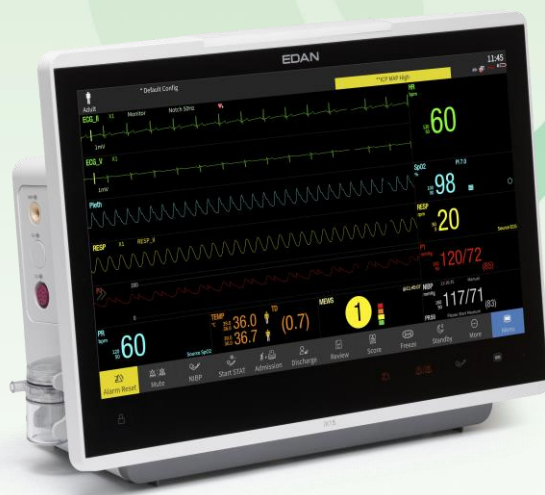


iX15

Patient Monitor

Version 1.0



Main Unit Specification

Physical Specifications

Dimension	385 mm (W) × 286 mm (H) × 162 mm (D)
Weight	< 4.9 kg (standard configuration, excluding battery, accessories, and recorder)

Power Supply

AC Voltage	100 V to 240 V~
Input Current	1.6 A to 0.8 A
Frequency	50 Hz/60 Hz
Over Current Fuse Protection	Support

Battery

Battery Type	Rechargeable lithium-ion battery
Operating Time	Two batteries (2×2500 mAh) ≥ 5 h
	Two batteries (2×5000 mAh) ≥ 10 h
Charge Time	Two batteries (2×2500 mAh) ≤ 5 h (monitor is off)
	Two batteries (2×2500 mAh) ≤ 10 h (monitor is running or in standby mode)
	Two batteries (2×5000 mAh) ≤ 10 h (monitor is off)
	Two batteries (2×5000 mAh) ≤ 20 h (monitor is running or in standby mode)

Display

Display screen	15.6-inch color TFT, supporting touch screen
Resolution	1920 × 1080
Messages	A maximum of 12 waveforms

Recorder

Record Width	48 mm
Paper Speed	12.5 mm/s, 25 mm/s, 50 mm/s
Channels	3
Recording types	Continual real-time recording 8-second real-time recording Trend graph recording Trend table recording C.O. measurement recording NIBP trigger recording ST VIEW recording QT VIEW recording

Data Storage

Trend data	2400 hours @ 1 second
NIBP Measurement	1200 sets
Alarm Events	1000 sets

Wi-Fi

IEEE	802.11a/b/g/n
Frequency Band	2.4 GHz ISM band & 5 G ISM band

Interfaces and Others

Nurse Call / Analog Output/ Defibrillator Synchronization	1
USB Interfaces	4
HDMI Interface	1
RS232 Interface	1
Wired Network Interface	1

ECG

Lead Mode	3 Electrodes: I, II, III
	5 Electrodes: I, II, III, aVR, aVL, aVF, V
	6 Electrodes: I, II, III, aVR, aVL, aVF, Va, Vb.
	10 Electrodes: I, II, III, aVR, aVL, aVF, V1-V6
Electrode Standard	AHA, IEC
Display Sensitivity	×0.125, ×0.25, ×0.5, ×1, ×2, ×4, AUTO gain
Sweep	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
Bandwidth (-3 dB)	Diagnosis: 0.05 Hz to 150 Hz
	Diagnosis 1: 0.05 Hz to 40 Hz
	Monitor: 0.5 Hz to 40 Hz
	Surgery: 1 Hz to 20 Hz
	Enhanced: 2 Hz ~18 Hz
	Customized: High-pass Filter and Low-pass Filter
CMRR	Diagnosis: > 95 dB
	Diagnosis 1: > 105 dB (when Notch is turned on)
	Monitor: > 105 dB
	Surgery: > 105 dB
	Enhanced: > 105 dB
	Customized: > 105 dB (Low-pass Filter < 40 Hz)
	> 95 dB (Low-pass Filter > 40 Hz)
Hum Filter	In diagnosis, Diagnosis 1, monitor, surgery, enhanced and customized modes: 50 Hz/60 Hz (Hum Filter can be turned on or off manually)
Recovery Time After Defibrillation	<5 s
ESU Protection	Cut mode: 300 W
	Coagulation mode: 100 W
	Restore time: ≤10 s
Pace pulse detection	one among I, II, III, aVR, aVL, aVF, V1-V6
Heart Rate	
Range	ADU: 15 bpm to 300 bpm

	PED/NEO: 15 bpm to 350 bpm
Accuracy	±1% or ±1 bpm, whichever is greater
Resolution	1 bpm

PVC

Range	ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min
Resolution	1 PVCs/min

Pause/min

Range	ADU/PED/NEO: (0 to 30) pauses/min
Resolution	1 pause/min

ST value

Range	-2.0 mV to +2.0 mV
Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.
Resolution	0.01 mV

QT measurement

Range	200 ms ~ 800 ms
Resolution	4 ms
Accuracy	± 30 ms

QTc measurement

Range	200 ms ~ 800 ms
Resolution	1 ms

ΔQTc measurement

Range	-600 ms ~ 600 ms
Resolution	1 ms

Arrhythmia analysis

Asystole, Sustain VT, V-Fib/V-Tach, ExtremeTachy, ExtremeBrady, V-Tach, Vent Brady, Tachy, Brady, Wide QRS Tachy, Non-Sustain VT, Afib, Vent Rhythm, Acc. Vent Rhythm, Pause, Pauses/min High, PVCs High, R on T, PVC Bigeminy, PVC Trigeminy, Pacer not Pacing, Pacer not Capture, Missed Beat, VEB, PVC, Couplet, Run PVCs, IPVC, Irr Rhythm, PAC Bigeminy, Multiform PVCs, PAC Trigeminy, Low Voltage (Limb)

12-lead ECG Synchronization Analysis

Average parameters of heart beat	PR interval (ms)
Heart rate (bpm)	QRS interval (ms)
Time limit of P wave (ms)	QT/QTc (ms)
P-QRS-T AXIS	

RESP

Method	Impedance between RA-LL, RA-LA
Measurement lead	Options are lead I and II. The default is lead II.
Measuring range	0 rpm to 200 rpm
Resolution	1 rpm
Accuracy	6 rpm to 200 rpm: ±2 rpm 0 rpm to 5 rpm: not specified
Gain Selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
Sweep	6.25 mm/s, 12.5 mm/s, 25.0 mm/s, 50.0 mm/s
Apnea Alarm Time	10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s

NIBP

Method	Oscillometry
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Mode	Manual, Auto, Continuous, Sequence
Measuring Interval in Auto Mode	1/2/2.5/3/4/5/10/15/30/60/90/120/180/240/360/480 min and User Define
Continuous	5 min, interval is 5 s
Measuring Type	SYS, DIA, MAP, PR

Measuring Range	
Adult Mode	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg
Pediatric Mode	SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg
Neonatal Mode	SYS: 25 mmHg to 140 mmHg DIA: 10 mmHg to 115 mmHg MAP: 15 mmHg to 125 mmHg

Cuff Pressure	
Measuring Range	0 mmHg to 300 mmHg
Pressure Resolution	1 mmHg
Maximum Mean Error	±5 mmHg
Maximum Standard Deviation	8 mmHg
Maximum Measuring Period	Adult/ Pediatric: 120 s Neonatal: 90 s
Typical Measuring Period	iCUFS measurement: 20 s to 35 s iFAST measurement: 15 s
Dual Independent Channel Overpressure Protection	Adult: (297±3) mmHg Pediatric: (245±3) mmHg Neonatal: (147±3) mmHg

CNBP

Measuring Range (Adult)	SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg
Measuring Range (Pediatric)	SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg
Alarm Type	SYS, DIA
Pressure Resolution	1 mmHg
Maximum Mean Error	±5 mmHg
Maximum Standard Deviation	8 mmHg

BPVI

Measuring Range	0~100%
Resolution	1%
Update Frequency	5 s

EDAN Module SpO₂

Measuring Range	0% to 100%
Resolution	1%
Data update period	1 s
Accuracy	Adult/Pediatric: ±2% (70% to 100% SpO ₂) Undefined (0% to 69% SpO ₂) Neon: ±3% (70% to 100% SpO ₂) Undefined (0% to 69% SpO ₂)

PI (Perfusion Index)

Measuring Range	0 to 20%, invalid PI value is -?.
Resolution	1% (10% to 20%) 0.1% (1.0% to 9.9%) 0.01% (0.00% to 0.99%)

Nellcor Module SpO₂

Measuring Range	1% to 100%
Resolution	1%
Data Update Period	1 s
Accuracy	
DS-100A, OXI-A/N (Adult)	
D-YS (Adult and Pediatric)	
OXI-P/I (Pediatric)	±3% (70% to 100% SpO ₂)
MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±2% (70%~100% SpO ₂)
MAX-A, MAX-AL, MAX-N, MAX-P, MAX-I, MAX-FAST (Adult and Pediatric)	±3% (60%~80% SpO ₂)

PR

PR (SpO₂)

Measuring range	EDAN: 25 bpm to 300 bpm Nellcor: 20 bpm to 300 bpm
Accuracy	EDAN: ±2 bpm Nellcor: ±3 bpm (20 bpm to 250 bpm)
Resolution	EDAN: 1 bpm Nellcor: 1 bpm

PR (NIBP)

Measuring range	EDAN: 40 bpm to 240 bpm
Accuracy	EDAN: ±3 bpm or 3.5%, whichever is greater
Resolution	EDAN: 1 bpm

PR (IBP)

Measuring range	EDAN: 20 bpm to 300 bpm
Accuracy	EDAN: 30 bpm to 300 bpm: ±2 bpm or ±2%, whichever is greater; 20 bpm to 29 bpm: undefined
Resolution	EDAN: 1 bpm

TEMP

Channel	2
Sensor Type	YSI-10K and YSI-2.252K
Technique	Thermal resistance
Measure Parameter	T1, T2, TD (the absolute value of T2 minus T1)
Position	Skin, oral cavity, rectum
Unit	°C, °F
Measuring Range	0°C to 50°C (32°F to 122°F)
Resolution	0.1°C (0.1°F)
Accuracy	±0.3 °C (± 0.1 °C exclude sensor error)
Transient Response Time	≤30 s

IBP

Channel	4
Technique	Direct invasive measurement
Measuring Range	
ART, Ao, UAP, BAP, FAP, LV, P1-P4	(-50 mmHg to +400) mmHg
PA	(-6 mmHg to +120) mmHg
CVP, ICP, LAP, RAP, UVP	(-10 mmHg to +40) mmHg
Resolution	1 mmHg
Accuracy	±2% or ±1 mmHg, whichever is greater
(not including sensor)	ICP: 0 mmHg to 40 mmHg: ±2 % or ±1 mmHg, whichever is greater; -10 mmHg to -1 mmHg: undefined
Unit	kPa, mmHg, cmH ₂ O

EDAN G2 Sidestream Module CO₂

Intended patient	Adult, pediatric, neonatal
Measure Parameters	EtCO ₂ , FiCO ₂ , AwRR
Unit	mmHg, %, kPa
Measuring Range	EtCO ₂ : 0 mmHg to 150 mmHg (0% to 20%) FiCO ₂ : 0 mmHg to 50 mmHg AwRR: 0 rpm to 150 rpm
Resolution	EtCO ₂ : 1 mmHg FiCO ₂ : 1 mmHg AwRR: 1 rpm
EtCO₂ Accuracy	
Typical conditions:	±2 mmHg, 0 to 40 mmHg
Ambient temperature: (25±3) °C	±5% of reading, 41 to 70 mmHg
Barometric pressure: (760±10) mmHg	±8% of reading, 71 to 100 mmHg
Balance gas: N ₂	±10% of reading, 101 to 150 mmHg
Sample gas flowrate: 100 ml/min	
All conditions	±12% of reading or ±4 mmHg, whichever is greater
AwRR Accuracy	±1 rpm
Sample Gas Flowrate	50 ml/min, 70 ml/min or 100 ml/min (optional), accuracy: ±15 ml/min
Warm-up Time	Display reading within 20 s; reach to the designed accuracy within 2 minutes.
Response Time	< 4 s (with 2 m gas sampling tube, sample gas flowrate: 100 ml/min&70 ml/min) < 5.5 s (with 2 m gas sampling tube, sample gas flowrate: 50 ml/min)
Barometric Pressure Compensation	Automatic (The change of barometric pressure will not add additional errors to the measurement values.)
Zero Calibration	Support
Calibration	Support
Apnea Alarm Delay	10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s

Responics Sidestream and Mainstream Module CO₂

Applicable Patient Type	Adult, pediatric and neonatal patients
Method	Infra-red Absorption Technique
Measure Parameters	EtCO ₂ , FiCO ₂ , AwRR
Unit	mmHg, %, kPa
Measuring Range	EtCO ₂ : 0 mmHg to 150 mmHg FiCO ₂ : 3 mmHg to 50 mmHg AwRR: 2 rpm to 150 rpm (Sidestream) 0 rpm to 150 rpm (Mainstream)
Resolution	EtCO ₂ 1 mmHg FiCO ₂ 1 mmHg AwRR 1 rpm
EtCO₂ Accuracy	±2 mmHg, 0 mmHg to 40 mmHg ±5% of reading, 41 mmHg to 70 mmHg ±8% of reading, 71 mmHg to 100 mmHg ±10% of reading, 101 mmHg to 150 mmHg ±12% of reading, RR is over 80 rpm (Sidestream) There will be no degradation in performance due to respiration rate. (mainstream)
AwRR Accuracy	±1 rpm
Apnea Alarm Delay	10 s, 15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s
Zero Calibration	Support
Sample Gas Flow Rate (Sidestream)	(50 ±10) ml /min
Barometric Pressure Compensation	User setup
CO₂ Rise Time/Response Time (Mainstream)	< 60 ms
Sensor Response Time (Sidestream)	< 3 seconds, includes transport time and rise time

Masimo Sidestream Module CO₂

Ambient CO ₂	≤ 800 ppm (0.08 vol%)
Sampling Flow Rate	(50 ± 10) sml/min
Respiration Rate	0 to 150 ± 1 breaths/min.
Calibration	No span calibration is required.
Warm-up Time	< 10 seconds
CO ₂ Rise Time At 50sml/min Sample Flow	≤ 200 ms
NomoLine ISA CO ₂ System Response Time	< 3 seconds
Apnea Alarm Delay	15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s
AwRR Range	0 rpm to 150 rpm
AwRR Accuracy	± 1 rpm
CO ₂ Accuracy	
Standard Conditions	±(0.2 vol% + 2% of reading), (0 to 15) vol% Unspecified, (15 to 25) vol%
All Conditions	±(0.3 kPa + 4% of reading)

Masimo Mainstream Module CO₂

Respiration Rate	0 to 150 ± 1 breaths/min.
Calibration	No span calibration required for the IR bench.
Warm-up Time	< 10 seconds
Rise Time (@ 10 l/min)	≤ 90 ms
Total System Response Time	Total system response time
Apnea Alarm Delay	15 s, 20 s (Default), 25 s, 30 s, 35 s, 40 s
AwRR Range	0 rpm to 150 rpm
AwRR Accuracy	± 1 rpm
CO ₂ Accuracy	
Standard Conditions	±(0.2 vol% + 2% of reading), (0 to 15) vol% Unspecified, (15 to 25) vol%
All Conditions	±(0.3 kPa + 4% of reading)

C.O.

Technique	Thermodilution Technique
Measure Parameters	C.O.: TB, TI
Measuring Range	C.O.: 0.1 L/min to 20 L/min TB: 23°C to 43°C (73.4°F to 109.4°F) TI: -1°C to 27°C (30.2°F to 80.6°F)
Resolution	C.O. : 0.1 L/min TB, TI : 0.1°C (+0.1°F)
Accuracy	C.O.: ±5% or ±0.2 L/min, whichever is greater TB: ±0.1°C (±0.18 °F) (not including sensor) TI : ±0.1°C (±0.18 °F) (not including sensor)

EDAN G7 (Sidestream) AG

Intended Patient	Adult, pediatric, neonatal
Measure Parameters	Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), CO ₂ , O ₂ , N ₂ O, AwRR, and MAC
Unit	HAL, ISO, ENF, SEV, DES, N ₂ O: %; CO ₂ , O ₂ : mmHg, %, kPa, default is %; AwRR: bpm;
Measuring Range	
CO ₂	0~15 vol%
N ₂ O	0~100 vol%
Halothane/ Enflurane/ Isoflurane	0~8 vol%
Sevoflurane	0~10 vol%

Desflurane	0~22 vol%
O ₂	0~100%
Resolution	N ₂ O, O ₂ : 1% CO ₂ , AG: 0.1%
AwRR	Measurement range: 2 ~ 150 rpm Measuring accuracy: ±1 bpm (120 bpm and below), Not specified (120 bpm above) Resolution: 1 rpm
Sampling Flow Rate	150 ml/min, accuracy ±15 ml/min
Warm-up Time	Display reading within 20 s; reach to the designed accuracy within 2 minutes
Response Time	< 4 s (with 2 m gas sampling tube, sample gas flowrate: 150 ml/min)

Masimo ISA Analyzer AG

Module Type	
ISA AX+	Displaying the concentration of CO ₂ , N ₂ O, and two anesthesia agent and identifying the anesthesia agent automatically (built-in module)
ISA OR+	Displaying the concentration of CO ₂ , O ₂ , N ₂ O, and two anesthesia agent and identifying the anesthesia agent automatically (built-in module)
Measurement Parameters	CO ₂ , N ₂ O, O ₂ , Halothane (HAL), Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), AwRR, MAC
Measurement Principle	CO ₂ , N ₂ O, Anesthesia Agent: Infra-red absorption characteristic; O ₂ : Paramagnetic method
Sampling Flow Rate	50 ± 10 ml/min
Compensations	Automatic compensation for pressure, temperature and broadening effects on CO ₂ .
Warm-up Time	< 20 s
Measurement Range	CO ₂ : 0 to 25 vol% O ₂ : 0 to 100 vol% N ₂ O: 0 to 82 vol% HAL, ENF, ISO, SEV, DES: 0-25 vol% AwRR: 0 rpm to 150 rpm
Resolution	CO ₂ : 0.1% HAL, ENF, ISO, SEV, DES: 0.1% N ₂ O: 1% O ₂ : 1% AwRR: 1 rpm
Accuracy(Standard Conditions)	
CO ₂	± (0.2 vol% + 2% of reading), 0 to 15 vol% Unspecified, 15 to 25 vol%
N ₂ O	± (2 vol% + 2% of reading), 0 to 82 vol%
HAL, ENF, ISO	± (0.15 vol% + 5% of reading), 0 to 8 vol % Unspecified , 8 to 25 vol %
SEV	± (0.15 vol% + 5% of reading), 0 to 10 vol % Unspecified, 10 to 25 vol %
DES	± (0.15 vol% + 5% of reading), 0 to 22 vol % Unspecified, 22 to 25 vol %
O ₂	± (1 vol% + 2% of reading), 0 to 100 vol %
Accuracy(All Conditions)	
CO ₂	±(0.3 kPa + 4% of reading)
N ₂ O	±(2 kPa + 5% of reading)
Agents	±(0.2 kPa + 10% of reading) (The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set)
O ₂	±(2 kPa + 2% of reading)
AwRR Accuracy	±1 rpm
Apnea Alarm Delay	20 s (Default), 25 s, 30 s, 35 s, 40 s

Masimo IRMA Module AG

Module Type: IRMA AX+	Displaying the concentration of CO ₂ , N ₂ O and two anesthesia agent and identifying two anesthesia agent
Measurement Parameters	CO ₂ , N ₂ O, HAL, Isoflurane (ISO), Enflurane (ENF), Sevoflurane (SEV), Desflurane (DES), AwRR, MAC
Measurement Principle	CO ₂ , N ₂ O, anesthesia agent: infra-red absorption characteristic
Barometric Pressure Compensation	Automatic
Warm-up Time	<20 seconds
Measurement Range	CO ₂ : 0 to 25 vol% N ₂ O: 0 to 82 vol% HAL, ENF, ISO, SEV, DES: 0 to 25 vol% AwRR: 0 to 150 rpm
Resolution	CO ₂ : 0.1% HAL, ENF, ISO, SEV, DES: 0.1% N ₂ O: 1% AwRR: 1 rpm
Accuracy(Standard Conditions)	
CO ₂	± (0.2 vol% + 2% of reading), 0 to 15 vol%
N ₂ O	± (2 vol% + 2% of reading), 0 to 82 vol%
HAL, ENF, ISO	± (0.15 vol% + 5% of reading), 0 to 8 vol %
SEV	± (0.15 vol% + 5% of reading), 0 to 10 vol %
DES	± (0.15 vol% + 5% of reading), 0 to 22 vol %
Accuracy(All Conditions)	
CO ₂	±(0.3 kPa + 4% of reading)
N ₂ O	±(2 kPa + 5% of reading)
Agents	±(0.2 kPa + 10% of reading) (The accuracy specification is not valid if more than two agents are present in the gas mixture. If more than two agents are present, an alarm will be set)
AwRR Accuracy	±1 rpm
Apnea Alarm Delay	20 s (Default), 25 s, 30 s, 35 s, 40 s

Safety Specifications

Compliant with Standards	IEC 60601-1: 2005+A1 :2012; IEC 60601-1-2: 2014; EN 60601-1: 2006+A1 :2013; EN 60601-1-2: 2015; IEC 80601-2-49: 2018
Anti-electroshock Type	Class I equipment and internal powered equipment
Anti-electroshock Degree	CF
Ingress Protection	IP22

Environmental Specifications

Temperature	Working: +0°C to +40°C (32°F ~ 104°F) Transport and storage: -20°C to +60°C (-4°F ~ 140°F)
Humidity	Working: 15%RH to 95%RH (non-condensing) Transport and storage: 10%RH to 95%RH (non-condensing)
Altitude	Working: 57 kPa to 107.4 kPa Transport and storage: 16 kPa to 107.4 kPa