

# COMEN

## Specification: N10/N12/N15



### **SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD**

Floor 10, Floor 11, and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

Tel: +86-755-26408879

Fax: +86-755-26431232

Email: [info@szcomen.com](mailto:info@szcomen.com)

Web: [en.comen.com](http://en.comen.com)

# 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 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
RR accuracy	0 - 120 rpm: $\pm 1$ rpm 121 - 200 rpm: $\pm 2$ 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
<b>NIBP</b>	
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	$\pm 3$ mmHg( $\pm 0.4$ kPa)
NIBP resolution	1 mmHg
Venous Puncture	Yes
<b>Comen NIBP</b>	
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 $\pm 3$ mmHg Neonate Mode: 147mmHg $\pm 3$ mmHg
Comen Initial pressure range(mmHg)	Adult: 80~290 mmHg Pediatric: 80~240 mmHg Neonate:60~140 mmHg
<b>Suntech NIBP</b>	
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 $\pm 3$ mmHg Neonate Mode: 147mmHg $\pm 3$ mmHg
Suntech Initial pressure range(mmHg)	Adult: 120~280 mmHg Pediatric: 80~170 mmHg Neonate:60~140 mmHg
<b>SpO<sub>2</sub></b>	
Meet standard of ISO 80601-2-61.	
SpO <sub>2</sub> module	Comen, Masimo, Nellcor SpO <sub>2</sub>
SpO <sub>2</sub> 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 <sub>2</sub>
Pitch tone	Yes
Response time	<30s
Data update time	1s
Dual-SpO <sub>2</sub>	Yes, SpO <sub>2</sub> , SpO <sub>2b</sub> , $\Delta$ SpO <sub>2</sub>
<b>PR</b>	
PR range	30-310bpm (COMEN NIBP) 30-220bpm (SUNTECH NIBP) 20-300pm (COMEN SpO <sub>2</sub> ) 25-240pm (Masimo SpO <sub>2</sub> ) 20-300bpm (Nellcor SpO <sub>2</sub> ) 20-350bpm (IBP)
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 SpO <sub>2</sub> ) $\pm 3$ bpm (Masimo SpO <sub>2</sub> ) $\pm 3$ bpm (Nellcor SpO <sub>2</sub> ) $\pm 1$ bpm or $\pm 1\%$ , whichever is greater (IBP)
<b>Temperature (Dual Channel)</b>	
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.

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
sample 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>

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%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
<b>Data review</b>		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	<b>Interfacing</b>	
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		
<b>Alarms</b>		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	<b>Recorder</b>	
<b>Special Functions</b>		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
<b>Wi-Fi Communications</b>		<b>Power</b>	
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)