# **GUARDIANPLUS** SEDATION MONITOR





### MONITOR SAFETY SPECIFICATIONS

#### The monitor is classified, according to IEC 60601-1:

Degree of protection against electrical shock	Type CF defibrillation proof for ECG, Resp, SpO2, NIBP, Temp Type BF defibrillation proof for CO2
Type of protection against electrical shock	Class I
Degree of protection against harmful ingress of water	IPX1
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Mode of operation	Continuous

### PHYSICAL SPECIFICATIONS

ltem	Maximum Weight	W x H x D (mm)	Comments
Main unit	4.0 kg (standard configuration and recorder, excluding battery and accessories)	271 x 226 x 173	3.2 kg (standard configuration, excluding battery, accessories and recorder)

### **ENVIRONMENTAL SPECIFICATIONS**

#### WARNING

- The monitor may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If the performance of the equipment is degraded due to aging or environmental conditions, contact your service personnel.
- When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

#### NOTE

• The environmental specification of unspecified parameter modules are the same as those of the main unit.

Main Unit			
Item	Temperature (C°)	Relative Humidity (noncondensing) (%)	Barometric
Operating Condition	0 to 40	15 to 95	427.5 to 805.5 mmHg (57 to 107.4 kPa)
Storage Condition	-20 to 60	10 to 95	120 to 805.5 mmHg (16 to 107.4 kPa)

Microstream CO2 Module			
Item	Temperature (C°)	Relative Humidity (noncondensing) (%)	Barometric
Operating Condition	0 to 40	15 to 95	430 to 790 mmHg (57.3 to 105.3 kPa)
Storage Condition	-20 to 60	10 to 95	430 to 790 mmHg (57.3 to 105.3 kPa)
Sidestream CO2 Module			
Item	Temperature (C°)	Relative Humidity (noncondensing) (%)	Barometric
Operating Condition	5 to 40	15 to 95	430 to 790 mmHg (57.3 to 105.3 kPa)
Storage Condition	-20 to 60	10 to 95	430 to 790 mmHg

### POWER SUPPLY SPECIFICATIONS

#### External Power Supply Specifications:

AC Power	
Line Voltage	100 to 240 VAC (±10%)
Input Current	2.0 to 0.9 A
Frequency	50/60 Hz (± 3 Hz)

#### Battery Specifications:

AC Power	
Battery Type	Rechargeable lithium-Ion battery (non-smart battery)
Battery Voltage	10.95V
Battery Capacity	4500 mAh
Maximum Number of Batteries Configured	Only one battery can be connected

Run Time	≥ 4 hours When the monitor is powered by a new fully-charged battery at 25 °C ±5 °C with 5-lead ECG and SpO2 cable connected, auto NIBP measurements at an interval of 15 minutes, and screen brightness set to 1. Shutdown delay: at least 15 minutes after the low battery alarm first occurs.
Charge Time	No more than 5 hours to 90% when the monitor is off No more than 10 hours to 90% when the monitor is on

# DISPLAY SPECIFICATIONS

Screen Type: Capacitive, multi-point color touchscreen

Screen Size (diagonal): 10.1 inches

Resolution: 1280 x 800 pixels

### LEDs

Alarm Lamp: 1 or 2 (three color-coded: red, yellow, and cyan)

Power-on LED: 1 (green)

AC power LED: 1 (green)

Battery LED: 1 (two color-coded: yellow and green) **RECORDER SPECIFICATIONS** 

Method: Thermal dot array

Horizontal Resolution: 16 dots/mm (25 mm/s paper speed)

Vertical Resolution: 8 dots/mm

Paper Width: 50 mm±1mm

Paper Length: 20 m

Paper Speed: 25 mm/s, 50 mm/s

Accuracy: ±5%

Number of Waveform Channels: A maximum of 3

### AUDIO INDICATOR

Speaker	Give alarm tones (45 to 85 dB), reminder tones, key tones, QRS tones; support PITCH TONE and multi-level tone modulation; alarm tones comply with IEC 60601-1-8.
Audio signal	Alarm tone: ISO mode with frequency of 600 Hz QRS tone: Short beep with frequency of 650 Hz Key tone: Short beep with frequency of 1000 Hz

### MONITOR INTERFACE SPECIFICATIONS

AC Power Input	1
Network Connector	1, standard RJ45 connectors, 100 Base-TX, IEEE 802.3

USB Connector	2, USB 2.0
Multifunctional Connector	1
Video Output Connector	1, 15-pin D-sub
Equipotential Grounding Terminalr	1

## SIGNAL OUTPUTS SPECIFICATIONS

Auxiliary Output	
Standard	Meets the requirements of IEC 60601-1 for short-circuit protection and leakage current
ECG Analog Output	
Bandwidth (-3dB; reference frequency: 10Hz)	Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Surgical mode: 1 to 20 Hz
Maximum QRS Delay	25 ms (in diagnostic mode, and non-paced)
Gain (reference frequency 10Hz)	1V/mV (±5%)
Pace Enhancement	Signal amplitude: Voh≥2.5V Pulse width: 10ms±5% Signal rising and falling time: ≤100µs
Nurse Call Signal	
Amplitude	High level: 3.5 to 5 V, ±5%, providing a minimum of 10 mA output current; Low level: < 0.5 V, receiving a minimum of 5 mA input current.
Rising and Falling Time	≤1 ms
Defib Sync Pulse	
Output Impedance	≤100 Ω
Maximum Time Delay	35 ms (R-wave peak to leading edge of pulse)

Amplitude	High level: 3.5 to 5 V, ±5%, providing a minimum of 10 mA output current; Low level: < 0.5 V, receiving a minimum of 5 mA input current.
Pulse Width	100 ms ±10%
Maximum Rising and Falling Time	l ms
Alarm Output	
Alarm delay time from the monitor to remote equipment	The alarm delay time from the monitor to remote equipment is ≤2 seconds, measured at the monitor signal output connector.
Alarm signal sound pressure level range	45 db(A) to 85 db(A) within a range of one meter

### DATA STORAGE

Trends	Standard-capacity memory card: up to 120 hours of trend data with the resolution no less than 1 minute, or up to 1200 hours of trend data with the resolution no less than 10 minutes. High-capacity memory card: up to 240 hours of trend data with the resolution no less than 1 minute, or up to 2400 hours of trend data with the resolution no less than 10 minutes.
Events	Standard-capacity memory card: 1000 events, including parameter alarms, arrhythmia events, technical alarms, and so on. High-capacity memory card: 2000 events, including parameter alarms, arrhythmia events, technical alarms, and so on.
NIBP Measurements	Standard-capacity memory card: 1000 sets. High-capacity memory card: 3000 sets.
Full-disclosure Waveforms	Standard-capacity memory card: up to 48 hours for one waveform. The specific storage time depends on the waveforms stored and the number of stored waveforms. High-capacity memory card: up to 48 hours for all parameter waveforms.
OxyCRG View	A maximum of 48 hours of OxyCRG events.

### ECG SPECIFICATIONS

FCG Standards: Meet standards of IEC 60601-2-27: 2011 & IEC 60601-2-25: 2011 Lead Set: 3-lead: I, II, III 5-lead: I, II, III, aVR, aVL, aVF, V ECG Standard: AHA, IEC Display Sensitivity: 1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/mV (×4), Auto, less than 5% error Sweep Speed: 6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s, less than 5% error Bandwidth (-3dB): Diagnostic mode: 0.05 to 150 Hz Monitor mode: 0.5 to 40 Hz Surgical mode: 1 to 20 Hz Common Mode Rejection Ratio: Diagnostic mode: >90 dB Monitor mode: >105 dB (with notch filter on) Surgical mode: >105 dB (with notch filter on) Notch filter: 50/60 Hz Monitor, surgical mode: notch filter turns on automatically Diagnostic mode: notch filter is turned on/off manually Differential input impedance ≥5 MΩ Input signal range ±8mV (peak-to-peak value) Accuracy of Signal reproduction: Use A and D methods based on IEC 60601-2-25 to determine frequency response. Electrode Offset Potential Tolerance: ±500 mV Lead-off Detection Current: Measuring electrode: <0.1 µA Drive electrode: <1 µA Input Offset Current: ≤0.1 µA, (drive lead≤1µA) Defibrillation Protection: Enduring 5000V (360 J) Baseline recovery time: <5 s (after defibrillation) Polarization recovery time: <10 s Defibrillation energy absorption:  $\leq 10\%$  (100 $\Omega$  load) Patient Leakage Current: <10 uA Calibration Signal: 1mV (peak-to-peak value) ±5% ESU protection: Cut mode: 300 W Coagulate mode: 100 W Recoverv time: ≤10 s In compliance with the requirements in clause 202.6.2.101 of IEC 60601-2-27 ALARM LIMIT

#### HR High:

Range: HR≤40 bpm: (low limit + 2 bpm) to 40 bpm HR > 40 bpm: (low limit + 5 bpm) to 295 bpm Step: HR≤40bpm:1bpm HR > 40 bpm: 5 bpm

#### HR Low:

Range: HR≤40 bpm: 16 bpm to (high limit - 2 bpm) HR > 40 bpm: 40 bpm to (high limit - 5 bpm) HR Measurement Range: Neonate: 15 to 350 bpm Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm Resolution: 1 bpm Accuracy:  $\pm 1$  bpm or  $\pm 1\%$ , whichever is greater. Sensitivity: 200 µV (lead II) HR Averaging Method: In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, the following method is used: If the last 3 consecutive RR intervals are greater than 1200 ms, the 4 most recent RR intervals are averaged to compute the HR. Otherwise, heart rate is computed by subtracting the maximum and minimum ones from the most recent 12 RR intervals and then averaging them. The HR value displayed on the monitor screen is updated no more than one second. Response to Irregular Rhythm: In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the heart rate after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy (waveform A1): 80±1 bpm Slow alternating ventricular bigeminy (waveform A2): 60±1 bpm Rapid alternating ventricular bigeminy (waveform A3): 120±1 bpm Bidirectional systoles (waveform A4): 90±2 bpm Response Time to Heart Rate Change: Meets the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 5). From 80 to 120 bpm: less than 11 s From 80 to 40 bpm: less than 11 s Time to Alarm For Tachycardia: Meets the requirements in Clause 201.7.9.2.9.101 b) 6) of IEC 60601-2-27. Waveform: <11 s B1h-range: <11 s B1-range: <11 s Bld-range: <11 s B2h-range: <11 s B2-range: <11 s B2d-range: <11 s Tall T-wave Rejection Capability: When the test is performed based on Clause 201.12.1.101.17 of IEC 60601-2-27, the heart rate calculation is not affected for QRS of 1 mV ampli tude and 100 ms duration, T-wave duration of 180 ms and amplitude lower than 1.2 mV, and QT interval of 350 ms. Arrhythmia Analysis Classifications: Asystole, V-Fib/V-Tach, V-Tach, Vent Brady, Extreme Tachy, Extreme Brady, Vent Rhythm, PVCs/min, Pauses/min, Couplet, Bigeminy, Trigeminy, R on T, Run PVCs, PVC, Tachy, Brady, Missed Beats, Pacer Not Pacing, Pacer Not Capture, Multiform PVC,

Nonsus V-Tach, Pause, Irr Rhythm, A-Fib

#### **RESP SPECIFICATIONS**

Technique: Trans-thoracic impedance I ead

Lead L Lead II Auto Respiration Excitation Waveform: <300 µA RMS, 62.8 kHz (±10%) Minimum Respiration Impedance Threshold: 0.3Ω **Baseline Impedance Range:** 200 to 2500 $\Omega$  (using an ECG cable with 1k $\Omega$  resistance) Bandwidth: 0.2 to 2.5 Hz (-3 dB) Sweep Speed: 3mm/s, 6.25 mm/s, 12.5 mm/s, 25 mm/s or 50 mm/s, less than 10% error Recovery Time: <15 s (after defibrillation) **RESPIRATION RATE** Measurement Range: Adult: 0 to 120 rpm Pediatric, Neonate: 0 to 150 rpm 7 to 150 rpm: ±2 rpm or ±2%, whichever is greater 0 to 6 rpm: not specified 10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s ALARM LIMIT **RR High:** 

Resolution: 1 rpm Accuracy: Apnea Alarm Delay:

Range (rpm): Adult, Pediatric: RR≤20 — (low limit + 2) to 20 RR≤20 — (low limit + 5) to 100 Neonate: RR≤20 — (low limit + 2) to 20 RR≤20 — (low limit + 5) to 150 Step (rpm): RR≤20:1 RR>20:5 RR Low:

Range (rpm): RR≤20 — 0 to (high limit - 2) RR≤20 — 20 to (high limit - 5)

### SPO2 SPECIFICATIONS

ALARM LIMIT SpO2 High: Range (%) (low limit + 2) to 100 1 Step (%) 1 SpO2 Low: Masimo: (Desat+1) to (high limit - 2) Nellcor: (Desat+1) or 20 (whichever is greater) to (high limit - 2) SpO2 Desat Low: 0 to (SpO2 low limit - 1) MASIMO SPO2 MODULE Standards: Meets the requirements of ISO 80601-2-61: 2011 Measurement Range: 1 to 100% Resolution: 1% Response =Time: ≤20 s (normal perfusion, no disturbance, SpO2 value sudden changes from 70% to 100%) Accuracy: 70 to 100%: ±2%ABS (measured without motion in adult/pediatric mode) 70 to 100%: ±3%ABS (measured without motion in neonate mode) 70 to 100%: ±3%ABS (measured with motion) 1% to 69%: Not specified. **Refresh Rate:** <15 SpO2 averaging time: 2-4 s, 4-6 s, 8 s, 10 s, 12 s, 14 s, 16 s Low perfusion conditions Pulse amplitude: >0.02% Light Penetration: >5% Low Perfusion SpO2 Accuracy: ±2% PI measurement Range: 0.02 to 20%

#### **NELLCOR SPO2 MODULE**

Measurement Range: 0 to 100% Resolution: 1% Refreshing Rate: ≤1 s Response Time: ≤30 s (normal perfusion, no disturbance, SpO2 value sudden change from 70% to 100%) Recovery Time: <15 s (after defibrillation) Accuracy: 70 to 100%: ±2%ABS (adult/pediatric) 70 to 100%: ±3%ABS (neonate) 0% to 69%: Not specified.

### **PR SPECIFICATIONS**

#### ALARM LIMIT

#### PR High:

Range: PR≤40bpm: (low limit + 2 bpm) to 40 bpm PR > 40 bpm: (low limit + 5 bpm) to 295 bpm Step: PR≤40: 1 bpm PR>40: 5 bpm

PR Low:

PR≤40bpm: 16 bpm to (high limit - 2 bpm) PR > 40 bpm: 40 bpm to (high limit - 5 bpm)

#### PR FROM MASIMO SPO2

Measurement Range: 25 to 240 bpm Resolution: 1 bpm Response Time: ≤20 s (with normal perfusion, no disturbance, and a PR value transition from 25 to 220 bpm) Accuracy: ±3 bpm (measured without motion)

±5 bpm (measured with motion) Refresh Rate: ≤1 s

#### PR FROM NELLCOR SPO2 MODULE

Measurement Range: 20 to 300 bpm Resolution: 1 bpm Response Time: ≤30 s (normal perfusion, no disturbance, PR value sudden change from 25 to 250 bpm) Accuracy: 20 to 250 bpm: ±3 bpm 251 to 300 bpm, not specified Refreshing Rate: ≤1 s

### **TEMP SPECIFICATIONS**

Standard: Meet the standard of ISO 80601-2-56: 2017 Technique: Thermal Resistance Operating Mode: Direct mode Measurement Range: 0 to 50 °C (32 to 122 °F) Resolution: 0.1°C Accuracy: ±0.1 °C or ±0.2 °F (excluding probe error) Refreshing Rate: ≤1 s Minimum Time for Accurate Measurement Body Surface: <100 s Body Cavity: <80 s Recovery Time: <15 s (after defibrillation)

#### ALARM LIMIT

TXX High (XX refers to temperature site): Range: (low limit +1.0) to 50.0 °C (low limit +2.0) to 122.0 °F Step: 0.1 °C 0.1 °F TXX Low (XX refers to temperature site): Range: 0.1 to (high limit - 1.0) °C 32.2 to (high limit - 2.0) °F ΔT High: Range: 0.1 to 50.0 °C 0.2 to 90.0 °F

### **NIBP SPECIFICATIONS**

Standard: Meet standard of IEC 80601-2-30: 2018 Technique: Oscillometry Mode of Operation: Manual, Auto, STAT Sequence Auto Mode Repetition Intervals: 1, 2, 2.5, 3, 5, 10, 15, 20, 30, 60, 90, 120, 180, 240 or 480 min STAT Mode Cycle Time: 5 min Max Measurement Time: Adult, Pediatric: 180 s Neonate: 90 s Heart Rate Range: 30 to 300 bpm Measurement Ranges (mmHg): Adult: Systolic: 25 to 290 Diastolic: 10 to 250 Mean: 15 to 260 Pediatric: Systolic: 25 to 240 Diastolic: 10 to 200 Mean: 15 to 215 Neonate: Systolic: 25 to 140 Diastolic: 10 to 115 Mean: 15 to 125 Accuracy Max: Mean error: ±5 mmHg Max standard deviation: 8 mmHg **Resolution:** 1mmHa Initial Cuff Inflation Pressure Range (mmHg): Adult: 80 to 280 Pediatric: 80 to 210 Neonate: 60 to 140 Default Initial Cuff Inflation Pressure (mmHg): Adult: 160 Pediatric: 140 Neonate: 90 Software Overpressure Protection: Adult: 297±3 mmHg Pediatric: 297±3 mmHg Neonate: 147±3 mmHg Static Pressure Measurement Range: 0 mmHg to 300 mmHg Static Pressure Measurement Accuracy: ±3 mmHg Recovery Time: <15 s (after defibrillation)

#### PR

Measurement Range: 30 to300 bpm Resolution: 1 bpm Accuracy: ±3bpm or ±3%, whichever is greater

#### ALARM LIMIT

NIBP-S High: Range: Adult: (low limit + 5) to 285 Pediatric: (low limit + 5) to 235 Neonate: (low limit + 5) to 135 NIBP-S Low: Range: 26 to (high limit - 5 NIBP-M High: Adult: (low limit + 5) to 255 Pediatric: (low limit + 5) to 210 Neonate: (low limit + 5) to 120) NIBP-M Low: 16 to (high limit - 5) NIBP-D High: Adult: (low limit + 5) to 245 Pediatric: (low limit + 5) to 195 Neonate: (low limit + 5) to 110 NIBP-D Low: 11 to (high limit - 5) NIBP-S Extreme High: NIBP-S high limit < 50 Adult: (NIBP-S high limit + 1) to 290 Pediatric: (NIBP-S high limit + 1) to 240 Neonate: (NIBP-S high limit + 1) to 140 NIBP-S high limit ≥ 50 Adult: (NIBP-S high limit + 5) to 290 Pediatric: (NIBP-S high limit + 5) to 240 Neonate: (NIBP-S high limit + 5) to 140 **NIBP-S Extreme Low:** NIBP-S low limit ≤ 50 25 to (NIBP-S low limit - 1) NIBP-S low limit > 50 25 to (NIBP-S low limit - 5) NIBP-M Extreme High: NIBP-M high limit < 50 Adult: (NIBP-M high limit + 1) to 260 Pediatric: (NIBP-M high limit + 1) to 215 Neonate: (NIBP-M high limit + 1) to 125 NIBP-M high limit ≥ 50 Adult: (NIBP-M high limit + 5) to 260 Pediatric: (NIBP-M high limit + 5) to 215 Neonate: (NIBP-M high limit + 5) to 125 NIBP-M Extreme Low: NIBP-M low limit ≤ 50 15 to (NIBP-M low limit - 1) NIBP-M low limit > 50 15 to (NIBP-M low limit - 5) **NIBP-D Extreme High:** NIBP-D high limit < 50 Adult: (NIBP-D high limit + 1) to 250 Pediatric: (NIBP-D high limit + 1) to 200 Neonate: (NIBP-D high limit + 1) to 115 NIBP-D high limit ≥ 50 Adult: (NIBP-D high limit + 5) to 250 Pediatric: (NIBP-D high limit + 5) to 200 Neonate: (NIBP-D high limit + 5) to 115 NIBP-D Extreme Low: NIBP-D low limit ≤ 50 10 to (NIBP-D low limit - 1) NIBP-D low limit > 50 10 to (NIBP-D low limit - 5)

#### CO2 SPECIFICATIONS

Measurement Mode: Sidestream Microstream Technique: Infrared Absorption Apnea Delay: 10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s ALARM LIMIT EtCO2 High: Range: (low limit + 2) to 99 mmHg Step: 1 mmHg EtCO2 Low: Range: 1 to (high limit - 2)mmHg Step: 1mmHg FiCO2 High:

Range: 1 to 99 mmHg Step: 1mmHg

SIDESTREAM CO2 MODULE Standard: Meet the standard of ISO 80601-2-55: 2011 CO2 Measurement Range: 0 to 150 mmHg CO2 Absolute Accuracy: Full accuracy mode: 0 to 40 mmHg: ± 2 mmHg 41 to 76 mmHg: ±5% of reading 77 to 99 mmHg: ±10% of reading 100 to 150 mmHg: ±(3 mmHg + 8% of reading) ISO accuracy mode: add ±2mmHg to the full accuracy mode CO2 Resolution: 1 mmHg Recovery Time: <15 s (after defibrillation) Accuracy Drift: Meet the requirement for measurement accuracy within 6 hours Sample Flowrate: Connected a DRYLINE II watertrap for adult and pediatric patient: 120 ml/min Connected a DRYLINE II watertrap for neonatal patient: 90 ml/min or 70 ml/min Sample Flowrate Tolerance: ±15% or ±15 ml/min, whichever is areater. Start-up time: Maximum: 90 s Typically: 20 s **Response Time:** Measured with a DRYLINE II neonatal watertrap and a 2.5-meter neonatal sampling line: ≤5.0 s @ 70 ml/min ≤4.5 s @ 90 ml/min

Measured with a DRYLINE II adult watertrap and a 2.5-meter adult sampling line:

≤5.0 s @ 120 ml/min

Rise Time: Measured with a DRYLINE II neonatal watertrap and a 2.5-meter neonatal sampling line: ≤250 ms@70 ml/min. ≤250 ms@90 ml/min. Measured with a DRYLINE II adult watertrap and a 2.5-meter adult sampling line: ≤300 ms@120 ml/min awRR Measurement Range: 0 to 150 rpm awRR Measurement Precision: ≤60 rpm: ±1 61 to 150 rpm: ±2 awRR Resolution: 1 rpm Data Sample Rate: 50 Hz **EFFECT OF INTERFERENCE GASES ON CO2 MEASUREMENTS** N20: Concentration: ≤60% Quantitative Effect: ±1 mmHg Hal: Concentration: ≤4% Quantitative Effect: ±1 mmHg Sev: Concentration: ≤5% Quantitative Effect: ±1 mmHg lso: Concentration: ≤5%

Quantitative Effect: ±1 mmHg

Enf:

Des:

Concentration: ≤5% Quantitative Effect: ±1 mmHg

Concentration:  $\leq 15\%$ Quantitative Effect: ±2 mmHg