



DEVICE DETAILS

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| 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 |
| 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 |

| NO | NAME OF DEVICE | IDENTIFIER |
|----|---|-----------------|
| 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 |
| 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 |

| NO | NAME OF DEVICE | IDENTIFIER |
|----|---|-----------------|
| 40 | Carry Bag (with EDAN logo) | 01.56.465635 |
| 41 | Carry Bag(without EDAN logo) | 01.56.465634 |
| 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 |

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| 63 | Battery Charger Stand kit (US),including: 1 x Ni-MH battery 1 x Charger stand with power cord | 83.60.113589 |
| 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 |

| NO | NAME OF DEVICE | IDENTIFIER |
|----|----------------|--------------|
| 85 | Service Manual | 01.54.109017 |



MEDICAL DEVICE AUTHORITY