

# COMEN

## Specification: N10MPro/N12MPro/N15MPro



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# Patient Monitor

## N10MPro/12MPro/15MPro

### Physical Characteristics

Size	N10MPro: 261x247x181mm
	N12MPro: 308x282x185mm
	N15MPro: 460.5 x 351 x 202.5 mm
Weight	N10MPro: 3.87kg
	N12MPro: 4.06Kg
	N15MPro: 5.10Kg
Color	Light/dark gray
Display	Medical-grade color TFT LCD, capacitive touch screen
	N10MPro: 1280x800, 10.1 inches
	N12MPro: 1280x800, 12.1 inches
	N15MPro: 1366x768, 15.6 inches
	N10MPro: Up to 8 waveforms
Display traces	N12MPro: Up to 10 waveforms
	N15MPro: 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 potential tolerance	±850mV
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	Suntech	Adult Mode: 20~200mmHg
RR accuracy	0 - 120 rpm: $\pm 1$ rpm 121 - 200 rpm: $\pm 2$ rpm	Diastolic range	Pediatric Mode: 20~120mmHg Neonate Mode: 20~100mmHg
RR resolution	1 rpm	Suntech	Adult Mode:26~220mmHg
Apnea time	Adult: 10~60s, resolution 5s Pediatric/Neonate:10~40s, resolution 5s	Mean range	Pediatric Mode:26~133mmHg Neonate Mode 26~110mmHg
Sweep speed	3, 6.25, 12.5, 25, 50mm/s	Suntech	Adult/Pediatric Mode:
<b>NIBP</b>		Over-pressure protection	297mmHg $\pm$ 3mmHg Neonate Mode: 147mmHg $\pm$ 3mmHg
Method	Automatic oscillation	Suntech	Adult: 120~280 mmHg
Work mode	Manual / Automatic/STAT, Sequence	Initial pressure range(mmHg)	Pediatric: 80~170 mmHg Neonate:60~140 mmHg
Parameters	Systolic, Diastolic, Mean	<b>SpO<sub>2</sub></b>	
Measurement Interval Setting	1-720min (Adjustable)	Meet standard of ISO 80601-2-61.	
Measurement Unit	mmHg / kPa selectable	SpO <sub>2</sub> module	Comen, Masimo, Nellcor SpO2
Static range	0~300mmHg(0kPa~40.0kPa)	SpO <sub>2</sub> range	0 to 100%
NIBP accuracy	$\pm 3$ mmHg( $\pm 0.4$ kPa)	Resolution	1%
NIBP resolution	1 mmHg	Accuracy	Ped/Adu: $\pm 2\%$ (70~100%) Neo: $\pm 3\%$ (70~100%);
Venous Puncture	Yes	Alarm range	1~100%
<b>Comen NIBP</b>		Perfusion index	Yes, for Comen and Masimo SpO2
Max measurement time	Adult/ Pediatric: 120s Neonate: 85s	Pitch tone	Yes
Comen Systolic range	Adult Mode: 25~290mmHg Pediatric Mode: 25~240mmHg Neonate Mode: 25~140mmHg	Response time	<30s
Comen Diastolic range	Adult Mode: 10~250mmHg Pediatric Mode: 10~200mmHg Neonate Mode: 10~115mmHg	Data update time	1s
Comen Mean range	Adult Mode:15~260mmHg Pediatric Mode:15~215mmHg Neonate Mode 15~125mmHg	Dual-SpO2	Yes, SpO2, SpO2b, $\Delta$ SpO2
Comen Over-pressure protection	Adult/ Pediatric Mode: 297mmHg $\pm$ 3mmHg Neonate Mode: 147mmHg $\pm$ 3mmHg	<b>PR</b>	
Comen Initial pressure range(mmHg)	Adult: 80~290 mmHg Pediatric: 80~240 mmHg Neonate:60~140 mmHg	PR range	30-310bpm (COMEN NIBP) 30-220bpm (SUNTECH NIBP) 20-300pm (COMEN SpO2) 25-240pm (Masimo SpO2) 20-300bpm (Nellcor SpO2) 20-350bpm (IBP)
<b>Suntech NIBP</b>		Accuracy	$\pm 3$ bpm or $\pm 3\%$ , whichever is greater (COMEN NIBP) $\pm 3$ bpm or $\pm 2\%$ , whichever is greater (SUNTECH NIBP) $\pm 2$ bpm (COMEN SpO2) $\pm 3$ bpm (Masimo SpO2) $\pm 3$ bpm (Nellcor SpO2) $\pm 1$ bpm or $\pm 1\%$ , whichever is greater (IBP)
Max measurement time	Adult: 130s Pediatric: 90s Neonate: 75s	<b>Temperature (Dual Channel)</b>	
Suntech Systolic range	Adult Mode: 40~260mmHg Pediatric Mode: 40~160mmHg Neonate Mode: 40~130mmHg	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	

## EtCO<sub>2</sub>

Meet standard of ISO 80601-2-55:2018

EtCO <sub>2</sub> module	Comen, Masimo, Respironics
Unit	mmHg, kPa

### Comen/Respironics Mainstream EtCO<sub>2</sub>

Rise time	<60ms
CO <sub>2</sub> range	0mmHg~150mmHg
CO <sub>2</sub> resolution	1mmHg or 0.1kPa or 0.1%
CO <sub>2</sub> 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
Sampling rate	50ml/min
Accuracy	±10 ml/min

### Masimo Mainstream EtCO<sub>2</sub>

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

### Comen/Respironics Sidestream EtCO<sub>2</sub>

Measurement 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 EtCO<sub>2</sub>

CO <sub>2</sub> range	0~190mmHg, 0%~25% (at 760mmHg)
CO <sub>2</sub> accuracy	0~114mmHg: ± (2.25 mmHg +4%×reading) 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

## Impedance Cardiograph (ICG)

Technique	impedance cardiogram
Parameters	ACI, VI, PEP, LVET, TFI, TFC, HR, C.O., C.I., SV, SVI, SVR, SVRI, PVR, PVRI, LCW, LCWI, LVSW, LVSWI, STR, VEPT.
C.O. range	HR: 40 to 250 bpm C.O: 0 to 30L/min SV: 5 to 250mL

Accuracy	HR: $\pm 2$ bpm C.O.: Unspecified SV: unspecified	Respiration rate	0 to 150 breaths/min
Alarm range	C.I.: 0~15.0L/min/m <sup>2</sup> TFC: 10~150K $\Omega$	Provide MAC value (calibrated by patient age). Support two mixed gas identify and monitoring. Up to 4 waveforms displayed.	
Alarm Deviation	C.I.: $\pm 0.1$ L/min/m <sup>2</sup> TFC: $\pm 1$ k $\Omega$	Rise time	CO <sub>2</sub> : $\leq 250$ ms; N <sub>2</sub> O: $\leq 350$ ms; anesthetic gases: $\leq 350$ ms; O <sub>2</sub> : $\leq 450$ ms
<b>Cardiac Output</b>		<b>BIS</b>	
Technique	Thermodilution	Technique	Bispectral Index
C.O. range	0.1 to 20L/min	Impedance range	0 to 999 k $\Omega$
C.O. accuracy	$\pm 5\%$ or $\pm 0.1$ L/min, whichever is greater	EEG bandwidth	0.25 to 100Hz
C.O. resolution	0.1 L/min	BIS range	0 to 100
TB range	25°C to 43°C	SQI range	0 to 100%
TI range	0°C to 25°C	ASYM	0 to 100%
TB, TI accuracy	$\pm 0.1$ °C	DSA trend	Yes
TB, TI resolution	0.1°C	<b>NMT</b>	
<b>Multi-gas (Masimo)</b>		Sensor type	Acceleromyograph sensor
Meet standard of ISO 80601-2-55		Stimulation modes	TOF, PTC, ST, DBS, Tetanus
Method	Infrared Radiation Absorption	Stimulation current range	0mA to 60mA
Gas	CO <sub>2</sub> , N <sub>2</sub> O, DES, ISO, ENF, SEV, HAL, O <sub>2</sub> (optional paramagnetic sensor)	Stimulation current accuracy	0.2ms $\pm 5\%$ whichever is greater
Warm-up time	<20s	Stimulation Pulse Width	200us
Sample flow rate	50 ml/m	Stimulation Pulse Width accuracy	$\pm 10\%$
Sample flow rate accuracy	$\pm 10$ ml/min or $\pm 10\%$ whichever is greater	Maximum skin impedance	5 kOhm
Response time	<3s (2m sampling tube)	TOF mode	TOF-Frat: 0%~200% TOF-Cnt: 0~4 Measurement Interval: Manual, 12s, 15s, 20s, 30s, 1min, 2min, 5min, 10min, 15min, 30min, 60min
CO <sub>2</sub> range	0~25%	PTC mode	PTC: 0~20 Measurement Interval: 2min
CO <sub>2</sub> accuracy	$\pm 0.2$ kPa+reading $\times 2\%$ (0 to 15%) Unspecified (15 to 25%)	ST mode	ST: 0%~200% Measurement Interval: Manual, 1s, 10s, 20s, 30s
O <sub>2</sub> range	0-100%	DBS mode	DBS-ratio: 0%~200% DBS-Count: 0~2 Measurement Interval: Manual, 15s, 20s, 30s, 1min, 2min, 5min, 10min, 15min, 30min, 60min
O <sub>2</sub> accuracy	$\pm 1\%$ +reading $\times 2\%$	Tetanus mode	Range: 50Hz. 100Hz
N <sub>2</sub> O range	0-100%		
N <sub>2</sub> O accuracy	$\pm 2$ kPa+reading $\times 2\%$		
Enf/Iso/Hal/Sev/Des range	0~25%		
Enf/Iso/Hal/accuracy	$\pm 0.15\%$ +reading $\times 5\%$ (0 to 8%) Unspecified (8 to 25%)		
Sev accuracy	$\pm 0.15\%$ +reading $\times 5\%$ (0 to 10%) Unspecified (10 to 25%)		
Des accuracy	$\pm 0.15\%$ +reading $\times 5\%$ (0 to 22%) Unspecified (22 to 25%)		
awRR range	0~150rpmq		
awRR accuracy	1rpm		

## RM

Technique	Diff-Pressure flow
Parameters	PEEP, Pmean, PIP, Pplat, PEF, PIF, MVe, MV <sub>i</sub> , TV <sub>e</sub> , TV <sub>i</sub> , RR, I:E, FEV1.0, Compl, RSBI, WOB, RAW, and loops.
Flow range	Adult/Pediatric: ± (2 to 120) L/min Neonate: ± (0.5 to 30) L/min
Flow accuracy	±1 L/min or ±10% <i>x</i> reading, whichever is greater
Flow resolution	0.1 L/min
Paw range	-20 to 100cmH <sub>2</sub> O
Paw accuracy	±1 cmH <sub>2</sub> O/±5% <i>x</i> reading, whichever is greater
Paw resolution	0.1 cmH <sub>2</sub> O
MVe/MV <sub>i</sub> range	Adult 2 to 20l/min Pediatric 0.5 to 5l/min
MVe/MV <sub>i</sub> accuracy	±1 L/min or ±10% <i>x</i> reading, whichever is greater
MVe/MV <sub>i</sub> resolution	0.01 L/min (MV <sub>e</sub> /MV <sub>i</sub> <10 L/min) 0.1 L/min (MV <sub>e</sub> /MV <sub>i</sub> ≥10 L/min)
TV <sub>e</sub> /TV <sub>i</sub> range	Adult: 150 to 2000ml Pediatric: 15 to 300ml
TV <sub>e</sub> /TV <sub>i</sub> accuracy	±10ml/±10% <i>x</i> reading (TV <sub>e</sub> ), ±15ml/±10% <i>x</i> reading (TV <sub>i</sub> ), whichever is greater
TV <sub>e</sub> /TV <sub>i</sub> resolution	1 ml
awRR range	0 to 100 rpm
awRR accuracy	1 rpm
awRR resolution	1 rpm

## Rainbow SET (Masimo)

Technique	Multi-wavelength light
Parameters	SpHb, SpOC, SpCO, SpMet, RRa, PR, PI, PVi
SpO <sub>2</sub> range	0%~100%
Accuracy	±2% (70~100%, Inf/Ped/Adu, non-motion) ±3% (70-100%, Inf/Ped/Adu, motion); ±3% (70-100%, Neo, motion and non-motion) ±2% (70~100%, Neo/Inf/Ped/Adu, low perfusion) 1-69% unspecified
Resolution	1%
PR range	25bpm to 240bpm

Accuracy	±3bpm (non-motion) ±5bpm (motion) ±3bpm (low perfusion)
Resolution	1bpm
SpCO range	0%~99%
Accuracy	±3% (1-40%, Ped/Adu)
Resolution	1%
SpHb range	0g/dL~25.0g/dL
Accuracy	±1g/dL (8g/dL~17g/dL, Ped/Adu)
Resolution	0.1g/dL
RRa range	0-120RPM
Accuracy	±1 (4-70, Adu) ±1 (4-120, Ped)
Resolution	1RPM
PI range	0~20%
PVI range	0%~100%
SPOC range	0ml/dl~35ml/dl
Accuracy	1.0ml/dl

## O<sub>2</sub>

Parameters	O <sub>2</sub> concentration
O <sub>2</sub> range	0 to 100%
O <sub>2</sub> accuracy	±1%
O <sub>2</sub> resolution	1
Response time	<15s (From 21% to 100%)

## Apnea wake-up

Stimulus mode	The beater vibrates
Stimulus intensity	15000±800 rpm
Stimulus cycle	5s (3s on, 2s off)
Response time	0 to 20s

## Data review

	Standard: 120 hours in 1 minute Optional: 240 hours in 1 minute and 2400 hours in 10 minutes
Tabular Trends	Standard: 120 hours Optional: 240 hours and 2400 hours in 10 minutes
Graphic Trends	120 hours
ST review	20 groups
12-lead ECG analysis	Standard: 1000 groups Optional: 3500 groups
NIBP measurement review	Standard: 1000 events Optional: 2500 events
Alarm Event View	48 hours

Full disclosure review 48 hours

## Alarms

Meet standard of IEC60601-1-8

Audible indicator 3 different alarm tones

Visible indicator Red/Yellow/Cyan light  
Prompt message

Volume level 1 to 10

## Special Functions

Clinical Assistive Application (CAA): SepsisGuide, EWS, GCS, 24 hours ECG Summary.

Calculations (drug, hemodynamic, Oxygenation, Ventilation, Renal), and Titration table.

Waveform Freezing (only for external display

Timer

External Display (Mirror-screen display, Independent-screen display)

## Wi-Fi Communications

Protocol IEEE 802.11a/b/g/n, internal wi-fi

Modulation Mode DSSS and OFDM

Operating IEEE 802.11b/g/n (2.4G):

Frequency ETSI/FCC/KC: 2.4~2.483 GHz

MIC: 2.4~2.495 GHz

IEEE 802.11a/n (5G):

ETSI: 5.15~5.35 GHz, 5.47~5.725 GHz

FCC: 5.15~5.35 GHz, 5.47~5.725

GHz, 5.725~5.82 GHz,

MIC: 5.15~5.35 GHz, 5.47~5.725 GHz

KC: 5.15~5.35 GHz, 5.47~5.725 GHz,

5.725~5.82 GHz

Output Power < 20dBm (CE requirement: detection mode- RMS)

< 30dBm (FCC requirement, detection mode- peak power)

Information transmission CMS connection, HL7

Information transmission

## Interfacing

Main unit AC power connector (1)  
Network connector (1)  
USB 2.0 connector (2)  
Ground Cable Connector (1)  
Integrated module slots: 2  
VGA (1)

ECG analog output

Barcode scanner Support

Keyboard&Mouse Support

Remote control Support

Thermal recorder 3 traces (50mm width)

Network printer Support

## Recorder

Type Built-in; Thermal array

Channel 3 channel waveforms

Speed 12.5mm/s, 25mm/s, 50mm/s

Record width 48mm

Real-time record time 8s, 16s, 32s or continual

Alarm record Yes

## Power

Line voltage 100-240V

Frequency 50/60Hz

Battery Rechargeable Lithium-ion battery

Standard, N10MPro: ≥3 hours

10.8V/2500mAH N12MPro/N15MPro: ≥2 hours

(N10/12MPro) N15MPro≥4.5hours

10.8V/5000mAh

(N15MPro)

Optional, N10MPro: ≥6 hours

10.8V/5000mAh N12MPro/N15MPro: ≥4.5 hours

(N10/12MPro) Two batteries: N15MPro≥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)