Cable for H100N (1m)	83.61.113578
61	DB9 to USB Cable for H100N (1m)	01.13.110200
62	Battery Charger Stand kit (Euro),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.112409
63	Battery Charger Stand kit (US),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.113589

NO	NAME OF DEVICE	IDENTIFIER
64	Battery Charger Stand kit (AR),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.316045
65	Battery Charger Stand kit (AU),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.316050
66	Battery Charger Stand kit (UK),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.316055
67	Battery Charger Stand kit (Euro,EDAN 2),including: 1 x Ni-MH battery 1 x Charger stand with power cord	83.60.316028
68	Battery Charger Stand (Euro),including: 1 x Charger stand with power cord	83.60.261429
69	Battery Charger Stand (US),including: 1 x Charger stand with power cord	83.60.261430
70	Battery Charger Stand (AR),including: 1 x Charger stand with power cord	83.60.261431
71	Battery Charger Stand (AU),including: 1 x Charger stand with power cord	83.60.261433
72	Battery Charger Stand (UK),including: 1 x Charger stand with power cord	83.60.261434
73	Battery Charger Stand (Euro,EDAN 2),including: 1 x Charger stand with power cord	83.60.261435
74	Rechargeable Ni-MH Battery	21.21.064164-12
75	Power Cord (Euro)	01.13.036639
76	Power Cord (US)	01.13.036117
77	Power Cord (AU)	01.13.036606
78	Power Cord (UK)	01.13.036693
79	Mounting Kit for H100 Series Pulse Oximeter	02.04.240101
80	Protective Cover (Gray)	01.51.110164
81	Protective Cover (Blue)	01.51.112408
82	Protective Cover (Green)	01.51.112407
83	Carry Bag (with EDAN logo)	01.56.465635
84	AA Size Battery	01.21.064086
85	Service Manual	01.54.109017