

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
	ND10: Up to 8 waveforms
Display traces	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	±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
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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 ₂ b, Δ SpO ₂

PR

PR range	20-300bpm (COMEN NIBP) 30-220bpm (SUNTECH NIBP) 20-300bpm (COMEN SpO ₂) 25-240bpm (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
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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%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	<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 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)

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

Thermal recorder

Network printer

Recorder

Type

Channel

Speed

Record width

Real-time record time

Alarm record

Power

Line voltage

Frequency

Battery

Standard,

10.8V/2500mAH (ND10/12/15)

Optional,

10.8V/5000mAh (ND10/12/15)

Charge time

Power off

Power on

Battery indicator

IT

Compatible system

Central monitor

Protocol

Interface

Middleware

Data port

Data share (real time)

Other bed view

Environment requirements

Temperature

Humidity

Support

3 traces (48mm width, 20 length)

Support

Built-in; Thermal array

3 channel waveforms

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

50mm

8s, 16s, 32s or continual

Yes

100-240V

50/60Hz

Rechargeable Lithium-ion battery

ND10/12: ≥4 hours

ND15: ≥2.5 hours

ND10/12: ≥8 hours

ND15: ≥6 hours

≥2.5h to 90% in 2500mAh

≥5h to 90% in 5000mAh

≥4.5h to 90% in 2500mAh

≥8h to 90% in 5000mAh

Yes

HIS, EMR

eCenter-CMS, START8800

HL7 V2.6 or Comen Protocol

LAN

eCenter-Gateway

USB

Parameters, ADT, Waveforms, Alarm events, Time

Yes

Operating: 5-40°C

Storage: -20 to 60°C

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)