

COMEN

Specification: ND10/ND12/ND15



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Patient Monitor

ND10/12/15

Physical Characteristics

Size	ND10:300x210x189mm
	ND12:340x236x185mm
	ND15:394x280x189mm
Weight	ND10: 3.5kg
	ND12: 4kg
	ND15: 5kg
Protection level	IPX1
Display	Medical-grade color TFT LCD, capacitive touch screen (optional)
	ND10: 800x600, 10.4 inches
	ND12: 800x600, 12.1 inches
	ND15: 1024x768, 15 inches
Display traces	ND10: Up to 8 waveforms
	ND12: Up to 8 waveforms
	ND15: Up to 10 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

38 classifications including:

Asystole, VF/VT, high PVCs/min, R on T phenomenon, multifocal and paired VPCs, tachycardia, bradycardia, extreme tachycardia, extreme bradycardia, missed beats, polymorphic VPCs, VT, non-sustained VT, ventricular rhythm abnormalities, cardiac pauses with high frequency, irregular rhythms, ventricular bradyarrhythmia, AFib, failure of pacemaker capture or pacing, irregular rhythm cessation, AFib cessation, supraventricular contractions per minute, SVT, atrial bigeminy and trigeminy, R-on-T phenomenon for PACs, ventricular escape beats, non-sustained atrial tachycardia, atrial rhythm, multifocal premature atrial contractions, coupled PACs, and wide QRS complex tachycardia.

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

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, adjustable
Response time	<30s
Data update time	1s
SIQ	Yes, Comen and Masimo
Dual-SpO ₂	Yes, SpO ₂ , SpO _{2b} , Δ SpO ₂

PR

PR range	20-300bpm (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	± 2 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
Temp range	0-50°C
Temp accuracy	$\pm 0.1^\circ\text{C}$ or $\pm 0.2^\circ\text{F}$
Temp resolution	0.1°C
Refreshing rate	1 s
Sensor type	CY, YSI

EtCO₂ (Only for ND12 and ND15)

Meet standard of ISO 80601-2-55.	
EtCO ₂ module	Comen, Masimo, CapnoTrak
Unit	mmHg, kPa
Comen/CapnoTrak Mainstream EtCO₂	
Rise time	<60ms

CO ₂ range	0mmHg-150mmHg
CO ₂ resolution	2mmHg or 0.2kPa or 0.2%
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
Accuracy	±10 ml/min

Masimo Mainstream EtCO₂

CO ₂ range	0mmHg-190mmHg, 0vol%- 25vol% (at 760mmHg)
CO ₂ Accuracy	0mmHg -114mmHg ,± (2.25 mmHg +4% of reading) 115mmHg -190mmHg, Undefined
awRR range	0rpm-150rpm
awRR Accuracy	±1rpm

Comen/CapnoTrak 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 (±12% of actual value when awRR exceeding 80rpm)

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	<5s (2m sampling line)

IBP (Only for ND12 and ND15)

Meet standard of IEC 60601-2-34	
Channel	Up to 2Channels
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
IBP simulation	Yes, dual channels
Support waveforms overlapping	

Cardiac Output (Only for ND12 and ND15)

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	23°C to 43°C
TI range	0°C to 27°C
TB, TI accuracy	±0.1°C
TB, TI resolution	0.1°C

Data review

Tabular Trends	240 hours @1 minute
Graphic Trends	240 hours @1 minute
ST review	120 hours
12-lead ECG analysis	20 groups
NIBP meas.	Standard: 3500 groups
Alarm event	Standard: 2500 events
ARR recall	48 hours
Waveform review	72 hours for single waveform

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
Alarm pauses	Yes
Pause duration	60-180s, or permanent
Alarm latching	Yes

Special Functions

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

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

Waveform Freezing (only for external display

Timer

Other bed viewing

Wi-Fi Communications

Protocol	IEEE 802.11a/b/g/n, internal wi-fi
Modulation Mode	DSSS and OFDM
Operating Frequency	IEEE 802.11b/g/n (2.4G): 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)
Data sharing	CMS, eCenter, HL7

Interfacing

Main unit	AC power connector (1) Network connector (1) USB 2.0 connector (2) Ground Cable Connector (opt, 1) VGA (1) Multi-functional connector (opt, 1) ECG analog output
Barcode scanner	Support
Keyboard & Mouse	Support

Remote control	Support
Thermal recorder	3 traces (48mm width, 20 length)
Network printer	Support

Recorder

Type	Built-in; Thermal array
Channel	3 channel waveforms
Speed	12.5mm/s, 25mm/s, 50mm/s
Record width	50mm
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, 10.8V/2500mAH (ND10/12/15)	ND10/12: ≥4 hours ND15: ≥2.5 hours
Optional, 10.8V/5000mAh (ND10/12/15)	ND10/12: ≥8 hours ND15: ≥6 hours
Charge time	
Power off	≥2.5h to 90% in 2500mAh ≥5h to 90% in 5000mAh
Power on	≥4.5h to 90% in 2500mAh ≥8h to 90% in 5000mAh
Battery indicator	Yes

IT

Compatible system	HIS, EMR
Central monitor	eCenter-CMS, START8800
Protocol	HL7 V2.6 or Comen Protocol
Interface	LAN
Middleware	eCenter-Gateway
Data port	USB
Data share (real time)	Parameters, ADT, Waveforms, Alarm events, Time
Other bed view	Yes

Environment requirements

Temperature	Operating: 5-40°C Storage: -20 to 60°C
Humidity	Operating: 15 to 95% (non-condensing) Storage: 10 to 95% (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)