

COMEN

Specification: N10/N12/N15



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Patient Monitor

N10/12/15

Physical Characteristics

Size	N10:261x247x181mm
	N12:308x282x185mm
	N15:460.5x351x202.5mm
Weight	N10: 3.65kg
	N12: 3.69Kg
	N15: 5.32Kg
Color	Light/dark gray
Display	Medical-grade color TFT LCD,
	capacitive touch screen
	N10: 1280x800, 10.1 inches
	N12: 1280x800, 12.1 inches
	N15: 1366x768, 15.6 inches
Display traces	N10: Up to 8 waveforms
	N12: Up to 10 waveforms
	N15: Up to 12 waveforms

ECG

Meet standards of IEC 60601-2-27 and IEC 60601-2-25	
Lead set	12-lead: I; II; III; aVR; aVL; aVF; V1-V6
	6-lead: I; II; III; aVR; aVL; aVF; Va; Vb
	5-lead: I; II; III; aVR; aVL; aVF; V
	3-lead: I; II; III
	Automatic 3/5/6/12-lead recognition
Input signal Range	±10mv (p-p)
Electrode offset	±850mV
potential tolerance	
Sweep Speed	6.25,12.5, 25, 50mm/s, error≤±10%
Gain	X0.125, X0.25, X0.5, X1, X2, X4, auto
Waveform format	Standard, Cabrera
CMRR	Diagnostic: >90dB
	Monitor, Surgical, ST mode: >106dB
Band width	Monitoring Mode: 0.5-40Hz
	Diagnosis mode: 0.05-150Hz
	Surgery mode:1-20Hz
	ST mode: 0.05-40Hz
Pace detection	Amplitude: ± 2 mV to ± 700 mV
	Width: 0.1 to 2 ms
	Rise time: 10 to 100 μs

Defib. Protection Withstand 5000VAC (360J) defibrillation

Defib. recovery time ≤ 5s

ESU recovery time ≤ 10 s

Provide Glasgow resting 12-lead ECG algorithm

Heart Rate

HR range Adult: 15~300bpm

Pediatric/Neonate: 15~350bpm

HR accuracy ±1% or ±1bpm (whichever is greater)

HR resolution 1 bpm

Arrhythmia Analysis

Intended use for adult pediatric and neonate

Multi-lead ECG monitoring analysis algorithm

27 classifications including:

Asystole, Vfib/Vtac, PVCs/min too high, R on T, VT>2, Run PVCs, Couplet, PVC, Bigeminy, Trigeminy, Tachy, Brady, Extreme Tachy, Extreme Brady, extreme bradycardia, Missed beats, multiform PVC, V-Tach, Nonsus V-Tach, Vent Rhythm, Heart Pause, Pause/min high, Irr Rhythm, Vent Brady, A-Fib, Pacer Not Capture, Pacer Not Pacing, Irr Rhythm End and A-Fib End.

ST Segment Analysis

Intended use for adult pediatric and neonate

ST range -2.5mV~+2.5mV (Automatic)

ST accuracy ±0.02mV or ±10%, whichever is greater (- 0.8 to + 0.8 mV)

ST resolution 0.01 mV

QT Analysis

Intended use for adult pediatric and neonate

Parameters QT, QTc, ΔQTc

QTc formula Bazett, Fridericia, Framingham, or Hodges

QT/QTc range 200 to 800 ms

QT accuracy ± 30 ms

QT resolution 4 ms

QTc resolution 1 ms

QT-HR range QT-HR: Adult 15 to 150 bpm

Pediatric/Neonate: 15 to 180 bpm

Respiration

Lead I, II, or auto (default: lead II)

Method RA-LL Impedance Method

RR range	0 to 200 bpm
RR accuracy	0 - 120 rpm: ± 1 rpm 121 - 200 rpm: ± 2 rpm
RR resolution	1 rpm
Apnea time	Adult: 10~60s, resolution 5s Pediatric/Neonate:10~40s, resolution 5s
Sweep speed	3, 6.25, 12.5, 25, 50mm/s
NIBP	
Method	Automatic oscillation
Work mode	Manual / Automatic/STAT, Sequence
Parameters	Systolic, Diastolic, Mean
Measurement Interval Setting	1-720min (Adjustable)
Measurement Unit	mmHg / kPa selectable
Static range	0~300mmHg(0kPa~40.0kPa)
NIBP accuracy	± 3 mmHg(± 0.4 kPa)
NIBP resolution	1 mmHg
Venous Puncture	Yes
Comen NIBP	
Max measurement time	Adult/ Pediatric: 120s Neonate: 85s
Comen Systolic range	Adult Mode: 25~290mmHg Pediatric Mode: 25~240mmHg Neonate Mode: 25~140mmHg
Comen Diastolic range	Adult Mode: 10~250mmHg Pediatric Mode: 10~200mmHg Neonate Mode: 10~115mmHg
Comen Mean range	Adult Mode:15~260mmHg Pediatric Mode:15~215mmHg Neonate Mode 15~125mmHg
Comen Over-pressure protection	Adult/ Pediatric Mode: 297mmHg ± 3 mmHg Neonate Mode: 147mmHg ± 3 mmHg
Comen Initial pressure range(mmHg)	Adult: 80~290 mmHg Pediatric: 80~240 mmHg Neonate:60~140 mmHg
Suntech NIBP	
Max measurement time	Adult: 130s Pediatric: 90s Neonate: 75s
Suntech Systolic range	Adult Mode: 40~260mmHg Pediatric Mode: 40~160mmHg Neonate Mode: 40~130mmHg

Suntech Diastolic range	Adult Mode: 20~200mmHg Pediatric Mode: 20~120mmHg Neonate Mode: 20~100mmHg
Suntech Mean range	Adult Mode:26~220mmHg Pediatric Mode:26~133mmHg Neonate Mode 26~110mmHg
Suntech Over-pressure protection	Adult/Pediatric Mode: 297mmHg ± 3 mmHg Neonate Mode: 147mmHg ± 3 mmHg
Suntech Initial pressure range(mmHg)	Adult: 120~280 mmHg Pediatric: 80~170 mmHg Neonate:60~140 mmHg
SpO₂	
Meet standard of ISO 80601-2-61.	
SpO ₂ module	Comen, Masimo, Nellcor SpO ₂
SpO ₂ range	0 to 100%
Resolution	1%
Accuracy	Ped/Adu: $\pm 2\%$ (70~100%) Neo: $\pm 3\%$ (70~100%);
Alarm range	1~100%
Perfusion index	Yes, for Comen and Masimo SpO ₂
Pitch tone	Yes
Response time	<30s
Data update time	1s
Dual-SpO ₂	Yes, SpO ₂ , SpO ₂ b, Δ SpO ₂
PR	
PR range	30-310bpm (COMEN NIBP) 30-220bpm (SUNTECH NIBP) 20-300pm (COMEN SpO ₂) 25-240pm (Masimo SpO ₂) 20-300bpm (Nellcor SpO ₂) 20-350bpm (IBP)
Accuracy	± 3 bpm or $\pm 3\%$, whichever is greater (COMEN NIBP) ± 3 bpm or $\pm 2\%$, whichever is greater (SUNTECH NIBP) ± 2 bpm (COMEN SpO ₂) ± 3 bpm (Masimo SpO ₂) ± 3 bpm (Nellcor SpO ₂) ± 1 bpm or $\pm 1\%$, whichever is greater (IBP)
Temperature (Dual Channel)	
Technique	Thermal resistance

Channels	2 channels	(±12% of actual value when awRR exceeding 80rpm)
Temp range	0~50°C	
Temp accuracy	±0.2°C or ±0.4°F	
Temp resolution	0.1°C	
Refreshing rate	1 s	
Sensor type	CY, YSI	

EtCO₂

Meet standard of ISO 80601-2-55.

EtCO ₂ module	Comen, Masimo, Respironics
Unit	mmHg, kPa

Comen/Respironics Mainstream EtCO₂

Rise time	<60ms
CO ₂ range	0mmHg~150mmHg
CO ₂ resolution	1mmHg or 0.1kPa or 0.1%
CO ₂ accuracy	0mmHg ~40mmHg should be±2mmHg 41mmHg ~70mmHg should be±5% 71mmHg ~100mmHg should be±8% 101mmHg~150mmHg should be±10%

awRR range	0 to 150rpm
awRR Accuracy	±1rpm
sample rate	50ml/min
Accuracy	±10 ml/min

Masimo Mainstream EtCO₂

CO ₂ range	0mmHg~190mmHg, 0vol%~ 25vol% (at 760mmHg)
CO ₂ Accuracy	0mmHg ~114mmHg ,± (1.52 mmHg +2% of reading) 114mmHg ~190mmHg, Undefined
awRR range	0rpm~150rpm
awRR Accuracy	±1rpm

Comen/Respironics Sidestream EtCO₂

Range	0mmHg~150mmHg, 0vol%~19.7vol% 0 - 20.0kPa (at 760mmHg)
Accuracy	Comen: 0 - 40 mmHg: ±2mmHg 41 - 70mmHg: ±5% of reading. 71 - 100mmHg: ±8% of reading. 101 - 150 mmHg: ±10% of reading. Respironics CapnoTrak: 0 - 38 mmHg: ±2mmHg of actual. 39 - 99.0 mmHg: ±10% of actual

Equilibrium gas	Helium, room air, nitrous oxide
awRR range	0rpm~150rpm
Accuracy	±1rpm

Masimo Capno Sidestream EtCO₂

CO ₂ range	0~190mmHg, 0%~25% (at 760mmHg)
CO ₂ accuracy	0~114mmHg: ± (2.25 mmHg +4%xreading) 115~190mmHg: undefined
awRR range	0~150rpmq
awRR accuracy	±1rpm
Sampling rate	50ml/min
Sampling rate accuracy	±10 ml/min
Data sampling rate	20Hz/each channel
System total response time	<3s (2m sampling line)

IBP

Meet standard of IEC 60601-2-34

Channel	Up to 4 Channels
Sensitivity	5 μV/V/mmHg
Impedance range	300 to 3000Ω
IBP range	-50 to 370 mmHg
IBP accuracy	±2% or ±1mmHg (whichever is greater)
IBP resolution	0.1kPa or 1mmHg
IBP range	-50 to 370 mmHg
PPV range	0~50%
SPV range	0-50mmHg
PAWP	Yes
Measured Pressure	ART, PA, CVP, RAP, LAP, ICP, LV, AO, UAP, BAP, FAP, UVP, IAP, CPP, P1, P2, P3, P4

Support waveforms overlapping

Cardiac Output

Technique	Thermodilution
C.O. range	0.1 to 20L/min
C.O. accuracy	±5% or ±0.1 L/min, whichever is greater
C.O. resolution	0.1 L/min
TB range	25°C to 43°C
TI range	0°C to 25°C

TB, TI accuracy	±0.1℃		KC: 5.15~5.35 GHz, 5.47~5.725 GHz,
TB, TI resolution	0.1℃		5.725~5.82 GHz
Data review		Output Power	<20dBm (CE requirement: detection mode- RMS)
	Standard: 120 hours@1 minute		<30dBm (FCC requirement, detection mode- peak power)
Tabular trends	Optional: 240 hours@1 minute and 2400 hours @10 minutes		
Graphic trends	Standard: 120 hours	Information transmission	CMS connection, HL7
ST review	Optional: 240 hours and 2400 hours	Interfacing	
12-lead ECG analysis	120 hours	Main unit	AC power connector (1)
NIBP measurement	20 groups		DC Power connector (1, optional, only for N10)
NIBP measurement review	Standard: 1000 groups		Network connector (1)
	Optional: 3500 groups		USB 2.0 connector (2)
Alarm Event View	Standard: 1000 events		Ground Cable Connector (1)
	Optional: 2500 events		VGA (1)
ARR Recall	48 hours		ECG analog output
Full disclosure review	48 hours		
Alarms		Barcode scanner	Support
Meet standard of IEC60601-1-8		Keyboard & Mouse	Support
Audible indicator	3 different alarm tones	Remote control	Support
Visible indicator	Red/Yellow/Cyan light	Thermal recorder	3 traces (48mm width, 20 length)
	Prompt message	Network printer	Support
Volume level	1 to 10	Recorder	
Special Functions		Type	Built-in; Thermal array
Clinical Assistive Application (CAA): SepsisGuide, EWS, GCS, 24 hours ECG Summary.		Channel	3 channel waveforms
Calculations (drug, hemodynamic, Oxygenation, Ventilation, Renal), and Titration table.		Speed	12.5mm/s, 25mm/s, 50mm/s
Waveform Freezing (only for external display		Record width	48mm
Timer		Real-time record time	8s, 16s, 32s or continual
External Display (Mirror-screen display, Independent-screen display)		Alarm record	Yes
Wi-Fi Communications		Power	
Protocol	IEEE 802.11a/b/g/n, internal wi-fi	Line voltage	100-240V
Modulation Mode	DSSS and OFDM	Frequency	50/60Hz
Operating	IEEE 802.11b/g/n (2.4G):	Battery	Rechargeable Lithium-ion battery
Frequency	ETSI/FCC/KC: 2.4~2.483 GHz	Standard,	N10: ≥3 hours
	MIC: 2.4~2.495 GHz	10.8V/2500mAH	N12/N15: ≥2 hours
	IEEE 802.11a/n (5G):	(N10, N12)	N15≥4.5hours
	ETSI: 5.15~5.35 GHz, 5.47~5.725 GHz	10.8V/5000mAh	
	FCC: 5.15~5.35 GHz, 5.47~5.725 GHz, 5.725~5.82 GHz,	(N15)	
	MIC: 5.15~5.35 GHz, 5.47~5.725 GHz	Optional,	N10: ≥6 hours
		10.8V/5000mAh	N12/N15: ≥4.5 hours
		(N10, N12)	Two batteries: N15≥9hours
		Charge time	≥2.5h to 90% in 2500mAh

Power off ≥4.5h to 90% in 5000mAh
 ≥3.5h to 90% in 2500mAh
Power on ≥6.5h to 90% in 5000mAh

Environment requirements

Temperature Operating: 5-40°C
 Storage: -20 to 60°C

Humidity

Operating: 15 to 93% (non-condensing)

Storage: 10 to 93% (non-condensing)

Barometric

Operating: 427.5 to 805.5mmHg
(57.0 to 107.4 kPa)

Storage: 120 to 805.5 mmHg (16.0 to
107.4 kPa)