Specification: ND10/ND12/ND15

SHENZHEN COMEN MEDICAL INSTRUMENTS CO., LTD

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COMEN
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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	±3mmHg(±0.4kPa)
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±3mmHg Neonate Mode: 147mmHg±3mmHg
Comen Initial pressure range(mmHg)	Adult: 80-290 mmHg Pediatric: 80-240 mmHg Neonate:60-140 mmHg

SpO_2

Meet standard of ISO 80601-2-61.

SpO_2 module	Comen, Masimo, Nellcor SpO2
SpO2 range	0 to 100%
Resolution	1%
Accuracy	Ped/Adu: ±2% (70-100%) Neo: ±3% (70-100%);
Alarm range	1-100%
Perfusion index	Yes, for Comen and Masimo SpO2
Pitch tone	Yes, adjustable
Response time	<30s
Data update time	1s
SIQ	Yes, Comen and Masimo
Dual-SpO2	Yes, SpO2, SpO2b, ΔSpO2

PR

PR range	20-300bpm (COMEN NIBP) 30-220bpm (SUNTECH NIBP) 20-300pm (COMEN SpO2) 25-240pm (Masimo SpO2) 20-300bpm (Nellcor SpO2) 20-350bpm (IBP)
Accuracy	±2bpm or ±3%, whichever is greater (COMEN NIBP) ±3bpm or ±2%, whichever is greater (SUNTECH NIBP) ±2bpm (COMEN SpO2) ±3bpm (Masimo SpO2) ±3bpm (Nellcor SpO2) ±1bpm or ±1%, whichever is greater (IBP)

Temperature (Dual Channel)

Technique	Thermal resistance
Channels	2 channels
Temp range	0-50°C
Temp accuracy	±0.1°C or ±0.2°F
Temp resolution	0.1°C
Refreshing rate	1 s
Sensor type	CY, YSI

$EtCO_2$ (Only for ND12 and ND15)

Meet standard of ISO 80601-2-55.

EtCO2 module	Comen, Masimo, CapnoTrak
Unit	mmHg, kPa

Comen/CapnoTrak Mainstream $EtCO_2$

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 $EtCO_2$

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 $EtCO_2$

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 $EtCO_2$

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℃
TB, TI resolution	0.1℃

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℃ Storage: -20 to 60℃
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)

Copyright

Version: B00

No.: 046-00001001-00

Product Name: Multi-parameter Patient Monitor

Product Model: ND10/ND10A/ND10C/ND10S/ND12/ND12A/ND12C/ND12S/ND15/ND15A/ND15C/ND15S

Software Version: V1.0

Revision Date: 05/2024

Service Life: 10 years

Company name: Shenzhen Comen Medical Instruments Co., Ltd.

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Statement

This manual is only intended for users as a reference for operation, maintenance and repair of Comen product ND10/ND10A/ND10C/ND10S/ND12/ND12A/ND12C/ND12S/ND15/ND15A/ND15C/ND15S. No one shall disclose the contents here of to any other person.

Comen shall assume no liability for misuse of the information contained herein or any incidental or indirect damages arising from improper operation or actual performance due to use of this manual. This Manual does not imply the transfer of any proprietary right under patent law to any third party. Comen shall not be liable for any legal consequences arising out of breach of the patent law or infringement of any third-party rights.

Please note that while every effort has been made to ensure that the data provided in this document are accurate, the information, figures, illustrations, tables, specifications, and schematics contained herein, are subject to change without prior notice.

Warranty

Comen will be responsible for the safety, reliability and performance of the product within the warranty period, if all of the following conditions are satisfied:

- The product is used in accordance with this ***Manual***.
- The product is installed, maintained or upgraded by approved or authorized personnel by Comen.
- The storage and operating environments for the product shall comply with the recommended information and product specifications contained in this manual.
- The serial number label or manufacturing mark of the product is clearly legible.
- The damage is not caused by human factors.

The product will be repaired or replaced free of charge within the warranty period. After the warranty period, Comen will charge for the service and replacement parts. If the products need to be returned to Comen for service, the freight charges (including the customs duty) should be on the customer's account.

Return

If the products need to be returned to Comen, please contact Comen After-sales Service Department to acquire the right to return the goods. You must provide product serial number, which can be found on the product's nameplate. If the serial number is illegible, your return request will be rejected. Please also present the manufacture date and briefly describe the reason for return.

After-Sales Service

Name: After-sales Service Department of Shenzhen Comen Medical Instrument Co., Ltd.

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Preface

This manual provides details on the performance, operations, maintenance, storage and safety instructions of ND10/ND10A/ND10C/ND10S/ND12/ND12A/ND12C/ND12S/ND15/ND15A/ND15C/ND15S Multi-Parameter Patient Monitor (hereinafter referred to as the “monitor”).

Intended Users

This manual is intended for trained professionals and personnel who are expected to have working knowledge of medical procedures, practices and terminology as required for monitoring patients.

Illustrations

All illustrations provided herein are for reference only. The menus, options, values and functions shown in the illustrations may not be exactly identical to what you see on the monitor.

Conventions

- —>: Indicates operating steps.
- **[Character]**: Indicates user screen text.

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Contents

Chapter 1 Safety

1.1 Safety Information

⚠ WARNING

- Information that alerts you to situations that may result in serious consequences or endanger personal safety. Failure to observe the warning information may cause severe injury or even death of the user or patient.

⚠ CAUTION

- Alerts you to potential dangers or unsafe operations, which, if not avoided, may result in minor injury, product failure or damage, or property damage, or cause more serious injury in the future.

⚠ NOTE

- Emphasizes important precautions and provides instructions or explanations for better use of the product.

⚠ WARNING

- This device is intended to be operated only by trained users, whose training records should be archived. No unauthorized or untrained persons are allowed to operate this device.
- No modification of this equipment is allowed.
- Before using this device, please read and understand the entire User Manual. Any attempt to use this device (and all other medical devices) without full understanding of the operating instructions may cause injury to the patient or user.
- Do not place the power plug/appliance coupler used to disconnect the device from supply mains in a position not easily accessible to the operator.
- Alarm volume and high/low alarm limits should be set depending on the patient. When a patient is monitored, do not exclusively rely on the audible alarm system. If the alarm volume is set too low or is completely turned off, the alarm will not be heard, and the patient may be put into danger. Pay close attention to the patient's actual clinical conditions continuously is the most reliable way.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth. If the power socket is not connected to a ground conductor, use the rechargeable battery to supply power to the monitor instead of using the supply mains.
- Do not open the housing of the monitor to avoid the potential risk of electric shock. The monitor must be maintained and upgraded by service technician trained and authorized by Comen.

- Follow the local laws and regulations or the waste disposal rules of the hospital when disposing of packaging materials. Keep the packaging materials out of the reach of children.
- Do not use the monitor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- MR unsafe: the device is not intended to be used within the Magnetic Resonance (MR) environment.
- The device is intended to be used within the electrosurgical environment.
- Carefully place the monitor power cord and accessories cables to avoid entanglement, potential strangulation, and electrical interference to the patient.
- For patients with pacemakers, the cardio tachometer may be used to record pacemaker pulse in the event of asystole or arrhythmia. Do not completely rely on the alarm function of the cardiotachometer. Patients with pacemakers must be closely monitored. For the pacemaker inhibiting function of the monitor, please refer to relevant section in this Manual.
- During defibrillation, the operator should not come into contact with the patient, the monitor or the supporting table; otherwise may result in serious injury or death. Before reusing the cables, check to confirm that their functions are normal.
- Any equipment connected to the monitor shall form an equipotential body (effective connection of protective ground).
- In order to avoid burns (resulted from electric leakage) to the patient, ensure that the monitor's sensors and sensor cables never come into contact with any high-frequency electrosurgical equipment or metal part.
- The physiological waveform and parameter, alarm message and other information displayed by the monitor are only reference to physicians, and not directly used as a basis for clinical decision.
- Electromagnetic field can affect the performance of the monitor. Therefore, equipment used near the monitor should conform to the applicable EMC requirements. For example, mobile phones and X-ray machines are potential sources of interference, since they transmit high-intensity electromagnetic radiation.
- This monitor is not therapeutic equipment.
- After defibrillation, the electrocardiogram (ECG) recover within 5s; other parameters would recover within 10s.
- For accessories provided in sterile, please refer to the operating instructions for accessories.
- Anyone connecting additional equipment to the signal input port or the signal output port configures a medical system, and, therefore, is responsible that the system complies with the requirements of the system standard IEC 60601-1. If in doubt, consult the technical service department or your local representative.
- Any touch of Signal Input/Signal Output connectors while simultaneously touching the patient is not allowed.
- If more than one piece of external equipment is connected to the monitor at one time through the patient cable connector, network connector or other signal ports, the total leakage current should be in accordance with the requirement specified in IEC 60601-1.
- Please use an external power supply in time before the battery runs out.
- Do Not adjacent to or stacked with other equipment, or it may result in improper operation. If such use is necessary, this equipment and the other equipment should be observed carefully to verify that they are operating normally.

- Only qualified service engineers authorized by the manufacturer can open the battery compartment and replace the battery, and batteries of the same model and specification should be used.
- Do not connect electrode or sensor lead wires into electrical outlets. Lead wire contact with electrical outlets presents a serious shock hazard.

⚠ CAUTION

- To avoid damage to the monitor, and ensure patient's safety, use accessories specified in this manual.
- Handle the monitor carefully to avoid damage caused by drop, collision, strong oscillation or other external mechanical forces.
- Before powering on the monitor, verify that the supply voltage and frequency conform to the specification of the monitor marked or in this manual.
- At the end of the monitor service life, the monitor and its accessories must be disposed of in accordance with the local laws and hospital's regulations.
- To achieve the galvanic isolation between the monitor and the input power supply, please disconnect the monitor power plug.
- Do not connect other multi-hole sockets and extension cords to this monitor.

⚠ NOTE

- Place the monitor at a position where observation, operation and maintenance are convenient and not obstructed.
- This manual is based on the maximum configuration; therefore, some contents may not be applicable to your monitor.
- Please read this entire manual before using the system for the first time. Keep this manual handy for your reference
- The monitor is not intended for home use.
- The monitor can only be used on one patient at a time.
- The operator should be within one meter of the monitor.

1.2 Contraindications

- It is forbidden to use the electrode on inflammatory or festering skin.
- Patients allergic to electrode conducting medium are forbidden to use the product.
- Patients with local skin damage on either upper arm are forbidden to use the blood pressure cuff.
- It is forbidden to long clip the SpO_2 probe at the same position.
- Patients allergic to rubber material are forbidden to use the product.
- It is forbidden to measure NIBP on patients with sickle cell disease.

1.3 Symbols

	Caution		Defibrillation-proof Type BF applied part
	Defibrillation-proof Type CF applied part		Serial number
	USB 2.0 connection		Equipotentiality
	on/off key		Computer network
	Battery status indicator/ Battery check		Input and Output
	Standby		Manufacturer
	Menu	IPX1	Protected against vertically falling water drops per IEC 60529
	Refer to instruction manual/ Follow instructions for use		Alternating current
	Unlocking		Correct Disposal of This Product (Waste Electrical & Electronic Equipment) Statement: Contact the local authorities to determine the proper method of disposal of potentially bio-hazardous parts and accessories.
	Warning	EC REP	Authorized representative in the European Community
	Medical Devices Regulation 2017/745 (EU)		Date of manufacture
MD	Medical device		Gas output
	Gas Input		Alarm reset

	Alarm paused		VGA connector
	NIBP start/stop	/	/

	This way up		Stacking limit by 4
	Fragile, handle with care		Keep dry
	Does not contain DEHP		Latex free
	Do not re-use		Use-by date
	Do not use if package is damaged and consult instructions for use		Do not re-sterilize

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Chapter 2 Overview

The monitor comes standard with rotary knob and can be equipped with an optional touch screen for direct touch operation. The device is designed in accordance with domestic and international safety standards in relation to medical electrical equipment.

2.1 Product Introduction

2.1.1 Product Composition

This monitor is mainly composed of power supply module, main control unit, ON/OFF key board, infrared transponder, main board of autonomous system, recorder, display screen and battery supply module.

2.1.2 Intended Use

ND series patient monitor is a multi-parameter physiological patient monitor intended for use in multiple areas and intra-hospital transport within a professional healthcare facility. The monitors support multiple non-invasive and invasive measurements, including ECG (3-lead, 5-lead, 6-lead or 12-lead selectable), Arrhythmia Analysis, ST Segment Analysis, QT Analysis, interpretation of resting 12-lead ECG, Heart Rate (HR), Respiration rate(impedance respiration and CO_2 airway gas), Temperature(Temp), Pulse Rate (PR), Pulse Oxygen Saturation (SpO_2), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP) , Pulmonary Artery Wedge Pressure (PAWP), Cardiac Output (C.O.), Carbon Dioxide (CO_2).

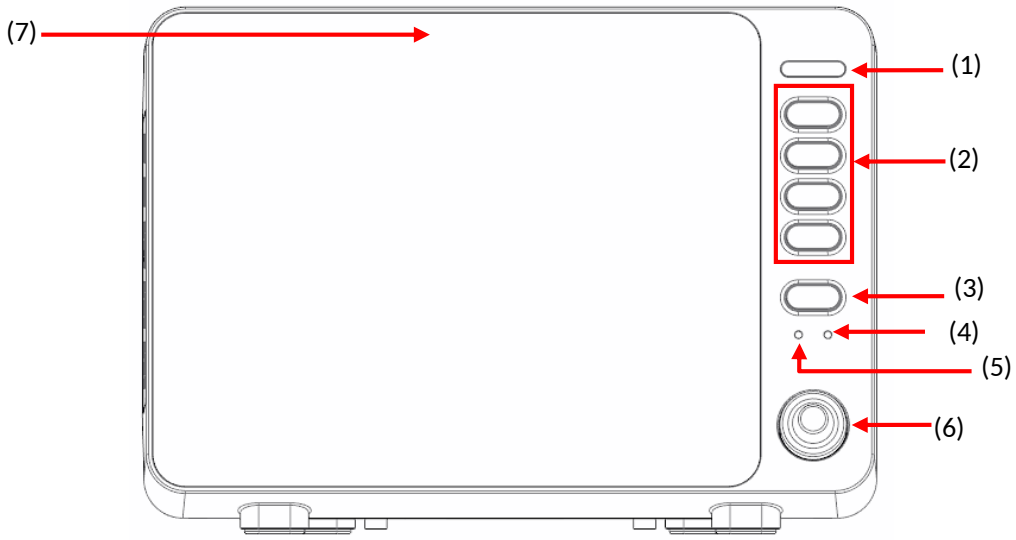
The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. The monitors are not intended for emergency and transport use or home use.

All the parameters can be monitored on single adult, pediatric and neonatal patients except for the following:

- C.O. measurement is intended for adult only.

2.2 Monitor Appearance

2.2.1 Front View



(1) Alarm indicator

(2) Function keys

: (Alarm reset) Press this key to reset current alarm.

: (Alarm pause) Press this key to pause or resume an alarm.

: (NIBP start/stop) Press this key to start or stop NIBP measurement.

: (Main menu) Press this key to enter main menu.

(3) Power switch

(4) Battery indicator

- Indicator light remains on: Battery is being charged.
- Indicator light blinks: Battery is used to supply voltage.
- Indicator light off: Battery is fully charged, is not installed or malfunctions.

(5) AC indicator

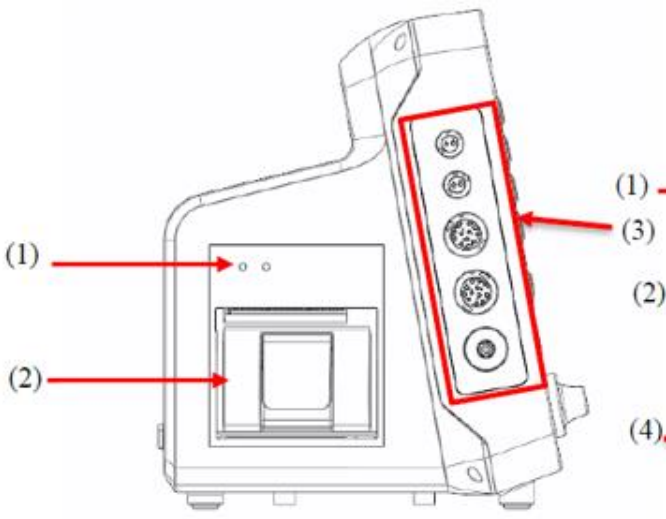
- Indicator light on: AC power supply is connected.
- Indicator light off: AC power supply is not connected.

(6) Rotary knob

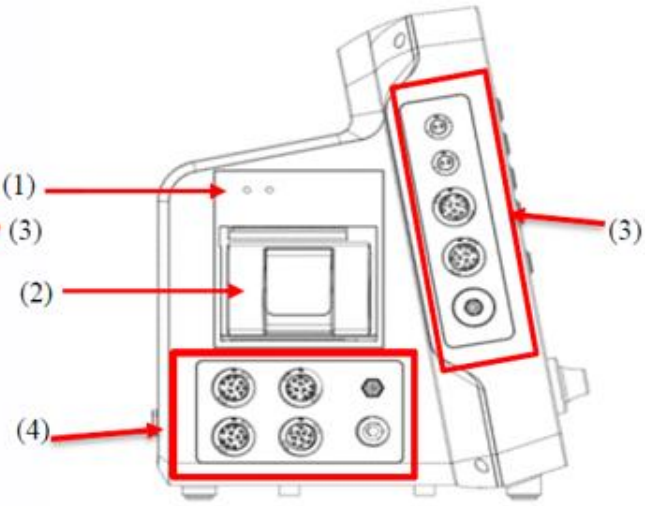
(7) Display screen

2.2.2 Left View

The ports shown in the figure below are provided on the left side of the monitor:



ND10/ND10A/ND10C/ND10S Left View



ND12/ND12A/ND12C/ND12S/
ND15/ND15A/ND15C/ND15S Left View

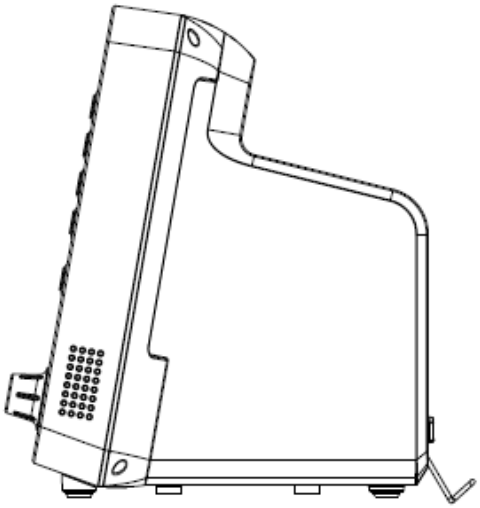
(1) Recorder indicator
- Left: Fault alarm light
- Right: Power indicator

(2) Recorder

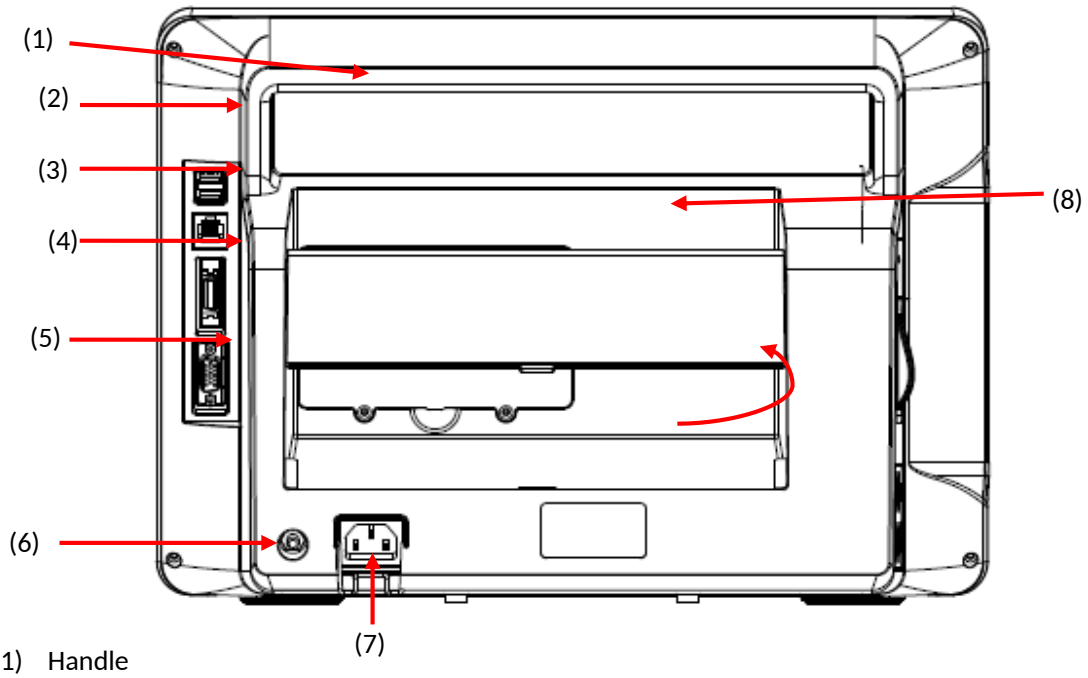
(3) Sensor Connectors

(4) Sensor Connectors

2.2.3 Right View



2.2.4 Rear View



(1) Handle

(2) USB ports of monitoring system

For patient monitor, the ports can be used to connect USB mouse, keyboard, printer, scanner and other USB devices.

(3) Network port

A standard network cable is used for networking to the central monitoring system or other devices.

(4) Multi-function port

- ◆ It can be used as the nurse call port. When it is connected to the nurse call system in the hospital, a call signal will be output to alert the nurse if an alarm is generated.
- ◆ It can be used as the synchronization defibrillation output port to output defibrillation synchronization signals.
- ◆ It can be used as the analog output port to output analog signals.

(5) VGA port

For patient monitor, it can be connected to an external HD display to show real-time monitored information displayed on the monitor. It enables medical workers to view information on a large screen conveniently, or allows presentation by the teaching staff. The maximum resolution of the external display is 1920*1080. The information on extender displayer is not for diagnostic.

(6) Equipotential conductor

When another device is used together with the monitor, a wire should be used to connect the equipotential port of that device to that of the monitor, thus to eliminate the earth potential difference between different devices and ensure safety.

(7) AC power socket

(8) Compartments: For storing accessories, operation guides, etc.

2.3 Cybersecurity

2.3.1 Operating Environment

Hardware configuration	Processing unit	AM3354
	memorizer	SDRAM(256M)
	Main Board	CM_ND_MAINBOARD_A00
	Parameter Board	CM_ND_PARAMETER_A00
	CM 80 Printer	/
	Battery	CMLI1X3N004A
	I/O connector	1) multi-function port: 1 2) USB connector: 2 3) network connector: 1 4) VGA connector: 1
Soft environment	System environment	Linux
	uboot	V1.0.0
	zImagedtb	V1.0.0
	rootfs.gz	V1.0.1
	Logo.gz	Comen
	Main	V1.0.0
	Single-Chip Microcomputer	V1.0.1
Network condition	Network interface	RJ-45
	Network type	Local area network(LAN)
	Network protocol	TCP/IP
	Bandwidth	100M
	Wired or wireless	wired, wireless
	LIS transport protocol	HL7 transport protocol
	Data type	Bin
	Storage medium	EMMC
	Storage format	Custom
	Storage capacity	8G
Software identification	Software name	ND Series Patient Monitor Software
	Software version	V1

2.3.2 User Access Control

Users should obtain a password from the vendor or administrator before entering the maintenance interface to make changes to module settings under user maintenance.

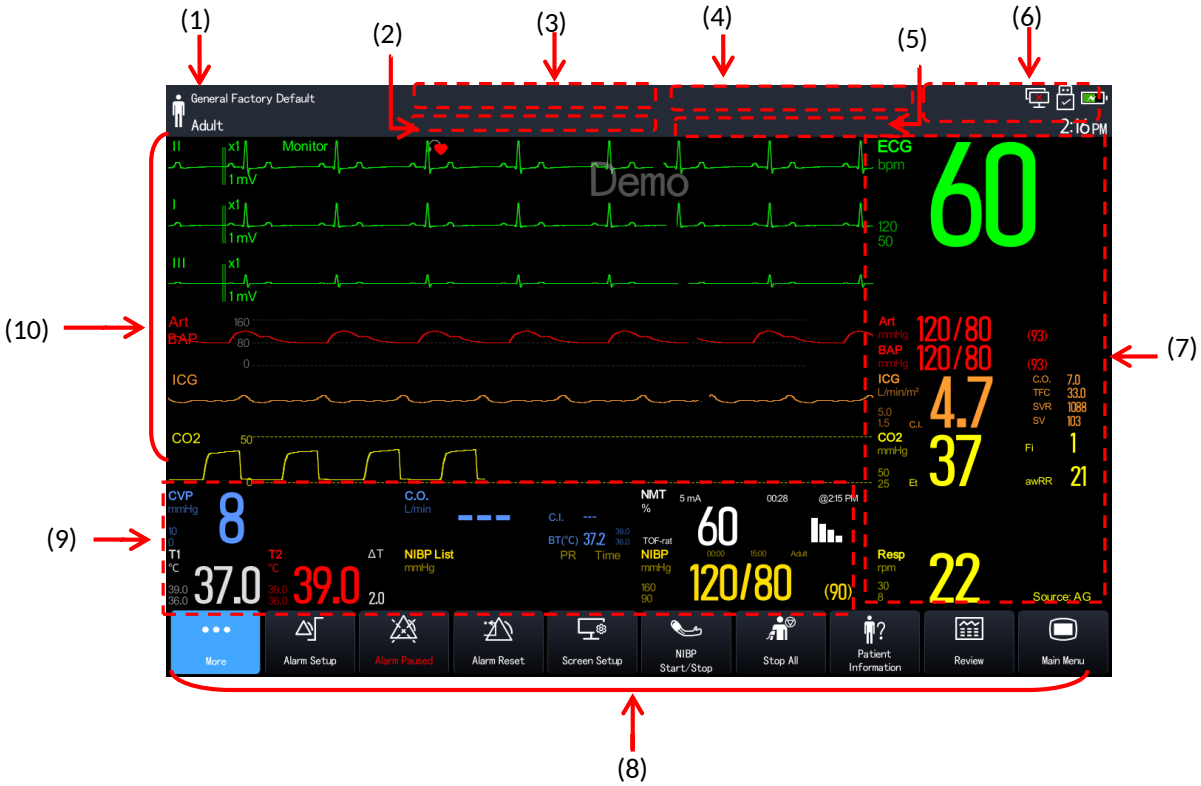
Only the supplier should use the password to enter the factory maintenance interface.

2.3.3 Software Update

Software updates are maintained by factory engineers only.

2.4 On-screen Display (OSD)

The figure below shows a general interface:



(1). Patient Information Area: Displays patient information, including department, current configuration, patient type, etc. Select this area to enter the **[Patient Management]** menu. See ***"Section 5 Patient Management"*** for details.

(2). Prompt Message Area: Displays prompt messages.

(3). Technical Alarm Message Area: Displays technical alarm messages.

(4). High Level Physiological Alarm Message Area: Displays high level physiological alarm messages.

(5). Medium and Low Level Physiological Alarm Message Area: Displays medium and low level physiological alarm messages.

(6). System Status Information Area: Displays alarm icon, battery icon, network, connection status of storage

device, and system time. See *"Section 2.4.1 Interface Symbols"* for details.

(7). Parameter Area: Displays parameter values, units, alarm limits, alarm states, etc. The user can select a parameter area to enter the corresponding parameter setup menu. See *"Section 4.3.1 Enter Parameter Setup Window"* for details.

(8). Quick Key Area: Displays quick keys.

(9). Waveform/Parameter Area: Displays parameter waveforms or parameter values, units, alarm limits, alarm states, etc. The user can select a parameter area or waveform area to enter the corresponding parameter setup menu. See *"Section 4.3.1 Enter Parameter Setup Window"* for details.

(10). Waveform Area: Displays parameter waveforms, etc. The user can select the waveform area of a parameter to enter the corresponding parameter setup menu. See "Section 4.3.1 Enter the Parameter Setup Window" for details.

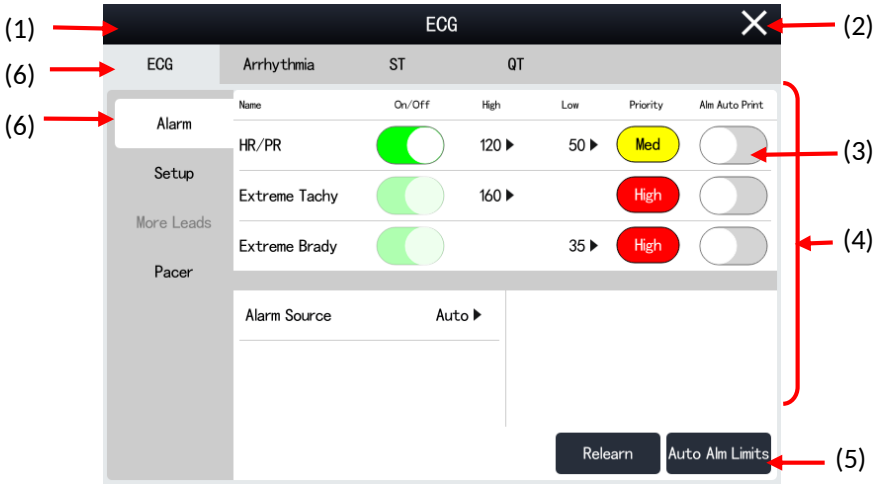
2.4.1 Interface Symbols

The table below lists the symbols shown in the System Information Area and their meanings:

Symbol	Description	Symbol	Description
	Adult, male		Adult, female
	Pediatric, male		Pediatric, female
	Neonate, male		Neonate, female
	Wired network/CMS has been connected		Wired network is not connected.
	Wireless network has been connected. The solid part indicates the network signal intensity; the icon will not be displayed when the wireless network is not connected.		Alarm sound paused
	Alarm paused		Alarm reset
	Audio off		Alarm off
	Very low battery. It should be charged immediately, otherwise the monitor will shut down automatically.		Low battery. Charging is needed.
	Battery powered; the green part indicates the remaining battery capacity.		The monitor is being charged.

	The battery is not installed or battery failure has occurred.		Disabled battery
	Wireless network is not connected		CMS is not connected

2.4.2 Menus



(1) Menu Title: Name of current menu

(2) Exit Button: Select it to exit the current menu

(3) Function On/Off:

- Green: This function is turned on
- Grey: This function is turned off

(4) Main Display Area: Displays menu options

(5) Operation Button: Click to initiate an operation

(6) Sub-menu tab button: Press each button to enter the corresponding sub-menu page

2.4.3 Quick Keys

Hot keys refer to some graphic quick keys shown in the lower part of the screen, allowing you to quickly access some functions. Generally, 10 quick keys are displayed in the Quick Key Area (8 for ND10/ND10A/ND10C/ND10S/ND12/ND12A/ND12C/ND12S). The **[Main Menu]** Quick Key is always displayed at the lower right corner of the Quick Key Area, and the **[More]** button is always displayed at the lower left corner of the Quick Key Area. Click **[More]** to show more predefined quick keys. You can define the quick keys to be displayed and their order on the screen.

2.4.3.1 Quick Key List

Icon of Quick Key	Name of Quick Key	Function	Icon of Quick Key	Name of Quick Key	Function
	Main Menu	Enter the main menu		More	Show more quick keys
	Alarm Setup	Enter the **[Alarm]** menu		Alarm Reset	Confirm the current alarm and reset the alarm system
	Alarm Sound Paused	Pause the alarm sound		Alarm Paused	Suspend the current alarm
	Review	Enter the **[Review]** menu		Standby	Enter standby mode
	Patient Information	Enter the **[Patient Information]** menu		Screen Setup	Enter the **[Screen Setup]** menu
	NIBP Start/Stop	Start NIBP measurement or stop the current NIBP measurement		Stop All	Stop all NIBP measurements
	NIBP STAT	Start NIBP STAT		NIBP Setup	Enter the **[NIBP Setup]** menu
	Zero IBP	Start zeroing IBP		C.O. Measure	Open the **[C.O. Measure]** window
	Parameter Setup	Enter the **[Parameter Setup]** menu		Venipuncture	Open the **[Venipuncture]** window
	Manual Event	Manually trigger and save events		Minitrends	Enter the Minitrends screen
	OxyCRG	Open the **[OxyCRG]** window		ECG Full-Screen	Enter the ECG 12-Lead Full Screen when it is in 12-Lead mode; and enter ECG Full Screen when in other ECG modes.
	Privacy Mode	Enter privacy mode		Night Mode	Enter night mode

Icon of Quick Key	Name of Quick Key	Function	Icon of Quick Key	Name of Quick Key	Function
	Cardio Pulmonary Bypass	Enter cardio pulmonary bypass mode		Intubation	Enter Intubation Mode
	Volume	Enter the **[Volume]** menu		Freeze	Freeze waveformsIntubation Mode
	Calculate	Enter the **[Calculate]** menu		Load Configuration	Enter the **[Load Configuration]** menu
	RT Print	Start the real-time printing task		RT Record	Start the recording task or stop the current recording task
	ECG Lead/Gain	Enter the **[ECG Lead/Gain]** menu		GCS	Enter the **[GCS]** screen
	EWS	Enter the **[EWS]** screen		Discharge	Enter the **[Discharge]** dialog box
	Sepsis Guide	Enter the **[Sepsis Guide]** menu		ECG 24h Summary	View ECG 24h Summary

2.4.3.2 Set Quick Keys Displayed on the Screen

You can set which quick keys to be displayed on the screen according to the following steps:

1. Enter the **[Display]** page in either of the following ways:
   - Select the **[Screen Setup]** quick key → select the **[Quick Keys]** tab; or
   - Select the **[Main Menu]** quick key → select **[Quick Keys]** from the **[Display]** column.
2. Select the **[Current]** tab to set the quick keys to be displayed on the screen: Select the area where a quick key is to be displayed from the top of this page; then select the desired quick key from the Quick Key List. For example, if you want to display the **[Screen Setup]** quick key at the first position of the Quick Key Area, click this position; then select **[Screen Setup]** from the Quick Key List.
3. Select the **[More]** tab to set the quick keys displayed when the **[More]** quick key on the bottom bar is clicked.

Chapter 3 Installation and Preparation

NOTE

- **To ensure normal operation of the monitor, please carefully read the contents of this chapter and the "Safety Information" chapters prior to use, and install the monitor according to requirements.**
- **This device shall be installed by personnel designated by our company.**

3.1 Installation

3.1.1 Unpacking and Checking

Carefully take the monitor and its accessories out of the packing box and check according to the following aspects.

1) Check whether all accessories are provided according to the Packing List.
2) Check for damage.
3) Check all exposed lead wires and connectors.
4) For any problem or inconsistencies, contact Comen or your distributor.
5) Keep the packaging materials for future use.

3.1.2 Environmental Requirements

The operating environment for this device must conform to the environmental requirements specified in this manual; otherwise the accuracy of the device may be affected, and damage to components and circuits may be caused.

The patient monitoring system should be used in an environment that can reasonably avoid vibration, dust, corrosive or explosive gases, extreme temperature and humidity, etc. Operating environment of this equipment must meet the environmental specifications in this manual.

When the monitor is installed in an enclosed space, make sure the space is well ventilated. Leave at least 2 inches (5cm) free space around the monitor for air circulation. Also, leave sufficient space around it for easy operation and maintenance.

The device is not intended for hyperbaric operation. Use in a hyperbaric chamber can result in harm to the patient and/or damage to the device.

Ensure that the monitor is free from condensation during operation. When the monitor is moved from one room to another, condensation may be formed due to exposure to damp air and temperature difference. In this case, do not use the monitor until it is dry.

NOTE

- **Condensation is the condensation of gas or liquid when it is cold, such as water vapor changing into water when it is cold, and water changing into ice when it is cold. The lower the temperature, the faster the condensation speed.**

3.2 Device Preparation

3.2.1 Connection of AC power supply cord

Before connecting the AC power supply cord, ensure that the AC supply voltage and frequency are consistent with the voltage and frequency indicated on the device.

Steps for connecting the AC power cord:

1) Use the power cord supplied with the monitor; connect one end of the power cord to the inlet of the monitor;
2) Insert the other end of the power cord to a mains socket outlet with protective earth.
3) Confirm that the AC power indicator turns on, which indicates that AC power supply is connected normally.

NOTE

- **Connect the power cord to hospital-level outlet.**
- **When a battery is provided, the battery must be charged after transportation or storage. If the battery is low, the monitor may fail to work without connecting an AC power supply. Once the monitor is connected to an AC power outlet, the battery will be charged whether the monitor is switched on or not.**
- **Connect equipotential grounding wire if necessary.**

3.2.2 Protective Grounding

To protect both the patient and the operator, the housing of the monitor must be grounded. The monitor is equipped with a detachable 3-wire power cord, which shall be inserted into a grounded power outlet to ensure that monitor is grounded. If grounded power outlet is not available, contact the maintenance department in your hospital.

WARNING

- **To avoid the risk of electric shock, this equipment must only be connected to a mains supply with protective earth.**

Connect the ground wire to the equipotential connector of the monitor. If you have any doubt about whether the equipment used may cause any electrical risks, such as the risk caused by the accumulation of leakage current, consult a professional technician to ensure the safety of all equipment.

3.2.3 Equipotential Grounding

The monitor must be connected to a mains socket with protective grounding and the equipotential grounding system. Use the green/yellow equipotential grounding cable and connect one end of the equipotential conductor (potential equalization conductor) to the equipotential connector on the rear panel of the monitor and the other end to a connector of the equipotential grounding system. In the event that the protective grounding system is damaged, it can provide protection to the patient and operator.

⚠ WARNING

- **If the protective grounding system is not stable, use the built-in battery to power the monitor.**

⚠ NOTE

- **If the use of the equipment is affected by the equipotential grounding, contact the Company's After-Sales Service Department or agents.**

3.3 Connection of Device Components

3.3.1 Connect patient leads and patient cable

Connect the sensors to the patient according to the subsequent parameter monitoring chapter.

3.4 Startup and Shutdown

3.4.1 Startup

1) Prior to startup, check to see if each component of the device has any mechanical damage;
2) Check whether the device can start up normally:
   - ◆ After the power switch is turned on, the device enters the self-test process. The red and cyan lights are simultaneously on for 1s; then the cyan light continues to be on for 1s; meanwhile the yellow light is on for 1s; after that, the company logo is displayed, and with a "beep" sound, the monitor enters the main screen.

3) Check whether the screen and each parameter interface display information normally.

WARNING

- **If any evidence of functional failure of the monitor is found or there is any error message, it is not allowed to use this device to monitor a patient. Please contact a service engineer of our Company or a biomedical engineer of your hospital.**

NOTE

- **The system sounds an alarm when a major error is detected in the self-test.**
- **Check all monitoring functions to ensure that the monitor can operate normally.**
- **The battery must be charged after each use to ensure that sufficient battery power is available.**
- **To extend the service life of the monitor, after shut-down, wait for at least 1 minute before restarting the monitor.**

3.4.2 Shutdown

1) Confirm that the device can be stopped.
2) Disconnect the device cable and sensor from the patient.
3) Save or clear patient data as per need.
4) Long press the power key for 3s to turn off the monitor. To completely disconnect the power supply, please pull out the power plug.

CAUTION

- **If the device cannot shut down normally under some special circumstances, you can long press the power key for 7s to realize forced shutdown. Forced shutdown is not suggested since it can result in loss of data.**

NOTE

- **In case of unexpected power supply interruption, if the monitor is restarted within 30min, it will load patient information, monitoring data and configuration data before power failure. If the power is restored after 30 min, it will load the default configuration set as normal startup/shutdown.**

Chapter 4 Basic Operations

4.1 Operation and Browsing

4.1.1 Use of Touch Screen

The monitor is equipped with a touch screen allowing touch operations. If you don't want to use the touch function, or to prevent misoperation, you can set to lock the screen.

Locking the screen:

- Hold the **[Main Menu]** quick key for 5 seconds to lock the screen. After locking, a "" will be shown above the **[Main Menu]** quick key.

Unlocking the screen:

- Hold the **[Main Menu]** quick key for 5 seconds to unlock the screen.

4.1.2 Use of Rotary Knob

This monitor is equipped with a rotary knob for selecting menus and switching settings.

- Rotate the rotary knob counterclockwise to select the previous area;
- Rotate the rotary knob clockwise to select the next area;
- Press the rotary knob in the selected area to enter/exit the area.

4.1.3 Use of Mouse

This monitor supports "plug and play" USB mouse. You can use the mouse for interface operations.

4.1.4 Use of Soft Keyboard

This monitor provides a soft keyboard for information input. The soft keyboard has the following functions:

- Select characters on the keyboard to input information
- Use the Delete key ← to delete the previous character.
- Use the shift key ▲ to switch between upper and lower case letters.
- Use the Enter key ↵ to confirm the input and close the soft keyboard.

If the monitor is connected with a physical keyboard, it can be used in conjunction with the soft keyboard.

4.1.5 Use of Scanner

This monitor supports barcode and QR code scanners which can be connected to the monitor via USB port.

NOTE

- **The QR code scanner customized by Comen can be used to scan QR codes and barcodes. Other QR code and barcode scanners can only output medical record number or registration number.**

4.1.5.1 Clear Data Format

If you use the QR code scanner customized by Comen, it is necessary to clear the previous data format and configure the scanner before initial use. Here are the steps for clearing data format:

1) Scan the barcode or engineering QR code for format clearing to clear the old data format.
2) Scan the engineering QR code used by the hospital to +obtain the QR code format special for this hospital.

NOTE

- **Please contact the scanner manufacturer or Comen to obtain the barcode or engineering QR code for format clearing.**

4.2 Work Mode

4.2.1 Monitor Mode

Monitor mode is a work mode for patient monitoring. Upon startup of the device, it will automatically enter monitor mode.

4.2.2 Night Mode

This monitor provides night mode that can avoid disturbing the patient in the nighttime. After exiting night mode, the monitor will restore settings before entering night mode.

In night mode, the monitor uses the following settings by default:

Brightness: 1

Alarm Volume: 2

QRS Volume: 1

Key Volume: 0

NIBP End Tone: OFF

Stop NIBP Measure: OFF

Activate Night Mode:

1) Select the **[Main Menu]** quick key → select **[Night Mode]** from the **[Display]** column.
   Or select **[Night Mode]** quick key directly.
2) Change the default settings of night mode.
3) Select **[Enter Night Mode]** to enter this mode.

> ⚠ **CAUTION**
>
> - **Before entering Night Mode, please confirm the settings of Brightness, Alarm Volume and QRS Volume. Please pay attention to potential risks if the settings are too low.**

Activated Night Mode Automatically:

Turn on the **[Auto Night Mode]** button, and the monitor will automatically activate Night Mode when the set time is reached.

To turn on **[Auto Night Mode]**:

1) Select the **[Main Menu]** quick key → select **[Night Mode]** from the **[Display]** column.
2) Turn on **[Auto Night Mode]** button.

The operations to set the start and end time for Auto Night Mode are as follows:

1) Select the **[Main Menu]** quick key → select **[Maintenance]** from the **[System]** column.
2) Select **[Time]** column→set **[Time Zone].**
3) Set the start and end time of Auto Night Mode.

Exit Night Mode:

1) Select the **[Exit Night Mode]** or **[Main Menu]** quick key → select **[Exit Night Mode]** from the **[Display]** column.
2) Select **[OK]**.

> ⚠ **NOTE**
>
> - **In night mode, if the monitor has been connected to the central monitoring system, it will automatically exit night mode when disconnected from the central monitoring system.**

4.2.3 Privacy Mode

When protection of the patient monitoring screen is required, privacy mode can be activated. This mode can be activated only under CMS (Central Monitoring System) monitoring. Monitoring data are only displayed on the central monitoring system.

You can enter privacy mode in either of the following ways:

- Select the **[Privacy Mode]** quick key;
- Select the **[Main Menu]** quick key → select **[Privacy Mode]** from the **[Display]** column.

Performance of the device when privacy mode is activated:

- The device interface is turned off, and the display of all parameters, waveforms and alarm messages is shielded.
- Patient monitoring continues; patient data are saved but can be seen only under the central monitoring system.
- Heartbeat sound and pulse sound from the monitor are shielded.

NOTE

- **When Department is set to OR, privacy mode is not supported.**
- **When the monitor generates the Low Battery alarm, it is impossible to enter privacy mode.**
- **Privacy mode is unavailable for ND15C/ND12C/ND10C monitor.**

You can exit privacy mode:

- by selecting **[Exit Privacy Mode]** on the screen; or
- by disconnecting from the CMS; or
- when the battery level is too low.

4.2.4 Standby Mode

If patient monitoring is not needed for the time being, but you don't want to shut down the device, standby mode can be used.

Here are the steps for entering standby mode:

1) Select the **[Standby]** or **[Main Menu]** quick key → select **[Standby]** from the **[Patient Management]** column.
2) Set the patient location in standby.
3) Select **[OK]**.

Performance of the device in standby mode:

- Stop all parameter measurements.
- All alarm messages (except Low Battery, Battery is critically low) and prompt messages are shielded.

Exit standby mode:

- Select **[Monitor]** to exit standby mode and restore monitoring for the current patient.
- Select **[Discharge Patient]** to discharge the current patient.

4.2.5 Demo Mode

Here are the steps for entering demo mode:

Select **[Main Menu]**; select **[Demo]** from the **[System]** column; input the password to enter demo mode.

WARNING

- **Demo waveforms are analog waveforms set by the manufacturer only for the purpose of demonstrating device performance and aiding user training. In actual clinical use, it is forbidden to use the demo function because medical workers may mistake the demo data for waveforms and parameters of the patient being monitored, which will affect patient monitoring and delay diagnosis and treatment.**

4.3 General Settings

4.3.1 Enter Parameter Setup Window

Each parameter shown on the screen can be set. User can enter the Setup window in the following ways:

- Select the waveform area or parameter area corresponding to a parameter.
- Select the **[Parameter Setup]** quick key in the main screen; then select the corresponding parameter.
- Select the **[Main Menu]** quick key; select **[Setup]** from the **[Param]** column; then select the corresponding parameter.

NOTE

- **Generally, the first method described above is used to enter parameter setup.**

4.3.2 Switch Screen

Normal screen, which is the so-called standard screen, is the most commonly used monitoring screen. The monitor enters the normal screen upon startup. You can also choose the screen as needed according to the following ways:

Way 1:

1) You can enter the **[Choose Screen]** page in either of the following ways:
   - Select the **[Screen Setup]** quick key → select **[Choose Screen]**.
   - Select the **[Main Menu]** quick key → select **[Choose Screen]** from the **[Display]** column.
2) Choose the screen type as needed.

Way 2: (only for touch screen)

1) Select **[Screen]** Setupquick key, enter setup menu.

2) Choose **[Change Screen]** from **[Main Screen]** column.

3) Choose Screens to be switched with a two-finger swipe. Up to 4 screens can be chose.

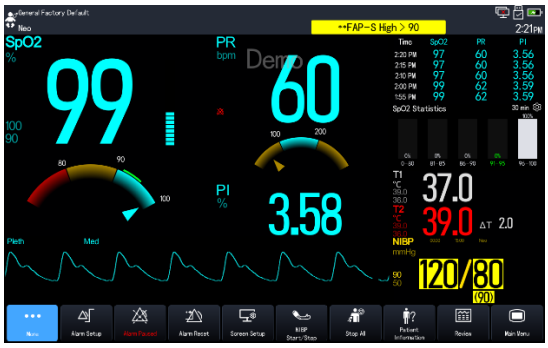
4.3.2.1 Single SpO_2

If monitoring the neonatal patient's SpO_2 and pulse rate only, the user can enter the Single SpO_2 interface. This interface uses large fonts to display the data related to SpO_2 parameters, real-time body temperature and blood measurement values.

> **NOTE**
>
> - **Single SpO_2 interface is serviceable only for neonates.**

4.3.2.2 Displays of Single SpO_2

The figure below is a Single SpO_2 interface, which will not exactly match the displays on your monitor.



4.3.2.3 Operating the Single SpO_2 Interface

The user can enter the parameter setup menu and review the parameter trends through this interface by the following steps:

- Click the data of SpO_2, PR, PI trends into **[Review]** page to read the **[Tabular Trends]** and **[Graphic Trends]**.
- Click the bar graph of SpO_2 statistics into the **[SpO_2 Statistics]** menu to set the end values of SpO_2 sections and choose the target section.
- Click the values of SpO_2, PR, PI, or click the dashboard or Pleth waveforms to enter the **[SpO_2]** setup menu.
- Click the Temp values to enter the **[Temp]** setup menu.
- Click the NIBP values to enter the **[NIBP]** setup menu.

4.3.3 Set Layout of Normal Screen

You can select parameters and waveforms to be displayed and their positions in the normal screen as per need according to the following steps:

1) Enter the **[Title Layout]** interface in either of the following ways:
   - ◆ Select the **[Screen Setup]** quick key → select **[Title Layout]**.
   - ◆ Select the **[Main Menu]** quick key → select **[Title Layout]** from the **[Display]** column.
2) Select a parameter area or waveform area, and select the parameters to be displayed in this area from the pop-up parameter list. All selected parameters and waveforms will be displayed according to the set positions; parameters and waveforms not selected will not be displayed on the screen.

4.3.4 Set Layout of Large Font Screen

You can select parameters and waveforms to be displayed and their positions in the large font screen as per need according to the following steps:

1) Enter the **[Large Fonts]** tab in either of the following ways:
   - ◆ Select the **[Screen Setup]** quick key → enter the **[Large Fonts]** tab; or
   - ◆ Select the **[Main Menu]** quick key → select **[Title Layout]** from the **[Display]** column → enter the **[Large Fonts]** tab.
2) Select each area; select the parameters to be displayed in this area from the pop-up parameter list. All selected parameters and waveforms will be displayed according to the set positions; parameters and waveforms not selected will not be displayed on the screen.

4.3.5 Language

You can switch languages according to the following way:

1) Select **[Main Menu]** → select **[Maintenance]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select **[Other]** → select **[Language]**.
3) Select **[OK],** and restart the monitor.

4.3.6 Date and Time

1) Select **[Main Menu]** → select **[Time]** from the **[System]** column
2) Select **[Date]** and **[Time]** to set the current date and time.
3) Set **[Date Format].**
4) If 12-hour time is required, turn off **[24-Hour Time]**.

When the monitor is connected to the central monitoring system, the system time of the monitor will be synchronous with that of the central monitoring system, and you cannot set the system time of the monitor.

4.3.7 Set Brightness

1) You can enter the **[Display]** page in either of the following ways:
   - Select the **[Screen Setup]** quick key → select **[Display]**.
   - Select the **[Main Menu]** quick key → select **[Display]** from the **[Display]** column.
2) If the monitor uses AC power supply, set **[Brightness]**; if the battery is used to supply voltage, set **[Brightness On Battery]**.

4.3.8 Set Unit

1) Select the **[Main Menu]** quick key → select **[Maintenance]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select **[Unit]** to set the measurement unit of each parameter.

4.3.9 Set Volume

Select the **[Volume]** quick key to respectively set **[Alarm Volume]**, **[High Alarm Volume]**, **[QRS Volume]** and **[Key Volume]**.

4.3.10 Set Parameters On/Off

You can turn on/off the measurement of a parameter as needed. Here are the steps:

1) Enter the **[Parameters On/Off]** screen in either of the following ways:
   - Select the **[Screen Setup]** quick key → select **[Parameters On/Off]**.
   - Select the **[Main Menu]** quick key → select **[Parameters On/Off]** from the **[Param]** column.
2) Turn on/off a parameter as needed.

4.3.11 Change Parameter Color

1) Select **[Main Menu]** → select **[Param Color]** from the **[Param]** column.
2) Set the display color of the parameter currently being monitored.

4.4 Waveform Freezing

During patient monitoring, you can freeze the waveforms displayed on the screen, and then review and print waveforms.

4.4.1 Freeze Waveforms

You can select the **[Freeze]** quick key to freeze active waveforms. Parameter data are refreshed normally.

In frozen state, the following windows and waveforms are normally displayed and refreshed:

- Minitrends Screen
- OxyCRG
- Remote View Window
- Score Window

4.4.2 View Frozen Waveforms

- Adjust the "◀◀" or "▶▶" button in the **[Freeze]** menu to view the previous and next frozen waveforms.
- Select a frozen waveform; then swipe left and right to view the previous and next frozen waveforms.

The time scale is displayed at the lower right corner of the nethermost waveform; the freeze moment is flagged as **[0s]**. With the rightward movement of the waveform, the time scale will change to **[-1s]**, **[-2s]**, **[-3s]** ... in sequence, indicating that the waveform currently displayed is the waveform content N second(s) before the freeze moment. This time scale applies to all frozen waveforms on the screen.

> ⚠ **NOTE**
>
> - **You can review frozen waveforms for 120s.**
> - **The time scale will not be displayed if waveforms are frozen in rescue mode.**

4.4.3 Unfreeze

Select "✕" at the upper right corner of the **[Freeze]** menu to unfreeze the waveforms.

4.4.4 Print Frozen Waveforms

Select "🖶" at the upper left corner of the **[Freeze]** menu; the printer will print the waveforms displayed on the current screen and all parameter values at the freeze moment.

4.5 Use of Timer

This monitor can simultaneously display at most 4 timers. You can respectively set each timer which will give a prompt when the set time is reached.

4.5.1 Timer Display

1) You can enter the **[Title Layout]** screen in either of the following ways:
   - Select the **[Screen Setup]** quick key → select the **[Title Layout]** tab.
   - Select the **[Main Menu]** quick key → select **[Title Layout]** from the **[Display]** column.
2) Select the position where the timer is to be displayed in the Parameter Area; select **[Timer 1]**, **[Timer 2]**, **[Timer 3]** or **[Timer 4]**.

4.5.2 Timer Operation

WARNING

- **DO NOT use the timer to perform timing tasks related to critical patients.**

The timer provides the following operation buttons:

- **[Start]**: The timer starts timing.
- **[Pause]**: The timer suspends timing.
- **[Resume]**: The timer resumes timing.
- **[Reset]**: Clear the current timing result and reset the timer.

4.5.3 Timer Setup

1) Select the Timer Area to enter the **[Timer Setup]** menu.
2) Set **[Timer Type]**;
   - **[Normal]**: The timer starts timing according to the set **[Run Time]**, and stops timing after the run time is reached.
   - **[Advanced]**: The timer starts timing according to the set **[Run Time]**, continues timing after the run time is reached, and displays the time beyond the run time.
   - **[Cycled]**: The timer performs timing tasks in a cycled manner. That is to say, the timer starts timing according to the set **[Run Time]**, and restarts timing after the run time is reached. The count of timing cycle is numerically shown in the Timer Area.
   - **[Unlimited]**: The timer displays the time elapsing after startup.

- **[Clock]**: The timer displays the system time.

3) Set **[Direction]**.
4) Set **[Run Time]**.
5) Set **[Reminder Volume]**. When there are 10s left before the timer stops timing, the monitor will produce a prompt tone, and the timer will remind you with red font that the counting will end soon.

NOTE

- **It is not allowed to set the timer when it is working.**
- **The settings of [Direction], [Run Time] and [Reminder Volume] are valid only when [Timer Type] is set to [Normal], [Advanced] or [Cycled].**

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Chapter 5 Patient Management

5.1 Discharge Patient

The previous patient should be discharged before monitoring a new patient. After discharge, the monitor will enter the idle state. Depending on the circumstance, you can select **[Monitor]** (Quick Admit) or **[Patient Management]** (Normal Admit) to select how to admit a patient.

WARNING

- **The previous patient should be discharged before monitoring a new patient; otherwise, data of the new patient will be saved to data of the un-discharged patient.**

The patient can be discharged manually in any of the following ways:

- Select the **[Discharge Patient]** quick key
- Select the Patient Information Area at the upper left corner of the screen → select **[Discharge Patient]**
- Select the **[Patient Information]** quick key → select **[Discharge Patient]**.
- Select **[Main Menu]**, and select **[Discharge Patient]** from the **[Patient Management]** column.

After selecting **[Discharge Patient]**, in the pop-up dialog box:

- Select **[Discharge]**: All patient data, including patient information, trend data and physiological alarm messages will be cleared; the technical alarm state will be reset; the system will restore to default configuration and enter the Standby screen.
- Select **[Clear]**: The current patient will not be discharged and the current configuration is still used, but all patient data will be cleared.

5.2 Admit Patient

WARNING

- **Whether a patient is admitted make sure the settings in [PAT Info] are consistent with the patient's actual conditions before monitoring.**
- **When the patient type is changed, the system loads the factory default configuration. Verify the alarm limits before patient monitoring to ensure that these alarm limits suit your patient. When the patient type is not changed, the current configuration is not changed.**
- **For the patient without pacemaker, [Pacer] must be set to [OFF]. Otherwise, the system cannot detect arrhythmia related to ventricular premature beats (including PVCs count), and ST segment analysis will**

not be carried out.

- **If the patient is admitted with a pacemaker, [Pacer] should be set to [ON]. Otherwise, pacemaker pulse may be counted as normal QRS wave, resulting in failure to detect the [ECG Lost] alarm.**

5.2.1 Quick Admit

When user does not have enough time to get patient information, the Quick Admit mode can be used. Later, user must complete other information of the patient.

Here are the steps:

1) After patient discharge, select **[Monitor]** to quickly admit a patient.
2) After admit, please input the patient information as fast as possible. See "***Section 5.3.2 Edit Patient Information***" for detailed instructions.

5.2.2 Normal Admit

After patient discharge, select **[Patient Management]** → input information of the new patient. See "***Section 5.3.2 Edit Patient Information***".

5.3 Patient Information

5.3.1 Enter Patient Management Menu

You can enter the **[Patient Management]** menu in any of the following ways:

- Select the Patient Information Area at the upper left corner of the screen.
- Select the **[Patient Information]** quick key.
- Select **[Main Menu]** → select **[Patient Information]** from the **[Patient Management]** column.

5.3.2 Edit Patient Information

After a patient is admitted, if the patient information is incomplete or needs change, you can edit the patient information according to the following steps:

Enter the **[Patient Management]** menu, and edit the patient information as needed.

If your monitor is connected with a barcode scanner, you can input the medical record number or registration number by scanning the barcode.

NOTE

- **When the patient type is changed, the monitor will reload the default configuration of the patient type.**

5.3.3 Set Items Displayed in the Patient Management Menu

You can set whether or not to display and edit the patient's room No., middle name, race, age and other information according to the following steps:

1) Select the **[Main Menu]** quick key → select **[Maintenance]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select the **[Patient Management]** tab → select the **[Field]** tab.
3) Select the patient information to be displayed and edited in the **[Patient Management]** menu.
4) If necessary, select the Custom Patient Information Area and input the name of this area.

NOTE

- **After the monitor is connected to the central monitoring system, the patient location and custom field will be synchronous with the central monitoring system.**

5.3.4 Set Monitor Information

You can set a name for the monitor in the following way:

1) Select the **[Main Menu]** quick key → select **[Maintenance]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select the **[Device Location]** tab.
3) Set **[Monitor Name]**, **[Facility]** and **[Department]**.

5.3.5 Set Device Location

If the location of the monitor is fixed, or it is not needed to move the monitor frequently, you can set **[Location]** to **[Fixed]**. Here are the steps for setting device location:

1) Select the **[Main Menu]** quick key → select **[Maintenance]** from the **[System]** column → input the maintenance password → press the Enter key.
2) Select the **[Device Location]** tab.
3) Set **[Location]**.
   - ◆ When **[Fixed]** is selected, the **[Patient Management]** menu can only display the patient's room No. or bed No., and you cannot modify the room No. or bed No..
   - ◆ When **[Unfixed]** is selected, you can enter the **[Patient Management]** menu to modify the patient's room No. and bed No..

4) Input **[Room No.]** and **[Bed No.]**.

NOTE

- **If [Location] is set to [Unfixed], Room No. and Bed No. will be cleared each time after patient discharge; you need to re-input Room No. and Bed No..**

Chapter 6 Manage Configuration

6.1 Summary

For continuous monitoring of a patient, the user/operator may require to adjust some settings according to the actual patient conditions. The collection of pre-set items used to operate the monitor is called a configuration. In order to configure the monitor more effectively and rapidly, this monitor provides a variety of configurations to meet the requirements of different patient types and different hospital departments. You can also customize a configuration according to actual conditions and save it as a user-defined configuration. Configuration info of the monitor mainly includes:

Parameter Configuration

Setting items related to parameter measurements, such as Wave Gain, Speed, Unit, Alarm ON/OFF, and Alarm Limit Setup.

General Configuration

The monitor's general setting items, such as Alarm Setup, Screen Layout, and Record.

Maintenance Configuration

Settings related to user maintenance.

Department options: General (General Monitoring)

OR (Operation Room/Anesthesia Monitoring)

ICU (Intensive Care Unit)

Neo (Neonatal Intensive Care Unit)

CCU (Coronary Care Unit)

Among them, each department contains three different patient types: adult, pediatric and neonate.

⚠ WARNING

- **Configuration management function is protected by password and must be operated and confirmed by professional clinical medical staff.**

⚠ CAUTION

- **Use of different configurations on the same or similar monitors in one area (e.g., ICU or Cardiac OR) may result in danger.**
- **When selecting a configuration, please ensure that it is appropriate for the patient being monitored.**

NOTE

- **The monitor will load the factory default settings when changing Department, admitting patient and changing patient type.**

6.2 Set Default Patient Type

You can set the patient type when admitting patient next time. Set as follows:

1) Click **[Main Menu]** quick key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key.
2) Select the drop-down list on the right of **[Default Patient Category]** to set the patient Category when admitting patient next time.

6.3 Change Department

1) Click **[Main Menu]** quick key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key
2) Click **[Change Department]** button.
3) Select the needed department.
4) Click **[OK]**.

6.4 Select Default Configuration

Default Configuration refers to the auto-loaded settings when:

- Admitting patient
- Changing patient type

Default Configuration can be chosen from the latest settings, defaults settings and user settings.

Select Default Configuration as follows:

1) Click **[Main Menu]** quick key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key
2) Click **[Select Default Config]** button.
3) Select **[Load the Latest Config]** or **[Load Specified Config]**
   - Select **[Load the Latest Config]**: the monitor will load the latest configuration when admitting patient or changing patient type.
   - Select **[Load the Specified Config]**: the monitor will load the specified configuration when admitting patient. The monitor will load Adu, Ped or Neo configuration according to the patient type. The factory default settings and user settings can be selected.

6.5 Save Current Settings

The Current configuration of the monitor can be saved as the user configuration under the current department.

Save Current Settings as the following steps:

1) Click **[Main Menu]** quick key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key.
2) Click **[Save Current setup]** button.
3) Input the Configuration Name.
4) Click **[OK]**.

6.6 Delete Configuration

1) Click **[Main Menu]** quick key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key
2) Click **[Delete Configuration]** button.
3) Select the settings to be deleted.
   - ◆ The user settings saved on the monitor and the U disk are displayed in the **[Delete Configuration]** menu.
4) Click **[Delete]** button.

6.7 Export Configuration

You can save the current user settings of the monitor to the U disk as follows:

1) Insert a U disk into the monitor.
2) Click **[Main Menu]** quick key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key.
3) Click **[Export Configuration]** button.
4) Select the settings to be exported.
5) Click **[Export]**.

6.8 Import Configuration

You can import the settings on a U disk into the monitor as follows:

1) Insert a U disk with settings file into the monitor.
2) Click **[Main Menu]** quick key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key.

3) Click **[Import Configuration]** button.
4) Select the settings to be imported.
5) Click**[Import]**

6.9 Load Configuration

1) Click **[Main Menu]** quick key → **[Configuration]** → **[Load]**.
2) Load the settings to be loaded.
   - The current settings on the monitor are displayed on the **[Local]** screen.
   - The saved settings on the U disk are displayed on the **[U disk]** screen.
3) Click **[Load]**.

6.10 Manage Configuration Password

1) Click **[Main Menu]** quick key → **[Configuration]** → **[Manage]**, enter the configuration password and hit the Enter key
2) Click **[Change Password]** button.
3) Input old password and new password respectively.
4) Click **[OK]**.

Chapter 7 Alarms

When a patient under monitoring has abnormal vital signs, or when failure occurs in the monitor, the system sounds audible and visual alarm to remind/warn the user.

When there are multiple alarms and prompt messages, messages scroll in a cycle. The alarm audio will be triggered at the highest priority.

7.1 Safety Information

⚠ WARNING

- **A hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre. The operator should check that the current alarm presets is appropriate prior to use on each patient.**
- **Both the bedside monitor and the CMS are provided with sound alarm function.**
- **When this monitor is connected to the CMS, you can use the same upper and lower alarm limits for the monitor and CMS. But if you enable alarm delay on this monitor, it will not give alarm when the CMS alarming.**
- **When multiple alarms of different levels are generated simultaneously, the monitor will activate the alarm sound and light for the highest-priority alarm condition.**
- **Some physiological alarms, such as cardiac arrest, ventricular fibrillation, ventricular tachycardia, no pulse and Resp heart disturbance, are of exclusive type. The acoustic and optical forms of these alarms are the same as that of the high alarms, but the alarm messages are displayed exclusively, i.e., only the exclusive-type alarm message is displayed when a normal alarm and an exclusive-type alarm are generated simultaneously.**
- **Users should set the alarm volume and the alarm limit according to the patent's actual condition. Do not monitor the patient only by relying on the sound alarm system. The patient may be put in a dangerous situation if the alarm volume is low. Set the minimum alarm volume should be higher than environmental noise.**
- **The operator should check that the current alarm preset is appropriate prior to use on patient.**
- **LIMITS to extreme values that can render the ALARM SYSTEM useless.**

⚠ NOTE

- **The sound pressure level of alarm signals generated by this monitor is 45-85db.**
- **The power-off time of the alarm system will be recorded in alarm system log. When the alarm system logs reach the maximum limit, the earliest one will be deleted.**

7.2 Alarm Type

Alarms generated by the monitor are classified into physiological and technical alarms.

- Physiological alarm

A physiological alarm is generated when a certain physiological parameter of the patient is beyond the high/low alarm limit or the patient has physiological disorder. Physiological alarm messages are displayed in the physiological alarm area in the upper part of the screen.

- Technical alarm

A technical alarm is triggered when the monitor does not operate normally or the monitoring result is unreasonable due to improper operation or system failure. A technical alarm message is displayed in the technical alarm area in the upper part of the screen.

NOTE: In addition to physiological and technical alarms, the monitor also shows messages about system status. Generally, these messages shown in the system message area are not related to vital signs of the patient.

7.3 Alarm Priority

- High-priority alarm: The patient is in critical condition or the device has serious failure, and immediate response is necessary
- Medium-priority alarm: The patient's physical signs are abnormal, the device has failure or is misoperated, and timely response is necessary
- Low-priority alarm: The patient's physical signs are abnormal, the device has failure or is misoperated, and the user is required to understand the current situation
- Prompt messages: Information on the patient and system status should be provided.

7.4 Alarm Signals

7.4.1 Alarm Indicator Light

The alarm indicator lights will indicate different priorities of alarms generated in different colors and flashing frequencies.

High-priority alarm: Red, fast blinking frequency.

Medium-priority alarm: Yellow, slow blinking frequency.

Low-priority alarm: Cyan, no blinking, light remaining on

7.4.2 Alarm Sound

Sound alarms refer to different priorities of alarms generated by the monitor with different sound characteristics:

- High-level alarm: beep-beep-beep--beep-beep----beep-beep-beep--beep-beep
- Medium-level alarm: beep-beep-beep
- Low-level alarm: beep

Prompt message： /

Volume Levels:

- Alarm Volume: 0~10, 11 levels in total, 1 means the lowest volume, 10 means the highest volume, and 0 means turn off the volume.
- QRS Volume: 0~10, 11 levels in total, 1 means the lowest volume, 10 means the highest volume, and 0 means turn off the volume.
- Key Volume: 0~10, 11 levels in total, 1 means the lowest volume, 10 means the highest volume, and 0 means turn off the volume.
- Reminder Volume: 0~10, 11 levels in total, 1 means the lowest volume, 10 means the highest volume, and 0 means turn off the volume. The reminder volume cannot be set to 0.

7.4.3 Alarm Message

The following signs are used in front of physiological alarm messages to differentiate the priorities of alarm:

- High-priority alarm:***
- Medium-priority alarm: **
- Low-priority alarm: *

Background colors corresponding to different levels of alarm messages:

- High-priority alarm: Red
- Medium-priority alarm: Yellow
- Low-priority alarm: Cyan

Background colors corresponding to Prompt messages: /

7.4.4 Alarm Parameter Forms

- High-priority alarm: red background with blinking
- Medium-priority alarm: yellow background with blinking

- Low-priority alarm: cyan background with blinking

7.4.5 Alarm Status Icon

 Alarm Pause

 Alarm Off

 Alarm Audio Pause

 Alarm Audio Off

 Alarm Reset

7.5 View Physiological Alarm Conditions

When there are multiple physiological alarms, select the Physiological Alarm Message Area to enter the **[Alarms]** window; if there is only one physiological alarm, select the Physiological Alarm Message Area will be directly into the review of the alarm details.

View physiological alarm as follows:

1) Select physiological alarm area to enter **[Alarm]** window.
2) Select **[Physiological Alarms]** Tab. The current alarms are in the list displayed.
3) Select **[Details]** to get more information.

7.6 View Technical Alarm Conditions

View technical alarm as follows:

1) Select technical alarm area to enter **[Alarm]** window.
2) Select **[Technical Alarms]** tab. The current alarms are in the list displayed.
3) Select **[Details]** to get more information.

7.7 Set Parameter Limits

7.7.1 Set Manually Adjust Alarm Limit

1) Enter **[Limits]** screen in any of the ways listed below:
   - Click **[Alarm Setup]** quick key.
   - Click **[Main Menu]** quick key → **[Alarm]** → **[Limits]**.

2) Set the alarm parameters in corresponding tabs as required.

You can also set the alarm for one parameter from the parameter menu.

7.7.2 Set Auto Alarm Limit

The monitor provides the Auto Alarm Limit Setup function. This function allows automatic setup of alarm limits through the currently measured parameter values based on the current patient type.

Before applying these alarm limits, please confirm whether they are appropriate for the current patient. If not, you will need to manually set the alarm limits.

1) Enter **[Limits]** screen in any of the ways listed below:
   - Click **[Alarm Setup]** quick key.
   - Click **[Main Menu]** quick key → **[Alarm]** → **[Limits]**.
2) Select **[Limits]** at the lower left corner of **[Auto Limit]** page.
3) Select **[OK]** on the pop-up dialog window.

You can also set the auto alarm limit for one parameter from the parameter menu.

7.8 Set Alarm Volume

7.8.1 Set Minimum Alarm Volume

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab → **[Audio]** tab.
3) Select **[Minimum Alarm Volume]**.

7.8.2 Set Alarm Volume

1) Enter **[Setup]** screen in any of the ways listed below:
   - Click **[Alarm Setup]** quick key → Select **[Setup]** tab.
   - Click **[Main Menu]** quick key → **[Alarm]** → **[Setup]**.
2) Set **[Alarm Volume]**. The range of alarm volume is X ~ 10. X represents the minimum alarm volume, which depends on the Minimum Alarm Volume setting.
3) Set **[High Alarm Volume]**.
4) Set **[Reminder Volume]**.

WARNING

- **When the alarm volume is set to 0, the monitor cannot sound an alarm even if a new alarm is generated. Therefore, you should consider this when setting the alarm volume to 0.**
- **Do not only rely on the audible alarm. Otherwise, patient safety may be at risk if the alarm volume is low. Pay close attention to the patient's actual clinical conditions.**
- **When the alarm volume is set to 0, the setting of [High Alarm Volume] is invalid.**
- **Maximum alarm volume is 10.**

7.8.3 Set Alarm Reminder

When the alarm volume is set to 0, or the alarm is reset, or the alarm function is turned OFF, the monitor will provide periodic alarm mute reminder to remind user of the situation that there is still activated alarm in the current system. Set alarm reminder as follows:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** button → **[Pause/Reset]** tab.
3) Set **[Alarm Reset Reminder]** and **[Alarm Off Reminder]**.
   - ◆ When **[On]** is selected, the monitor will generate alarm reminder at set intervals.
   - ◆ When **[Re-alarm]** is selected, the confirmed physiological alarm and the non-clearable technical alarm will be generated again after the set time of **[Reminder Interval]** ends if the condition that trigger the alarm still exists.
   - ◆ When **[Off]** is selected, the monitor will not generate the alarm reminder, and the confirmed physiological alarm and the non-clearable technical alarm will be muted forever.
4) Select **[Reminder Interval]**.

7.8.4 Set Alarm Sound Effect

The monitor provides the following three modes of alarm sound effects:

ISO: beep-beep-beep

Mode 1: ding-ding-ding

Mode 2: Tick-Tick-Tick

Set alarm sound effect as follows:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** button → **[Audio]** tab.
3) Set **[Alarm Audio]**.

7.8.5 Set Auto Increase Volume

The monitor has the function of alarm volume enhancing. If the alarm is not confirmed after the specified time, its volume will be increased automatically. Set as follows:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** → **[Audio]**.
3) Set **[Auto Increase Volume]** as **[Level 2]**, **[Level 1]** or **[Off]**.
   - **[Level 2]**: If the alarm is not confirmed after the specified time, its volume will be increased by Level 2 automatically.
   - **[Level 1]**: If the alarm is not confirmed after the specified time, its volume will be increased by Level 1 automatically.
   - **[Off]**: If the alarm is not confirmed after the specified time, its volume will be no change.
4) Set **[Increase Volume Delay]** and select the increase volume delay time.

7.9 Alarm Paused/Alarm Audio Paused

7.9.1 Pause Definition

You can enable the function of alarm pause or alarm sound pause, which depends on the pause setting. Set as follows:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** tab → **[Pause/Reset]** tab.
3) Set **[Pause]** to **[Alarm Pause]** or **[Alarm Sound Pause]**. The default value is **[Alarm Pause]**.

7.9.2 Alarm Paused

If the alarm function is defined as **[Alarm Pause]**, Click **[Alarm Pause]** quick key to pause the alarm. This function will:

- Mute all physiological alarms.
- Mute the sound of all technical alarms except the alarm lights and alarm messages of them.
- Display the remaining time of alarm pause in the physiological alarm message area.
- Display the alarm pause icon in the message area.

The monitor will recover from alarm pause state after the alarm pause time expires. You can also press **[Alarm Pause]** quick key to cancel the alarm pause manually.

7.9.3 Set Alarm Pause Time

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** tab → then **[Pause/Reset]** tab.
3) Set **[Pause time]**: **[1min]**, **[2min]**, **[3min]**, **[Permanent]**.

7.9.4 Delay Alarm Pause Time

When the monitor is in the alarm pause state, you can delay the pause time of this alarm temporarily. For example: when the pause time is set to **[1min]**, and then set the delayed alarm pause time to **[pause for 5 minutes]**, then the alarm pause time will be extended from 1 minute to 5 minutes. This function is turned on by default. Set as follows:

1) Select physiological alarm message area
2) Select **[Pause 5 min]**, **[Pause 10 min]** or **[Pause 15 min]** on the pop-up menu.

Close the function of delay alarm audio pause time as follows:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** tab → **[Pause/Reset]** tab.
3) Deselect **[Pause 5 min]**, **[Pause 10 min]** or **[Pause 15 min]** as need.

7.9.5 Alarm All Off

If **[Pause Time]** is set to **[Permanent]** (refer to *"Section 7.9.3 Set Alarm Pause Time"*), all alarms will be shut down if **[Alarm Pause]** quick key is pressed. When the alarm function is shut down,

- the light and sound of physiological alarm will be mute.
- the sound of technical alarm will be muted except the alarm light and alarm message of it.
- **[Alarm Off]** with red background will appear in the physiological message area.
- the alarm pause icon and the alarm audio pause icon will be shown in the message area.

Click **[Alarm Pause]** quick key again to exit the alarm off state.

WARNING

- **Risk may exist if the alarm function is paused or turned off. The user should pay close attention to the actual clinical conditions of patients**

7.9.6 Alarm Audio Pause

If the alarm function is defined as **[Alarm Sound Pause]**, Click **[Alarm Sound Pause]** quick key will pause the alarm. When the monitor is in alarm audio pause state,

- The sounds of physiological alarm and technical alarm will be mute in the specified time.
- The remaining time of alarm audio pause will appear in the physiological alarm message area.
- The alarm pause icon will be displayed in the message area.

The monitor will exit the alarm sound state automatically when the specified time of alarm audio pause expires. You can also click **[Alarm Sound Pause]** quick key to cancel the state of alarm sound pause.

7.9.7 Set Alarm Audio Pause Time

Set alarm audio pause time: **[1min]**, **[2min]**, **[3min]**, **[Permanent]**. Set alarm audio pause time as the steps in "*Section 7.9.3 Set Alarm Pause Time*".

7.9.8 Delay Alarm Audio Pause Time

When the monitor is in the alarm audio pause state, you can increase the sound pause time of this alarm temporarily. For example: when the pause time is set to **[1min]**, and then set the delayed alarm pause time to **[pause for 5 minutes]**, then the alarm pause time will be extended from 1 minute to 5 minutes. Increase alarm audio pause time as the steps in "*Section 7.9.4 Delay Alarm Pause Time*".

7.9.9 Alarm Audio Off

If **[Pause Time]** is set to **[Permanent]** (refer to **"*Section 7.9.3 Set Alarm Pause Time*"**), all alarms will be shut down if **[Alarm Pause]** quick key is pressed. When the alarm sound is muted,

- The sounds of physiological alarm and technical alarm will be muted.
- The alarm audio pause icon will be displayed in the message area.

Click **[Alarm Sound Pause]** quick key again to exit the alarm audio off state.

⚠ WARNING

- **Risk may exist if the alarm sound is paused or turned off. The user should pay close attention to the actual clinical conditions of patients.**

7.10 Alarm Reset

Click **[Alarm Reset]** quick key will confirm the existing alarms and reset the alarm system. If the alarm to be reset is not clearable, the alarm reset icon will appear in the system status information area.

NOTE

- **If a new alarm is generated when the monitor is in alarm reset state, the alarm reset icon will disappear and the sound/light of the new alarm will function normally**

7.10.1 Physiological Alarm Reset

When the physiological alarm is reset,

- The sound of existing physiological alarm will be mute.
- A check mark will appear before the alarm message, indicating that the alarm has been confirmed.
- The background of the measured value of the parameter will be kept on but not flash.

7.10.2 Technical Alarm Reset

When the technical alarm is reset,

- Fully clearable technical alarms will be cleared. The monitor will give no warning of the cleared technical alarms.
- Clearable sound and light alarms will be displayed as a prompt message.
- Not fully clearable technical alarms will be muted. A check mark will appear before the alarm message, indicating that the alarm has been confirmed.

7.10.3 Alarm Light Status Set after Alarm Reset

The alarm light defaults to **[On]**. It can by turned off as follows:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Click **[Alarm]** tab → **[Pause/Reset]** tab.
3) Set **[Alarm Light]**
   - **[On When Reset]**: The light of existing alarm will flash but the sound of it will be mute after alarm reset.
   - **[Off When Reset]**: The light and sound of existing alarm will be both turned off after alarm reset.

7.11 Alarms at Remote View

7.11.1 Set Remote View Reminder

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and click the Enter key.
2) Select **[Alarm]** tab → **[Network]** tab.
3) Set **[Remote View Reminder]**.
   - **[Light + Sound]**: the alarm light and alarm sound will be kept on when alarming.
   - **[Only Light]**: Only the alarm light will be kept on when alarming.

7.11.2 Set Remote View Priority

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and click the Enter key.
2) Select **[Alarm]** tab → **[Network]** tab.
3) Set **[Alarm Priority]**:
   - **[All]**: The monitor will alarm when the other bed generates any level of alarm.
   - **[High&Med]**: The monitor will alarm when the other bed generates a high level alarm and medium level alarm.
   - **[High Only]**: The monitor will alarm when the other bed generates a high level alarm.

7.11.3 Remote View Reset

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and click the Enter key.
2) Select **[Alarm]** tab → **[Network]** tab.
3) Select **[Remote View Reset]**. The **[Alarm Reset]** appear at the lower left corner of **[Remote View]** window. Click **[Alarm Reset]** button; then Remote View alarm will be reset.

7.11.4 Alarm Reset by Remote View

User can reset the alarms occurring on the remote devices that are viewed on the Remote View screen of the monitor. To enable this function, follow this procedure:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and click the Enter key.
2) Select **[Alarm]** tab → **[Network]** → **[Remote View]**.

3) Switch ON of OFF the **[Alarm Reset by Remote View]**.

7.12 Set Nurse Call

If the nurse call is set on, the monitor will send request signal to nurse call system for calling a nurse when the user set alarm is triggered. The monitor provides a nurse call interface. After the monitor is connected with the hospital nurse-call system through the specified cable provided in the accessory bag, this interface can realize the Nurse Call function.

The nurse call function will be triggered when the monitor meets all requirements as follows:

- Nurse call function in enable.
- The user set alarm is triggered.
- No alarm pause or reset.

7.12.1 Nurse Call Setup

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab → **[Nurse Call]** tab.
3) Select **[Trigger mode]** to set the work mode of the relay of nurse call system.
4) Select **[Alarm Level]** to set the priority of alarm that can trigger the nurse call function.
5) Select **[Alarm Category]** to set the type of alarm that can trigger the nurse call function.

WARNING

- **Do Not rely on the Nurse Call only as the main alarm resource, paying close attention to patient's clinical symptoms is also necessary.**

7.13 Set Alarm Delay Time

Alarm delay time can be set for the alarm triggered by continuous over-limit parameters. The monitor will not make alarm if the conditions that trigger the alarm disappear in the delay time. Set as follows:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab → **[Other]** tab.
3) Set **[Alarm Delay]**.

HR alarm has no time-delay function; the delay time of no breath alarm, HR alarm, NIBP alarm, ECG arrhythmia alarm and ST alarm is not influenced by the alarm delay time, and can be set respectively.

7.14 Set the Switch of SpO_2 Desat Alarm

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab → **[Other]** tab.
3) Set **[SpO_2 Desat Alm Off]:**
   - **[Disabled]**: SpO_2desat alarm will be kept on, and cannot be turned off.
   - **[Enable]**: SpO_2desat alarm can be turned off.

7.15 Set the Switch of Apnea Alarm

1) Click **[Main Menu]** → **[System]** → **[Maintenance]**, then enter the maintenance password and click the Enter key.
2) Select **[Module]** tab → **[Other]** tab.
3) Select **[Apnea Alarm Off]**:
   - when **[Disabled]** is selected: The Apnea Alarm is in its working state, thus any apnea alarms cannot be switched off.
   - when **[Enable]** is selected: The Apnea Alarm can be switched off.

7.16 Set the Switch of CMS Disconnection Alarm

If the monitor is expected to alarm upon disconnecting from the Central Monitoring System (CMS), user is allowed to set the switch status by following steps:

1) Select **[Main Menu]** →**[System]**→**[Maintenance]**→input password→click Enter key
2) Select **[Alarm]** tab→**[Other]** tab
3) Switch ON or OFF the **[CMS Disconnection Alarm]**: if OFF is selected, the alarm information **[CMS Disconnected]** will not be generated when the monitor is disconnected from the CMS.

7.17 Set the Switch Status of CMS Alarm System Control

User can choose whether to allow the CMS monitoring system to control the Monitor's alarm system by:

1) Select **[Menu]** quick key →**[System]**--- **[Maintenance]**→input password→click Enter key
2) Select **[Alarm]** tab→**[Other]** tab
3) Switch ON or OFF the **[CMS Alarm System Control]**.

7.18 Cardiopulmonary Bypass (CPB) Mode

CPB Mode (Cardiopulmonary Bypass Mode) should be selected when a patient is admitted in **[OR]** (Operating Room) department to have CPB treatment. In the CPB ModeCPB Mode, except for Sedline related alarms, all the physiological alarms and technical alarms are switched off. When performing CPB, the information **[CPB Mode]** is displayed in the physiological alarm area with a red background color.

7.18.1 Enter CPB Mode

Enter the Cardiopulmonary Bypass Mode in either way as follows:

- Click **[CPB Mode]** quick key; or
- Click **[Main Menu]** quick key → **[Alarm]** → **[CPB Mode]**.

NOTE

- **NIBP measurement will be terminated when the monitor enters the CPB ModeCPB Mode. You can start NIBP measurement again under CPB ModeCPB Mode.**

7.18.2 Exit CPB Mode

Exit CPB ModeCPB Mode as follows:

- Click **[CPB]** quick key; or
- Click **[Main Menu]** quick key → **[Alarm]** → **[Exit CPB Mode]**.

7.19 Intubation Mode

The monitor provides the Intubation Mode when monitoring the parameters of Resp and CO_2. Intubation Mode is a unique monitoring mode which is suitable for surgeries under general anesthesia, for it will block the physiological alarms of Resp and CO_2. The alarm off icon appears in the parameter area under this mode.

7.19.1 Enter Intubation Mode

Enter the Intubation Mode in either way as follows:

- Click **[Intubation Mode]** quick key;
- Click **[Intubation Mode]** button under the menu of **[Resp]** or **[CO_2]**; or
- Click **[Main Menu]** quick key → **[Alarm]** → **[Intubation Mode]**.

7.19.2 Set Intubation Mode Duration

Set Intubation Mode Duration as follows:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab → **[Other]** tab.
3) Set **[Intubation Mode Duration]**

7.19.3 Exit Intubation Mode

Exit Intubation Mode in either way as follows:

- Click **[Intubation Mode]** quick key;
- Click **[Intubation Mode]** button under the menu of **[Resp]** or **[CO_2]**; or
- Click **[Main Menu]** quick key → **[Alarm]** → **[Exit Intubation Mode]**.

7.20 Alarm Auto Print

Set the waveform printing duration when an alarm occurs as follows:

1) Enter **[Setup]** screen by any of the following methods:
   - Click **[Alarm Setup]** quick key.
   - Click **[Main Menu]** quick key → **[Alarm]** → **[Setup]**.
2) Select **[Setup]** tab.
3) Set **[Printing Duration On Alarm]**.
4) After completing the above settings, and turning on the **[Alm Auto Print]** switch, then, when an alarm is triggered, the monitor will automatically print the alarm event and the parameter waveform at the same time.

7.21 Restore Alarm Default

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab.
3) Press the **[Restore Defaults]** button on the below.

7.22 Alarm System Self-test

Upon startup of the device, the alarm system will perform self-test of alarm light and sound.

Phenomena during self-test:

- The red alarm light is on for 1s; then the yellow light and the cyan light is on for 1s simultaneously; and then the alarm light is turned off.
- At the time of alarm light self-test, the alarm system makes a “beep” sound for alarm self-test and performs alarm sound self-test.

If the further testing of alarm system is needed, you can use relative simulator to perform it, and adjust the alarm limits to verify whether the correct alarm response can be triggered.

Chapter 8 ECG Monitoring

8.1 Overview

Electrocardiography (ECG) monitors continuous electrical activity of the patient's heart, which is reflected on the monitor in the form of wave and value, to accurately assess the current physiological status of the patient. Therefore, you must make sure the ECG cables are connected properly to obtain correct measurement values.

8.2 Safety information

⚠ WARNING

- The monitor is not indicated for direct cardiac application.
- When connecting the electrodes or patient cable, ensure that the patient does not come into contact with any other conductive parts or the ground. Confirm that all ECG cables and electrodes (including the neutral electrode) are attached the patient's body, and not in contact with any other conductive parts including ground
- An ECG cable with defibrillation-proof protection should be used when conducting defibrillation.
- During defibrillation, do not contact the patient, table or equipment.
- Before monitoring, ensure that ECG cable is properly connected. If the ECG cable is disconnected from the connector, the monitor displays the prompt message "ECG Lead Off" and sounds an alarm.
- Use only ECG electrodes and cables specified by Comen.
- Equipment such as a defibrillator and remote measurement unit can generate a filtered ECG signal. When this signal is used as the input signal for bedside monitor, it is filtered again. Such a signal used for arrhythmia algorithm analysis may cause pace pulse detect error pacer not capture or fault detection of asystole, and is harmful for patients with pacemakers.
- During defibrillation, the ECG cable connected to the patient may get damaged. When reusing such cables, you should check that function properly.
- When a defibrillator is applied to a patient, the cardiograph may have transient disorders in the display of waveforms. The defibrillation recovery time for ECG is 5 seconds.
- The device does not incorporate a means to protect the patient against burns or device malfunction when used with high frequency (HF) surgical equipment.
- When the monitor is connected to an electrosurgical unit (ESU), take care to protect the patient from injury or burns, and do not put the sensors and cables of the equipment in contact with the ESU.
- Do not expose the monitor to X-ray and high-intensity magnetic fields, or MRI environment.
- Pacemaker patients: Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter alarm signals. Keep pacemaker patients under close surveillance. Check this manual for disclosure of the pacemaker pulse rejection capability of this instrument.

- **Pacer pulse rejection must be switched on for a paced patient. Switching this function off may result in pacer pulses being counted as regular QRS complex, which would prevent an asystole event being detected.**

8.3 ECG Display

Heart beat markers: N indicates normal heart beat; A indicates abnormal heart beat; P indicates pacing heartbeat.

(1) Lead

(2) Gain

(3) Filter mode

(4) Notch filter frequency

(5) Pacer mode icon: Set **[Pacer]** as yes, the icon indicates. Set **[Pacer]** as no, no such icon display.

(6) Parameter name

(7) HR unit

(8) HR value

(9) HR alarm limit

(10) 1mV scale

NOTE

- **The display of ECG parameter tile and waveform tile will be different for different lead types and settings.**

8.4 Preparations before Monitoring

8.4.1 Prepare for Skin

To achieve good contact between electrodes and skin, it is very important to prepare the patient's skin since skin is poor conductor.

1) Choose a skin area without any damage or abnormality.

2) When necessary, shave body hair at positions where electrodes will be placed.
3) Use soap water to thoroughly clean the skin. (Do not use diethyl ether or pure alcohol because these substances may increase the skin impedance).
4) Air-dry the skin completely.
5) Use ECG preparation paper and gently rub the skin, so as to remove dead skin and improve the conductivity at the position where the electrode is attached.

8.4.2 Connect ECG Cable

1) Place the electrode on the patient's body. If the electrode does not contain conductive paste, apply conductive paste prior to placement on the skin.
2) Connect the electrode leads with the patient cable.
3) Insert the patient cable into the ECG port on the monitor. The monitor shows the ECG wave and value.

⚠ WARNING

- **Do Not use electrodes of different metal materials.**
- **Do Not mix different types and brands of electrodes for it may lead to large baseline drift or prolonged recovery time after defibrillation.**
- **Check whether the ECG electrode patch irritate skin every day. If there is any sign of allergy, replace the electrode or change its position.**
- **Use the electrode immediately after opening the package.**

8.4.3 Place ECG Leads

The table below lists the names of leads in European and American standards. (RA, LA, RL, LL and V are used to represent leads in American standards, whereas R, L, N, F and C are used in European standards):

	U.S.A. Standard		EU Standard	
Application site	Mark	Color	Mark	Color
Right arm	RA	White	R	Red
Left arm	LA	Black	L	Yellow
Right leg	RL	Green	N or RF	Black
Left leg	LL	Red	F	Green
Chest 1	V1	Red	C1	Red
Chest 2	V2	Yellow	C2	Yellow
Chest 3	V3	Green	C3	Green
Chest 4	V4	Blue	C4	Brown

Chest 5	V5	Orange	C5	Black
Chest 6	V6	Violet	C6	Violet

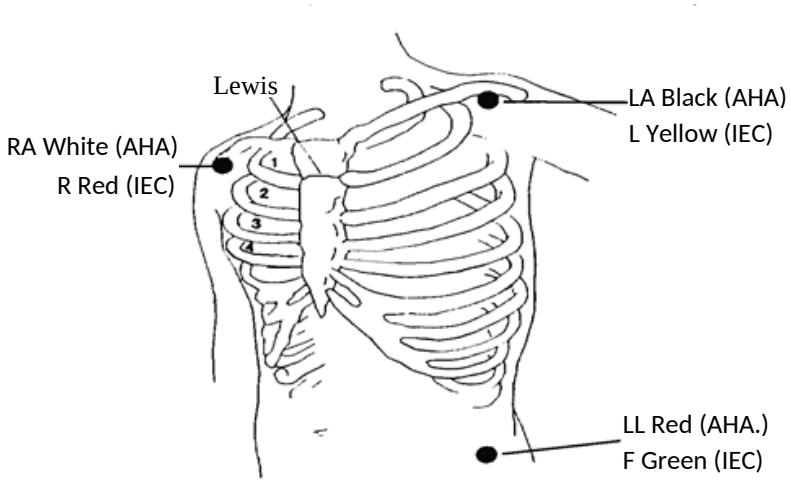
8.4.3.1 Place 3-lead Electrodes

Refer to American and European standards for placing electrodes of 3-lead unit:

White/red (right arm) electrode — Place it below the clavicle, near the right arm.

Black/yellow (left arm) electrode — Place it below the clavicle, near the left arm.

Red/green (left leg) electrode — Place it at the left lower abdomen



8.4.3.2 Place 5-lead Electrodes

Refer to American and European standards for placing electrodes of 5-lead unit:

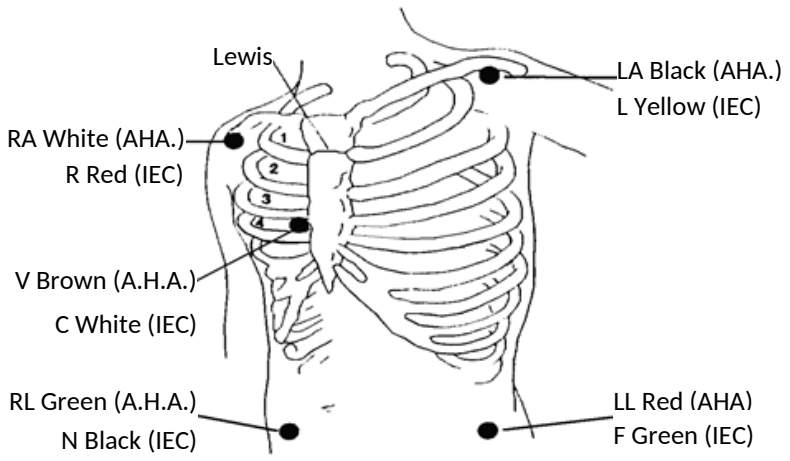
White/red (right arm) electrode — Place it below the clavicle, near the right arm.

Black/yellow (left arm) electrode — Place it below the clavicle, near the left arm.

Green/black (right leg) electrode — Place it at the right lower abdomen

Red/green (left leg) electrode — Place it at the left lower abdomen

Brown/white (chest) electrode — Place it on the chest wall.



For 5-lead configuration, place the chest (V) lead electrode at one of the following positions:

V1: 4th intercostal space, at the right sternal border.

V2: 4th intercostal space at the left sternal border.

V3: In the middle position between V2 and V4.

V4: 5th intercostal space at the left midclavicular line.

V5: In the left anterior axillary line, just parallel to V4.

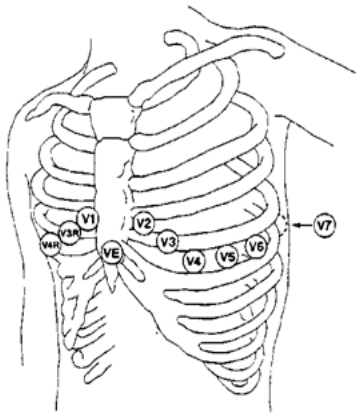
V6: In the left mid-axillary line, just parallel to V4.

V3R-V6R: On the right side of the chest wall, corresponding to the left-side position.

VE: At the xiphoid eminence position.

V7: 5th intercostal space in the left posterior axillary line at the back.

V7R: 5th intercostal space in the right posterior axillary line at the back.



8.4.3.3 Place 6-lead Electrodes

Place 6-lead electrodes in the positions of 5-lead electrodes. However, the two chest leads (Va and Vb) can be placed in any two positions of V1-V6. You can define the positions of Va and Vb; please refer to "*Section8.5.8.3 Set Va and Vb Markers*" for more information.

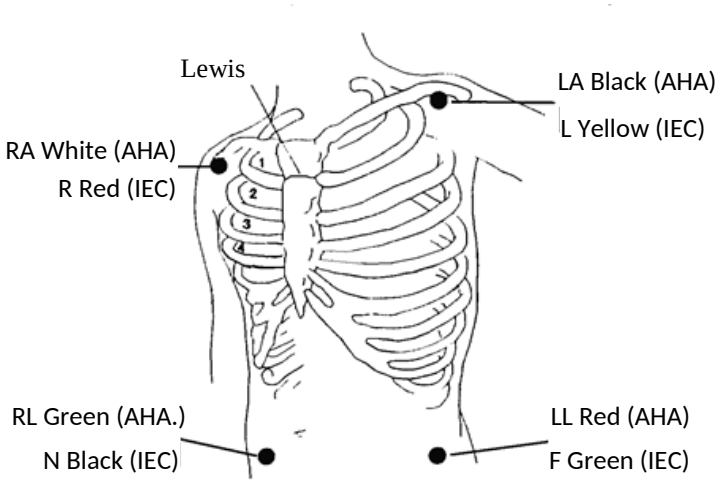
8.4.3.4 Place 12-lead Electrodes

White/red (right arm) electrode — Place it below the clavicle, near the right arm.

Black/yellow (left arm) electrode — Place it below the clavicle, near the left arm.

Green/black (right leg) electrode — Place it at the right lower abdomen

Red/green (left leg) electrode — Place it at the left lower abdomen



There are generally six electrode positions on the chest, using intercostal gap to pinpoint the positions, V1 ~ V6:

V1: 4th intercostal space, at the right sternal border.

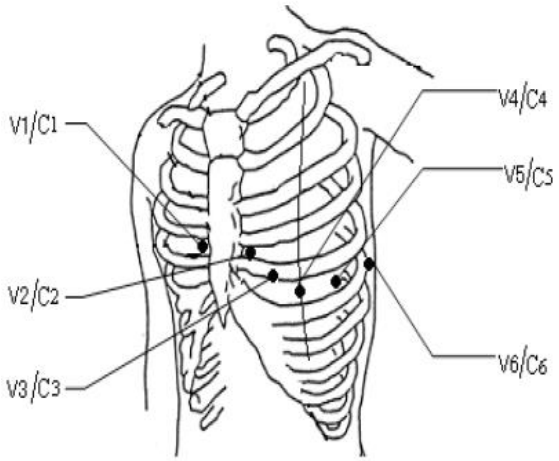
V2: 4th intercostal space at the left sternal border.

V3: In the middle position between C2 and C4.

V4/C4: 5th intercostal space at the left midclavicular line

V5/C5: on the left anterior axillary line, horizontal with the C4 electrode position

V6/C6: on the left mid-axillary line horizontal with the V4 electrode position



8.4.3.5 Recommended ECG Lead Connection for Surgical Patient

WARNING

- **When using an Electrosurgical Unit (ESU), never place electrodes close to the ground plate of the ESU; otherwise there is too much interference against the ECG signal.**

- **When the monitor is connected to an electrosurgical unit (ESU), in order to protect the patient from injury caused by leakage current, do not put the sensors and cables of the equipment in contact with the ESU.**

The placement of ECG lead depends on the type of operation to be performed. For example, when a thoracotomy is to be performed, the electrode can be placed on the side of the chest or on the back. In the OR, artifacts may affect ECG waveform due to the use of an ESU. In order to reduce artifacts, the electrodes can be placed at the left and right shoulders, close to the left and right sides of the abdomen; the chest lead can be placed left to the middle of the chest. Avoid placing the electrode on the upper arm, or the ECG waveform may become very small.

NOTE

- **When monitoring the patient with pacemaker, [Pacer] must be set to [Yes]. If it is set to [No], pacemaker pulses may be counted as QRS complex, resulting in failure to detect asystole. When changing patient info or admitting/discharging a patient, check whether [Pacer] is set correctly.**

8.5 ECG Setup

8.5.1 Set ECG Lead Type

1) Touch ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Set **[Lead Set]** based on the lead used. If **[Auto]** is selected, the Monitor will automatically detect the type of ECG lead connected.

8.5.2 Check Pacer Status

It is very important to set the patient's pacer status correctly before ECG monitoring. If the **[Pacer]** is set to **[Yes]** and pacing signal is detected, "|" will be shown above the ECG waveform, and will be shown in the ECG waveform tile; if the **[Pacer]** is set to **[No]**, there will be no icon or symbol displayed.

Steps to set the pacers status:

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Pacer]** tab.
3) Set **[Pacer]** to **[Yes]** or **[No]**.

If the pacer status is set to **[No]**, the icon will blink in ECG waveform tile and the message prompt **[Please check if the patient has a pacemaker.]** will be displayed when a pacing signal is detected.

8.5.3 Set Pacer Rejection

The Monitor is designed with the function of rejecting the display of pacing signal, and the setting steps for pacers reject are as follows:

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Pacer]** tab.
3) Set **[Pacer Rejection]** to ON or OFF.

NOTE

- **The setting of [Pacer Rejection] will not affect the display of pacemaker pulse symbol "|".**
- **You can set [Pacer Rejection] only if [Pacer] is set to [Yes].**

8.5.4 Choose ECG Screen

During ECG monitoring, you can select the screen as needed.

- For use of 3-lead ECG, only the Normal Screen is available.
- For use of 5-lead ECG, the Normal Screen, the 7-Lead Full-Screen and 7-Lead Half-Screen are available.
- For use of 6-lead ECG, the Normal Screen, the 8-Lead Full-Screen and 8-Lead Half-Screen are available.
- For use of 12-lead ECG, the Normal Screen, the Multi-leads Full-screen, the Multi-leads Half-screen and 12-Lead Full-Screen are available.

Steps to select a screen:

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab and click **[Half-screen]**, **[Full-screen]** or **[12-Lead]** at the bottom of the menu to select a screen.

8.5.5 Set ECG Alarm

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

8.5.6 Set Alarm Source

You can set the parameters that trigger an ECG alarm. The setup steps are as follows:

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Alarm]** tab.
3) Set **[Alarm Source]**: **[HR]**, **[PR]**, **[HR+PR]** or **[Auto].**

8.5.7 Set QRS Volume

QRS volume setup is the same with alarm source setup. Steps to set QRS volume are as follows:

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Set **[QRS Volume]**.

When there is a valid SpO_2 measurement, the system will adjust QRS tone (Pitch Tone) according to the level of SpO_2.

8.5.8 Set ECG Waveform

8.5.8.1 Set Lead Name for ECG Waveform Displayed

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Select **[ECG]** to set the lead name for each ECG waveform.
4) If more than 3 waveforms are displayed, select **[More Leads]** tab and then **[ECG]** to set the lead name for other ECG waveforms.

The lead waveform selected should have the following characteristics:

- Tall, narrow and without notch.
- R wave is tall and completely above or below the baseline.
- P wave and T wave should be less than 0.2mV.

CAUTION

- **Please make sure to select the best ECG lead, which is very important to identify heart rate and ventricular fibrillation.**

8.5.8.2 Set ECG Waveform Gain

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Select **[ECG Gain]** to set the gain for each ECG waveform.
4) If more than 3 waveforms are displayed, select **[More Leads]** tab and then **[ECG Gain]** to set the gain for other ECG waveforms. If you select **[Auto]**, the Monitor will automatically adjust the ECG waveform gain.

8.5.8.3 Set Va and Vb Markers

During 6-lead ECG monitoring, you can select the marker for Va and Vb leads according to their positions. Steps are as follows:

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Set **[Va]** and **[Vb]** according to the electrode positions of Va and Vb leads.

8.5.8.4 Set ECG Waveform Speed

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Set **[Waveform Speed]**.

8.5.8.5 Set ECG Filter Mode

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Set **[Filter]**.
   - **[Diag.]**: Select it when there is a requirement for diagnostic quality. In this mode, you can see the changes in waves, such as the notch of R wave, ST segment elevation or depression.
   - **[Monitor]**: Select it for normal monitoring.
   - **[Surgery]**: Select it for high-frequency or low-frequency interference of signals. High-frequency interference usually causes high-amplitude sharp pulses, making ECG signals irregular. Low-frequency interference usually leads to baseline drift or thicker baseline. The use of **[Surgery]** mode in operating room can reduce artifacts and interference from electrosurgical equipment. However, the use of this mode under normal monitoring may inhabit the display of QRS complex.
   - **[ST]**: Select it for ST segment analysis.

8.5.8.6 Set Notch Filter

Notch filter can inhibit the 50Hz or 60Hz frequency component in the signals acquired. When the filter mode is not Diagnosis, the system will turn on **[Notch Filter]** automatically; when the filter mode is **[Diag.]**, **[Notch Filter]** can be turned on or off as needed.

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Set **[Notch Filter]** as follows:
   - **[Strong]**: Select it when the wave jitters frequently (e.g., the wave has burrs).

- **[Weak]**: Select it when the wave jitters infrequently.
- **[Off]**: Notching will not be performed. It can be set only when filter mode is set to **[Diag.]**.

8.5.8.7 Set Notch Filter Frequency

You can set the notch filter frequency according to the local power supply frequency. Steps are as follows:

1) Select **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Other]** tab.
3) Set **[Notch Filter]** to **[50Hz]** or **[60Hz]** according to grid power supply frequency.

8.5.8.8 Set Heart Beat Marker

User can set whether to display the heart beat marker (N indicates normal heart beat; A for abnormal heart beat and P for pacing heartbeat) above the ECG waveform. Steps are as follows:

1) Click on ECG parameter area or waveform area to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Set **[Smart Lead]** to **[ON]** or **[OFF]**

8.5.9 Set Smart Lead Off

If the lead of the first waveform falls off after the smart lead off is set to **[ON]**, the screen will automatically switch to the waveform with lead on, and recalculate the patient's heart rate for detection and analysis of arrhythmia. If the fallen lead is connected again, the screen will automatically switch to the original waveform.

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Set **[Smart Lead]** to **[ON]** or **[OFF]**.

8.5.10 Set Lead Off Alarm Priority

1) Select **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab → **[Other]** tab.
3) Set **[ECG Lead Off]**.

8.6 Arrhythmia Analysis

Arrhythmia analysis is intended for adult, pediatric and neonate patients.

8.6.1 Safety Information on Arrhythmia

⚠ WARNING

- Arrhythmia may affect the heart rate. During monitoring of patients with arrhythmia, do not completely rely on the alarm function of the cardiotachometer, and patients with arrhythmia should be closely monitored.
- The arrhythmia function is suitable for detection of some ventricular and atrial arrhythmias, but not for all of them. Sometimes, it may give a wrong result of arrhythmia detection. Thus, the doctor must combine more clinical manifestations to analyze arrhythmia information.
- The atrial fibrillation detection is not intended for pediatric and neonate patients.
- The accuracy of R on T detection might be compromised on a patient with implantable cardiac defibrillator or pacemaker.
- Patients with intermittent ventricular pacing often trigger false ventricular alarms, especially when the nurse has neglected to activate the Pace Mode feature.

⚠ CAUTION

- A complete and reliable ECG signal input is the basis for arrhythmia analysis and arrhythmia alarm. The ECG signal quality and the setting of arrhythmia threshold will affect the sensitivity of arrhythmia detection and heart rate calculation. At least a 5-lead ECG cable is recommended for monitoring, and 12-lead ECG cable is favorable.
- The amplitude of the ECG waveform and the setting of QRS threshold will affect the sensitivity of arrhythmia detection and heart rate calculation.
- If the QRS amplitude is too low the Monitor may fail to calculate the heart rate, or detect incorrect asystole.
- During ECG relearning the arrhythmia defection function may not be available. Therefore, the patient should be closely monitored during and within a few minutes after the ECG relearning.
- If Run PVCs and PVCs/min High are detected and alarming the clinician is called to monitor for frequent PVC's and deterioration to more serious rhythms.

8.6.2 Arrhythmic Events

This section lists all arrhythmic events that can be detected by the Monitor and their criteria.

8.6.2.1 Lethal Arrhythmia

Arrhythmic Events	Description
Asystole	No QRS complex detected within the set time interval in the absence of ventricular fibrillation or chaotic signal.
V-Fib/V-Tach	A fibrillatory wave lasting for 6 consecutive seconds, or a dominant rhythm of adjacent PVCs and the ventricular rate is greater than the V-tach rate limit.
V-Tach	The number of sustained PVCs is greater than or equal to the limit of V-Tach PVCs, and ventricular rate is greater than or equal to the limit of V-Tach rate.
Vent Brady	The number of sustained PVCs is greater than or equal to sustained ventricular bradycardia threshold, and ventricular heart rate is below the ventricular bradycardia rate threshold.
Extreme Tachy	The heart rate is greater than or equal to the limit of extreme tachycardia.
Extreme Brady	The heart rate is less than the limit of extreme bradycardia.

8.6.2.2 Non-lethal Arrhythmia

Arrhythmic Events	Description
R on T	R on T PVC is detected.
Run PVCs	More than two consecutive PVCs, but lower than the V-Brady PVCs limit, and the ventricular rate is lower than the V-Tach rate limit.
Couplet	A couplet of premature ventricular contractions in between normal beats.
PVC	A single premature ventricular contraction in between normal beats.
Bigeminy	The dominant rhythm of N, V, N, V, N, V
Trigeminy	The dominant rhythm of N, N, V, N, N, V, N, N, V
Tachy	The heart rate is greater than the limit of tachycardia
Brady	The heart rate is lower than the limit of bradycardia
Pacer Not Capture	No QRS complex is detected for 300 ms following a pace pulse (for paced patients only)
Pacer Not Pacing	There is no pace pulse for 1.75 times of average R-to-R interval following a QRS complex (for paced patients only)
Missed Beats	At least 3 consecutive Ns, and the current RR interval is greater than 1.5 times of the previous RR interval, and the next RR interval is lower than 1.5 times of the average RR interval; the heart rate is lower than 100 and the current RR interval is greater than 1.75 times of the average RR interval, or the heart rate is greater than or equal to 100 and the current RR interval is greater than 1000ms.
Irr Rhythm	Sustained irregular heart rhythm (N: change of irregular RR interval exceeds 12.5%)
Nonsus V-Tach	The number of consecutive PVCs is lower than the limit of V-tach PVCs but greater than 2, and the ventricular heart rate is greater than or equal to the limit of V-tach rate.
Vent Rhythm	The number of consecutive PVCs is greater than or equal to the limit of V-Brady PVCs, and the ventricular rate is greater than or equal to the limit of V-Brady rate, but lower than the limit of V-tach rate.
Heart Pause	No QRS complex is detected within the set heart pause time threshold
Irr Rhythm End	Arrhythmia is not detected within the delay time after the end of Arrhythmia
A-Fib	Normal beat RR intervals are irregular and P wave is absent.

PVCs/min High	PVCs/min exceeds high limit
Pauses/min High	Pauses/min exceeds high limit
A-Fib End	Atrial fibrillation is no longer detected within the delay time after the end of atrial fibrillation
Multiform PVC	Multiform PVCs exceed the set threshold
SVCs/min High	SVC s/min exceeds high limit
SVT	Run PVCs≥ SVCs limit, and supraventricular heart rate ≥supraventricular heart rate limit.
PAC Bigeminy	The dominant rhythm of N, V, N, V, N, V
PAC Trigeminy	The dominant rhythm of N, N, V, N, N, V, N, N, V
IPVC	The PVC between two normal sinus rhythms appears ≥ 3 within 30s.
VEB	The delayed ventricular contractions occurs ≥ 2 between normal beats.
Nonsus S-Tach	The continuous premature supraventricular contractions>2, and less than SVCs limit; and the supraventricular heart rate is high than or equal to the supraventricular heart rate limit.
Atrial Rhythm	The continuous premature supraventricular contractions ≥ SVCs limit; and the supraventricular heart rate is lower than the supraventricular heart rate limit.
RUN SVCs	The continuous premature supraventricular contractions>2, and less than SVCs limit; and the supraventricular heart rate is lower than the supraventricular heart rate limit.
PAC Couplet	A couplet of premature supraventricular contractions in between normal beats.
Wide QRS Tachy	The conditions for the occurrence of tachycardia are met, and the QRS wave width is 160ms or more.

Remark: N: Normal Heartbeat; V: Ventricular Heartbeat

8.6.3 Arrhythmia Setup

8.6.3.1 Set Arrhythmia Alarm

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Arrhythmia]** tab → **[Alarm]** tab.
3) Set the alarm for each kind of arrhythmia as needed.

NOTE

- **The Alarm Level of lethal arrhythmia is fixed to high, which cannot be modified by the user.**

8.6.3.2 Set Lethal Arrhythmia Alarm Switch

1) Select **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab → **[Other]** tab.
3) Set **[Lethal Arrhy Alarm Off]**.

◆ **[Lethal Arrhy Alarm Off]** defaults to **[Disable]**: The lethal arrhythmia alarm is fixed to **[ON]**, and you cannot turn it off.

◆ **[Lethal Arrhy Alarm Off]** is set to **[Enable]**: You can turn the lethal arrhythmia alarm off. Please refer to "*Section8.5.3.1 Set Arrhythmia Alarm*" for more information.

WARNING

- **Dangerous occurrences arise if the monitor fails to trigger arrhythmia alarms due to switching off all arrhythmia alarms by users. Thus users shall pay close attention to the patient's actual clinical conditions.**

NOTE

- **If a lethal arrhythmia alarm is turned off, the message prompt [Lethal Arrhythmia Alarm Off] will be displayed in ECG waveform tile.**

8.6.3.3 Set Arrhythmia Threshold

Thresholds for some arrhythmias can be set. When the value of an arrhythmia exceeds its threshold, an alarm will be triggered. Steps to set the arrhythmia threshold are as follows:

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) **[Arrhythmia]** tab → **[Threshold]** tab.
3) Set the threshold for all kinds of arrhythmias.

NOTE

- **The setting of [Asystole Delay] is associated with ECG relearning, so when HR is below 30 bpm, it is recommended to set [Asystole Delay] to 10s.**

8.6.3.4 Arrhythmia Threshold Range

Parameter	Range
PVCs/min	1~100
Asystole Delay	3s~10s
Tachy (HR High)	17 bpm-295 bpm
Brady (HR Low)	16bpm-290 bpm
Extreme Tachy	60bpm-300 bpm
Extreme Brady	15bmp~120bmp
Vbrd Rate	15bpm~60bpm

Multif PVCs Window	3 beats ~ 31 beats
Vtac Rate	100bmp~200bmp
Vtac PVCs	3 beats ~15 beats
Heart Pause Time	1.5s, 2.0s, 2.5s, 3.0s, 3.5
Vbrd PVCs	3 beats ~99 beats
Pauses/min	1~15
AF/Irr Rhy End Time	0min, 1min, 2min, 3min, 4min, 5min, 10min, 15min, 30min
SVCs	3 ~99
SV-tach Rate	100bpm ~300bpm
SVCs/min High	1 ~100

8.7 Heart Rate Variability

HRV (heart rate variability) are statistical results calculated from consecutive RR intervals to reflect the variability of sinus heart rate. The main mechanism of its occurrence is that the heart rhythm is directly regulated and restricted by both cardiac sympathetic and vagal nerves. HRV analysis is a commonly used quantitative index to identify autonomic nervous activity. It is of great clinical significance since it can be used to predict sudden cardiac death, and evaluate the pathological state related to the activity and balance of cardiac autonomic nerves.

8.7.1 Enter HRV Menu

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab and then **[HRV]** button at the bottom of the menu to enter HRV menu.

8.7.2 View HRV Parameters

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab and then **[HRV]** button at the bottom of the menu to enter HRV menu.
3) Select **[Parameter]** tab.

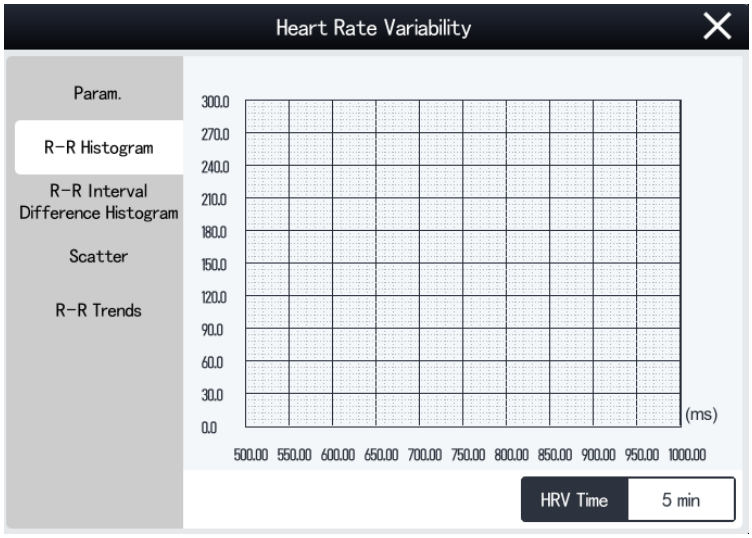
HRV Parameters	Description	Unit
MEAN	Mean value of RR intervals	ms
SDANN	Standard deviation of the averages of RR intervals for all 5-miute segments	ms
SDNN	Standard deviation of the RR intervals of all sinus heart beats	ms
SDNNI	Standard deviation of the RR intervals for all 5-minute segments	ms
RMSSD	Root mean square of the successive differences	ms
NN50	The number of pairs of successive NN intervals that differ by more than 50ms	set

PNN50	The proportion of NN50 divided by the total number of NN intervals	%

8.7.3 View Histogram R-R

Histogram R-R reflects the distribution and proportion of RR interval values. Steps to view the histogram are as follows:

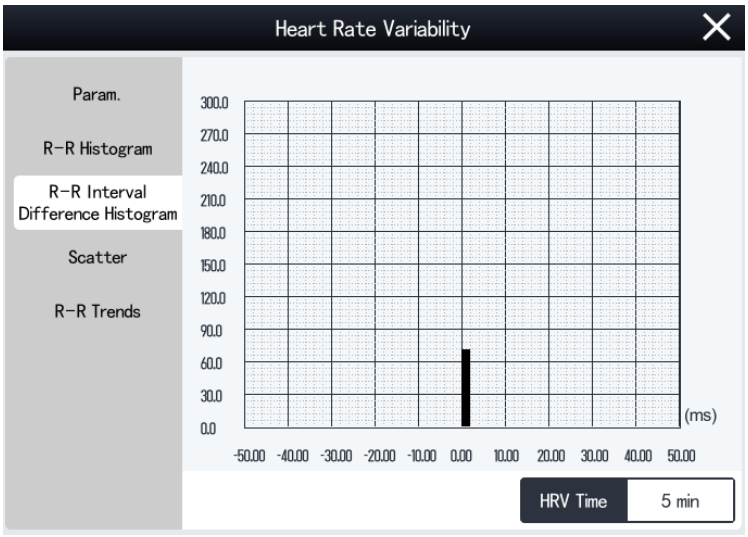
1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab and then **[HRV]** button at the bottom of the menu to enter **[HRV]** menu.
3) Select **[Histogram R-R]** tab.



- The x-coordinate indicates the time value of RR intervals.
- The y-coordinate indicates the number of RR intervals.

8.7.4 View Difference Histogram R-R

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab and then **[HRV]** button at the bottom of the menu to enter **[HRV]** menu.
3) Select **[Difference Histogram R-R]** tab.

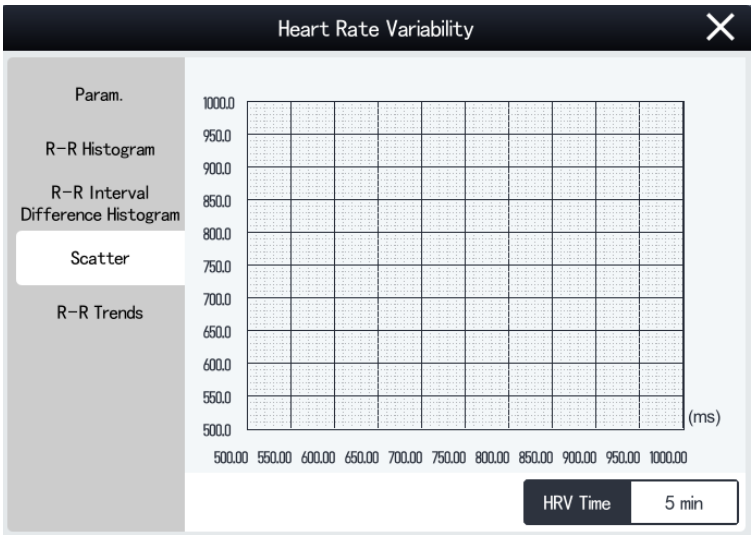


- The x-coordinate indicates the differences of successive RR intervals.
- The y-coordinate indicates the number of RR intervals.

8.7.5 View Scatter

The scatter contains the linear and nonlinear trends of HRV, gives a visual display of heartbeats and reveals nonlinear processes and aperiodic movements. The density of dots is expressed by the depth of the color (blue (low) ~ red (high)).

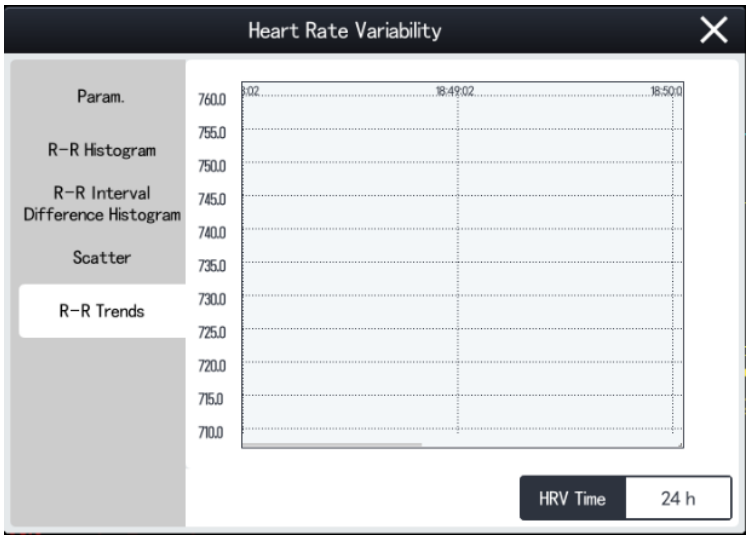
1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab and then **[HRV]** button at the bottom of the menu to enter **[HRV]** menu.
3) Select **[Scatter]** tab.



- The x-coordinate indicates an R-R interval.
- The y-coordinate indicates the next R-R interval.

8.7.6 View R-R Trend

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab and then **[HRV]** button at the bottom of the menu to enter **[HRV]** menu.
3) Select **[R-R Trend]** tab.



- The x-coordinate indicates the time.
- The y-coordinate indicates the mean value of RR intervals within the time period.

8.7.7 Analysis Period Selection

The Monitor saves HRV data of the latest 24 hours at most. You can select the data of a certain period to draw Histogram R-R, Difference Histogram R-R, Scatter and R-R Trend. Steps are as follows:

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab and then **[HRV]** button at the bottom of the menu to enter **[HRV]** menu.
3) Set **[Tempo]**.

8.8 ST Segment Analysis

ST segment of ECG wave is an interval between the end of ventricular depolarization and the beginning of ventricular repolarization, or a section between the end of the QRS complex (the J point) to the beginning of the T wave. ST segment analysis is chiefly used to monitor the patient's oxygen supply and myocardial viability. The function of ST segment analysis is intended for adult, pediatric and neonate patients.

8.8.1 Safety Information about ST

WARNING

- **Factors such as anti-arrhythmia drugs, metabolism and conduction disturbance may affect ST values.**
- **Since ST is calculated based on the fixed delay after the J point, it may be affected by HR changes.**
- **The ST algorithm had been tested for ST level change for adult patient. The clinical significance should be determined by the doctor.**

8.8.2 ST Analysis On/Off

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[ST]** tab → **[Setup]** tab.
3) Set **[ST Analysis]** to **[On]** or **[Off]**.

Some clinical situations may result in difficulty to achieve reliable ST monitoring. For example:

- ✧ Lead of low noise cannot be obtained.
- ✧ Presence of arrhythmia (e.g., atrial fibrillation/atrial flutter) that can cause irregular baseline.
- ✧ The patient is under continuous ventricular pacing.
- ✧ The patient has left bundle branch block.

Under such circumstances, you should consider turning off ST monitoring.

WARNING

- **This monitor provides info about changes in ST level, the clinical significance of which should be determined by the doctor.**

8.8.3 Set ST Alarm

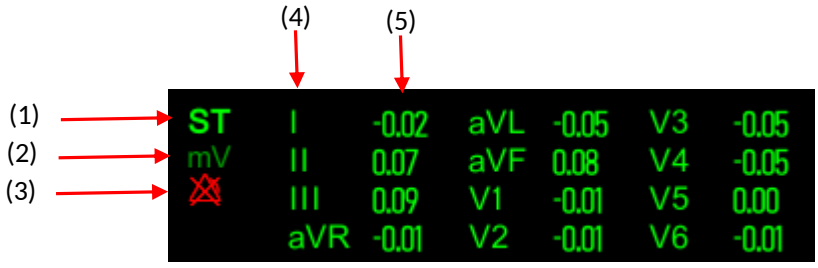
1) Select ECG parameter tile, waveform tile or ST parameter tile to enter **[ECG]** menu.
2) Select **[ST]** tab → **[Alarm]** tab.
3) Set **[ST Alarm Mode]** to **[Absolute]** or **[Relative]**.
   - ◆ If select **[Absolute]**, you can set the properties of each ST alarm separately.
   - ◆ If select **[Relative]**, you can set the properties of **[Single ST Alarm]** and **[Multiple ST Alarms]** separately.
4) Set the properties of ST alarms as needed.

8.8.4 Display ST Parameters

1) Enter the **[Tile Layout]** screen in any of the following ways:
   - Select **[Screen Setup]** quick key → **[Tile Layout]**
   - Select **[Main Menu]** quick key → **[Display]** → **[Tile Layout]**.
2) Click on the parameter tile to display ST parameters and select **[ECG]** → **[ST]**.

   Depending on the type of lead used, the ECG parameter tile displays different ST parameters.
   - 3-lead: 1 ST parameter is displayed in the ECG parameter tile, not the ST parameter tile.
   - 5-lead: 7 ST parameters, i.e. ST-I, ST-II, ST-III, ST-aVR, ST-aVL, ST-aVF and ST-V, are displayed in the ST parameter tile.
   - 6-lead: 8 ST parameters, i.e. ST-I, ST-II, ST-III, ST-aVR, ST-aVL, ST-aVF, ST-Va and ST-Vb, are displayed in the ST parameter tile.
   - 12-lead: 12 ST parameters, i.e. ST-I, ST-II, ST-III, ST-aVR, ST-aVL, ST-aVF, ST-V1, ST-V2, ST-V3, ST-V4, ST-V5 and ST-V6, are displayed in the ST parameter tile.

Taking 12-lead type as an example, the ST parameter tile is shown as follows:



(1) Parameter name (2) ST unit (3) ST alarm off icon

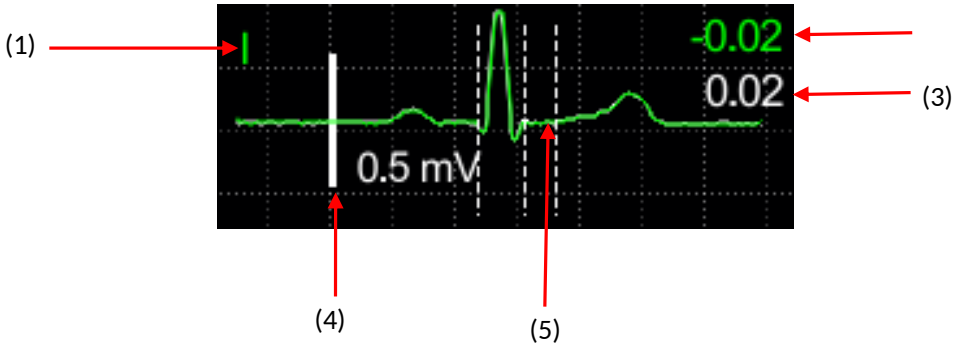
(4) Lead name (5) ST value: a positive number indicates ST elevation and negative for ST depression

8.8.5 Display ST Segment in Waveform Area

1) Enter the **[Tile Layout]** screen in any of the following ways:
   - Select **[Screen Setup]** quick key → **[Tile Layout]**.
   - Select **[Main Menu]** quick key → **[Display]** → **[Tile Layout]**.
2) Click on the waveform tile to display ST segment and then select **[ECG]** → **[ST Segment]**.

The ST waveform tile displays the current ST segment waveform and baseline waveform, the current ST value and the baseline value. Typically, the current ST segment and parameter values are displayed in green, and the baseline segment and parameter values are displayed in white.

(2)



(1) ST lead (2) ST value (3) ST baseline value

(4)1mV marker (5) ST segment（green） and ST baseline（white）

8.8.6 Select Lead for ST Segment Displayed in Waveform Area

The Monitor displays the ST segments of the three leads that have changed the most by default. You can manually select the lead you want to display as follows:

1) Select ECG parameter tile, waveform tile or ST parameter tile to enter **[ECG]** menu.
2) Select **[ST]** tab→**[Setup]** tab.
3) Select **[ST Segment]** to set the lead to be displayed. You can select ST segments of up to three leads to display.

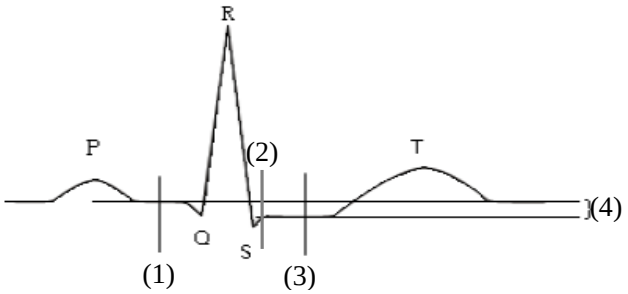
8.8.7 Display Position Markers of ISO Point, J Point and ST Point

Position markers of ISO point, J point and ST point are not displayed in ST segment by default. If you want to show these markers, follow the steps below:

1) Select ECG parameter tile, waveform tile or ST parameter tile to enter **[ECG]** menu.
2) Select **[ST]** tab→**[Setup]** tab.
3) Turn on the **[Show Markers]** switch.

8.8.8 Locate ST Point, J Point and ISO Point

ST measurement, or ST segment deviation, refers to the vertical distance between the isoelectric line (ISO) and ST point. The isoelectric line is located between the end point of P wave and the beginning point of QRS complex, providing a measurement baseline. ST point is in the middle of ST segment; J point is the end point of QRS complex. Since the distance between J point and ST point is fixed, you can accurately locate the position of ST point by J point.



(1).ISO Point (2). J Point (3). ST Point (4). ST Value

CAUTION

- **If the HR or ECG wave of the patient changes obviously, the position of ISO and ST points should be adjusted. During ST segment analysis, abnormal QRS complex is not considered.**
- **Please ensure that the position of ST measuring point is suitable for the patient being monitored.**

Set ST point, J point and ISO point as follows:

1) Select ECG parameter tile, waveform tile, ST parameter tile or ST segment waveform tile to enter **[ECG]** menu.
2) Select **[ST]** tab→ **[Adjust ST]** tab.
3) Select **[ST Point]** to set the position of ST point.
4) **[Auto Adjust]** switch defines the adjustment mode of ISO point and J point. The Auto Adjust switch defaults to **[On]**, and then the module automatically adjusts the position of ISO point and J point based on the current model. If the **[Auto Adjust]** switch is set to **[Off]**, you can click on the arrows to the right of **[ISO]** and **[J]** to manually adjust the position of ISO point and J point
   - The ISO point cursor indicates the position of the isoelectric point relative to R wave crest. The ISO point is located at the middle of the flattest part of the baseline (between P wave and Q wave).
   - The J point cursor indicates the position of J point relative to R wave crest. It helps to locate ST point correctly. The J point is located at the end of QRS complex and the beginning of ST segment.
   - The distance between ST point and J point is fixed, so move J point to make ST point in the middle of ST segment. The ST point may be located at J+60/80, J+40, J+60 or J+80. If **[J+60/80]** is selected, the system will automatically adjust the position of ST point according to the patient's heart rate: when the patient's heart rate is greater than 120bpm, the system will select J+60 to locate ST point; when the patient's heart rate is less than or equal to 120bpm, the system will select J+80 to locate ST point.

8.8.9 ST View

ST View displays a complete QRS waveform segment of each ST lead. You can enter **[ST View]** to view these ST segments. The color of the current ST segment and ST value is usually green, the same as the color of ECG

waveform. When the ECG waveform color is non-white, the ST baseline segment and baseline value are white; when the ECG waveform color is white, the ST baseline segment and baseline value are green.

You can enter the **[ST View]** screen by selecting ST segment waveform tile or through the following steps:

1) Select ECG parameter tile, waveform tile or ST parameter tile to enter **[ECG]** menu.
2) Select **[ST]** tab.
3) Select **[ST View]** button at the bottom of the menu.

8.8.10 Save ST Baseline

A valid template is required for ST analysis, and please set the ST baseline after ST value is stable. If you do not set the baseline, the Monitor automatically saves a set of baselines about 5 minutes after the emergency of valid ST measurements. You can select **[Set Baseline]** in **[ST View]** to update the baseline manually.

You can also make the following settings in the ST View screen:

- Select **[Display Baseline]** or **[Hide Baseline]** to display or hide ST baseline segment and parameter value.
- Select **[Display Marker]** or **[Hide Marker]** to display or hide the position of ISO point, J point and ST point.

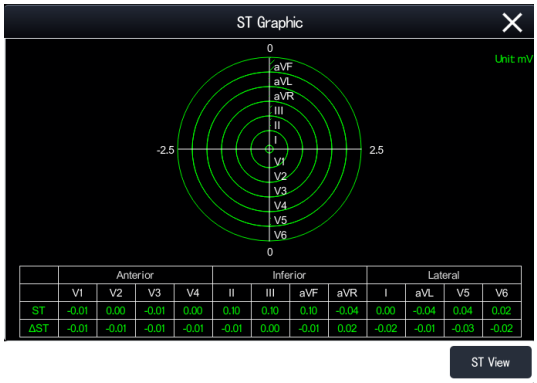
CAUTION

- **The change of ST baseline affects ST alarm.**

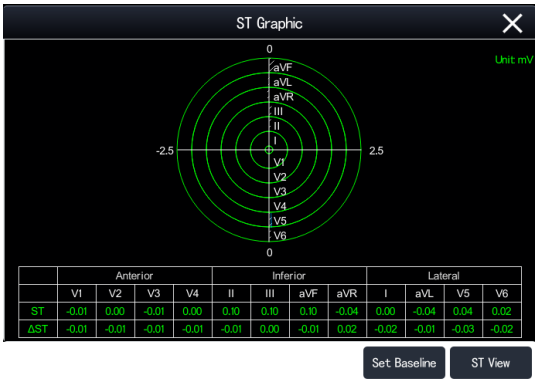
8.8.11 Enter ST Graphic Window

1) Select the ECG parameter, waveform, or ST parameter area to enter **[ECG]** menu.
2) Select **[ST]** tab.
3) Select **[ST Graphic]** at the bottom of the menu.

   The figure below shows the ST Graphic when **[ST Alarm Mode]** is set to **[Absolute]**. The upper semicircle indicates limb leads: I-II-III-AVF-AVR-AVL, and the lower semicircle indicates chest leads: V1-V2-V3-V4-V5-V6. The green diagonal line's drawing indicates the ST real-time value. The vertical center axis is 0mV. When the ST value is in the range of 0~2.5mV, it is drawed from the vertical center axis anticlockwise to the right. When the ST value is in the range of -2.5mV~0, it is drawn from the vertical axis clockwise to the left:



The figure below shows the ST Graphic when **[ST Alarm Mode]** is set to **[Relative]**. The grey diagonal line's drawing indicates the ST real-time value. The vertical center axis is 0mV. When the ST value is in the range of 0~2.5mV, it is drawn from the vertical center axis anticlockwise to the right. When the ST value is in the range of -2.5mV~0, it is drawn from the vertical axis clockwise to the left. The blue drawing parts indicates ΔST value, it starts from the ST baseline end position. When ΔST>0, it is drawn anticlockwise. When ΔST<0, it is drawn clockwise:



8.9 QT/QTc Monitoring

QT interval is the time from the start of QRS complex to the end of T wave, and it represents the total time taken for ventricular action potential depolarization (QRS interval) and repolarization (ST-T). QT monitoring is helpful to identify long QT syndrome (LQTS).

QT interval is negatively correlated with heart rate. The QT interval is shorter when the heart rate is faster, and vice versa. Therefore, several formulas are engaged in the algorithm to correct QT interval based on the heart rate. The QT interval corrected on the basis of heart rate is called QTc.

QT/QTc monitoring is intended for adult, pediatric and neonate patients.

Change QTc Formula as follows:

1) Select **[Main Menu]** quick key →**[System]** →**[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Module]** → **[ECG]**tab.
3) Select **[QTc Formula]**.

8.9.1 Restrictions on QT/QTc Measurement

The following situations may affect the accuracy of QT measurements:

- Low amplitude of R wave
- Ventricular tachycardia
- Unstable RR interval
- Occupation of the end of the previous T wave by P wave due to high heart rate
- Flat T wave or unclear boundary of T wave
- Difficulty in definition of the end of T wave due to the existence of U wave

8.9.2 Unstable QTc measurement

- Noise, asystole, ventricular fibrillation or ECG lead off

In the above cases, you need to choose a lead with good T wave amplitude, no visible wobble, and no dominant U wave or P wave.

In some cases, such as left / right bundle branch block and cardiomegaly, the QRS complex may be broadened. If a long QTc is observed, check and make sure it is not caused by QRS broadening.

QT measurement cannot be performed when there is bigeminy, because normal heart beat accompanying with ventricular beat is excluded in the analysis.

QT measurement cannot be performed when the heart rate is extremely high (over 150bpm in adults, over 180bpm in neonate and pediatric patients). When the heart beat changes, the QT interval becomes stable after several minutes. Thus, in order to obtain reliable QTc calculation results, it is vital to avoid heart rate changes.

8.9.3 Enable QT/QTc Monitoring

QT/QTc monitoring is set to **[OFF]** by default, so you should first enable this function.

Enable QT/QTc monitoring in the following steps:

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[QT]** tab→**[Setup]** tab.
3) Enable **[QT Analysis]**.

8.9.4 Display QT/QTc Parameters and Waves

Steps to display QT/QTc parameters and waves are as below:

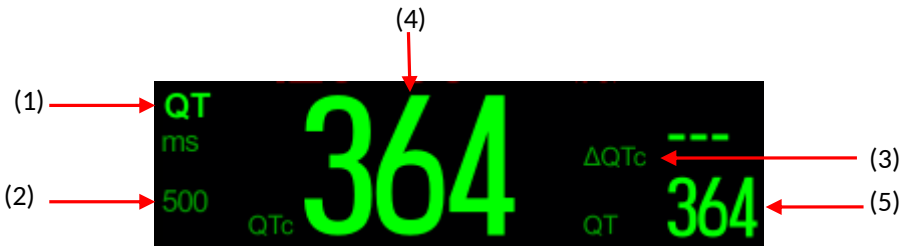
1) Enter **[Tile Layout]** page by any of the following ways:
   - Select **[Screen Setup]** quick key → **[Tile Layout]** tab.
   - Select **[Main Menu]** quick key →**[Display]** → **[Tile Layout]**.

2) Click on the parameter tile to display QT parameters and select [ECG]→[QT/QTc].

NOTE

- **QTc value is calculated based on QT-HR, not the ECG calculation lead. You can enter QT View to view QT-HR. Please refer to "*Section8.9.5 Enter QT View*" for more information.**

QT parameter tile is shown as below, and your monitor may have a different display due to its settings.



(1) Parameter name

(2) QTc alarm limit (if QTc alarm is OFF, then here the alarm-off icon is displayed instead).

(3) ΔQTc value (the difference between QTc value and baseline. If ΔQTc alarm is OFF, then here the alarm off icon is displayed to the left of the value).

(4) QTc value

(5) QT value

8.9.5 Enter QT View

QT View window shows the current measured QT values, waveform and base line. As the steps below:

1) Select QT parameter area into **[QT]** menu.

2) Select the **[QT View]** button.

QT View example:

◆ The current waveform is displayed at the top of the QT View screen in the same color (usually green) as the ECG waveform.

- The baseline segment is displayed below and in white color.
- The location of QRS complex and T wave end point is marked with vertical lines.
- In some cases, the QT measurements results cannot be displayed because of poor signal quality. In this case, the reasons of analysis failure are displayed below the QT parameter area, and the message "Cannot Analyze QT" is appear in alarm message area of the main screen display.
- Select the left and right arrows below to switch leads and highlight the waveform of the corresponding lead.

8.9.6 QT Setup

8.9.6.1 QT Alarm

1) Select QT parameter tile, ECG parameter tile or ECG waveform tile to enter **[ECG]** menu.
2) Select **[QT]** tab.
3) Set the properties of QTc and ΔQTc alarms in **[Alarm]** page.

8.9.6.2 QT Leads

You can select one or all of the available leads as QT leads. Steps to select QT leads are as follows:

1) Select QT parameter tile, ECG parameter tile or ECG waveform tile to enter **[ECG]** menu.
2) Select **[QT]** tab.
3) Select **[Setup]** tab.
4) Set **[QT Leads]**. The default is **[All]**, that is, all leads are selected as QT leads.

8.10 ECG Relearn

Changes in the ECG templates may lead to false arrhythmia alarm and/or inaccurate heart rate.
This Monitor provides the function of ECG Relearn, which enables the Monitor to learn new ECG templates, thus to correct arrhythmia alarms and heart rate values. After the completion of ECG relearning, the Monitor saves learned QRS waveforms as templates for the patient's normal ECG waveform. During ECG monitoring, you may need to start an ECG Relearn process if you suspect that there is an abnormal arrhythmia alarm.

8.10.1 Start ECG Relearn Automatically

ECG Relearn starts automatically in the following situations:

- Upon startup of the device.
- Change of lead type or name.

- Reconnection of lead after falling off for over 60s.
- Change of the patient's pacer setup.

8.10.2 Start ECG Relearn Manually

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Relearn]** button under the **[ECG]** menu to start ECG Relearn.

⚠ CAUTION

- **Please start ECG Relearn during normal rhythm and when ECG signal is relatively noiseless. ECG Relearn during the arrhythmia period may result in relearning the wrong QRS complex as the ECG template, and thus missing the arrhythmia.**

8.11 Defibrillation Synchronization

The Defibrillation Synchronization function is to output +5V defibrillation synchronization signal during 100ms via the multi-function port every time the onitor detects R wave; such signal is for use by the defibrillator.

⚠ WARNING

- **Improper use of the defibrillation function may cause injury to the patient; the user should judge whether defibrillation is needed or not according to the patient's actual condition.**
- **Prior to defibrillation, the user should set the filter mode to [Diag.]. At the end of defibrillation, the user can select the filter mode as required.**
- **Prior to defibrillation the operator should ensure that the defibrillator and the monitor are compatible.**
- **Prior to synchronous defibrillation with a defibrillator it is necessary to ensure that the Monitor is used together with the defibrillator to send a synchronous electric shock within 60ms after detection of the next R wave, and that the ECG output signal is delayed for no more than 30 ms.**

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Chapter 9 12-Lead Resting ECG Analysis

9.1 About 12-Lead Resting ECG Analysis

This Monitor can be configured with Glasgow 12-lead ECG Analysis Algorithm. The module configured with Glasgow 12-lead ECG Analysis Algorithm is marked with the Glasgow logo.

Glasgow 12-lead ECG Analysis is intended for adult, pediatric and neonate patients.

9.2 Enter 12-Lead

You can enter 12-lead screen via **[ECG]** menu. Steps are as follows:

1) Select ECG parameter tile or waveform tile to enter **[ECG]** menu.
2) Select **[Setup]** tab.
3) Set **[Lead Set]** to **[12-Lead]**.
4) Select **[12-Lead]** button on the bottom of the menu.

You can also enter the 12-Lead by any of the following ways:

- Select **[Screen Setup]** quick key → **[Choose Screen]** → **[ECG 12-Lead]**.
- Select **[Main Menu]** quick key → **[Display]** → **[Choose Screen]** → **[ECG 12-Lead]**.

9.3 Start 12-Lead Resting ECG Analysis

Prior to 12-lead resting ECG analysis, please make sure that all electrodes and cables are properly connected, that the patient's information is set correctly, and that the patient keeps quiet all times.

Press **[Analyze]** button in the lower left corner of 12-Lead to start resting ECG analysis.

9.4 12-Lead Analysis Setup

Set as follows:

- Input patient information
- Set thresholds of tachycardia and bradycardia
- Set 12-lead report

9.4.1 Input Patient Information (For Glasgow Algorithm Only)

Some of the patient information directly affects the result of 12-lead analysis, so it is essential to complete the right patient information diagnostic and medical treatment. Please input patient information before performing 12-lead analysis.

Steps to input patient information are as follows:

1) In the 12-Lead Full-Screen, select **[Setup]** to enter **[12-Lead Setup]** menu.
2) Input or edit patient information on the **[Patient Management]** page.

NOTE

- **Prior to 12-lead resting ECG analysis please remember to check the patient information is complete and correct.**
- **For pediatric patients below 16 years old it is recommended to place chest leads at V4R, V1, V2, V4-V6. This is a routine procedure for pediatric patients.**

9.4.2 Set the filter

1） On the ECG 12-Lead screen, select **[Setup]** into **[12-Lead]** menu.
2） Select **[Setup]** tab
3） Set **[Filter]** as: **[Diagnostic]** or **[ST]**.
After enteringthe 12-Lead screen, the filter mode is automatically set to **[Diagnostic]**. When exiting 12-Lead screen **[Filter]** reverts to the previous settings before entering 12-Lead screen.

9.4.3 Set the Tachy and Brady

Set Tachy and Brady Thresholds (Available for Glasgow Algorithm Only).

1) In the 12-Lead Full-Screen, select **[Setup]** to enter **[12-Lead Setup]** menu.
2) Select **[Setup]** tab.
3) Set **[Tachy]** and **[Brady]**.

9.4.4 Set 12-Lead Report

1) In the 12-Lead Full-Screen, select **[Setup]** to enter **[12-Lead Setup]** menu.
2) Select **[Report]** tab.
3) Set the format and contents of the 12-Lead Report.

9.5 Save 12-Lead Report

After 12-lead resting ECG analysis has been completed select **[Save]** on the 12-Lead Report page to save the report. You can review the saved 12-Lead Report. Please refer to "***Section17.8 12-Lead Report Review***" for more information.

9.6 Print 12-Lead Report

After completion of the 12-lead resting ECG analysis, select **[Record]** or **[Print]** on the 12-Lead Report page to output the report by recorder or printer.

9.7 Exit 12-Lead Analysis window

Press **[Exit]** key below the 12-Lead screen to exit.

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Chapter 10 Resp Monitoring

10.1 Resp (Respiration) Measurement

The monitor measures the respiration based on the thoracic impedance between the two electrodes. The changes of such impedance caused by thoracic movements generate a respiratory waveform on the screen. The RR is calculated from such a waveform.

Respiration measurement is intended for adult, pediatric and neonate patients.

10.2 Safety Information

⚠ WARNING

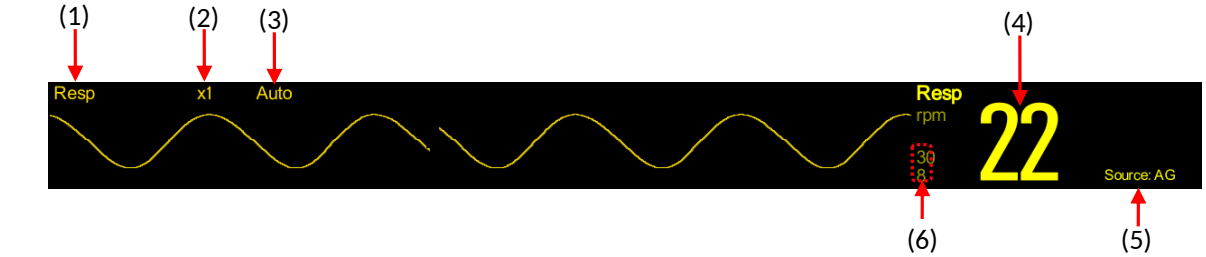
- **Do not use anti-ESU ECG cable during Resp monitoring.**
- **If the Resp detection level is not set correctly in manual calculation mode, the monitor may fail to detect apnea. If the detection level is set to low, the monitor may misinterpret a heartbeat as a breath during apnea since it is easier to detect a heartbeat.**
- **Apnea alarm cannot identify the cause of apnea and thus cannot be used for diagnosis.**
- **When the monitor works under conditions in compliance with IEC60601-1-2 (anti-radiation ability: 3V/m), the field with intensity over 3V/m may result in wrong measurements in all frequency ranges. Therefore, it is advised not to use equipment of high EMC radiation near Respiration detection equipment.**
- **Impedance Resp measurement may cause a change in the pacing frequency of minute ventilation adaptive pacemaker, in which case minute ventilation Response mode of the pacemaker or impedance Resp measurement should be turned off.**
- **When using high-frequency Electrosurgical Unit (ESU), place the negative plate of ESU close to the surgical area, and do not put electrode between the surgical site and ESU's negative plate for fear of burn.**

⚠ CAUTION

- **Please check whether the packing of electrode is intact and within its validity before use. Please use the electrode immediately after unpacking. Do not use a dry electrode.**

- **Resp measurement is not intended for patients with a large range of activities, otherwise it may lead to a false alarm.**

10.3 Resp Display



(1) Parameter (2) Waveform gain (3) Resp Lead

(4) Respiration Rate(RR) (5) RR source (6) RR alarm limit

10.4 Placement of Electrodes

In Resp measurement, it is important to prepare the skin properly for electrode placement. Refer to the ECG measurement for relevant information.

The Resp signals are measured through the two ECG electrodes. When the ECG electrodes are placed in standard position, the Resp can be measured through the electrode RA and electrode LL.

10.4.1 Optimization of Lead Position

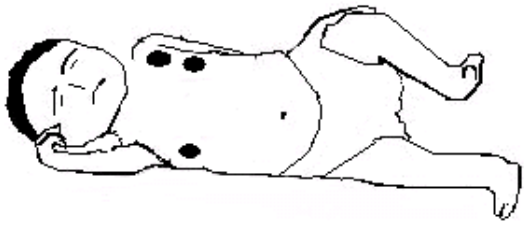
To measure the ECG and Resp simultaneously it may be necessary to adjust the positions of the two electrodes for some patients. Non-standard placement of ECG electrodes may cause changes to the ECG waveform and affect the ST segment analysis and ARR analysis.

1) Cardiovascular Artifact

The cardiac activities affecting the Resp waveform are defined as cardiovascular artifact, which accurs when the electrodes collect the impedance changes caused by rhythmatic blood flow. Proper placement of electrodes can reduce cardiovascular artifact. Avoid the liver area and ventricles to be in the line between the electrodes, which is especially important to neonates.

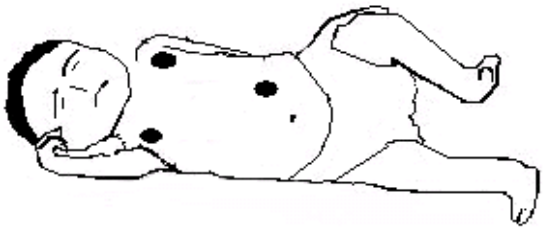
2) Lateral Thoracic Expansion

The thoracic cage of some patients, especially neonates, may expand to both sides. To obtain the best Resp waveform place the two electrodes respectively at the right mid-axillary line and left outer chest with strongest Resp movements, as shown below:



3) Abdominal Respiration

Some patients may have restricted thoracic movements and rely mainly on abdominal respiration. To obtain the best Resp waveform, place the electrode LL on the left abdomen with strongest expansion, as shown below:



10.5 Resp Setup

10.5.1 Set Resp Alarm

1) Select Resp parameter tile or waveform tile to enter **[Resp]** menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

10.5.2 Set Apnea Time

No-breath detection is to detect the longest interval between two adjacent Resps. When the actual no-breath time of the patient exceeds the set no-breath time, the Monitor will respond to no-breath alarms according to the value of **[Apnea Time]**.

To set **[Apnea Time]**:

1) Select the Resp parameter area or waveform area to enter **[Resp]** menu.
2) Select **[Alarm]** tab.
3) Set **[Apnea Time]**.

10.5.3 Set RR Source

1) Select Resp parameter tile or waveform tile to enter **[Resp]** menu.

2) Select **[Setup]** tab.
3) Set **[RR Source]**:
   - If you select **[Auto]**, the system will automatically select RR source based on the priority, which is CO_2, RM and ECG.
   - If there is no valid measurement for the currently set RR source, the system will automatically switch **[RR Source]** to **[Auto]**.

10.5.4 Set Resp Lead

Resp lead indicates the source of the current Resp waveform. If you select **[Auto]**, the monitor will automatically select an appropriate Resp lead.

1) Select Resp parameter tile or waveform tile to enter **[Resp]** menu.
2) Select **[Setup]** tab.
3) Set **[Resp Lead]**

If the Resp waveform is still poor or you suspect that the RR measurement is inaccurate after Resp lead adjustment, you can adjust the position of electrodes.

10.5.5 Set Gain

Gain is used to adjust the amplitude of the Resp wave. Steps to set gain are as follows:

1) Select Resp parameter tile or waveform tile to enter **[Resp]** menu.
2) Select **[Setup]** tab.
3) Set **[Gain]**.

10.5.6 Set Waveform Speed

1) Select Resp parameter tile or waveform tile to enter **[Resp]** menu.
2) Select **[Setup]** tab.
3) Set **[Waveform Speed]**.

10.5.7 Set Filter

Filter is designed to filter out the Resp interference. Steps to set filter are as follows:

1) Select Resp parameter tile or waveform tile to enter **[Resp]** menu.
2) Select **[Setup]** tab.
3) Set **[Filter]** to **[On]** or **[Off]**.

10.5.8 Set Auto Threshold Detection

1) Select Resp parameter tile or waveform tile to enter **[Resp]** menu.
2) Select **[Setup]** tab.
3) Turn on or off **[Auto Threshold Detection]**.
   - On: the monitor automatically adjusts the detection level of Resp wave, i.e. detection threshold.
   - Off: you need to manually adjust the detection threshold of Resp wave; please refer to "***Section10.5.9 Manually Adjust Detection Threshold***" for more information.

When **[Auto Threshold Detection]** is **[On]** during Resp Monitoring and ECG Monitoring is **[Off]**, the monitor cannot detect the overlay of heart heat by comparing ECG and RR. In this case, Resp detection level is automatically set to high so as to avoid the possibility of detecting the overlay of heart beat as breath wrongly. When **[Auto Threshold Detection]** is **[Off]**, the overlay of some heart beats may be counted as respiratory rate, resulting in wrong indication of high respiratory rate or apnea detection failure. If you suspect that the overlay of heart beats is regarded as respiratory rate, please adjust the upper and lower dotted lines properly to increase Resp detection level so that it is higher than the overlay of heart beats. If the detection level cannot be raised due to small Resp wave, you may need to optimize the electrode position.

10.5.9 Manually Adjust Resp Wave Detection Threshold

You may need to manually adjust Resp wave detection threshold in the following situations:

- RR is close to HR.
- The patient is under intermittent mandatory ventilation (IMV).
- Weak breath. Try to relocate the electrode to improve signal quality.

Steps to adjust Resp wave detection threshold are as follows:

1) Select Resp parameter tile or waveform tile to enter **[Resp]** menu.
2) Select **[Threshold]** tab.
3) Set **[Upper Scale]** and **[Lower Scale]**.

Once set, the detection level will not automatically adapt to different respiratory depths. Thus, if respiratory depth changes, you may need to adjust detection level.

10.6 Enter Intubation Mode

If the currently monitored patient is under the intubation process of a general anesthesia surgery, the monitor can be set to Intubation Mode to shield unnecessary alarms. Steps for setup are as follows.

1) Select Resp parameter tile or waveform tile to enter **[Resp]** menu.
2) Select **[Intubation Mode]**.

Please refer to "***Section7.19 Intubation Mode***" for more information.

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Chapter 11 SpO_2 Monitoring

11.1 Overview

The SpO_2 plethysmography measures the arterial SpO_2, namely, the percentage of the oxyhemoglobin count. The SpO_2 is measured with the pulse oximetry; a continuous noninvasive method measuring how many of the lights emitted from the sensor (light source) can penetrate the patient's tissues (fingers or ears) and reach the receiver.

The monitor measures the following parameters (for Comen SpO_2, Masimo SpO_2 and Nellcor SpO_2):

- Arterial SpO_2: the ratio of the oxyhemoglobin to the sum of oxyhemoglobin and deoxyhemoglobin (functional arterial SpO_2).
- Pleth waveform: a visible indication of the patient's pulse.
- PR (calculated from pleth waveform): the patient's pulse count per minute.
- PI (perfusion index): the pulsatile blood flow value (PI measurement is unavailable for Nellcor SpO_2).

WARNING

- **If there is any carboxyhemoglobin (COHb), methemoglobin (MetHb) or dye dilution chemical, the SpO_2 value will have a deviation.**

11.1.1 Identification of SpO_2 Type

The type of SpO_2 module is displayed in SpO_2 menu. Appearance and logo of SpO_2 modules are as below:

- Comen SpO_2: round cable interface; no manufacturer's logo.
- Masimo SpO_2: round cable interface; logo: Masimo.
- Nellcor SpO_2: round cable interface; logo: Nellcor.

The information about wavelength range and maximum optical output power of the sensor is useful to the clinician for some therapy, for example, photodynamic therapy.

- The Comen SpO_2 sensor can measure a wavelength of 660nm (red LED) or 905nm (IR LED).
- The Masimo SpO_2 sensor can measure a wavelength of 660nm (red LED) or 905nm (IR LED).
- The Nellcor SpO_2 sensor can measure a wavelength of 660nm (red LED) or 900nm (IR LED).
- The maximum optical output power of the sensor is lower than 15mW.

NOTE

- Functional test equipment or SpO_2 simulator cannot be used to verify the accuracy of SpO_2 monitor and pulse oximeter sensor. The accuracy of SpO_2 monitor and pulse oximeter sensor needs to be verified by clinical data.
- Functional test equipment or SpO_2 simulator can be used to evaluate the accuracy of PR.
- This monitor and its supporting SpO_2 sensor and sensor extension cord have been tested for compliance with ISO 80601-2-61.

11.2 Safety Information

WARNING

- The Monitor is compatible with the SpO_2 sensor specified by Comen only.
- Before monitoring the patient, please check if the sensor and extension cord are compatible with the Monitor. Incompatible accessories may reduce the performance of the Monitor.
- Before monitoring the patient, please check if the sensor cable works properly. Remove the SpO_2 sensor cable from the sensor interface, and the Monitor will display the prompt message "SpO_2 sensor off" and trigger the alarm sound.
- If the SpO_2 sensor or its package seems damaged, do not use it but return it to the manufacturer.
- Long-time continuous monitoring may increase the risk of undesired skin characteristic changes (extremely sensitive, turning red, blistered or pressure necrosis), especially for neonates or the patients with perfusion disorder or variable or immature skin morphology diagram. Align the sensor with the light path, fix it properly and check its position regularly based on skin quality changes (change the sensor position in case of reduced skin quality). Perform such check more frequently if necessary (subject to the condition of the patient).
- Make sure the sensor cable and electrosurgical equipment cable are not intertwined.
- Do not place the sensor on a limb with ductus arteriosus or intravenous tube.
- Setting the upper SpO_2 alarm limit to 100% will disable the upper-limit alarm. Premature infants may get infected with crystalline posterior fibrous tissue diseases in case of high SpO_2. Please set the upper SpO_2 alarm limit cautiously based on recognized clinical practices.
- The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient.

- Do not start or operate the pulse oximeter unless the setup was verified to be correct.
- Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not use the pulse oximeter if it appears or is suspected to be damaged.
- Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- To protect against injury, follow the directions below:
  - Avoid placing the device on surfaces with visible liquid spills.
  - Do not soak or immerse the device in liquids.
  - Do not attempt to sterilize the device.
  - Use cleaning solutions only as instructed in this operator's manual.
  - Do not attempt to clean the device while monitoring a patient.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning.
- Inaccurate SpO_2 readings may be caused by:
- Improper sensor application and placement
- Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Elevated levels of bilirubin
- Elevated levels of dyshemoglobin
- Vasospastic disease, such as Raynaud's, and peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Severe anemia
- Very low arterial perfusion
- Extreme motion artifact
- Abnormal venous pulsation or venous constriction
- Severe vasoconstriction or hypothermia
- Arterial catheters and intra-aortic balloon
- Intravascular dyes, such as indocyanine green or methylene blue
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
- Skin color disorders

- Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
- The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- The pulse oximeter is not an apnea monitor.
- The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse oximeter should not be used for arrhythmia analysis.
- SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary.
- Check the patient's skin every two hours to ensure good skin quality and lighting. In case of any skin change, move the sensor to another part. Change the wearing part at least every four hours.
- During a technical alarm condition, the SpO_2 monitoring, both displayed values and waveform might not accurate, and the operator should additionally validate the values and the patient's status.

⚠ CAUTION

- Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
- When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Do not place the pulse oximeter on electrical equipment that may affect the device, preventing it from working properly.
- If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of· the irradiation period.
- Ensure that alarm limits of SpO_2 and PR are appropriate for the patient being monitored.
- Variation in measurements may be significant and may be affected by sampling techniques as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed

by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

- Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.
- Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

  Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.

⚠ NOTE

- A functional tester cannot be used to assess the accuracy of the pulse oximeter.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse oximeter to obtain vital sign readings.
- Make sure your fingernails block the light inside the probe. The probe cable should be placed on the back of the hand.
- Do not place the SpO_2 sensor and NIBP cuff on the same limb, because blood flow occlusion during NIBP measurement will affect the functional oxygen saturation reading.
- The displayed SpO_2 waveform is normalized.
- The pulse oximeter device is calibrated to display functional blood oxygen saturation.
- Validation of the accuracy of SpO_2 measurement: The accuracy of Masimo SpO_2 has been validated in comparison with the reference value of arterial blood samples measured by CO-oxygen manometers in clinical investigation. The pulsation oximeter measurement results conform to the statistical distribution. Compared with the CO-oximeter measurement results, it is expected that about two-thirds of the measurement results will fall within the specified accuracy range.
- Masimo SpO_2 has induced a hypoxic state in human blood with a SpO_2 of 70% to 100% in healthy adult volunteers. By comparing with the laboratory combined photoelectric oximeter and high flow respiratory humidification therapy device, validated the accuracy under no motion. This variation equals plus or minus one standard deviation. Plus, or minus one standard deviation encompasses 68%of the population weight.
- Masimo SpO_2 has been validated for motion accuracy in human blood studies on healthy adult male and

female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

11.2.1 Masimo SpO_2 Specific Information

⚠ CAUTION

- If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
- Change the application site or replace the sensor and/or patient cable when a “Replace sensor” and/or “Replace patient cable”, or a persistent poor signal quality message (such as “Low SIQ”) is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
- Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

⚠ NOTE

- When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.
- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
- Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

11.3 Measurement Restrictions

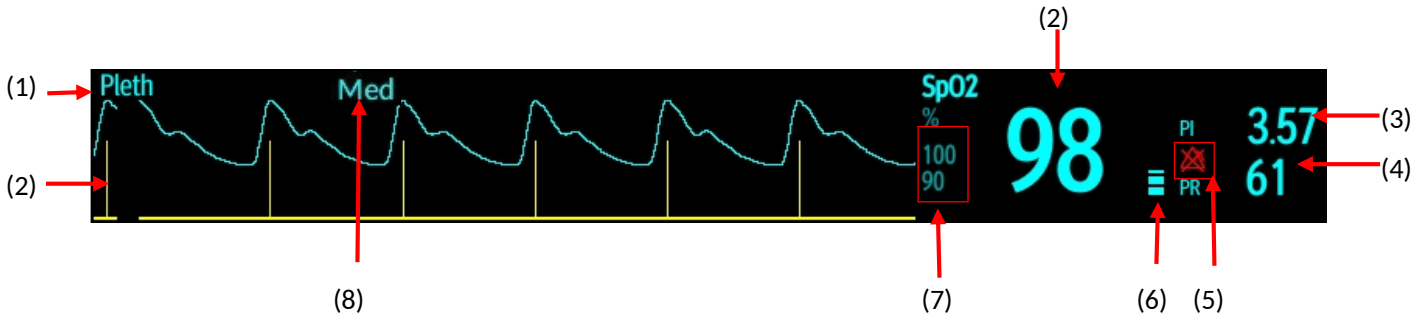
Inaccurate SpO_2 readings may be caused by the following factors:

1) High-frequency radio interference, whether from the host system or from the electrosurgical equipments

connected to the host system. To minimize radio interference, other electrical equipment that emits radiofrequency transmissions should not be in close proximity to the instrument.

2) Do not use the oximeter or SpO_2 sensor in the MRI process, or the induced current may cause burns.
3) Intravenous dyes.
4) The patient moves frequently.
5) Ambient optical radiation
6) The sensor is fixed improperly or to an improper position on the patient.
7) Improper sensor temperature (optimum temperature: 28℃~42℃).
8) The sensor is placed on a limb with blood pressure cuff, ductus arteriosus or intravenous tube.
9) Concentration of the non-functional hemoglobin, like COHb or MetHb.
10) Low SpO_2.
11) Poor circulation perfusion at the tested part.
12) The shock, anemia, hypothermia and application of vasoconstrictors may reduce the arterial blood flow to a non-measurable level.
13) The SpO_2 measurement accuracy depends also on the absorption of the lights with special wavelength by oxyhemoglobin and reduced hemoglobin. If any other substance also absorbs such lights, like COHb, MetHb, methylene blue or indigo carmine, you may obtain a false or low SpO_2 value.

11.4 SpO_2 Display



(1) Plethysmographic (Pleth) waveform: the amplitude of Pleth waveform can directly reflect the intensity of the patient's pulse signal.
(2) Saturation of pulse oxygen (SpO_2/SpO_2b) value (unit of %SpO_2). When the value is invalid, "----" will be displayed here.
(3) PI (Perfusion indicator): available for Masimo SpO_2 and Comen SpO_2.
(4) PR: pulse rate (unit of 1/min, bpm).
(5) Alarm Off
(6) Bar graph: proportional to the pulse intensity. Bar graph can reflect the filling state of blood.
(7) Value of SpO_2 difference (ΔSpO_2).
(8) SpO_2 sensitivity.

11.5 Monitoring Steps

11.5.1 Comen SpO_2 Measurement Steps

1) Choose a proper SpO_2 sensor according to the patient type.
2) Insert SpO_2 cable connector into the SpO_2 interface of the monitor.
3) Fix the sensor to an appropriate position on the patient. Please refer to "***Section11.6 Placement of SpO_2 Sensor***" for more information.

11.5.2 Masimo SpO_2 &Nellcor SpO_2 Measurement Steps

1) Choose a proper SpO_2 sensor according to the module type and patient type.
2) Connect SpO_2 patch cord to SpO_2 sensor.
3) Insert the other end of SpO_2 patch cord into the SpO_2 interface of the monitor.
4) Fix the sensor to an appropriate position on the patient. Please refer to "***Section 11.6 Placement of SpO_2 Sensor***" for more information.

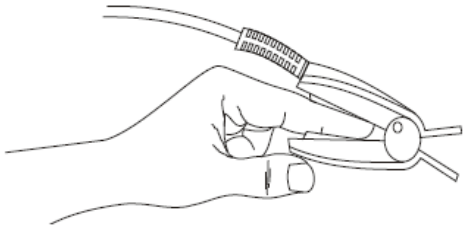
11.6 Placement of the SpO_2 Sensor

WARNING

- **Check the patient's skin every two hours to ensure good skin quality and lighting. In case of any skin change, move the sensor to another part. Change the wearing part at least every four hours.**
- **Place the SpO_2 sensor properly based on the SpO_2 sensor type compatible with the Monitor. This is especially important for neonates.**

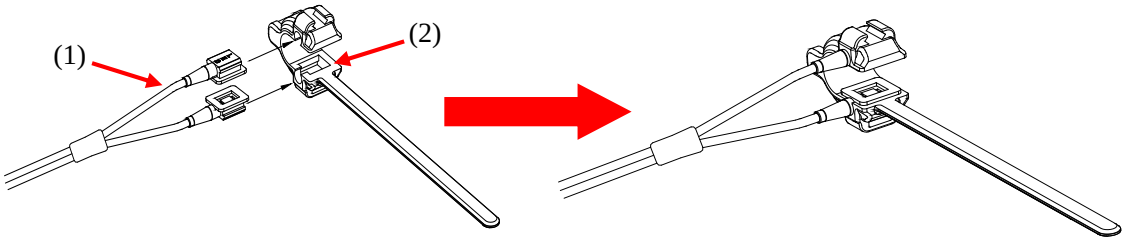
11.6.1 Placement of Adult SpO_2 Sensor

The location of the Adult SpO_2 sensor is shown in the figure below:



11.6.2 Placement of Neonatal/Pediatric SpO_2 Sensor

1) Assembly of Neonate SpO_2 sensor: Embed the LED end and PD end of the Y-shaped SpO_2 sensor respectively in the upper and lower groove of the Neonate SpO_2 sensor sheath, as shown in the figure below:



(1) Y-shaped SpO_2 Sensor (2) Neo SpO_2 Sensor Sheath

2) Placement of SpO_2 sensor: fix it on the foot of neonate, or the finger of pediatric patient.

11.7 SpO_2 Setup

11.7.1 Set SpO_2 Alarm

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

If you use two SpO_2 modules at the same time, you can set the alarm forΔSpO_2.

NOTE

- **Only when the [SpO_2Desat Alarm Off] is set to [Enable], can you turn off SpO_2Desat Alarm. Please refer to "*Section7.10 Set SpO_2 Desat Alarm*" for more information.**

11.7.2 Set Off Priority

You can set SpO_2 sensor off Alarm Level by the following steps:

1) Select **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Alarm]** tab→**[Other]** tab.
3) Set **[SpO_2 Finger Sensor Off]**.

11.7.3 Set Waveform Speed

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Speed]** to the appropriate value.

11.7.4 Set NIBP Simul

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[NIBP Simul]** to **[On]** or **[Off]**.
   - ◆ On: to prevent weak perfusion caused by NIBP measurement when NIBP and SpO_2 measurements are performed on the same limb of a patient, which will lead to inaccurate SpO_2 measurements and even trigger SpO_2 physiological alarms.

11.7.5 Set Sat-Seconds (Available for Nellcor SpO_2 Only)

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Sat-Seconds]** to the appropriate time.

The smart alarm is designed to reduce false alarms and keep the clinician informed of the SpO_2 changes more accurately and timely. For example, if you set **[Sat-Seconds]** to **[50]** and the upper and lower alarm limit of Nellcor SpO_2 Respectively to 97% and 90%, maintain the measured SpO_2 value at 80% for 3s and then reduce it to 78% for 2s, the Monitor will trigger the alarm sound and indicator 5s after the SpO_2 value goes beyond the alarm limit and the circle beside the SpO_2 value will return to the origin.

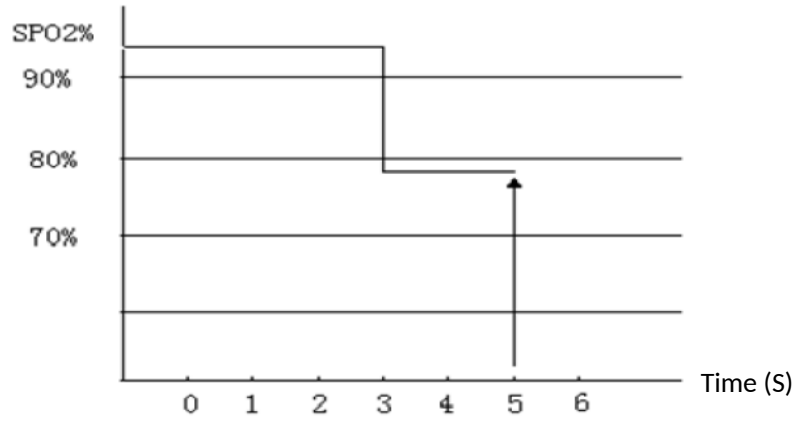
Calculation method:

Percentage points × seconds = Sat-Seconds (integer)

The calculated Sat-Seconds is displayed as follows:

%SpO_2	Seconds	Sat-Seconds
（90%-80%）	× 3 =	30
（90%-78%）	× 2 =	24

Total Sat-Seconds = 54



In the above Sat-Seconds example:

About 4.9s later, the Monitor will report a Sat-Seconds alarm because you've set **[Sat-Seconds]** to **[50]**, smaller than 54.

The SpO_2 value may fluctuate in seconds rather than remain unchanged. The patient's SpO_2 value usually fluctuates within the alarm limit and sometimes goes beyond the alarm limit discontinuously. The Monitor will accumulate the positive and negative percentage points until the set value of **[Sat-Seconds]** is reached or the patient's SpO_2 value remains beyond the alarm limit.

11.7.6 Set Sensitivity (Available for Masimo SpO_2 Only)

[Sensitivity] can be set to **[Normal]**, **[High]** or **[APOD]**. **[High]** represents the highest sensitivity. In typical monitoring conditions, please select **[Normal]**. If the sensor is likely to come off the patient due to wet skin, violent movements or other causes, please select **[APOD]**. If the patient's perfusion level is extremely low, please select **[High]** to increase the sensitivity.

Steps to set **[Sensitivity]**:

1) Select the SpO_2 parameter tile to enter **[SpO_2 Setup]** → **[Sensitivity]**.
2) Select an appropriate **[Sensitivity]** for Masimo & Rainbow SpO_2: **[Normal]**, **[High]** or **[APOD]**.

11.7.7 Set Average Time (Unavailable for Nellcor SpO_2)

The SpO_2 value displayed on the monitor screen is the average of data collected within a specific time. The shorter the averaging time is, the quicker the monitor responds to changes in the patient's oxygen saturation level. Similarly, the longer the averaging time is, the slower the monitor responds to changes in the patient's oxygen saturation level, but the SpO_2 measurement is more stable. For critically ill patients, selecting a shorter averaging time will help with understanding the patient's state.

11.7.7.1 Average Time for Masimo SpO_2

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[SpO_2 Setup]** tab.
3) Set **[Average Time]** to **[2s-4s]**, **[4s-6s]**, **[8s]**, **[10s]**, **[12s]**, **[14s]** or **[16s]**.

11.7.7.2 Average Time for Comen SpO_2

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[SpO_2 Setup]** tab.
3) Set **[Sensitivity]** to **[High]**, **[Med]** or **[Low]**, and the corresponding average time will increase in turn.

11.7.8 Set Smart Tone (Available for Masimo SpO_2 Only)

When smart tone is set to on the QRS volume would still be heard in case of an unstable signal or ambient noise.

To set **[Smart Tone]**:

1) Select the SpO_2 parameter area to enter **[SpO_2]** menu.
2) Turn on or off **[Smart Tone]**.

11.7.9 Set Signal IQ (Unavailable for Nellcor SpO_2 Only)

The magnitude of the SpO_2 SIQ waveform provides an assessment of the confidence in the measurement displayed. A higher value indicates higher confidence in the measurement whereas a smaller value indicates lower confidence in the displayed measurement.

Movements usually affect the signal quality. When the arterial pulse reaches the peak, the monitor marks its location on the vertical line (signal indicator). The smart tone volume (if enabled) remains consistent with the indication in the vertical line (the volume of the smart tone will increase or decrease accordingly when the SpO_2 value increases or decreases).

The height of the vertical line represents the quality of the measured signal (the higher line, the higher quality).

Set **[Signal IQ]**:

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Turn on or off **[Signal IQ]**.

11.7.10 Display PI (Unavailable for Nellcor SpO_2 Only)

[Display PI] defaults to **[On]**. Steps to set it to Off:

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Display PI]** to **[Off]**.

11.8 PR Setup

11.8.1 Set PR Alarm

You can set the PR alarm by the following steps:

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu.
2) Select **[PR]** tab →**[Alarm]** tab.
3) Set the alarm as needed.

11.8.2 Set PR Source

The color of the PR parameter area is the same as the display color of PR source parameters.

You can set the PR source in the following way:

1) Select the SpO_2 parameter area or waveform area to enter **[SpO_2]** menu.
2) Select **[PR]** tab → **[Setup]** tab.
3) Select **[PR Source]**, and select an appropriate PR source in the drop-down list.

The drop-down list of **[PR Source]** shows the currently valid PR sources by their priority. If you select **[Auto]** the system will automatically use the first option in the list as the PR source. If the PR source you set doesn't exist, the system will automatically switch **[PR Source]** to **[Auto]**. If you select **[IBP]** the system will automatically use the first pressure marker as the PR source.

11.8.3 Set Pulse Volume

1) Select SpO_2 parameter tile or waveform tile to enter **[SpO_2]** menu →**[PR]** tab.
2) Select **[Setup]** tab.
3) Set **[Pulse Volume]** to a proper value.

When there is a valid SpO_2 measurement value, the system will also adjust the pulse tone (Pitch Tone) according to the value of SpO_2.

11.9 Masimo Information

1) Masimo Patent Information

Masimo Patents: www.masimo.com/patents.htm

2) No Implied License Statement

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

3) Other Information

Chapter 12 NIBP Monitoring

12.1 Overview

The monitor uses the oscillometric method (measure the cuff pressure vibration amplitude) to measure the noninvasive blood pressure (NIBP). Blood pressure changes will cause cuff vibrations. The cuff pressure at the highest vibration amplitude is the mean pressure. The systolic pressure and diastolic pressure are calculated from the mean pressure.

The blood pressure measured by the equipment is equivalent to that measured by invasive method, and its error meets the requirements of IEC80601-2-30. Brachial artery was selected for verification in invasive clinical trials.

NIBP measurement is applicable in electrosurgical operations and defibrillator discharges according to IEC80601-2-30.

NIBP monitoring is applicable to adult, pediatric and neonate patients.

12.2 Safety Information

⚠ WARNING

- **Before the NIBP measurement, make sure the selected monitoring mode is appropriate for the patient (adult, pediatric or neonate). It is dangerous to select a non-neonatal mode for neonatal patients.**
- **Do not place the cuff on a limb with intravenous tube or cannula, or the tissues around the cannula may be damaged when the infusion is slowed or blocked in the cuff inflation process.**
- **Make sure the inflation tube connecting the blood pressure cuff to the Monitor is not obstructed or tangled.**
- **Do not perform the NIBP measurement to a patient with sickle cell disease or existing or expected skin lesions.**
- **For a patient with severe disturbances of blood coagulation, please determine the applicability of automatic NIBP measurement based on clinical evaluation, or the limb contacting the cuff may suffer from hematoma due to friction.**
- **Frequent measurements may cause blood flow interference and injure the patient.**
- **To prevent further injury, do not place the cuff on any wound.**
- **Do not place the blood pressure cuff on a limb under intravenous infusion, intravenous therapy or arteriovenous shunt, or the transient blood flow interference will injure the patient.**
- **Do not place the cuff on the arm at the same side as mastectomy.**

- **The increasing cuff pressure may cause transient function failure to other monitoring equipment used on the same limb.**
- **If the measurement time is too long (such as repeated use interval and continuous measurement mode), friction between the cuff and the limb may cause purpura. Ischemia and nerve damage. When monitoring patients, always check the color, temperature, and sensitivity of the distal limbs. Once any abnormality is found, the cuff placement position should be changed or blood pressure measurement should be stopped.**

⚠ **NOTE**

- **If you have any doubt about the reading accuracy, check the patient's vital signs first before checking the Monitor's functions.**
- **When unexpected values are measured, check the potential causes, such as**
  - the incorrect cuff size was used or the cuff is not placed at heart level.
  - Excessive patient movement.
  - Measurement over-range.

12.3 Measurement Restrictions

The oscillometric method has some restrictions depending on the patient's condition. The oscillometric method detects the regular pulse wave generated by arterial pressure. If the patient's condition makes it difficult to detect such waves, the measured value is unreliable, and the cuff inflation time increases. In the following cases, the NIBP measurement is impossible:

1) Patient Movement

If the patient is moving, trembling or under cramps, which may affect the detection of arterial pressure pulse, the NIBP measurement is unreliable or impossible and the pressure measurement time will increase.

2) Arrhythmia

If the patient has irregular heartbeats due to arrhythmia, the NIBP measurement is unreliable or impossible and measurement time increases.

3) Heart-lung Machine

Do not perform the NIBP measurement if the patient is connected to a heart-lung machine.

4) Pressure Changes

If the patient's blood pressure changes rapidly within a certain time when the monitor analyzes the arterial pressure pulse for measurement purpose, the NIBP measurement is unreliable or impossible.

5) Severe Shock

If the patient is under severe shock or hypothermia, the NIBP measurement is unreliable as the reduced blood flow to the periphery will cause lower arterial pulse.

6) Extreme HR

Do not perform the NIBP measurement if the HR is lower than 40bpm (beats per minute) or higher than 240bpm.

7) Obese Patient

Due to the thick fat layer of the limb, the vibration from the artery fails to reach the cuff, which causes lower measurement accuracy than in normal weight cases.

8) Patient with Hypertension

To measure the NIBP of a patient with hypertension accurately, follow the steps below:

- Adjust his/her sitting posture until:
  - He/she sits comfortably;
  - His/her legs are not crossed;
  - His/her feet are laid flat on the ground;
  - He/she leans his/her back against the chair and puts his/her hands on the desk;
  - The middle part of the cuff is at the same level as his/her right atrium.
- Ask the patient to relax as much as possible and not talk during the measurement.
- 5 min elapses before the first reading taken.

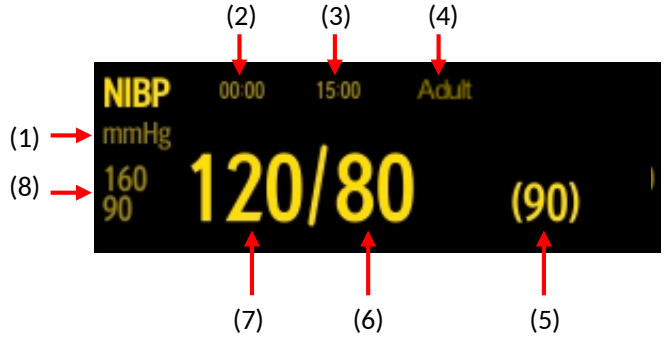
NOTE

- **The effectiveness of NIBP on pregnant women, including those with preeclampsia, has not been verified.**

12.4 NIBP Display

1) Enter **[Tile Layout]** in any of the following ways:
   - Select **[Screen Setup]** quick key → Select **[Tile Layout]** tab.
   - Select **[Main Menu]** quick key → **[Display]** → **[Tile Layout]**.
2) Click on the area where NIBP is to be displayed, and select **[NIBP]** from the drop-down list.

During measurement, the cuff pressure is indicated on the NIBP parameter area. After one NIBP determination the NIBP measurement results are displayed in the parameter area. The figure below is for reference only. The actual display interface of the monitor may be slightly different from this figure.



(1). NIBP unit

(2). Time of the previous measurement

(3). Measurement mode: display measurement interval in auto measurement or sequence measurement mode

(4). Patient type: Adu (Adult), Ped (Pediatric), or Neo (Neonate)

(5). Mean Arterial Pressure (MAP) (in the measurement process, display the cuff pressure)

(6). Diastolic Arterial Pressure(DIA)

(7). Systolic Arterial Pressure (SYS)

(8). Systolic Arterial Pressure (SYS) Alarm Limit

12.5 Display NIBP List

You can display multiple sets of NIBP results measured recently in parameter tile by the following steps:

1) Enter **[Tile Layout]** in any of the following ways:
   - Select **[Screen Setup]** quick key → **[Tile Layout]**
   - Select **[Main Menu]** quick key → **[Display]** → **[Tile Layout]**.
2) Click on the part where NIBP list is to be displayed, and select **[NIBP]** → **[NIBP List]** from the drop-down list.

12.6 NIBP Setup

12.6.1 Set Patient Type

Patient type includes Adu, Ped, and Neo. Please select an appropriate type for the monitored patient, and it should be consistent with the type set in **[Patient Type]** under **[Patient Management]**.

1) Select the NIBP parameter area to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Set **[Patient Category]**: **[Adult]**, **[Ped]** or **[Neo]**.

12.6.2 Set NIBP Alarm

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

12.6.3 Set Initial Pressure

1) Select NIBP parameter tile to enter **[NIBP]** menu.

2) Set **[Initial Pressure]**: select a proper initial pressure for cuff as needed.

12.6.4 NIBP End Tone

The monitor will give a single tone prompt when the NIBP measurement is completed. **[NIBP End Tone]** defaults to **[Off]**, but you can turn it on by the following steps:

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Turn on **[NIBP End Tone]**.

12.6.5 Set NIBP Measure Sequence

NIBP sequence measure includes up to five measurement cycles: A, B, C, D and E. You can separately set the times and interval for each measurement cycle by the following steps:

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Sequence]** tab.
3) Set **[Times]** and **[Interval]** for each sequence.

12.6.6 Set NIBP Timeout

NIBP measurements will be displayed as hollow numbers if they exceed the set time, lest the expired measurements are regarded as current NIBP values. You can set NIBP Timeout by the following steps:

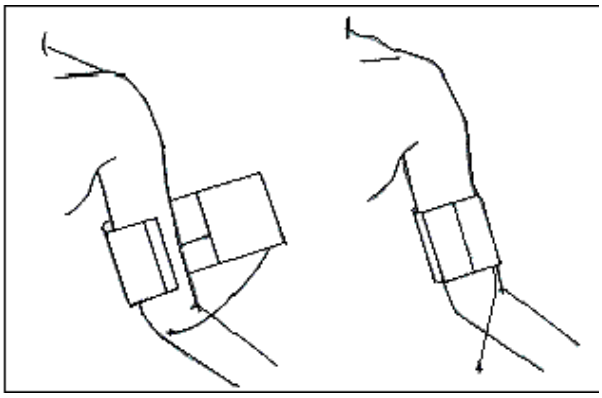
1) Select **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Module]** tab → **[Other]** tab.
3) Set **[NIBP Timeout]**.

12.7 NIBP Measurement

12.7.1 Preparations for Measurement

1) Connect the inflation tube to the blood pressure cuff.
2) Connect the inflation tube to the NIBP connector of the monitor without compressing or blocking the pressure tube.
3) Use the correct size cuff for the patient categaory and make sure the airbag is not folded or twisted.
   - ◆ An incorrect cuff size or a folded or twisted airbag causes inaccurate measurement. Make sure the cuff is deflated thoroughly. The cuff width should be 40% (50% for neonates) of the limb perimeter

or 2/3 of the upper arm length. The inflated part of the cuff should be long enough to circle 50~80% of the limb.



4) Wrap and secure the cuff around the limb and make sure the cuff is at the same level as the patient's heart. If you fail to do so, use the following methods to correct the measurement result:
   - ◆ Make sure the mark "φ" is located at an appropriate artery. Do not wrap or secure the cuff too tightly, or the distal extremity may suffer from discoloration or ischemia. Regularly check the skin condition of the contact part and the color, temperature and feeling of the limb which wears the cuff. If the skin condition changes or the blood circulation of the limb is affected, move the cuff to another body part for continued measurement or stop the NIBP measurement immediately. In auto measurement mode, observe the skin condition frequently.
   - ◆ If the cuff is not at the same level as the heart, use the following correction formulas:
     - ✧ If the cuff is at a higher level than the heart: displayed NIBP value + 0.75mmHg (0.10kPa) × level difference (cm).
     - ✧ If the cuff is at a lower level than the heart: displayed NIBP value - 0.75mmHg (0.10kPa) × level difference (cm).

12.7.2 Start NIBP Measurement

12.7.2.1 Start Manual Measure

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Set **[Interval]** to **[Manual]**.
4) Set **[Start Mode]** to **[Interval]**.
5) You can select **[NIBP Start/Stop]** quick key, select **[Start NIBP]** in **[NIBP]** menu or press the **[NIBP Start/Stop]** keyboard to start NIBP measurement.

12.7.2.2 Start Interval Measure

Select **[NIBP Measure]** quick key → select the interval to start interval measurement, or start interval measurement by the following steps:

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Select the drop-down list of on the right of **[Interval]** and set the specific measurement interval.
4) Set **[Start Mode]** to **[Interval]**.
5) Select **[NIBP Start/Stop]** quick key, select **[Start NIBP]** in **[NIBP]** menu or select **[NIBP Setup]** → **[Interval]** to start the first measurement.

After the first measurement is completed, the monitor will automatically repeat the measurement with the set interval.

12.7.2.3 Start Clock Measure

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Set **[Start Mode]** to **[Clock]**.
4) Select the drop-down list on the right of **[Interval]** and set the specific measurement interval.
5) Select **[NIBP Start/Stop]** quick key or select **[Start NIBP]** in **[NIBP]** menu to start the first measurement.

Or you can select **[Clock]**, and then **[NIBP Setup]** → **[Interval]** to start the first measurement.

After the first measurement is completed, the monitor will automatically repeat the measurement with the set interval. For example, if the first measurement begins at 08:23, and the interval is set to **[5 min]**, the monitor will automatically start the next measurement at 08:25. Subsequent NIBP measurements are made synchronously with the clock, then at 08:30, and so on.

NOTE

- **Only when the [Interval] is set to 5 min or more, the monitor performs the clock measurement.**

12.7.2.4 Start NIBP STAT

You can start NIBP STAT in any of the following ways:

- Select **[NIBP STAT]** quick key.
- Select **[NIBP Measure]** quick key → **[NIBP STAT]**.
- Enter **[NIBP]** measure → select **[NIBP STAT]**.

NIBP STAT process lasts for 5 mins.

12.7.2.5 Start Sequence Measure

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[Setup]** tab.
3) Set **[Interval]** to **[Sequence]**.
4) Set **[Start Mode]** to **[Interval]**.
5) Set parameters for the sequence; please refer to "*Section 12.6.5 Set NIBP Measure Sequence*" for more information.
6) Select **[NIBP Start/Stop]** quick key or enter **[NIBP]** menu→ select **[Start NIBP]** or **[NIBP Measure]** quick key →select **[Sequence]** to start the first measurement.

After the first measurement is completed, the monitor will start measurement automatically in the times and interval of the set sequence.

12.7.3 Stop NIBP

12.7.3.1 Stop Ongoing Measurement

You can stop the ongoing NIBP measurement in any of the following ways:

- Select **[NIBP Start/Stop]** quick key.
- Select NIBP parameter tile to enter **[NIBP]** menu → select **[Stop NIBP]**.
- Press the **[NIBP Start/Stop]** keyboard.

12.7.3.2 Stop NIBP STAT

You can stop NIBP STAT in any of the following ways:

- Select **[NIBP Start/Stop]** quick key.
- Select **[NIBP STAT]** quick key.
- Select NIBP parameter tile to enter **[NIBP]** menu → select **[Stop NIBP]**.
- Select NIBP parameter tile to enter **[NIBP]** menu → select **[Stop All]**.
- Press the **[NIBP Start/Stop]** keyboard.

12.7.3.3 Stop All NIBP Measurements

You can stop all measurements in any of the following ways:

- Select **[Stop All]** quick key.
- Select NIBP parameter tile to enter **[NIBP]** menu →select **[Stop All]**.

12.8 Venipuncture

Inflate the NIBP cuff to a pressure approximate to the diastolic pressure to block the vein vessel and assist in the completion of venipuncture. Steps are as follows:

1) Select NIBP parameter tile → Select **[Setup]** tab.
2) Set **[Venipuncture Pressure]**.
3) Select **[Venipuncture]** button on the lower right corner of the menu or press **[Venipuncture]** quick key at the bottom of the monitor.
4) Puncture the vein and take the blood sample.
5) Select **[NIBP Start/Stop]** quick key to deflate the cuff manually. If manual deflation is not performed, the venipuncture process lasts for 125s for adult and pediatric patients and 87s for neonate patients. The cuff deflates automatically after the said time period.

In the venipuncture process, the NIBP parameter tile will display the cuff pressure and remaining time of venipuncture.

12.9 NIBP Analysis

At the NIBP analysis interface, you can view the patient's normal values of systolic pressure and diastolic pressure, the percentage of higher/lower values and the average, maximum and minimum systolic pressure and diastolic pressure within the measurement time.

1) Select NIBP parameter tile to enter **[NIBP]** menu.
2) Select **[NIBP Dynamic Analysis]** button → **[NIBP Dynamic Analysis]** page.

You can also set the following parameters in NIBP Analysis:

[Daily Start Time]: set the NIBP data statistics starting time (hour or minute).

[Daily End Time]: set the NIBP data statistics ending time (hour or minute).

[SYS Normal High] and **[SYS Normal Low]**: set the high and low limits of systolic pressure.

[DIA Normal High] and **[DIA Normal Low]**: set the high and low limits of diastolic pressure.

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Chapter 13 Temp Monitoring

13.1 Overview

The monitor has two Temp measurement channels and uses a Temperature probe to measure the Temp. Place the Temp probe under the patient's axilla or on the patient's anus, depending on the probe type. To obtain an accurate measurement result, leave the probe in place to measure the Temp for at least 1min. Temp measurement is intended for adult, pediatric and neonate patients.

13.2 Set Temperature Display Area

1) Enter **[Tile Layout]** in any of the following ways:

- Select **[Screen Setup]** quick key → Select **[Tile Layout]** tab.
- Select **[Main Menu]** quick key → **[Display]** → **[Tile Layout]**.

2) Click on the part where Temp is to be displayed, and select **[Temp]** from the drop-down list.

13.3 Temperature Display

The figure below shows the Temp display interface, which may be slightly different from the actual display interface of the monitor.

(1) Temperature Value (2) Temperature Unit

(3) Temperature Alarm Limits (4) Temperature Difference (ΔT)

13.4 Temp Measurement

1) Select an appropriate Temp sensor type and size.
2) Insert Temp cable to the Temp cable interface of the monitor

3) Fix the Temp sensor to the patient reliably.

4) Set the Temp sensor type; please refer to "*Section 13.5.3 Set Temp Type*" for more information.

WARNING

- **Before Temp measurement, ensure that temperature probe cable is in good condition. If temp sensor cable is removed from the temp probe connector, and the monitor displays a prompt message [T1 (T2) sensor off] and triggers an alarm.**
- **Handle the Temp probe and cable with caution. When they are not in use, coil them loosely. Tight coiling may cause mechanical damage to the cable.**
- **Calibrate the Temperature at least every two years or as required by the hospital's regulations. Contact the manufacturer for calibration when necessary.**

NOTE

- **The Temperature probe works in Direct Mode.**
- **The intended measurement site includes but is not limited to: skin surface, axilla arterial, rectal, esophageal, esophageal.**
- **To obtain accurate measurements the recommended minimum measurement time for surface temperature probe is 180s, for cavity temperature probe is 150s.**
- **The transit response time between is not in excess of 40s.**

13.5 Temp Setup

13.5.1 Set Temp Alarm

1) Select Temp parameter tile to enter **[Temp]** menu.

2) Select **[Alarm]** tab.

3) Set the alarm as needed.

13.5.2 Display Temp Difference

You need to turn on the Temp difference switch to display the difference of two Temp values (ΔT). Steps are as follows:

1) Select Temp parameter tile to enter **[Temp]** menu

2) Select **[Setup]** tab.

3) Set **[ΔT]** to On.

13.5.3 Set Temp Type

1) Select **[Main Menu]** → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Module]** → **[Temp]** tab.
3) Set **[Temp Type]** based on the type of Temp sensor used.

13.5.4 Turn Off Dual Temp Display

[Dual Temp Display] defaults to **[On]**; To turn off T2 channel measurement, you can turn off **[Dual Temp Display]** in the following steps:

1) Select **[Main Menu]** → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Module]** → **[Temp]** tab.
3) Turn off **[Dual Temp Display]**.

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Chapter 14 IBP Monitoring

14.1 Overview

This monitor supports 2-channel invasive blood pressure (IBP) measurement, and can be directly used to measure IBP.

IBP measurement is intended for adult, pediatric and neonate patients.

14.2 Safety Information

⚠ WARNING

- **Only use the accessories compliant with the safety requirements on medical equipment.**
- **Do not touch the metal parts connected to electrical equipment when connecting or using any accessory.**
- **When the monitor is connected to the high-frequency electrosurgical equipment, to protect patient from burns (resulted from electric leakage), do not allow the sensors and monitor cables to contact high-frequency electrosurgical equipment.**
- **Use the pressure sensor specified herein only.**
- **Never reuse the disposable pressure sensor.**
- **Before monitoring the patient, check that sensor cable works properly. Remove the IBP sensor cable from the sensor connector, and the monitor displays the prompt message [IBP sensor off]and triggers the alarm sound.**
- **If any liquid other than the solution used for the perfusion pressure tube and sensor splashes onto the monitor or its accessories, especially when it is likely to flow into the monitor or its sensors, please contact the maintenance department of the hospital.**
- **All invasive measurements pose a risk to patients. Aseptic technology should be applied in the measurement, and manufacturer's instructions should be followed.**
- **Mechanical impacts on IBP sensor may lead to significant changes in zero balance and wrong readings.**

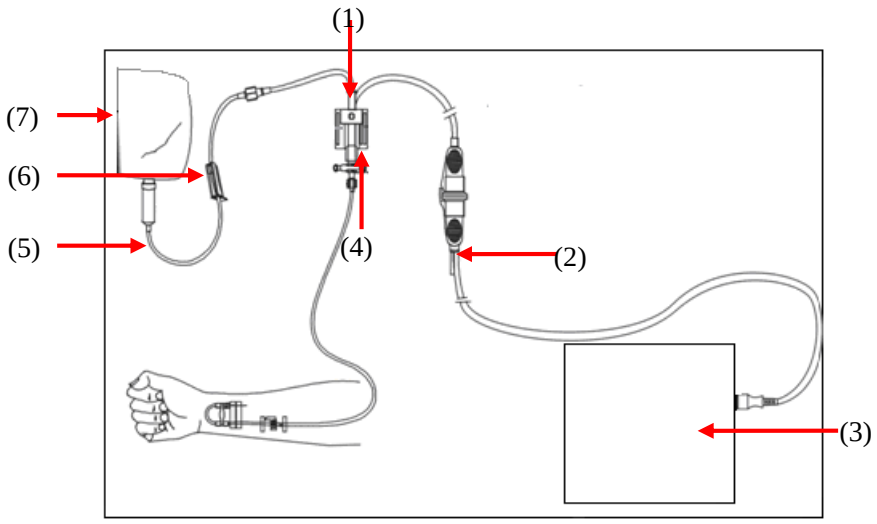
With the protection against electric shock and against the effects of defibrillators, the pressure sensor specified herein can be used for surgical operations. The pressure waves may become disordered in the defibrillation process. Once the defibrillation is completed, the Monitor will go back to normal work with its operation mode and user configurations remaining unaffected.

NOTE

- **Calibrate the sensor, whether new or used, regularly according to the relevant procedures of the hospital.**
- **Avoid subclavian puncture on patients with severe coagulation disorder.**
- **Choose a different puncture site for patients with local skin infection.**
- **Avoid internal jugular and subclavian puncture on patients with hemopneumothorax.**

14.3 Monitoring Steps

14.3.1 Connection of IBP Sensor



(1). Pressure sensor (2). Pressure sensor interface cable (3). Monitor

(4). Three-way switch (5). Pipette (6). Valve

(7). Solution

14.3.2 Measurement Steps

1) Insert the IBP module into the monitor.
2) Insert one end of the IBP sensor cable into IBP interface, and connect the other end to IBP sensor.
3) Exhaust air in IBP sensor according to the instructions provided by IBP sensor manufacturer, usually filling the sensor with saline solution.
4) Connect IBP sensor to the patient and ensure that there is no air inside.
5) Place the sensor on the same horizontal level of the patient's heart, approximately at the mid-axillary line.
6) Select IBP measurement marker; please refer to "***Section14.5.2 Change Pressure Marker***" for more information.
7) Zero the sensor as specified in "***Section 14.3.3 Zero the Pressure Sensor***"; after zero success, turn off the

channel to the atmosphere and turn on the channel to the patient.

WARNING

- **If there is any bubble in the pressure tube or sensor, use the infusion solution to flush the system, or it will lead to inaccurate measurement.**
- **To perform the ICP measurement to a sitting patient, adjust the sensor to the same level as the patient's ears. Incorrect sensor position leads to inaccurate measurement.**

NOTE

- **Once the monitor detects a disconnected arterial catheter it will activate a high priority alarm condition "XX (IBP label) pulse not found".**
- **Once the monitor detects a transduce wire or IBP cable fault (opened or shorted), or transducer connector unplugged, it will activate a technical alarm condition. If the prompt information "XX (IBP label) cable shorted???" is shown, please pay attention to check the integrity of the IBP cable and transducer. Replace them if necessary. Or start zeroing again before further use.**
- **If the transducer connector, adapter cable or modules are intentionally disconnected by the clinical operator, use [Alarm Reset] to disable the alarm light and message.**

14.3.3 Zero the Pressure Sensor

To prevent inaccurate measurement, please zero the sensor on a daily basis or as required by the relevant policies of the hospital.

In addition, the sensor should be zeroed in the following cases.

- When using a new pressure tube or transducer;
- When connecting the sensor to the Monitor; or
- If you believe that the measurement results are inaccurate.

To zero the sensor:

1) Turn off the three-way switch valve to the patient.
2) Open the sensor channel to the atmosphere.
3) Select the parameter area or waveform area of the pressure to be zeroed to enter parameter menu, select **[Zero]** button at the bottom of the menu, and the zeroing results will be displayed after zeroing is finished. Select **[Zero IBP]** quick key in the lower menu bar to zero it. Or press the Zero hard key on the plug-in module for zeroing.
4) After successful zeroing, close the sensor channel to the atmosphere, and open the channel to the patient.

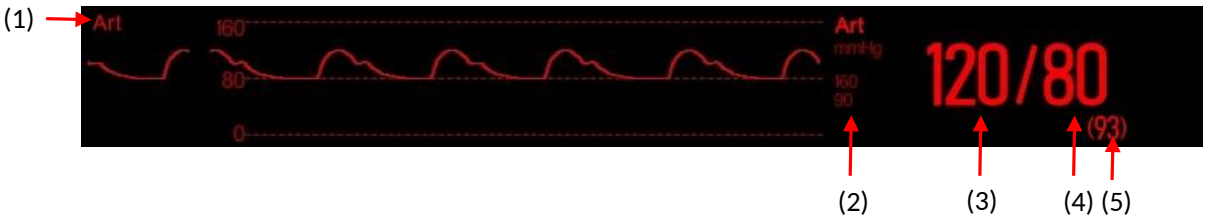
Note: Troubleshooting the Zero failed

Potential causes may be: equipment malfunction; cable fault; excessive offset or continuous unstable signal;

Corrective action: inspect if the transducer is vented to air and try again. If this fails, replace the cable extender and/or the transducer and try again. Contact the service personnel if still not resolved.

14.4 IBP Display

For arterial pressure, the IBP parameter area displays systolic blood pressure, diastolic blood pressure and mean blood pressure. For venous pressure, the IBP parameter area only displays mean blood pressure. The figure below shows Art waveforms and parameters.



(1) Parameter (2) Systolic pressure alarm limit (3) Systolic pressure

(4) Diastolic pressure (5) Mean Pressure

14.5 IBP Setup

14.5.1 Set IBP Alarm

1) Select IBP parameter tile or waveform tile to enter the corresponding IBP menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

14.5.2 Change Pressure Marker

1) Select IBP parameter tile or waveform tile where the marker needed to be renamed to enter the corresponding pressure menu.
2) Select **[Setup]** tab.
3) Select **[IBPX Marker]** (X represents IBP channel), and select the appropriate marker.

Marker	Description	Marker	Description
Art	Arterial pressure	Ao	Aortic pressure
PA	Pulmonary artery pressure	UAP	Umbilical artery pressure
CVP	Central venous pressure	BAP	Brachial artery pressure
RAP	Right atrial pressure	FAP	Femoral artery pressure
LAP	Left atrial pressure	UVP	Umbilical venous pressure
ICP	Intracranial pressure	IAP	Intra-abdominal pressure

Marker	Description	Marker	Description
P1/P2	Expansion pressure	CPP	Cerebral perfusion pressure
LV	Left ventricular pressure	/	/

NOTE

- **IBP channel names cannot be selected repeatedly.**
- **CPP (Cerebral Perfusion Pressure) is calculated from Art and ICP. When both Art and ICP are present, the CPP parameter will be displayed in the ICP parameter area.**

14.5.3 Display Pressure Type

If the current pressure is an expansion pressure (P1, P2 and other channels), you can select the pressure type displayed in the parameter tile by the following steps:

1) Select expansion pressure parameter tile or waveform tile to enter the corresponding pressure menu.
2) Select **[Setup]** tab.
3) Select **[Measure]**:
   - If the current expansion pressure is arterial pressure, you can set **[Measure]** to **[All]**, and then the parameter tile corresponding to the pressure shows all the pressures: SYS, DIA, and MEAN.
   - If the current expansion pressure is venous pressure, you can set **[Measure]** to **[Mean Only]**, and then only MEAN is displayed in the parameter tile corresponding to the pressure.

14.5.4 Set IBP Waveform Speed

1) Select IBP parameter tile or waveform tile to enter the corresponding pressure menu.
2) Select **[Setup]** tab.
3) Set **[Speed]**.

14.5.5 Set IBP Scale

1) Select IBP parameter tile or waveform tile to enter the corresponding pressure menu.
2) Select **[Setup]** tab.
3) Set **[Scale]**: if you select **[Auto]**, the upper and lower scales of IBP waveform will automatically change according to the wave amplitude; if you select **[Manual]**, you need to set **[Upper Scale]** and **[Lower Scale]** respectively.

14.5.6 Change Pressure Unit

1) Select **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Unit]** tab.
3) Set **[Pressure Unit]**, **[CVP Unit]** and **[ICP Unit]**.

14.5.7 Set Filter Mode

1) Select **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Module]** tab → **[Other]** tab.
3) Set **[IBP Filter]**: There are four filters to be choose: smooth, normal, 8Hz, 20hz. The smoothness of the waveform after the four filtering modes is as follows: 8Hz>Smooth >20Hz>Normal.

14.5.8 Enable PPV Measure

PPV is pulse pressure variability. When measuring arterial pressure (excluding PA), you can enable PPV Measure by the following steps:

1) Select IBP parameter tile or waveform tile to enter the corresponding pressure menu.
2) Select **[PPV Setup]** tab.
3) Enable **[PPV Measure]**.

WARNING

- **The monitor calculates PPV based on any arterial pressure between heartbeat and heartbeat. The conditions of PPV measurement, the clinical significance, applicability and reliability of PPV value calculation must be determined by the doctor.**
- **Only the doctor can determine the clinical value of PPV information. According to recent scientific literature, the clinical relevance of PPV information is limited to sedated patients undergoing controlled mechanical ventilation and without arrhythmias.**
- **The PPV value calculated may be inaccurate under the following circumstances:**
  - **◆ RR is below 8 rpm;**
  - **◆ Tidal volume is below 8 ml/kg during ventilation;**
  - **◆ The patient suffers from acute right ventricular dysfunction (i.e. pulmonary heart disease).**
- **PPV measurement has been verified only on adult patients.**

14.6 PAWP Measure

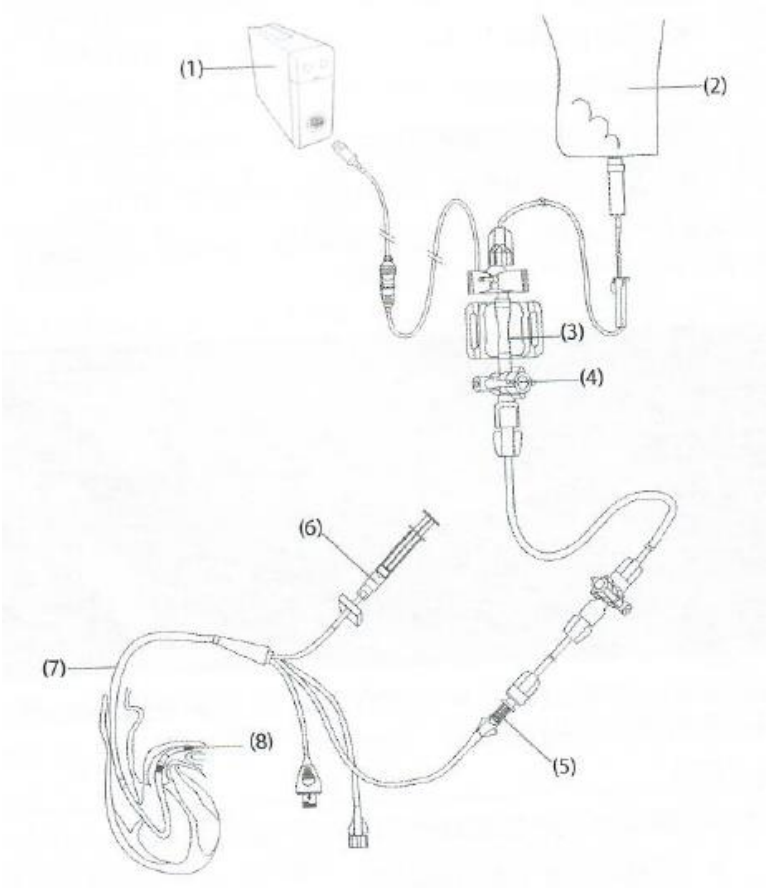
As an important index of hemodynamic monitoring, pulmonary artery wedge pressure (PAWP) is pressure measured by catheter tip after a balloon-tipped Swan-Ganz catheter is wedged to the arteriole to block the forward blood flow.

PAWP reflects the changes of intracranial pressure during the whole respiratory cycle. When the airway pressure and valvular function normally, PAWP is the left ventricular end-diastolic pressure. The PAWP value measured at the end of a respiratory cycle is the most accurate since the intracranial pressure is fairly constant.

14.6.1 Enter PAWP Measure Screen

Select **[Screen Setup]** quick key → **[Choose Screen]**, select **[PAWP]** to enter PAWP measurement screen.

14.6.2 PAWP Equipment Assembly



(1). IBP Module
(2). Solution
(3). IBP Sensor
(4). Three-way Switch
(5). Remote PA Interface
(6). Balloon Charge Valve
(7). Swan-Ganz Catheter
(8). Balloon

14.6.3 Preparations for Measurement

WARNING

- **Before measurement, please read the instructions for Swan-Ganz catheter and IBP sensor thoroughly.**

1) Connect IBP sensor, IBP cable and module; please refer to "*Section14.3 Monitoring Steps*" for more information.
2) Connect PA port of Swan-Ganz catheter and the patient port of IBP sensor.
3) Zero the pressure sensor. please refer to "*Section14.3.3 Zero the Pressure Sensor*" for more information.
4) Set the IBP marker to **[PA]**, and PAWP is measured based on PA. Please refer to "*Section14.5.2 Change Pressure Marker*" for more information.

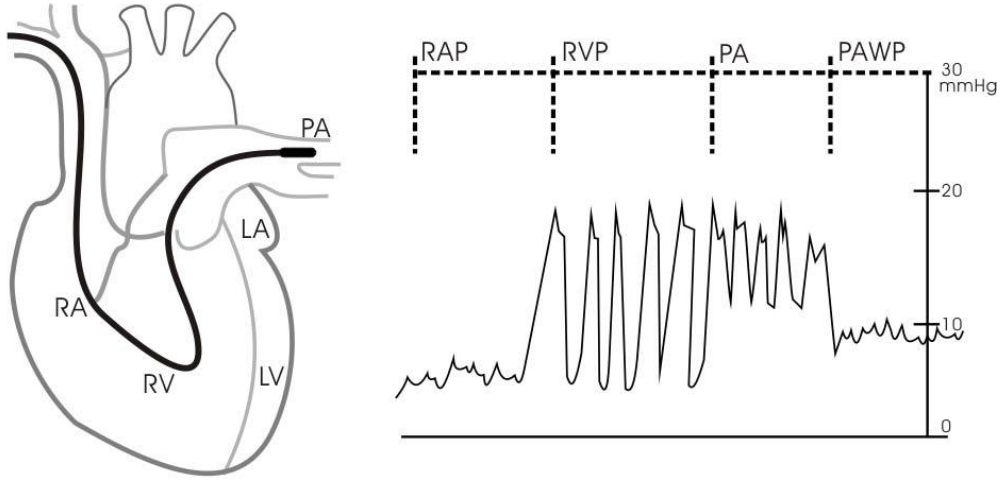
NOTE

- **PA alarm will be disabled when entering PAWP Measure screen.**
- **PAWP measurement is not intended for neonates.**

14.6.4 Measurement Steps

1. Select PA parameter tile or waveform tile

Wedge the tip of Swan-Ganz catheter into the patient's pulmonary arteriole properly and then inflate the balloon, and the PA waveform displayed by the monitor will change. Please pay close attention to the change of PA waveform, shown as the figure below:



2. After the PAWP waveform becomes stable, click **[Freeze]** to freeze the stable waveform on the screen, and then deflate the balloon.

3. Click on  buttons to view the frozen waveforms leftward and rightward; click on  buttons to adjust the size of PAWP waveform displayed on the screen; click **[Confirm]** to save a set of PAWP measurements.

4. If you want to obtain multiple sets of PAWP measurements, please repeat above steps.

⚠ WARNING

- **In order to avoid thrombosis or pulmonary hemorrhage caused by inflation of the balloon for long periods, inflate the balloon for the minimum time necessary for accurate measurements.**
- **Over inflation of the balloon may lead to a rupture of the pulmonary artery, so please inflate the balloon moderately. Take appropriate action according to good clinical practice and standard procedure.**
- **If the measured PAWP value is higher than PA systolic pressure, please deflate the balloon and report the accident in accordance with hospital policy. Besides, the measured PAWP value can only reflect the pressure of the catheter or balloon, not the patient's hemodynamic status.**

14.6.5 PAWP Setup

Click **[Setup]** on PAWP screen to enter **[PAWP Setup]** menu, where you can set the following parameters:

Item	Setting Range	Descrition
Reference Waveform1	All available ECG leads	Select an ECG waveform to display in PAWP waveform area as the first reference waveform.
Reference Waveform2	Resp; CO_2	Select a respiration waveform or CO_2 waveform t displayin PAWP waveform area as the second reference waveform
Speed	12.5mm/s;25mm/s;50mm/s	Set the sweep speed of IBP waveform. The higher the value, the faster the sweep speed, and the wider the waveform. This seeting is only applicable for waveforms in the PAWP interface.
PA Scale	Auto; Manual	Select how to set the size of the PA waveform on the PAWP screen. **[Auto]**: the system automatically selects the appropriste scales according to current wave amplitude. The waveform is displayed as large as possible within the range of upper scale and lower scale. **[Manual]**: the upper and lower scales can be manually set according to actual situation.
Upper Scale	10~120mmHg	
Lower Scale		

14.6.6 Hemodynamic Calculation

Click **[Calculations]** on PAWP screen to enter **[Hemodynamic]** window. Please refer to "***Section19.4 Hemodynamic Calculation***" for more information.

14.6.7 Record

After saving the current measurements on PAWP screen, click **[Record]** to record the current frozen waveforms and measurements.

Chapter 15 CO_2 Monitoring

15.1 Overview

The monitor uses the CO_2 measurement to monitor the patient's respiration status and control patient's ventilation. There are two methods of measuring the CO_2 in the patient's airway:

- Sidestream measurement method: take sample from the respiratory gas module in the patient's airway at a constant flow rate and use the built-in remote CO_2 module in the measurement system to analyze them.
- Mainstream measurement method: install the CO_2module onto the airway connector inserted directly into the respiratory system of the patient.

In the above two methods, the measurement principle is IR emission. Use the optical detector to measure the intensity of the infrared rays penetrating the respiratory system. The intensity depends on the CO_2 concentration as some infrared ray is absorbed by CO_2 molecules.

CO_2 measurement is intended for adult, pediatric and neonate patients.

15.1.1 Indication on CO_2 Module

Masimo Mainstream Module:

The LED located on the IRMA probe is used to signal the following conditions:

LED Indication	Status
Steady green light	System OK
Flashing green ligt	Zeroing in progress
Steady red light	Sensor error
Flashing red light	Check adapter

Masimo Sidestream Module:

The light emitting gas inlet (LEGI), detects the presence of a NomoLine sampling line and presents color coded status information:

LEGI Indication	Status
Steady green light	System OK
Flashing green light	Zeroing in progress
Steady red light	Sensor error
Flashing red light	Check sampling line

15.2 Safety Information

WARNING

- Place sampling line and other pipes well to prevent the patient from being entangled and thus suffering from apnea.
- Never use this device in an environment with inflammable anesthetic gases.
- Only the trained professionals familiar with this Manual are allowed to operate the device.
- If the patient is connected to mechanical ventilation equipment supplied by oxygen 93 or an oxygen concentrator, the accuracy of CO_2/AG monitoring may not be maintained. It shall not be used with gas supplied from oxygen concentrators.
- All parts or accessories except the Respironics pathway adaptor does not contain phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic.
- The Respironics pathway adaptor contains phthalates, such an indication is marked on the packaging.
- Take increased care during the treatment of children and the treatment of pregnant and nursing women, who may have an allergy to this substance.
- Masimo CO_2 has the automatic barometric pressure compensation function.
- Respironics and Comen CO_2 sensors have no function of barometric pressure compensation, and have been set with a fixed value before delivery. If the value needs updating due to altitude, contact the maintenance personnel.
- If Luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.

CAUTION

- When the patient is being treated with nebulized drugs, the measured $EtCO_2$ value may be inaccurate, and thus it is not recommended to use it under such a circumstance.
- The $EtCO_2$ measured by CO_2 module may differ slightly from the partial pressure of carbon dioxide (PCO_2) measured by arterial blood gas analyzer.

NOTE

- The CO_2 module is designed with auto alarm inhibition function, and it triggers a physiological alarm only when a respiratory wave is detected. To monitor the patient with a CO_2 module, please make sure that the device is connected properly to the patient.

15.3 Adverse Effects on Performance (Masimo)

1) The following factors are known adverse effects on the specified performance:

- Quantitative effects of gas sample humidity or condensate;
- Quantitative effects of barometric pressure;
- Interfering gas or water vapor;
- Leaks or internal venting of sampled gas;
- Cyclical pressure of up to 10 kPa (100 cmH_2O);
- Other sources of interference.

2) Gas Measurement Unit

Use volume percentage as the gas concentration unit. The concentration calculation formula is:

$$\%gas = \frac{Partial\ pressure\ of\ gas\ component}{Total\ pressure\ of\ gas\ mixture} * 100$$

Use the cup-making pressure sensor of the ISA gas analyzer to measure the total pressure of the gas mixture. To convert into any other unit, use the actual barometric pressure sent from the ISA sidestream (IRMA mainstream).

CO_2 (mmHg) = (CO_2 Concentration) x (Barometric Pressure from ISA (kPa)) x (750 / 100).

Take 5.0 vol% CO_2 @ 101.3kPa as an example: 0.05 x 101.3 x 750 / 100 = 38 (mmHg).

3) Effects of RH

The partial pressure and volume percentage of the CO_2, N_2O, O_2 and anesthetic gas depend on the water vapor content in the measured gas. Calibrate the O_2 measurement, and the displayed value at the ambient temperature and RH level will be 20.8 vol%, not the actual partial pressure. The 20.8 vol% O_2 represents the actual O2 concentration of the room air (water concentration: 0.7 vol %) (for example, 25℃ and 23% RH @ 1013hPa). The monitor displays the actual partial pressure at the current RH level when measuring the CO_2, N2O and anesthetic gas (like all gases measured by infrared cell).

In the patient's alveoli, the water vapor in the respiratory gas is saturated (BTPS) at the body temperature. Before the acquired respiratory gas in the sampling tube is transferred to the ISA sidestream gas analyzer, its temperature becomes approximate to the ambient temperature. No water enters the ISA gas analyzer after the Nomoline sampling tube removes all condensed water. The RH of the acquired gas is approximately 95%. Use the following formula to calculate the CO_2 value at BTPS:

$$EtCO2(BTPS) = EtCO2 * \left(1 - \left(\frac{3.8}{Pamb}\right)\right)$$

In the above formula:

$EtCO_2$: $EtCO_2$ value **[vol%]** sent from ISA

Pamb: barometric pressure **[kPa]** sent from ISA

3.8: typical partial pressure **[kPa]** of the water vapor condensed between the patient circuit and ISA

$EtCO_2$ (BTPS) = $EtCO_2$ concentration **[vol%]** at BTPS

It is assumed that the O_2 is calibrated by the room air at 0.7 vol% H_2O (RH).

15.4 CO_2 Display

(1) CO_2 Waveform

(2) Fractional inspired CO_2 ($FiCO_2$)

(3) Airway Respiratory Rate (awRR)

(4) End-tidal CO_2 ($EtCO_2$)

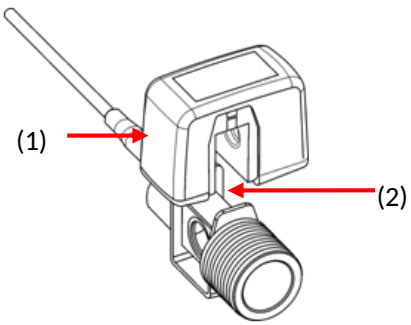
15.5 CO_2 Measurement

WARNING

- **Check the airway adapter before use. Replace it if there are any exterior damage or breakage on the airway adapter.**
- **Turn it off when the CO_2 module is idle, or it will remain in working and lead to a shorter service life.**

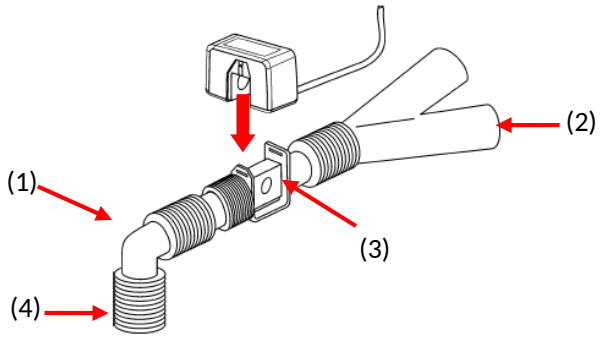
15.5.1 Preparations for Mainstream CO_2 Sensor Connection

1) Connect the mainstream sensor to the CO_2 interface of the monitor.
2) Wait for the sensor to warm up, until the sensor reaches its working temperature and a stable thermal state.
3) Fix the sensor to the airway adapter.



(1) Sensor (2) Airway adapter

4) Zero the sensor; please refer to "***Section 15.6 Zero CO_2 Sensor***" for more information.
5) Install the airway adapter onto one end of the respiration circuit, exactly speaking, between the elbow tube and the Y-shaped tube (see figure below).



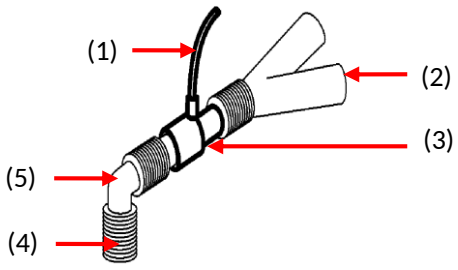
(1) Elbow tube (2) Y-shaped tube (3) Airway adapter (4) Respiration circuit port

6) Make sure the airway is tight.
7) Set CO_2 parameters; please refer to "***Section 15.7 CO_2 Setup***" for more information.
8) Start measurement.

15.5.2 Preparations for Sidestream CO_2 Sensor Connection

15.5.2.1 Preparations for Respironics Sidestream CO_2 Sensor

1) Connect one end of Respironics patch cable to the CO_2 sensor cable.
2) Connect the other end of patch cable to the CO_2 interface of monitor.
3) Wait for the sensor to warm up, until the sensor reaches its working temperature and a stable thermal state.
4) Insert sampling line into the interface of CO_2 sensor reliably until you hear a "click" sound, shown as the figure below.
5) Zero the sensor; please refer to "***Section 15.6 Zero CO_2 Sensor***" for more information.
6) Set CO_2 parameters; please refer to "***Section 15.7 CO_2 Setup***" for more information.
7) For the patient with tracheal cannula: install the airway adapter of sampling line onto one end of the respiration circuit, exactly speaking, between the elbow tube and the Y-shaped tube, shown as the figure below:



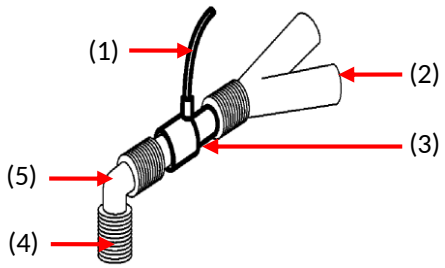
(1) Sampling line (2) Y-shaped tube (3) Airway adapter (4) Respiration circuit port (5) Elbow tube

8) Wear the nasal cannula for the patient without tracheal cannula: wear the nasal or oral-nasal O2 cannula onto the patient's face, connect the O2 supply tube to the O2 supply system and set the O2 flow as directed.

9) Connect an exhaust pipe to the vent on the sensor so as to exhaust waste gases into the waste gas treatment system.
10) Start the measurement after confirming the airway tightness.

15.5.2.2 Preparations for Masimo Sidestream CO_2 Sensor

1) Connect one end of Masimo patch cable to the CO_2 sensor cable.
2) Connect the other end of patch cable to the CO_2 interface of monitor.
3) Wait for the sensor to warm up, until the sensor reaches its working temperature and a stable thermal state.
4) Insert sampling line into the interface of CO_2 sensor reliably until you hear a "click" sound.
5) Zero the sensor; please refer to "***Section 15.6 Zero CO_2 Sensor***" for more information.
6) Check before its use; please refer to "***Section 15.5.3 Checks before Use for Masimo CO2 Module"*** for more information.
7) Set CO_2 parameters; please refer to "***Section 15.7 CO_2 Setup***" for more information.
8) For the patient with tracheal cannula: install the airway adapter onto one end of the respiration circuit, exactly speaking, between the elbow tube and the Y-shaped tube, shown as the figure below:



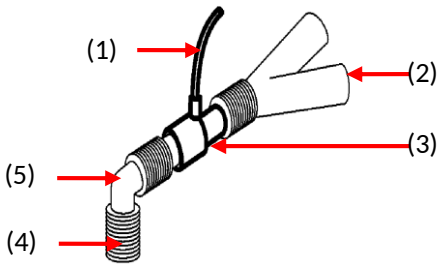
(1) Sampling line (2) Y-shaped tube (3) Airway adapter (4) Respiration circuit port (5) Elbow tube

9) Wear the nasal cannula for the patient without tracheal cannula: wear the nasal or oral-nasal O_2 cannula onto the patient's face, connect the O_2 supply tube to the O_2 supply system and set the O_2 flow as directed.
10) Connect an exhaust pipe to the vent on the sensor so as to exhaust waste gases into the waste gas treatment system.

15.5.2.3 Preparations for Comen Sidestream CO_2 Sensor

1) Insert CO_2 cable to the monitor's CO_2 interface.
2) Wait for the sensor to warm up, until the sensor reaches its working temperature and a stable thermal state.
3) Insert sampling line into the interface of CO_2 sensor reliably until you hear a click sound.
4) Zero the sensor; please refer to "***Section15.6 Zero CO_2 Sensor***" for more information.
5) Set CO_2 parameters; please refer to "***Section15.7 CO_2 Setup***" for more information.
6) For the patient with tracheal cannula: install the airway adapter of sampling line onto one end of the

respiration circuit, exactly speaking, between the elbow tube and the Y-shaped tube, shown as the figure below:



(1) Sampling line (2) Y-shaped tube (3)Airway adapter (4) Respiration circuit port (5) Elbow tube

7) Wear the nasal cannula for the patient without tracheal cannula: wear the nasal or oral-nasal O2 cannula onto the patient's face, connect the O2 supply tube to the O2 supply system and set the O2 flow as directed.
8) Connect an exhaust pipe to the vent on the sensor so as to exhaust waste gases into the waste gas treatment system.
9) Start the measurement after confirming the airway tightness.

15.5.3 Checks before Use for Masimo CO_2 Module

Perform the following operations before connecting the Nomoline sampling tube to the respiration circuit:

1) Connect the sampling tube to the gas inlet of the ISA CO; $_2$module.
2) Check if the LED remains a steady green (an indication of normal system).
3) Exhale into the sampling tube and check if the monitor displays the effective CO_2 waveform and value.
4) Block the sampling tube with a fingertip and wait for 10s.
5) Check if the prompt message “Sampling line clogged” appears and the LED flashes in red.
6) Check the tightness of the patient circuit connected to the sampling tube when appropriate.

⚠ WARNING

- **Unless HME is used to protect the IRMA sensor, the LED state indicator should face upwards all the time during IRMA sensor placement.**
- **Do Not pull the cable of the side-stream gas analyzer.**
- **Do not operate the ISA side-stream Gas Analyzer in the environment beyond the designated operating temperature.**
- **Make sure all connections are firm and reliable. Any leakage will result in the inclusion of ambient air in the patient’s respiratory gas, which leads to a wrong reading.**

NOTE

- **To prevent the condensed water from dropping into the gas sampling tube and blocking it, the gas sampling tube connection end of the airway adapter should point upwards.**

15.6 Zero CO_2 Sensor

WARNING

- **If the alarm message "CO_2 Need Zero" appears directly after zeroing, please re-zero it.**

15.6.1 Zero Masimo CO_2 Sensor

The Masimo CO_2 sensor performs auto zeroing by switching the gas sample source from respiration circuit to ambient air. Auto zeroing starts after the sensor reaches its working temperature (usually 30min after startup) and is performed then every 24 hours. Masimo CO_2 sensor finishes auto zeroing within 3s.

15.6.2 Zero Respironics &Comen Mainstream CO_2 Sensors

In order to eliminate the effect of baseline drift on measurement results and obtain accurate measurement results, please zero it before using CO_2 sensor to monitor the patient. Usually, the CO_2 sensor will be auto zeroed when necessary. You can zero it manually when you consider it necessary by the following steps:

1) Connect the sensor to CO_2 module.
2) After preheating, connect the sensor to airway adapter.
3) Expose the sensor to room air and keep it away from all CO_2 sources, including ventilator, patient's breath and user's breath.
4) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
5) Select **[Zero]** to zero CO_2 sensor, and the message **[Zeroing...]** will be displayed on the screen; after zero calibration, the corresponding message will also be displayed on the screen.

15.6.3 Zero Respironics &Comen Sidestream CO_2 Sensors

1) Connect the sampling line to CO_2 sensor.
2) After preheating, expose the sampling line to room air and keep it away from all CO_2 sources, including ventilator, patient's breath and user's breath.
3) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
4) Select **[Zero]** to zero CO_2 sensor, and the message **[Zeroing...]** will be displayed on the screen; after zero calibration, the corresponding message will also be displayed on the screen.

NOTE

- **For the best zeroing result, please zero Respironics CO_2 sensor after preheating for 5min.**

15.7 CO_2 Setup

15.7.1 Set CO_2 Alarm

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

15.7.2 Set No Breath Alm Delay

No-breath detection is to detect the longest interval between two adjacent Resp. When the actual no-breath time of the patient exceeds the set no-breath time, the monitor will respond to no-breath alarms according to the value of **[Apnea Timeout]**. Steps to set **[Apnea Timeout]** are as follows:

Set [Apnea Timeout]:

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Alarm]** tab.
3) Set **[Apnea Timeout]**.

15.7.3 Set Work Mode

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Work Mode]** to **[Measure]** or **[Standby]**.
   - Standby: when stopping CO_2 measurement, it is recommended to set the Work Mode to Standby so as to extend the service life of CO_2 module.
   - Measure: when measuring with CO_2 module, make sure the Work Mode is set to Measure.

15.7.4 Set Waveform Speed

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Speed]** of CO_2 waveform.

15.7.5 Set Scale

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Scale]** of CO_2 waveform.

15.7.6 Set Waveform Type

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Waveform Type]** of CO_2 waveform.

15.7.7 Set Gas Compensation

In some cases, such as ventilating with an anesthetic machine or ventilator, the patient's respiratory gas is mixed with other gases that interfere with CO_2 measurement, and then gas compensation is required to eliminate the interference of these gases in CO_2 measurement. The concentration of gas compensation should be set based on the actual concentration of interfering gases.

Set gas compensation for CO_2 modules as below:

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set gas compensation as below:

Masimo CO_2 Module:

- **[O_2 Compensation]**:

  [High]: The default O2 Compensation is 85%.

  [Med]: The default O2 Compensation is 50%.

  [Low]: The default O2 Compensation is 21%.
- **[N_2O Compensation]**: set as needed.

Respironics CO_2 Module:

- **[O_2 Compensation]**: Choose the appropriate value according to the O_2 content in the measured gas.

Comen CO_2 Module:

- **[O_2 Compensation]**: Choose the appropriate value according to the O_2 content in the measured gas.

WARNING

- **Please set gas compensation based on the actual conditions, or the measurement results may differ greatly from the actual values to cause misdiagnosis.**

15.7.8 Set Balance Gas

Manual setup of balance gas is available for Respironics and Comen CO_2 modules only, and balance gas is set automatically for Masimo CO_2 module.

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Balance Gas]**.

15.7.9 Set CO_2 Unit

1) Select **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Unit]** tab.
3) Set **[CO_2 Unit]**.

15.7.10 Set Elevation

Respironics and Comen CO_2 sensors have no function of atmospheric pressure compensation, and have been set with a fixed value before delivery. If the value needs to be updated due to the altitude, contact the maintenance personnel.

For the Masimo ISA sidestream CO_2 module, automated compensation for pressure and temperature are provided, and manual compensation for broadening effect on CO_2.

For the Respironics and Comen CO_2 modules:

1) Select the CO_2 parameter area or waveform area to enter **[CO_2]** menu.
2) Select **[Setup]** tab.
3) Set **[Altitude Unit]**.
4) Set **[Altitude]** and **[Barometric Pressure]**: barometric pressure will be displayed automatically based on the elevation value set.

Altitude, Barometric Pressure & $ETCO_2$ Table

Altitude		Barometric Pressure	5% CO_2
Feet	Meters	mmHg	$EtCO_2$mmhg
Sea Level (0)	Sea Level (0)	760	38
500	152.4	745	37
750	228.6	738	37
1,000	304.8	731	37
1,500	457.2	717	36

2,000	609.6	704	35
2,500	762	690	35
3,000	914.9	677	34
3,500	1066.8	665	33
4,000	1219.2	652	33
4,500	1371.6	640	32
5,000	1524	628	31
5,500	1676.4	616	31
6,000	1828.8	604	30
6,500	1981.2	593	30
7,000	2133.6	581	29
7,500	2286	570	29
8,000	2438.4	560	28
8,500	2590.8	549	27
9,000	2743.2	539	27
10,000	3048	518	26
10,500	3200.4	509	25
11,000	3352.8	499	25
11,500	3505.2	490	24
12,000	3657.6	480	24
12,500	3810	471	24
13,000	3962.4	462	23
13,500	4114.8	454	23
14,000	4267.2	445	22
14,500	4419.6	437	22
15,000	4572	428	21
15,500	4724.4	420	21
16,000	4876.8	412	21
16,500	5029.2	405	20
16,800	5120.6	400	20

Note: It is assumed that the sea level is of 760mmHg and 0℃, and that the ambient temperature is 0℃ when calculating barometric pressure based on elevation. For details, please refer to the table.

⚠ WARNING

- **The monitor has no automatic air compensation function. Set the correct altitude before using the CO_2 measurement function for the first time. Incorrect altitude causes incorrect CO_2 reading (5% CO_2 error per 1,000m altitude difference).**

15.7.11 Enter Intubation Mode.

If a patient is under the intubation process of a general anesthesia surgery, the monitor can be set to Intubation Mode to shield unnecessary alarms.

Enter Intubation Mode as follows:

1) Select CO_2 parameter tile or waveform tile to enter **[CO_2]** menu.
2) Select **[Intubation Mode]**.

Please refer to "***Section 7.19 Intubation Mode***" for more information.

15.8 Discharging Waste Gases

When nitrous oxide and/or an anesthetic gas are/is used, prevent these gases from polluting the operating room. The gas discharging outlet should be connected to an Anaesthetic Gas Scavenging System.

⚠ WARNING

- **Anesthetics: If you measure the parameter of a patient who is using or recently has used an anesthetic, the gas discharging port on the module must be connected to a scavenging system or the patient circuit (on the anesthesia machine or the ventilator), so as to prevent medical personnel from inhaling the anesthetic.**
- **Connect the vent to the exhaust gas system when using sidestream CO_2 module, or the sampled gas will returned to the respiratory system and lead to cross-contamination.**

15.9 Information on Masimo Mainstream &Sidestream Gas Modules

15.9.1 Safety Information

15.9.1.1 Sidestream Gas Module

⚠ WARNING

- The gas analyzerof the Masimo ISA sidestream module is intended for use by authorized healthcare professionals only.
- Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
- Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.
- Do not lift the NomoLine ISA CO_2 by the NomoLinecapnography sampling line as it could disconnect from the NomoLine ISA CO_2, causing the device to fall on the patient.
- Dispose of Nomoline Family sampling lines in accordance with local regulations for biohazardous waste.
- Use only airway T-adapters with the sampling point in the center of the adapter.
- Do only use sample lines intended for anesthetic agents if N_2O and/or anesthetic agents are being used.
- Do not use T-adapter with infants, as this adds 7 ml dead space to the patient circuit.
- Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
- Since a successful zeroing requires the presence of ambient air (21% O2 and 0% CO_2), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.
- Never sterilize or immerse the ISA sidestream gas analyzer in liquid.
- The ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
- Measurements can be affected by mobile and portable RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment specified in this manual.
- Replace the sampling line if the sampling line input connector starts flashing red, or the monitor shows a “CO_2 Line Blocked” message.
- No modification to the equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
- The ISA sidestream gas analyzers are not designed for MRI environments.
- During MRI scanning, the ISA must be placed outside the MRI suite.

- Use of high frequency electrosurgical equipment in the vicinity of the ISA/medical device may produce interference and cause incorrect measurements.
- To avoid water condensation inside the NomoLine ISA Capno Module and the connecting tubing, ensure that the surrounding temperature of the NomoLine ISA Capno module and the connecting tubing does not fall below the ambient temperature of the NomoLine sampling line.
- Too strong positive or negative pressure in the patient circuit might affect the sample flow.
- Strong scavenging suction pressure might affect the sample flow.
- NomoLine ISA CO_2 is not intended to be used for returning exhaust gases to the patient circuit. Exhaust gases should be returned to a scavenging system.
- NomoLine ISA CO_2 should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.
- Use of high-frequency electrosurgical equipment in the vicinity of NomoLine ISA CO_2 may produce interference and cause incorrect measurements.
- NomoLine ISA CO_2 should be mounted securely to avoid risk of damage to the NomoLine ISA CO_2.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.
- Do not use NomoLine ISA CO_2 if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause patient harm.
- Do not adjust, repair, open, disassemble, or modify the NomoLine ISA CO_2. Damage to the device may result in degraded performance and/or patient injury.
- Do not use the NomoLine ISA CO_2 during magnetic resonance imaging (MRI) or in an MRI environment.
- Do not re-use disposable single-patient use NomoLine Family sampling lines due to the risk of cross contamination.
- Do not start or operate the NomoLine ISA CO_2 unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.
- Do not place the NomoLine ISA CO_2 or accessories in any position that might cause it to fall on the patient.
- Only use Masimo authorized devices with NomoLine ISA CO_2. Using unauthorized devices with NomoLine ISA CO_2 may result in damage to the device and/or patient injury.
- Do not use the NomoLine Infant/Neonate Airway Adapter Sets for adults/pediatrics as they may cause excessive flow resistance (0,7 ml dead space).
- Do not use the NomoLine Adult/Pediatric Airway Adapter Sets for infants/neonates as the airway adapter adds 6 ml dead space.
- Do not apply negative pressure to remove condensed water from the NomoLine Family sampling line.
- Disconnect the device from AC mains by removing the device cable connection from the host device.

- Properly apply sampling lines according to the sampling lines directions for use. Misapplied sampling lines that become partially dislodged may cause no or incorrect readings.
- To avoid electric shock, always physically disconnect the NomoLine ISA CO_2 and all patient connections before cleaning.
- Do not attempt to remanufacture, recondition or recycle the NomoLine ISA CO_2 as these processes may damage the electrical components, potentially leading to patient harm.
- Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.
- Do not operate NomoLine ISA CO_2 outside of the specific operating environment.
- Dispose NomoLine Family sampling lines in accordance with local regulations for biohazardous waste.

⚠ CAUTION

- **The ISA analyzers should be securely mounted in order to avoid the risk of damage to the ISA.**
- **Do not operate the ISA sidestream gas analyzer outside the specified operating environment.**
- **(US Only) Caution: Federal law restricts this device to sale by or on the order of a physician.**
- **For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**
- **Do not operate the ISA sidestream gas analyzer outside the specified operating environment.**
- **NomoLine ISA CO_2 is to be operated by, or under the supervision of, qualified personnel only. Read this Operator's Manual, accessories directions for use, all precautionary information, and specifications before use. Refer to the host device operator's manual or user's guide for additional safety information, warnings and cautions.**
- **Do not sterilize or immerse NomoLine Family sampling lines in liquid.**
- **To avoid permanent damage to the NomoLine ISA CO_2, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended.**
- **Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the NomoLine ISA CO_2. These substances affect the device's materials and device failure can result.**
- **Do not submerge the NomoLine ISA CO_2 in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.**
- **To prevent damage, do not soak or immerse NomoLine ISA CO_2 in any liquid solution.**
- **Disposal of Product: Comply with local laws in the disposal of the device and/or its accessories.**

NOTE

- **Disconnect the device from AC mains by removing the device cable connection from the host device.**
- **Use and store the NomoLine ISA CO_2 in accordance with specifications. See the Specifications section in this manual.**

15.9.1.2 IRMA Mainstream Gas Module

WARNING

- **The IRMA mainstream analyzers should be securely mounted in order to avoid the risk of damage to the IRMA.**
- **Do not operate the IRMA sidestream gas analyzer outside the specified operating environment.**
- **(US Only) Caution: Federal law restricts this equipment to sale by or on the order of a physician.**
- **For professional use. See the instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**
- **The IRMA probe is intended for use by qualified medical personnel only.**
- **The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
- **Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.**
- **Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.**
- **Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.**
- **Do not use the IRMA Infant airway adapter with adults as this may cause excessive flow resistance.**
- **Do not use IRMA with metered-dose inhalers or nebulized medications as this may affect the light transmission of the IRMA Airway Adapter windows.**
- **Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.**
- **Make sure that IRMA is used in the electromagnetic environment specified in this manual.**
- **Use of high-frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.**
- **The IRMA probe is not designed for MRI-environments.**
- **Do not lift the NomoLine ISA CO_2 by the NomoLinecapnography sampling line as it could disconnect from the NomoLine ISA CO_2, causing the device to fall on the patient.**
- **Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.**

- **To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.**
- **Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.**
- **Incorrect zeroing of IRMA will result in false gas readings.**
- **Replace the airway adapter if rainout/condensation occurs inside the airway adapter.**
- **Use only IRMA Airway Adapters manufactured by Masimo.**
- **The IRMA probe is not intended to be in patient contact.**
- **If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.**
- **No modification of this equipment is allowed.**
- **IRMA should only be used for the purpose and in the manner described in this manual.**
- **Do not adjust, repair, open, disassemble, or modify the IRMA or IRMA Airway Adapters. Damage to the device may result in degraded performance and/or patient injury.**
- **Light transmission can be affected by secretions and moisture pooling on the IRMA Airway Adapter XTP™ windows. When using heated humidifiers special care should be paid to position the Airway Adapter in a vertical position and to change Airway Adapter if necessary.**
- **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.**
- **To avoid electric shock, always physically disconnect the IRMA and all patient connections before cleaning.**
- **Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.**

⚠ CAUTION

- **IRMA is to be operated by, or under the supervision of, qualified personnel only. Read this Operator's Manual, accessories directions for use, all precautionary information, and specifications before use. Refer to the medical backboard devices operator's manual or user's guide for additional safety information, warnings and cautions.**
- **Never submerge or saturate IRMA in water or any other liquid solution this may cause permanent damage to the IRMA.**
- **Do not apply excessive pressure on the IR-windows.**
- **Only perform maintenance procedures specifically described in the manual; otherwise, return IRMA for servicing. Improper maintenance may result in damage to the internal parts. Damage to internal parts may result in no or inaccurate readings.**
- **Do not clean IRMA with any chemical other than those specified in Maintenance and Cleaning of this manual. These substances may affect the device's materials and damage internal parts.**

- **The IRMA and IRMA Airway Adapters are non-sterile devices. Do not submerge IRMA or IRMA Airway Adapters in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.**
- **Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended in Maintenance and Cleaning of this manual. Permanent damage to IRMA may occur if other unspecified solutions are used.**
- **Disposal of Product: Comply with local laws in the disposal of the device and/or its accessories.**
- **IRMA Airway Adapters shall be disposed of in accordance with local regulations for bio hazardous waste.**

⚠ **NOTE**

- **Disconnect the device from power by removing the device cable connection from the medical backboard device.**
- **Use and store the IRMA in accordance with specifications. See the Specifications section in this manual.**
- **A trained medical professional must determine the proper IRMA Airway Adapter model for each patient application. No hardware or software configuration changes result from the IRMA Airway Adapter model selected.**
- **The presence of ambient air (0% CO_2) in the IRMA Airway Adapter is of crucial importance for a successful Zeroing. Special care should be taken to avoid breathing near the IRMA Airway Adapter before or during the Zeroing procedure.**

15.9.2 Airway Obstruction

When the anesthetic gas airway is obstructed, on the screen there will be such a prompt message as “Sampling Line Clogged”; under such a circumstance, replace the Nomoline sampling line.

⚠ **WARNING**

- **Do not use the ISA gas analyzer together with a quantitative spraying agent or pulverization treatment; otherwise it may result in the clogging of the germ filter.**

15.9.3 Leakage Check

1) Connect a new Nomoline sampling line with male Luer lock to the ISA gas inlet connector and check that the gas inlet connector shows a steady green light.
2) Connect a short silicon tubing with an inner diameter of 3/32” (2.4 mm) to the Nomoline male Luer.
3) Exhale a long breath into the silicon tubing until the CO_2 concentration is greater than 4.5 vol% or 34

mmHg.

4) Quickly connect the silicon tubing tightly to the exhaust port.

5) Wait 1 minute until the CO_2 concentration has stabilized. Note the value.

6) Wait 1 minute and check that the CO_2 concentration has not decreased more than 0.4 vol% or 3 mmHg. If it has decreased more there is a major leakage in the unit or in the Nomoline. Do not operate the ISA if there is a major leakage in the unit.

15.9.4 Safety Symbols

Symbol	Text, Color Code and Text Format	Description
	Warning: additional information.	"Warning" indicates the hazardous conditions causing possible personal injuries or death. The warning symbol should comply with ISO 7010-W001.
	User's Manual	Refer to the User's Manual.
	Reference No.	/
	Serial No.	/
	Lot No.	/
	Valid until [YYYY-MM-DD]	Do not use the Monitor after such date.
	Temperature limit	/
	Pressure limit	/
	RH limit	/
	No reuse	/
	WEEE directive	Recycle this electrical and electronic equipment according to 2002/96/EC.
	Contain Pb	/
IPX4	IP grade	The IP grade indicates the water ingress protection performance.
IP44	IP grade against water and solid object ingress	Protection against tools and short cable ends (>1mm). Protection against water sprays from all directions.
	Sold on prescription only	Warning (U.S.): that Monitor shall be sold by medical practitioners or on prescription according to U.S. federal laws.

	CO_2	The IRMA/ISA analyzer measures CO_2 only.
	Multiple gases (AX+ or OR+)	The IRMA/ISA analyzer can measure multiple gases.
	Gas inlet	/
	Gas (exhaust) outlet	/
	Connect to patient circuit	Illustrate the connection between Nomoline and patient circuit.
	Connect to ISA	Illustrate the connection between Nomoline and ISA.
	Not sterile, latex free	The Monitor is latex free and not sterile.

15.9.5 Patents and Trademarks

(1) Patent Statement

Masimo Sweden AB owns the following patents for relevant products described in this operating instruction manual: SE519766; SE519779; SE523461; SE524086. Other patents are being applied.

(2) Trademark

Masimo IRMA™, Masimo ISA™, Masimo XTP™, Sigma Multigas Technology™, LEGI™, Nomoline™, IRMA EZ Integrator™, Masimo GasMaster™ and ISA MaintenanceMaster™ are trademarks of Masimo Sweden AB.

15.9.6 Consumables

15.9.6.1 ISA Nomoline Family

ISA samples gas from the respiratory circuit through the Nomoline Family sampling line at a rate of 50 sml/min, making measurements of CO_2 possible for adult, pediatric and infant patients.

The Nomoline Family sampling lines incorporate a unique water separation (NO MOisture) section, which removes condensed water. The NOMO section is also fitted with a bacteria filter that protects the gas analyzer from water intrusion and cross contamination.

As long as no sampling line is connected, the ISA gas analyzer remains in a low-power sleep mode. Once the sampling line is connected, the ISA gas analyzer switches to measuring mode and starts delivering gas data.

The Nomoline Family sampling lines are available in a wide variety of versions for both intubated and spontaneously breathing patients and in both disposable and re-sposable configurations –intubated patients can for instance be monitored using the disposable Nomoline Airway Adapter Set or a com-bination of the

multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter. Spontaneously breathing patients could similarly be monitored using a disposable Nomoline Nasal CO_2 Cannula or a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Nasal CO_2 Cannula with Luer Connector.

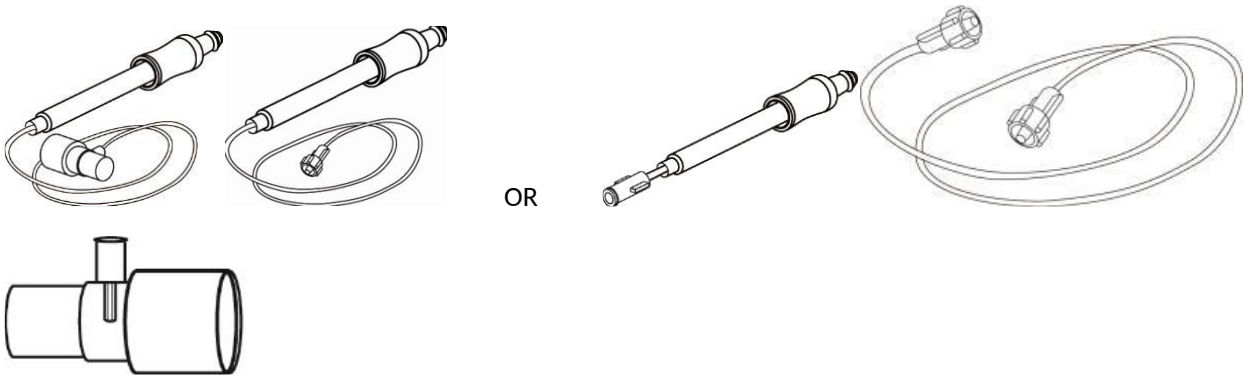


Figure 1.The disposable Nomoline Airway Adapter Set is an alternative to using a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter.

The Nomoline Adapter may be used with other third party sampling lines and cannulas. Please however note that the Nomoline Family of sampling lines are designed for optimal performance and measure-ment fidelity when used with the ISA gas analyzers. For instance, when connecting to a respiratory circuit, the Masimo T-adapter provides a central gas sampling point thereby minimizing the the risk of sampling line occlusion (see below)

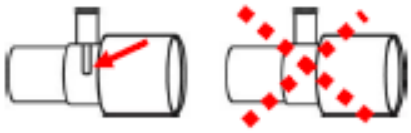


Figure 2. For optimal water handling, always use T-adapters with the sampling point in the center of the adapter, as shown to the left above.

⚠NOTE

- **Using sample tubes or cannulas with larger inner diameter than 1 mm will increase ISA's total system response time.**

Nomoline Family sampling line replacement

Nomoline Family sampling lines should be replaced according to good clinical practice or when the sampling line gets occluded. Occlusion occurs when water, secretion etc. is aspired from the respiratory circuit to such extent that ISA cannot maintain the normal 50 sml/min sample flow. This situation is indicated by a red flashing gas inlet connector and an alarm message "Sampling Line Clogged"; Replace the Nomoline and wait until the gas inlet connector switches to green indicating that the ISA gas analyzer is ready for use.

15.9.6.2 IRMA Airway Adapter

The IRMA airway adapter is inserted between the endotracheal tube and the Y-piece of the breathing circuit. The respiratory gas measurements are obtained through the XTP™ windows in the sides of the adapter. The XTP windows are transparent to light in the wavelength ranges of interest and they are specially designed using the latest advances in material technology to provide a window minimizing the impact of water vapor on light transmission.

⚠WARNING

- **Replace the airway adapter if rainout/condensation occurs inside the airway adapter.**

The IRMA airway adapter is designed as a non-sterile single patient use disposable for both Adult/Pediatric and Infant applications. The IRMA Infant airway adapter has specially designed connectors for minimizing the dead space and can be used even for very small patients.

IRMA airway adapters: Adult/Pediatric (REF: 106220) and Infant (REF: 106260)

⚠WARNING

- **Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.**
- **Do not use the IRMA Infant airway adapter with adults/pediatrics as this may cause excessive flow resistance.**

15.9.7 Maintenance

The user should verify gas readings regularly; If any problem, contact an engineer of the manufacturer for maintenance.

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Chapter 16 C.O. Monitoring

16.1 Overview

C.O. (cardiac output) measurement uses the regular thermodilution method to measure the C.O. and other hemodynamic parameters in an invasive way. The monitor can measure the blood temperature, and calculate cardiac output and hemodynamics.

Place the drift catheter into the vein and then let the tube reach the pulmonary artery. Then inject a certain dose of low-temperature injection solution via the drift catheter. When the injection solution is mixed with the blood outputted from the heart, the blood temperature changes. The C.O. value is obtained from the blood temperature change (after the injection is injected) curve based on the heat balance principle.

In C.O. measurement, you can use the infusion system or a syringe to inject the room-temperature injection solution or ice water. The monitor saves the results of up to 6 measurements. If more than 6 measurements are performed before editing the measurement results, the result of the earliest measurement will be deleted.

C.O. measurement is only intended for adults.

16.2 Safety Information

⚠ WARNING

- **C.O. measurement results may be inaccurate during electrosurgical operation.**
- **All invasive measurements pose a risk to the patient. Aseptic technology should be used in the measurement, and manufacturer's instructions should be followed.**
- **Please use the accessories specified herein, and avoid contact with electrically connected metal parts during connection and use of accessories.**

16.3 C.O. Measurement Limitations

- **Factors causing measurement error:**
  - ✧ Patient movements in the measurement;
  - ✧ Anxious patient;
  - ✧ HR and rhythm changes;
  - ✧ Cardiac disorders (like alular insufficiency);
  - ✧ Inflated balloon in the measurement;

- ✧ Improper catheter location;
- ✧ Catheter damage;
- ✧ Improper injection time;
- ✧ Inaccurate/improper injection volume.

- **To ensure accurate C.O. measurement, please:**
  - ✧ Keep the injection solution temperature lower than the patient's blood temperature;
  - ✧ Inject the solution quickly and steadily;
  - ✧ Inject the solution at the end of expiration;
  - ✧ Wait for 1min until the stable baseline of blood temperature resumes before starting the next measurement.

16.4 C.O. Display

(1) C.O. (2) Unit (3) Measured value

(4) Average time for C.O. calculation (5) C.O. index (6) Alarm limit of blood temperature

(7) Blood temperature (BT)

16.5 C.O. Setup

16.5.1 Set BT Alarm

1) Select C.O. parameter tile to enter **[C.O.]** menu.
2) Select **[Alarm]** tab.
3) Set the alarm as needed.

16.5.2 Set Temp Unit

1) Select **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Unit]**.
3) Set **[Temp Unit]**.

16.5.3 Set C.O. Timeout

If the C.O. measurement value is not updated again within the set time the measurement value will be displayed in a hollow form to indicate that such value becomes invalid. Set C.O. Timeout in the following way:

1) Select **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Set **[Module]** tab.
3) Set **[Other]** tab.
4) Set **[C.O. Timeout]**.

16.5.4 Set Patient Information

1) Select C.O. parameter tile to enter **[C.O.]** menu.
2) Select **[Setup]** tab.
3) Input **[Height (cm)]** and **[Weight (kg)]**.

16.5.5 Set Interval

In order to ensure accurate measurement results, the next measurement should be carried out when the blood temperature returns to normal standard, thus an interval should be set between two measurements.

1) Select C.O. parameter tile to enter **[C.O.]** menu.
2) Select **[Setup]**.
3) Set **[Interval (s)]**: the minimum time interval between two measurements; the next measurement will not be carried out until the set interval is reached.

16.5.6 Set C.O. Coefficient

1) Select C.O. parameter tile to enter **[C.O.]** menu.
2) Select **[Setup]** tab.
3) Set **[C.O. Coefficient]**: C.O. Coefficient is related to Swan-Ganz catheter and inject volume. It should be adjusted according to the manufacturer's instructions when the catheter is replaced.

16.5.7 Set Injection Temp

1) Select C.O. parameter tile to enter **[C.O.]** menu.
2) Select **[Setup]** tab.
3) Set Injection Temp (IT):

- If **[Auto IT]** is set to On, injection temperature will be measured automatically.
- If **[Auto IT]** is set to Off, you need to manually input the injection temperature at **[IT (℃)]**.

16.5.8 Set Measure Mode

Measure Mode defaults to **[Manual Measure]**, but you can set it to Auto Measure by the following steps:

1) Select C.O. parameter tile to enter **[C.O.]** menu.
2) Enable **[Auto Start]**. C.O. measurement will start automatically at the set **[Interval]**, and you needn't to select **[Start]** button. If **[Start]** is switched to **[Stop]**, please start the injection and measurement immediately.

If **[Auto Start]** is disabled, you need to select **[Start]** for each measurement.

16.6 Cardiac Output Measurement

WARNING

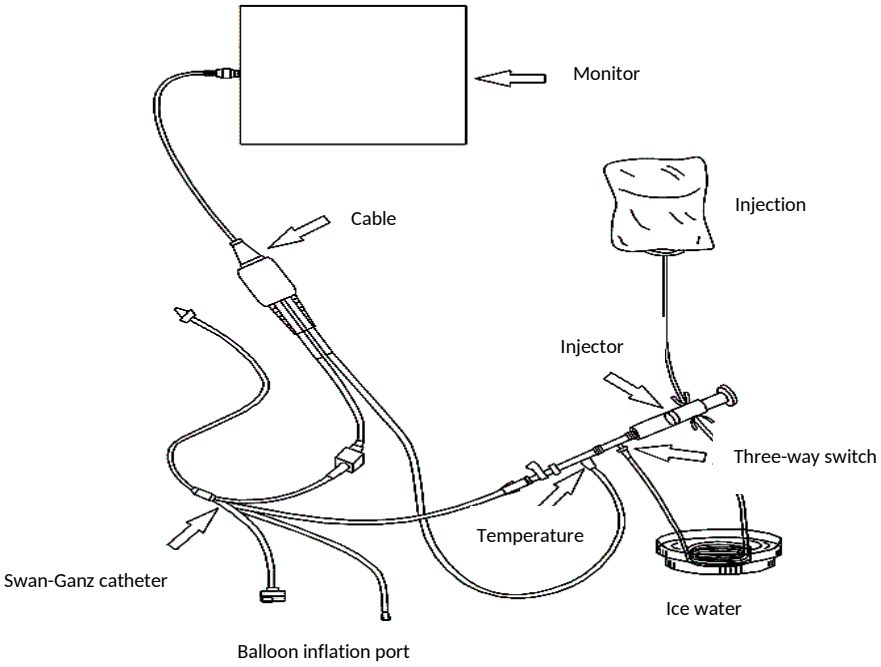
- **Do not touch any conductive metal when an accessory is used.**
- **Select an injection solution volume and computation coefficient for the drift catheter. Enter the computation coefficient as instructed in the User's Manual of the drift catheter after replacement.**
- **Use the cable, catheter and probe recommended by the manufacturer only.**

NOTE

- **No settings can be changed in the C.O. measurement process.**

16.6.1 Preparations for Measurement

1) Insert C.O. module into the monitor's interface.
2) Insert C.O. cable into C.O. interface.
3) Connect Swan-Ganz catheter, syringe and other components according to the manufacturer's instructions, as shown in the figure below:



16.6.2 Measurement Setup

Before C.O. measurement, set as below:

1) Select C.O. parameter tile to enter **[C.O.]** menu.
2) Select **[Setup]** tab.
3) Set the parameters according to "***Section16.5 C.O. Setup***".

16.6.3 C.O. Measure

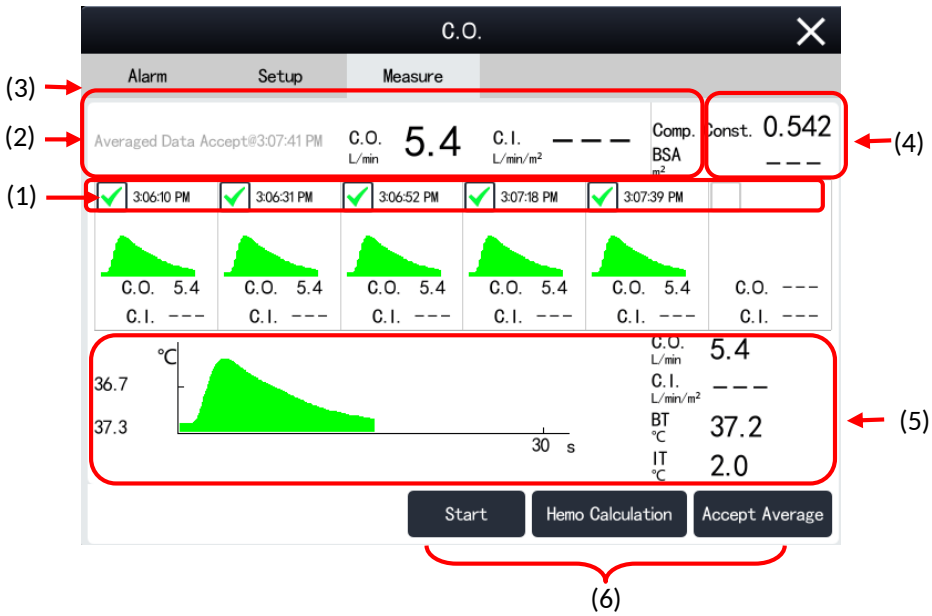
Set C.O. Measure as follows:

1) Select the C.O. parameter area to enter **[C.O.]** menu.
2) Select **[Measure]** tab.
   - If **[Auto Start]** is disabled, select **[Start]** to start fast injection (do not exceed 4s). The Thermodilution curve will be displayed in the C.O. Measure window in real time. At the end of each measurement, the measurement results will be displayed in the measurement history window. Wait for one minute and select **[Start]** for the next measurement.
   - If **[Auto Start]** is enabled, the C.O. measurement will start automatically at the set **[Interval]**, and you do not need to select the **[Start]** button. If **[Start]** is switched to **[Stop]**, please start the injection and measurement immediately.
3) Obtain the average value of C.O. and C.I. After completing multiple measurements, select multiple measurement curves as required in the measurement history window to calculate and display the average value of C.O. and C.I., and then select **[Avg.]** to save and display the average value in the parameter area.

When injecting, the stopcock to the thermodilution catheter is open and the stopcock to the injectate solution is closed. After completing the measurement, turn off the stopcock to the thermodilution catheter and turn on the stopcock to the injectate solution, and then draw the injectate solution into the injectate syringe.

In addition, the following functions area available in the C.O. Measure window:

- **[Start]**: start a C.O. measurement.
- **[Stop]**: stop the ongoing measurement.
- **[Hemodynamic]**: enter **[Hemodynamic]** window, input the value to be calculated in **[Input]** and click **[Calculate]** to get the result. Please refer to "***Section 19.4 Hemodynamic Calculation***" for more information.



(1) Measurement history window
(2) Check box (select the C.O. curve for average calculation)
(3) Average
(4) C.O. Coefficient and Body Surface Area (BSA)
(5) Currently measured values and C.O. curve
(6) Functional keys

NOTE

- **If the blood temperature (BT) is unstable during measurement, it may lead to measurement failure.**
- **BT alarm is unavailable during C.O. measurement. After the measurement, BT alarm becomes available automatically.**
- **Please determine [C.O. Coefficient] and [Inject Volume] with reference to the operating instructions of pulmonary artery thermodilution catheter.**

Chapter 17 Data Review

17.1 Overview

On the Review screen, you can view the trend data, alarm event records and waveform information. You can also go to the Minitrends screen or OxyCRG screen to view trend data. Here we explain how to view such stored data.

17.2 Review Screen

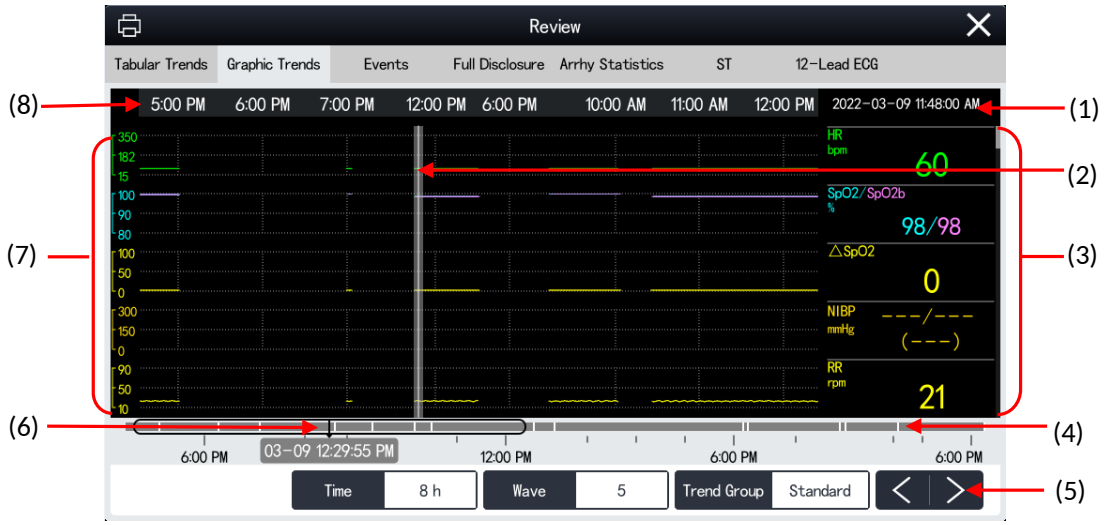
17.2.1 Enter the Review Screen

Follow any path described below to go to the Review screen:

1) Click **[Review]** quick key;
2) Click **[Main Menu]** quick key → **[Review]** and then click the desired tab.

17.2.2 Review Screen Display

The Review Screens have a common structure. The Graphic Trends Review Screen is shown here as an example:



(1) The cursor time.

(2) Cursor.

(3) Parameter area: displays the parameter values at the cursor time. The parameter values are displayed on a background of different colors, depending on their respective Alarm Priority.

(4) Timeline buttons.

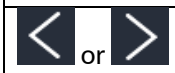
(5) Button area.

(6) Slider: indicates the position of the current screen as part of the full time period. You can move the slider left or right to locate the trend data at a specific time, and the trend data displayed in the current screen will be updated accordingly.

(7) Waveform area: displays the trend curve of parameters. The trend curve is displayed in the same color as the corresponding parameter name.

(8) Current window time bar: indicates the time range of the current window.

17.3 Icons on Review Screen

Icon	Description
	Slider: indicates the position of the current screen as part of the full time period. You can move the slider left or right to locate the trend data at a specific time, and the trend data displayed in the current window will be updated accordingly.
	Locate the previous or next event.
	Event list: displays events in the order of the time they occurred. The event that occurred at the last moment is displayed at the top of the list. The number of "*" marks in front of the event indicates the Alarm Priority.
	Record button: click it to output data through the recorder.
	Print button: click it to output data through the external printer.

17.4 Tabular Trends

Tabular trends are a table of patient data displayed over time.

17.4.1 Enter the Tabular Trends Page

Follow either path described below to go to the Tabular Trends page:

- Click **[Review]** quick key → **[Tabular Trends]** tab; or
- Click **[Main Menu]** quick key → **[Review]** → **[Tabular Trends]**.

17.4.2 Select the Trend Group

Set the **[Trend Group]** on the **[Tabular Trends]** page.

17.4.3 Edit the Trend group

The trend group defines the trend data displayed on the Tabular Trends page and the contents printed in the trend report.

You can select **[Trend Group Setup]** on the Tabular Trends page to edit the trend group. If **[Trend Group]** is set to **[All]** or **[Standard]**, you will fail to edit the trend group.

17.4.4 Change the Time Step of Tabular Trends

Time step refers to the time interval of the trend data displayed on the screen. You can select a larger time step for neonatal patients as their clinical conditions may change rapidly, and select a smaller time step for adult patients as their clinical conditions will change relatively slowly.

Follow the steps below to set the time step:

1) On the **[Tabular Trends]** page, set **[Interval]** to:

- **[5s]** or **[30s]**: to observe the parameter trends of the last 4h at a 5s or 30s interval;
- **[1min]**, **[5min]**, **[15min]**, **[30min]**, **[1h]**, **[2h]** or **[3h]**: to observe the parameter trends of the last 120h at the selected interval; or
- **[NIBP]** or **[C.O.]**: to display the values of such parameter at the time of measurement.

17.4.5 Print the Tabular Trends Report

1) On the Tabular Trends page, click "  " to go to the **[Print Setup]** menu.
2) Set the Tabular Trends Report. See ***"Section 21.6.3 Set the Tabular Trends Report"***.
3) Click "  " to print the tabular trends report.

17.5 Graphic Trends

Graphic trends are a set of patient data displayed graphically over time.

17.5.1 Enter the Graphic Trends Page

Follow either path described below to go to the Graphic Trends page:

- Click **[Review]** quick key → **[Graphic Trends]** tab; or
- Click **[Main Menu]** quick key → **[Review]** → **[Graphic Trends]**.

17.5.2 Select the Trend Group

Refer to "**Section *17.4.2 Select the Trend Group***".

17.5.3 Edit the Trend group

Refer to "**Section *17.4.3 Edit the Trend group***".

17.5.4 Set the Window Time

You can follow the steps below to set the time length of the trend data displayed in each screen:

1) Enter the Graphic Trends page;
2) Set **[Zoom]** to:
   - **[8min]**: to display 8min trend data in each screen (you can view the trends of the last 1h);
   - **[30min]**, **[1h]**, **[2h]** or **[4h]**: to display the trend data of the selected time length in each screen (you can view the trends of the last 4h); or
   - **[8h]**, **[12h]**, **[24h]** or **[48h]**: to display the trend data of the selected time length in each screen (you can view the trends of the last 120h).

17.5.5 Set the Number of Waveforms

You can follow the steps below to set the number of waveforms displayed in graphic trends:

1) Enter the **[Graphic Trends]** page;
2) Set the value of **[Wave]**.

17.5.6 Print the Graphic Trends Report

1) Enter the Graphic Trends page.
2) Click "  " at the top left corner to go to the **[Print Setup]** menu;
3) Set the graphic trends report. See "***Section 21.6.4 Set the Graphic Trends Report***".
4) In the **[Graphic Trends Report]** menu, click "  " to print the graphic trends report.

NOTE

- **In the graphic trends report, if any parameter name is preceded by a "+" mark, that means this is the trend data of an external device.**

17.6 Events Review

The monitor can save alarm events in real time, including physiological alarm events, technical alarm events, manual events and operational events. When an event occurs, the monitor will save the values of corresponding parameters at the time of the event and totally 32s waveforms before and after the event.

NOTE

- **The stored events will never be lost due to power failure.**
- **When recorded events exceeding 2500, the earliest record will be overwritten by the latest event.**
- **The system will save the logs before the power is cut off normally. When the power is cut off abnormally, ensure that the logs are saved 3s before the power cut.**
- **The time of a normal powering down is captured in the log, but the time of sudden powering down is not captured in the log.**
- **No matter how long the power loss, the log will be saved.**
- **The contents of the alarm system log cannot be erased or modified by the healthcare professional operator.**

17.6.1 Enter the Events Review Page

Follow either path described below to go to the Events page:

1) Click **[Review]** quick key → **[Events]** tab; or
2) Click **[Main Menu]** quick key → **[Review]** → **[Events]**.

On the Events page, the events are listed in the order of occurrence time. The event that occurred at the last moment is displayed at the top of the list. The number of "*" marks in front of the event indicates the Alarm Priority.

The identification bar on the left of the listed events uses different color blocks to identify events:

- Red: high-priority alarm event.
- Yellow: medium-priority alarm event.
- Cyan: low-priority alarm event.
- Green: manual event.
- White: operational event.

The total number of desired events and the sequence number of the current event are displayed at the top right corner of the event list. For example, "3/5" means that a total of 5 events are filtered out and the current event is the third event.

17.6.2 Set Event Searching Conditions

1) Enter the Events page;
2) Click **[Search]**.
3) Click **[Search Setup]**. You can filter out the desired events by time, Alarm Level, alarm category and parameter type. Then the desired events will appear in the event list.

17.6.3 Edit Events

1) On the Events page, check the events to be edited;
2) Click **[...]** to edit the checked events:
   - **[Delete]**: delete the selected event.
   - **[Select All]**: check the whole event list.
   - **[Note]**: enter a note to the event.
   - **[Cancel All]**: uncheck all events.
   - **[Rename]**: rename the selected events. Only Manual Events can be renamed.

17.6.4 View Details of Events

1) Enter the Events page;
2) Click **[Details]**.

In the Details window, you can perform the following operations:

- Set the **[ECG Gain]**.
- Set the **[Speed]**.
- Click **[...]** to select **[Note]** or **[Rename]**.

You can click **[Event List]** to return to the event list.

17.6.5 Print Events

1) Enter the Events page;
2) Click "  " or "  " to go to the **[Print Setup]** menu;
3) Select an option as needed and then click **[Print]**:
   - **[Print All Event List]**: print the whole event list.
   - **[Print Displayed Event Details]**: print the currently displayed waveform and parameter details.

17.7 Full-Disclosure Waveforms

On the Full-Disclosure Waveforms page, you can review up to 72h waveform data. You can view compressed waveforms, full waveforms.

17.7.1 Enter Full-Disclosure Waveforms Page

Follow either path described below to go to the Full-Disclosure Waveforms page:

- Click **[Review]** quick key → **[Full-Disclosure Waveforms]** tab; or
- Click **[Main Menu]** quick key → **[Review]** → **[Full-Disclosure Waveforms]**.

17.7.2 Select Compressed Waveforms

To review compressed waveforms, you must first follow the steps below to select the parameter waveforms to be stored and displayed:

1) Enter the Full-Disclosure Waveforms page;
2) Click **[Setup]** tab and select the waveforms to be stored;
3) Click **[Waveform]** and select the stored waveforms to be displayed.

⚠NOTE

- **If you select a large number of waveforms to be stored, they will be stored for a short time (probably less than 72h) due to the limited memory size. Please control the number of waveforms to be stored.**

When an alarm occurs, the wave band at the alarm time (on the compressed waveform) will be displayed on a colored background, depending on the Alarm Priority.

- Red: High-priority alarm.
- Yellow: Medium-priority alarm.
- Cyan: Low-priority alarm.
- Gray: Arrhythmia alarm for missed beats

17.7.3 View Details of Compressed Waveforms

Follow the steps below to view the full version and parameter values of the compressed waveforms:

1) Enter the Full-Disclosure Waveforms page;
2) Click the desired compressed waveform area to display the details above such area.

17.7.4 Set the Waveform Gain of Details Area

1) Enter the **[Full-Disclosure Waveforms]** page;
2) Set the **[ECG Gain]**.

17.7.5 Print the Full-Disclosure Waveforms Report

1) Enter the **[Full-Disclosure Waveforms]** page;
2) Click "  ", set the time length of the waveform to be printed and click **[Print]**.

17.8 12-Lead Report Review

On the 12-Lead Report Review page, you can review the last 20 12-lead ECG events and their analysis and diagnosis results. See ***"Section 9 12-Lead Resting ECG Analysis"*** for more 12-lead ECG information.

17.8.1 Enter the 12-Lead ECG Page

Follow any path described below to enter the 12-Lead ECG page:

- When the 12-lead ECG analysis is completed, click **[Review]** in the **[12-Lead Resting ECG Results]** window;
- Click **[Review]** quick key → **[ECG 12-Lead]** tab; or
- Click **[Main Menu]** quick key → **[Review]** → **[ECG 12-Lead]**.

17.8.2 View the Average Template (for Glasgow algorithm)

On the average template waveform of each lead, the starting position and ending position of the P wave and QRS wave and the ending position of the T wave are marked with short vertical lines. When the average template is displayed, a rhythm lead waveform will be displayed on the page. Follow the steps below to view the average template:

1) Enter the **[ECG 12-Lead]** page.
2) Select any of the patient data on this page and select **[Details]**.
3) Click **[Median Complex]**.

On this page, you can click **[Waveform]** to return to the **[ECG 12-Lead]** page.

17.8.3 Set the Waveform Displayed in ECG 12-Lead Page

1) Enter the **[ECG 12-Lead]** page;
2) Click **[Waveform Speed]** to change the sweep speed of ECG waveform;

3) Click **[Gain]** to change the gain of ECG waveform;
4) Click **[Layout]** to change the layout of ECG waveform.

17.8.4 Print the ECG 12-Lead Report

Follow the steps below to print the 12-lead ECG report:

1) Enter the **[12-Lead ECG]** page;
2) Click "  " to print the 12-lead ECG report.

17.9 ST

If the ST Analysis option is enabled, the Monitor will save the ST-segment data and waveforms at an interval of 5min. You can go to the ST page to view such data and waveforms.

17.9.1 Enter the ST Page

Follow either path described below to go to the ST page:

- Click **[Review]** quick key → **[ST]** tab;
- Click **[Main Menu]** quick key → **[Review]** → **[ST]**.

17.9.2 Set the Reference Template

You can follow the steps below to save the current ST data as the reference template:

1) Enter the ST page;
2) Click **[Save Ref.]**.

17.9.3 Show/Hide Reference Template

1) Enter the ST page;
2) Click **[Display Reference]** or **[Hide Reference]**.

17.9.4 Show/Hide Markers

1) Enter the ST page;
2) Click **[Display Marker]** or **[Hide Marker]**.
   - **[Display Marker]**: on the ST template, the ISO point, J point and ST point are marked with white vertical lines.

- **[Hide Marker]**: on the ST template, the ISO point, J point and ST point are not displayed.

17.9.5 Print ST-segment Data

1) Enter the ST page;
2) Locate the desired time point;
3) Click "  ".

17.10 Minitrends

The Minitrends window is located in the left of the waveform area and displays the trends of a series of parameters in the most recent period. If the Monitor is integrated with an external device, you can also view the Minitrends of the external device in the Minitrends window.

17.10.1 Enter the Minitrends Page

Follow any path described below to go to the Minitrends page:

- Click **[Minitrends]** quick key;
- Click **[Screen Setup]** quick key → **[Minitrends]**; or
- Click **[Main Menu]** quick key → **[Display]** → **[Choose Screen]** → **[Minitrends]**.

In the Minitrends window, the corresponding parameter name is displayed above each trend curve and the trend scale is displayed on the left.

17.10.2 Select the Parameters to be reviewed

1) Enter the **[Minitrends]** page;
2) Click the Minitrends area to go to the **[Trend Setup]** menu;
3) Select the desired parameters. If you want to select the default parameters, select **[Default Parameters]**.

17.10.3 Set the Trend Time

1) Enter the **[Minitrends]** page;
2) Click the Minitrends area to go to the **[Trend Setup]** menu;
3) Set the **[Trend Length]**.

17.10.4 Exit the Minitrends Page

Follow either path described below to exit the Minitrends page:

- Click **[Screen Setup]** quick key and select the page you want to enter; or
- Click **[Main Menu]** quick key→ **[Display]** → **[Choose Screen]** and select the page you want to enter.

17.11 OxyCRG

Follow either path described below to go to the OxyCRG screen:

- Click **[Screen Setup]** quick key → **[OxyCRG]**; or
- Click **[Main Menu]** quick key → **[Display]** → **[Choose Screen]** → **[OxyCRG]**.

Two trend curves and one compressed waveform are displayed on the OxyCRG screen.

17.11.1 Select Parameters and Scale

1) Enter the **[OxyCRG]** screen;
2) Click **[Setup]**;
3) Set **[Trend1]**, **[Trend2]** and **[Compressed Waveforms]** respectively;
4) Click **[Scale]** tab and set the scale of each parameter.

17.11.2 Set the Window Time

1) Enter the OxyCRG screen;
2) Set **[Zoom]** to **[1min]**, **[2min]**, **[4min]** or **[8min]**.

17.12 Close Unnecessary Review Items

You can follow the steps below to close the unnecessary review items:

1) Click **[Main Menu]** → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key;
2) Click **[Review]** tab;
3) Click **[Tabs]** tab and uncheck the unnecessary review items.

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Chapter 18 Clinical Assistant Assessment (CAA)

18.1 SepsisGuide

The Sepsis-3 function provides sepsis screening and treatment tracking tools according to Sepsis-3 (Third International Consensus Definitions for Sepsis and Septic Shock) and the *Surviving Sepsis Campaign - International Guidelines for Treatment of Severe Sepsis and Septic Shock - 2012* ("SSC Guidelines"), for the user to screen patients for sepsis at the bedside and track sepsis patients for achievement of resuscitation goals and completion of therapy.

NOTE

- **Due to the limited screen size, the measures suggested by the SepsisGuide function of the Monitor cannot be as detailed as complete procedures.**
- **SepsisGuide is not a diagnostic or therapeutic tool and cannot replace the professional judgment of a physician.**
- **The SepsisGuide function is applicable only to adult patients with sepsis or suspected sepsis.**

18.1.1 Enter the SepsisGuide Menu

Click **[Main Menu]** quick key → **[CAA]** → **[SepsisGuide]**.

18.1.2 Sepsis Screening

SepsisGuide supports two scores: qSOFA score (Quick SOFA score) and SOFA score. The qSOFA score is used for rapid screening of sepsis; the SOFA score is used for further screening of sepsis on patients with a positive qSOFA screening result.

18.1.2.1 qSOFA Score

The patient is scored based on his/her respiration rate, systolic blood pressure and mental state.
If the patient is undergoing Resp and NIBP monitoring the Monitor will automatically obtain the RR value and BP-SYS value for scoring purposes. It also supports manual entering of parameter values and manual selection of the patient's mental state. The Monitor will automatically calculate the qSOFA score based on such parameter values.

Click " " and enter the parameter values manually. The keyboard symbol to the right of the parameter value indicates that such values were entered manually.

If the total score of sepsis is suspected to be equal to or greater than 2, please select **[SOFA >>]** to obtain the SOFA score.

You can select **[Reset]** to clear the current score.

NOTE

- **If the score value is a question mark "?", that means more parameter values are needed for scoring.**

18.1.2.2 SOFA Scoring

The SOFA score is the score of systemic infection-related organ failure or the score of sequential organ failure. Check each scoring item or enter the parameter value of each scoring item manually, and the Monitor will automatically calculate the total score.

You can select **[Reset]** to clear the current score.

Further examination and confirmation will be required if the SOFA score indicates that the sepsis screening criteria have been met.

18.1.3 Treatment

SepsisGuide provides SSC Bundle Therapy and Supportive Therapy. SSC Bundle Therapy allows the user to track the achievement of the resuscitation goals during the first 6h and the completion of the therapy items to be completed in 3h and 6h respectively. Supportive Therapy allows the user to track the completion of supportive therapy items.

18.1.3.1 SSC Bundle Therapy

In the SepsisGuide menu, click **[SSC Bundle Therapy]** tab to go to the **[SSC Bundle Therapy]** page.

On the **[SSC Bundle Therapy]** page, you can perform the following operations:

- Tick off the completed therapy items to mark the completed time. The completed time will be recorded and displayed automatically. You can change the completed time manually.
- Click "..." on the right side of each item to view the specific suggestions under SSC Guidelines. The "★" mark indicates the recommendation level of therapy items: "★★" represents key therapy item and "★" represents general therapy item.
- Select **[Reset]** to clear the records.

18.1.3.2 Supportive Therapy

In the SepsisGuide menu, click **[Supportive Therapy]** tab to go to the **[Supportive Therapy]** page.

On the **[Supportive Therapy]** page you can perform the following operations:

- Tick off the completed therapy items to mark the completed time. The completed time will be recorded and displayed automatically. You can change the completed time manually.
- Click "..." on the right side of each item to view the specific suggestions under SSC Guidelines. The "★" mark indicates the recommendation level of therapy items: "★★" represents key therapy item and "★" represents general therapy item.
- Select **[Reset]** to clear the records.

18.1.4 SSC Setup

In the SepsisGuide menu, click **[Setup]** to set the following parameters:

- In the **[Screening]** area, set the positive threshold of RR and BP-S (qSOFA scoring parameters).
- In the **[Unit]** area, set the unit of Creatinine and Bilirubin.
- In the **[Goals of Initial Resuscitation]** area, set the resuscitation goals during the first 6h.

18.2 Early Warning Score (EWS)

The early warning score can help identify early signs of deterioration on the patient, serving as an early warning indicator of critical or potentially critical illness.

The early warning score system obtains the corresponding scores by monitoring and observing the patient's vital signs and condition, and then suggests measures based on the score results.

The Monitor provides the following early warning score system:

- Modified early warning score (MEWS) system.
- National Early Warning Score（NEWS）
- National Early Warning Score 2（NEWS2）

The system is a total score system.

- Total score system: score each selected parameter and then calculate the total score. The scores of such parameters are identified by different colors, indicating their criticality level. The user needs to take action if the total score goes beyond the acceptable range limits

MEWS, NEWS and NEWS2 are only applicable to adult patient.

⚠ WARNING

- **EWS scoring is not intended for neonates and pediatric patient**
- **The early warning score results and the suggested measures are provided for reference only, and are**

not provided as the direct basis for clinical treatment.

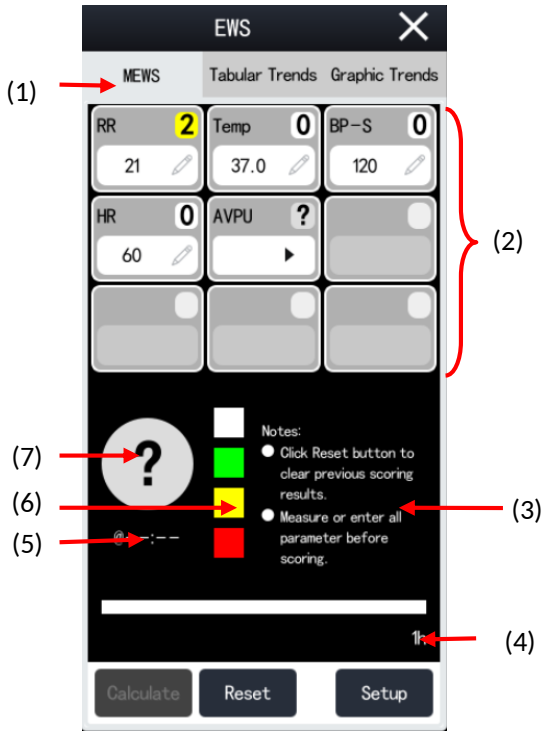
- **The early warning score cannot be used as a predictor of patient development or overall prognosis; it is not a tool for clinical judgment and cannot completely replace the clinician's assessment of patients.**
- **The early warning score system is not intended for pregnant women, COPD (chronic obstructive pulmonary disease) patients or patients under 16 years old.**

18.2.1 Enter the EWS Screen

The Monitor provides an independent EWS screen. Follow one of the steps below to go to the EWS screen:

- Select **[EWS]** quick key.
- Select **[Screen Setup]** → **[Choose Screen]** tab→**[EWS]**
- Click **[Main Menu]** quick key → **[Display]** → **[Choose Screen]** → **[EWS]**.

Take MEWS as an example, the EWS screen is illustrated below. The actual EWS screen may be different, depending on the selected scoring system and settings.



(1) Score system name.

(2) Parameter area: displays the parameter value and score of individual parameters. The keyboard symbol indicates that the parameter value was entered manually.

(3) Suggested measures.

(4) Scoring interval.

(5) Current scoring time.

(6) Score level boxes: the criticality level increases gradually from top to bottom. The current score level is indicated in the circle.

(7) Total score. The color of the circle indicates the current score level. Red means early warning, and white

means normal.

18.2.2 Score Calculation

1) Click **[Reset]** to clear the last score results and refresh the parameter values and their scores automatically obtained from the Monitor.
2) Measure the values of other parameters or enter them manually.
3) Click **[Calculate]** to obtain the score results.

NOTE

- **Please click [Reset] to clear the last score results before each scoring.**
- **The keyboard symbol to the right of the parameter value indicates that such value was entered manually.**
- **To calculate the scores, make sure the values of all parameters involved in the calculation are valid.**

18.2.3 Auto Scoring

1) On the EWS screen, click **[MEWS]** tab → **[Setup]**.
2) In the **[Auto Scoring]** area, check an option as required:
   - **[Interval Mode]** the Monitor will automatically calculate scores at the selected interval

18.2.4 EWS Setup

18.2.4.1 Select a Score System

The Monitor provides a default score system. You can also follow the steps below to select other score systems as required:

1) On the EWS screen, click **[MEWS]** tab → **[Setup]**.
2) Set the **[Score]**.

18.2.4.2 Set the Scoring Interval

1) On the EWS screen, click **[MEWS]** tab → **[Setup]**.
2) Set the Measure Interval:
   - If **[Interval Mode]** in the **[Auto Scoring]** area is not checked: set the countdown time of manual scoring.
   - If **[Interval Mode]** in the **[Auto Scoring]** area is checked: set the measurement interval of automatic scoring.

18.2.4.3 Set the Timeout of Parameters

You can follow the steps below to set the timeout of manually entered parameter values:

1) On the EWS screen, click **[MEWS]** tab → **[Setup]**.
2) Set the **[EWS Data Timeout]**.

18.2.5 EWS Review

On the EWS screen, click **[Tabular Trends]** or **[Graphic Trends]** tab to view the measured/entered values and scores of all involved parameters.

18.3 Glasgow Coma Scale (GCS)

The Glasgow Coma Scale (GCS) can be used on comatose patients induced by a variety of causes to express their state of consciousness objectively. GCS scoring involves three aspects: eye opening, verbal response and motor response. The three scores add up to the GCS score.

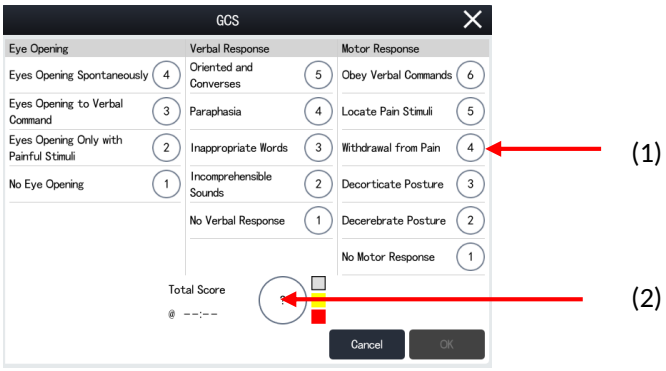
GCS scoring is intended for adult and pediatric patients.

NOTE

- **The GCS score is provided for reference only. Please make a diagnosis in combination with other clinical evidence.**
- **GCS scoring is not intended for comatose patients induced by sedative, muscle relaxant, artificial airway, drunkenness or status epilepticus.**
- **GCS scoring is not intended for people with impaired language, deaf-mute or mental disorder.**
- **GCS scoring is prone to score deviation when used on children under 5 years old or the unresponsive elderly.**

18.3.1 Enter the GCS Screen

Click **[Main Menu]** quick key → **[CAA]** → **[GCS]**.



(1) Individual Score (2) Total Score

18.3.2 GCS Scoring

1) On the GCS screen, check an option in the **[Eye Opening]**, **[Verbal Response]** and **[Motor Response]** area respectively based on the patient's actual condition.
2) Click **[OK]** to confirm the score results.

The score range and background color of each score level is listed in the table below:

Level	Score Range	Background Color	Description
Mild	13~15 points	Grey	Normal or slightly impaired brain function
Moderate	9~12 points	Yellow	Moderately or severely impaired brain function
Severe	3~8 points	Red	Brain death or vegetative

18.4 ECG 24h Summary

ECG 24h Summary provides the current patient's ECG activity statistics for the last 24 hours. On the ECG 24h Summary screen, you can view the following information:

- HR statistics;
- Arrhythmia statistics;
- Statistics of QT/QTc measurements;
- Statistics of maximum and minimum ST values for each lead;
- Pacer statistics;
- Typical ECG waveforms.

NOTE

- **ECG 24h Summary only applies to the current patient.**
- **Pacer statistics only apply to patients wearing pacemakers.**
- **The ECG summary report is designed to store, count and centrally display the real-time data measured by the Monitor.**
- **The access to ECG 24h Summary review function requires a License.**

18.4.1 Enter the ECG 24h Summary Window

- Click **[Main Menu]** quick key → **[CAA]** → **[ECG 24h Summary]**.
- Select **[ECG 24h Summary]** quick key directly.

18.4.2 Select Typical ECG Waveforms

The typical ECG waveforms under the following conditions are displayed in the Typical ECG Waveforms area:

- Maximum HR value;
- Minimum HR value;
- Four arrhythmia alarm events.

You can select a typical ECG waveform under each condition. For example, to select the typical ECG waveform of arrhythmia alarm, please:

1) Click the current ECG waveform of arrhythmia alarm;
2) Select a typical ECG waveform of arrhythmia alarm from the arrhythmia alarm events during the last 24h.

18.4.3 ECG 24h Summary Review

On the **[ECG 24h Summary]** window, you can review various ECG data:

- Click **[Full Disclosure]** to review Full-Disclosure waveforms (refer to "*Section 17.7 Full-Disclosure waveforms")* for more information.

18.5 CCHD (Critical Congenital Heart Disease) Screening

The pulse-oximetry monitoring can be used for screening for critical congenital heart disease (CCHD). CCHD screening primarily targets seven specific lesions: hypoplastic left heart syndrome, pulmonary atresia, Tetralogy of Fallot (TOF), total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia and truncus arteriosus.

This Monitor provides two set of CCHD screening rules: American Standard and Two Standards:

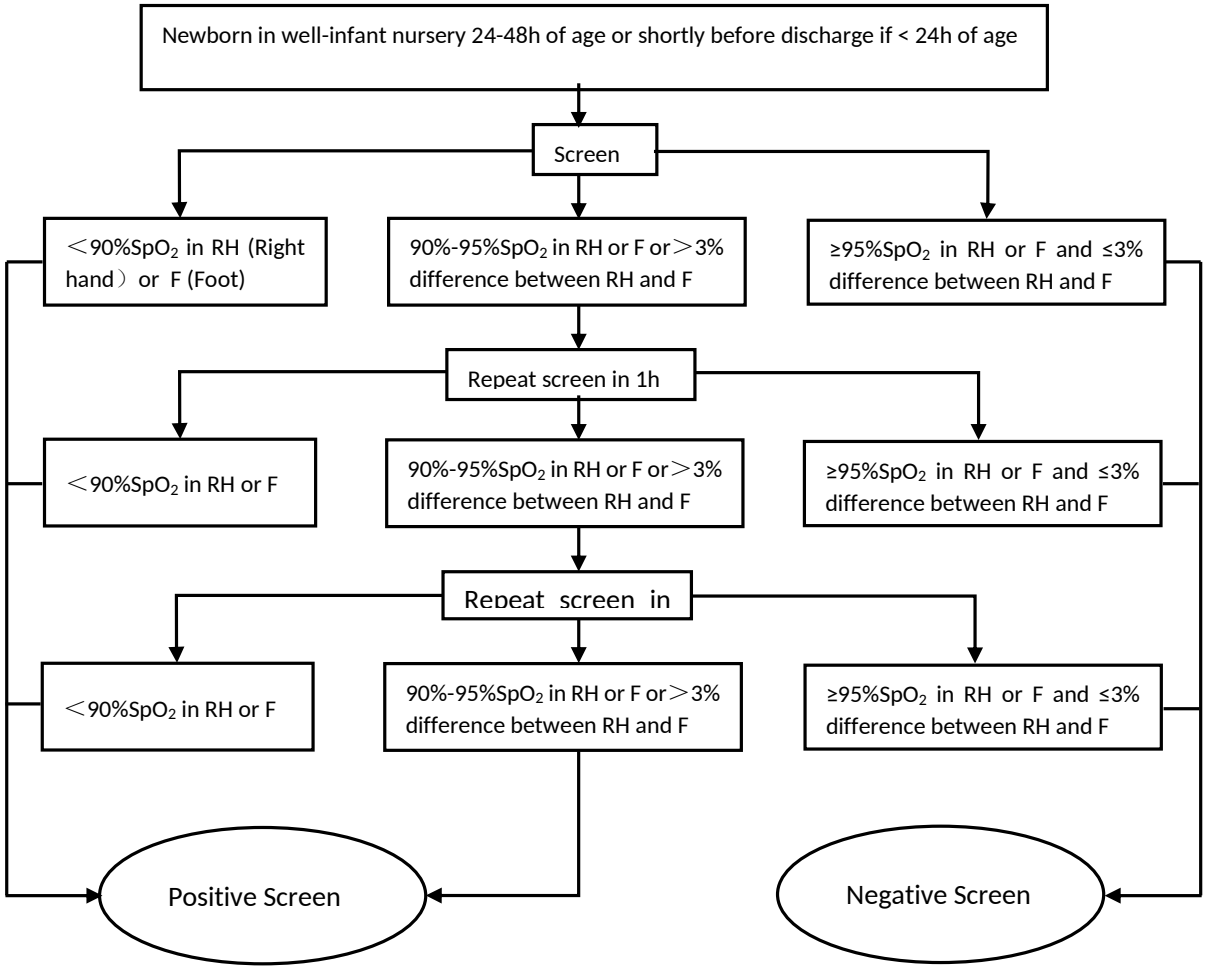
American Standard recommends that the screening for CCHD should be carried out on neonates between 24 and 28 hours after birth. Neonates who are less than 24 hours old and waiting to be discharged from the hospital should be screened for CCHD as soon as possible. The CCHD is carried out by measuring the neonatal patient's right hand and one foot for SpO_2 values, and then comparing the difference between these two values for ΔSpO_2.

Two Standards uses pulse oximetry combined with cardiac auscultation in screening for CCHD, which is recommended to be carried out to the neonates between 6 -72 hours after birth by measuring both the neonatal patient's right hand and one foot for SpO_2 values and comparing these two values for ΔSpO_2, and combining the heart murmur level for final results.

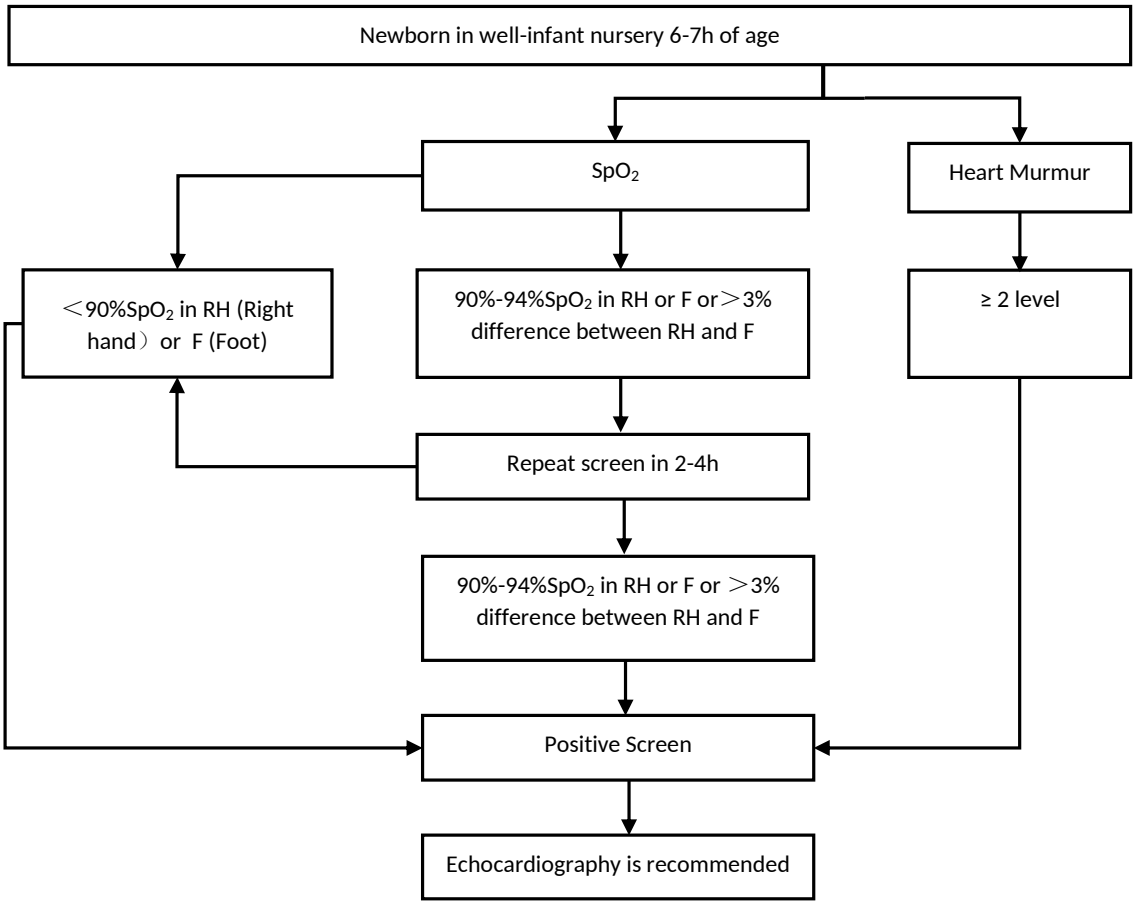
CCHD screening is only applicable to neonatal patients.

18.5.1 CCHD Detection procedure

American Standard, one of the screening rules provided in this monitor, comes from the neonatal screening procedures recommended by a working group composed of the members designated by Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC), American Academy of Pediatrics (AAP), American College of Cardiology Foundation (ACCF) and American Heart Association (AHA). The procedure is shown below:



Another screening rule of CCHD is Two Standards (SpO_2 and Heart Murmur), which follows the procedure as shown below:

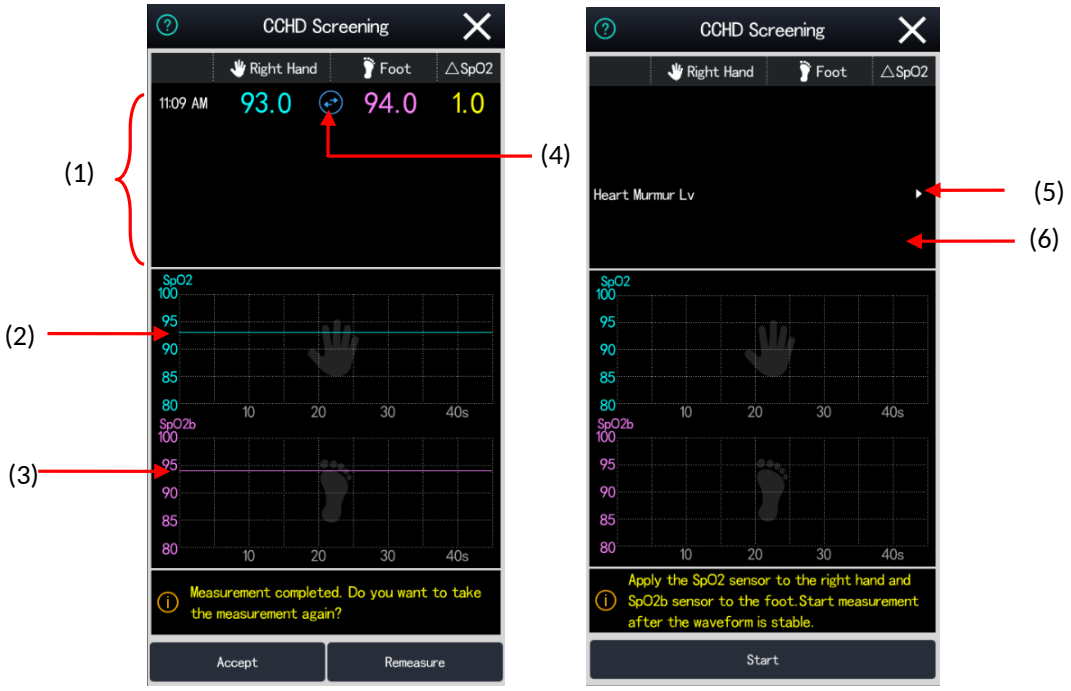


18.5.2 Select CCHD Screening Rule

The user is allowed to select either the American Standard or Two Standards by:

1) Select **[Main Menu]** → **[System]** → **[Maintenance]** → input Maintenance password → click Enter.
2) Select **[CAA]** tab → **[CCHD]** tab.
3) Set **[Screening Rule]**
   - **[American Standard]**: by screening SpO_2 values.
   - **[Two Standards]**: by screening SpO_2 values and heart murmur level.

The figures below show examples of CCHD screening on the Monitor. The actual results may vary depending on the operation and measurements.



American Standard **Two Standards**

(1) SpO_2 measurement values and measuring time

(2) SpO_2 value measured on the right hand

(3) SpO_2 value measured on one foot

(4) Click on this icon to switch the SpO_2 measurement values between right hand and foot if required

(5) Set heart-murmur level

(6) Screening results and recommended actions

18.5.3 Access to the CCHD Screening

You can access the CCHD Screening window in either of the following ways:

- Select **[CCHD]** quick key, or
- Select **[Main Menu]** quick key → **[CCA]** → **[CCHD]**

18.5.4 Start CCHD Screening

Only one SpO_2 module is configured in the monitor, you can measure the SpO_2 on the right hand first and then change to the foot. This screening steps can be done in the following way:

1) Enter CCHD screening, see "***Section 18.5.3 Access to CCHD Screening***" for detailed information.
2) Measure SpO_2 values
3) Check if the SpO_2 values displayed correspond to the measurement sites. If not, click the icon ⇄ to record the SpO_2 in right hand or foot.
4) Select heart murmur level if the **[Two Standards]** screening rule is applied,

5) Select **[Accept]** to acknowledge current measurement results and complete a CCHD screening.

The SpO_2 measurement result and the CCHD screening result are displayed on the CCHD screening window:

- "Positive": the CCHD screening is completed.
- "Negative": the CCHD screening has failed and Echocardiography is strongly recommended.
- "Repeat screen in 1 hour" (American Standard) : the CCHD screening is not confirmed and the user should repeat the measurement in one hour.
- "Repeat screen in 2-4 hour" (Two Standards): the CCHD screening is not confirmed and the user should repeat the measurement after 2-4 hours.

NOTE

- **During the measurement of SpO_2, keep the newborn calm.**

18.5.5 Screening again

If you have doubts about the screening result, please repeat the CCHD screening again. This action will clear the measurement result and the screening result.

Select **[Repeat CCHD]** button, click **[Yes]** to start again.

Chapter 19 Calculation

19.1 Overview

This monitor provides the calculation function. The calculated result is not patient data directly measured, but is result calculated by the monitor according to appropriate data provided by the user.

Calculations that can be performed on the monitor include:

- Drug calculation
- Hemodynamic calculation
- Ventilation calculation
- Oxygenation calculation
- Renal function calculation

19.2 Safety Precautions

⚠ WARNING

- **The drug dose must be decided by the attending physician.**
- **Please check the correctness of entered parameter values and the suitability of calculation results carefully when performing calculations. We shall not be held liable for any consequences caused by incorrect inputs or operations.**

19.3 Drug calculation

The monitor provides the calculation and titration display functions for 15 drugs

Types of drugs that can be calculated in the system include: Aminophylline, Dobutamine, Dopamine, Epinephrine, Heparin, Isuprel, Lidocaine, Nipride, Nitroglycerin, and Pitocin; besides, drugs A, B, C, D and E are provided to represent any drug.

19.3.1 Drug Calculation Steps

1) Follow either path described below to go to the Drug Calculate page:
   - Click **[Calculations]** quick key → **[Drug]** tab; or
   - Click **[Main Menu]** quick key → **[Calculations]** → **[Drug]**.

2) Set the **[Drug Name]**, **[PAT Type]** and **[Weight]**.
3) Enter the values of Amount, Drop Size and Dose.
4) Click **[Calculate]** to start the calculation.

NOTE

- **When you arrive at the Drug Calculate page for the first time, the values of Patient Category and Weight recorded in the Patient Management menu will be automatically called into the Drug Calculation menu. However, you can still set the Patient Category and Weight manually, which will not change their values recorded in the Patient Management menu.**

19.3.2 View the Titration Table

The titration table shows the relevant information of the current drug. Follow the steps below to view the titration table, where you can check the dose received by the patient at different infusion rates.

1) Follow either path described below to go to the Drug Calculate page:
   - Click **[Calculations]** quick key → **[Drug]** tab; or
   - Click **[Main Menu]** quick key→ **[Calculations]** → **[Drug]**.
2) Click **[Titration]** tab.
3) Click **[Dose]** at the bottom to choose a unit for the drug dose in the titration table.
4) Click **[Step]** to set the interval between two adjacent items in the titration table.

You can choose a sorting method for the titration table. Set **[Basic]** to:

- **[Dose]**: to sort the titration table in order of increasing dose;
- **[Infusion Rate]**: to sort the titration table in order of increasing infusion rate; the step size of infusion rate is 0.01;

19.3.3 Drug Calculation Formula

Drug dose is calculated by the following equation:

Concentr. = Amount / Volume

Infusion Rate = Dose / Concentr.

Duration = Amount / Dose

19.4 Hemodynamic Calculation

19.4.1 Calculation Steps

1) Follow either path described below to go to the Hemodynamic page:
   - Click **[Calculations]** quick key → **[Hemodynamic]** tab; or
   - Click **[Main Menu]** quick key → **[Calculations]** → **[Hemodynamic]**.
2) Enter the correct value of each parameter. For the patient being monitored, the Monitor will take the measured value as the input value and call the height and weight value from the entered patient information.
3) Click **[Calculate]** to calculate the value of each output parameter.

On the Hemodynamic page, you can also perform the following operations:

- Click **[Range]** to display the normal range of each parameter. Then you can check whether the calculation results fall within the normal range.
- Click **[Unit]** to display the unit of each parameter.

19.4.2 Input Parameters

Abbreviation	Unit	Full Name
Height	cm	Height
Weight	kg	Weight
HR	bpm	Heart rate
C.O.	l/min	Cardiac output
PAWP	mmHg	Pulmonary artery wedge pressure
MAP	mmHg	Artery mean pressure
MPAP	mmHg	Pulmonary artery mean pressure
CVP	mmHg	Central venous pressure
EDV	ml	End-diastolic volume

19.4.3 Output Parameters

Abbreviation	Unit	Full Name
C.I.	L/min/m2	Cardiac index
BSA	m2	Body surface area

SV	ml	Stroke volume
SVI	ml/m2	Stroke index
SVR	DS/cm5	Systemic vascular resistance
SVRI	DS.m2/cm5	Systemic vascular resistance index
PVR	DS/cm5	Pulmonary vascular resistance
PVRI	DS.m2/cm5	Pulmonary vascular resistance index
LCW	Kg.m	Left cardiac work
LCWI	Kg.m/m2	Legt cardiac work infex
LVSW	g.m	Left ventricular stroke work
LVSWI	g.m/m2	Left ventricular stroke work index
RCW	Kg.m	Right cardiac work
RCWI	Kg.m/m2	Right cardiac work infex
RVSW	g.m	Right ventricular stroke work
RVSWI	g.m/m2	Right ventricular stroke work index
EF	%	Ejection fraction

19.5 Renal Function Calculation

1) Follow either path described below to go to the Renal page:
   - Click **[Calculations]** quick key → **[Renal]** tab; or
   - Click **[Main Menu]** quick key → **[Calculations]** → **[Renal]**.
2) Enter the correct value of each parameter.

For the patient being monitored, the height and weight value will come from the entered patient information.

3) Click **[Calculate]** to calculate the value of each output parameter.

On the Ventilation page, you can also perform the following operations:

- Click **[Range]** to display the normal range of each parameter. Then you can check whether the calculation results fall within the normal range.
- Click **[Unit]** to display the unit of each parameter.

19.5.1 Input Parameters

Abbreviation	Unit	Full Name
URK	mmol/L	Urine pstassium
URNa	mmol/L	Urinary sodium
Urine	ml/24h	Urine
Posm	mOsm/kgH_2O	Plasm osmolality
Uosm	mOsm/kgH_2O	Urine osmolality
SerNa	mmol/L	Serum sodium
Cr	μmol/L	Creatinine
UCr	μmol/L	Urine creatinine
BUN	mmol/L	Blood urea nitrogen
Height	Cm	Height
Weight	Kg	Weight

19.5.2 Output Parameters

Abbreviation	Unit	Full Name
URNaEx	mmol/24h	Urine sodium excretion
URKEx	mmol/24h	Urine potassium excretion
Na/K	%	Sodium potassium ratio
CNa	ml/24h	Clearance of sodium
Clcr	ml/min	Creatinine clearance rate
FENa	%	Fractional excretion of sodium
Cosm	ml/min	Osmolar clearance
CH_2O	ml/h	Free water clearance
U/P osm	/	Urine to plasma osmolality ratio
BUN/Cr	mmol/L	Blood urea nitrogen creatinine ratio
U/Cr	/	Urine-serum creatinine ratio

19.6 Ventilation Calculation

1) Follow either path described below to go to the Ventilation page:
   - Click **[Calculations]** quick key → **[Ventilation]** tab; or
   - Click **[Main Menu]** quick key → **[Calculations]** → **[Ventilation]**.
2) Enter the correct value of each parameter.

For the patient being monitored, the Monitor will take the measured value as the input value. If the Monitor is connected to an anesthesia machine or ventilator, the patient parameter values that support calculation will be automatically loaded.

3) Click **[Calculate]** to calculate the value of each output parameter.

   On the Ventilation page, you can also perform the following operations:
   - Click **[Pressure Unit]**, and the corresponding parameter values will be converted and refreshed automatically.
   - Click **[Range]** to display the normal range of each parameter. Then you can check whether the calculation results fall within the normal range.
   - Click **[Unit]** to display the unit of each parameter.

19.6.1 Input Parameters

Abbreviation	Unit	Full Name
FiO_2	%	Percentage fraction of inspired oxygen
RR	Rpm	Respiration rate
$PeCO_2$	mmHg	Partial pressure of mixed expiratory CO_2
$PaCO_2$	mmHg	Partial pressure of carbon dioxide in the arteries
PaO_2	mmHg	Partial pressure of oxygen in the arteries
TV	Ml	Tidal volume
RQ	None	Respiration quotient
ATMP	mmHg	Atmospheric pressure

19.6.2 Output Parameters

Abbreviation	Unit	Full Name
PAO_2	mmHg	Partial pressure of oxygen in the alveoli
$AaDO_2$	mmHg	Alveolar-arterial oxygen difference
Pa/FiO_2	mmHg	Oxygenation ratio
a/AO_2	%	Arterial to alveolar oxygen ratio
MV	L/min/m2	Minute volume
Vd	Ml	Volume of physiological dead space
Vd/Vt	%	Physiologic dead space in percent of tidal volume
VA	L/min	Alveolar volume

19.7 Oxygenation Calculation

1) Follow either path described below to go to the Oxygenation page:
   - Click **[Calculations]** quick key → **[Oxygenation]** tab; or
   - Click **[Main Menu]** quick key → **[Calculations]** → **[Oxygenation]**.
2) Enter the correct value of each parameter. For the patient being monitored, the Monitor will take the measured value as the input value and call the height and weight value from the entered patient information.
3) Click **[Calculate]** to calculate the value of each output parameter.

On the Oxygenation page, you can also perform the following operations:

- Click **[OxyCont Unit]**, **[Hb Unit]** and **[Pressure Unit]** respectively, and the corresponding parameter values will be converted and refreshed automatically.
- Click **[Range]** to display the normal range of each parameter. Then you can check whether the calculation results fall within the normal range.
- Click **[Unit]** to display the unit of each parameter.

19.7.1 Input Parameters

Abbreviation	Unit	Full Name
C.O.	l/min	Cardiac output
FiO_2	%	Percentage fraction of inspired oxygen
$PaCO_2$	mmHg	Partial pressure of carbon dioxide in the arteries

PaO_2	mmHg	Partial pressure of oxygen in the arteries
SaO_2	%	Arterial oxygen saturation
PvO_2	mmHg	3+Partial pressure of oxygen in venous blood
SvO_2	%	Venous oxygen saturation
Hb	g/L	Hemoglobin
CaO_2	ml/L	Arterial oxygen content
CvO_2	ml/L	Venous oxygen content
VO_2	ml/min	Oxygen consumption
RQ	/	Respiration quotient
ATMP	mmHg	Atmospheric pressure
Height	Cm	Height
Weight	Kg	Weight

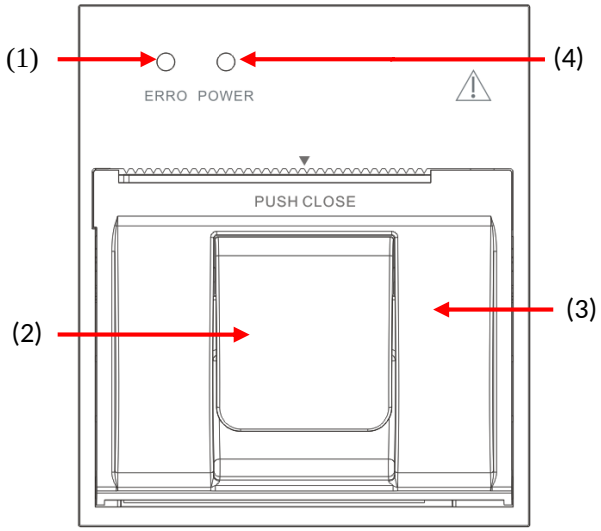
19.7.2 Output Parameters

Abbreviation	Unit	Full Name
BSA	m2	Body surface area
VO_2 calc	ml/min	Oxygen consumption
$C(a\text{-}v)O_2$	ml/L	Arteriovenous oxygen content difference
O_2ER	%	Oxygen extraction ratio
DO_2	ml/min	Oxygen transport
PAO_2	mmHg	Partial pressure of oxygen in the alveoli
$AaDO_2$	mmHg	Alveolar-arterial oxygen difference
CCO_2	ml/L	Capillary oxygen content
Qs/Qt	%	Venous admixture
C.O.calc	L/min	Calculated cardiac output

Chapter 20 Record

20.1 Description of Recorder

This monitor can be equipped with a thermal arraycorder, which supports a variety of recording types and can output patient information, measurement data, and review up to 3-channel waveforms.



(1) Fault alarm light (2) On/Off latch lock (3) Recorder door (4) Power indicator

20.2 Start Recording

20.2.1 Start Recording Manually

- Click "" in the current menu or window to start recording.

20.2.2 Start Recording Automatically

You can set the recorder to start recording automatically in the following cases:

- In timed recording case. (refer to "*Section 20.4 Set the Recorder*").
- When any parameter alarm occurs (refer to "*Section 20.5 Set to Automatic Recording*").

20.3 Stop Recording

20.3.1 Stop Recording Manually

Stop recording manually by any of the following ways:

- In the recording process, click "  " to stop recording.
- Enter the **[Record Setup]** menu to click **[Clear Record Task]**. (refer to ***"Section 20.6 Clear Record Task"***).

20.3.2 Stop Recording Automatically

The Recorder will stop recording automatically in the following cases:

- The recording task has been completed;
- The recorder has run out of paper; or
- The recorder fails to work properly due to a technical fault.

20.4 Set the Recorder

1) Click **[Main Menu]** quick key → **[Report]** → **[Record Setup]**.
2) Set the **[Record Wave1]**, **[Record Wave2]** and **[Record Wave3]** and select their waveform labels from the pop-up list. The recorder can output up to 3 waveforms at a time.
3) Set the **[RT Record Time]**.
4) Set the **[Timed Record Interval]**. The recorder will automatically start recording at the selected interval.
5) Set the **[Record Speed]**. This set value will be applied to all recording tasks involving waveform.

20.5 Set to Automatic Recording

The default value of **[Print on Alarm]** is **[Printer]**. To use the recorder to print parameter alarms, follow the steps below to set **[Print on Alarm]** to **[Recorder]**:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]** and enter the maintenance password.
2) Click **[Alarm]** tab → **[Other]** tab.
3) Set **[Print on Alarm]** to **[Recorder]**.

Besides, you need to follow the steps below to enable the parameter alarm function:

1) Follow any path described below to go to the Alarm Setup page:
   - Click **[Alarm Setup]** quick key;
   - Click the corresponding parameter tile or waveform tile → **[Alarm]** tab; or
   - Click **[Param Setup]** quick key, select the desired parameter and then click **[Alarm]** tab.

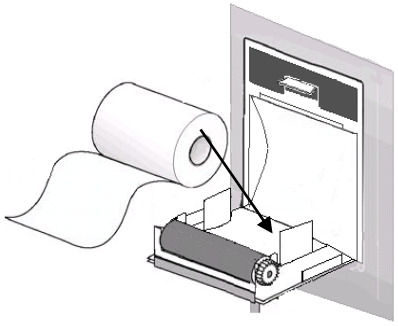
2) Enable **[Alarm Output]**.

20.6 Clear Record Task

1) Click **[Main Menu]** quick key → **[Report]** → **[Record Setup]**.
2) Click **[Clear Record Task]** to clear all reports to be output and to stop the current recording task.

20.7 Install Recording Paper

1) Operate the latch to open the recorder door.
2) Remove the empty paper core to load new roll paper, and then fix the paper core back to the paper clip.
3) The paper will be ejected from the bottom to cross the top of recorder door. Make sure at least one inch of paper will stretch beyond the edge of recorder door.
4) Turn the recorder door upward to close it tightly.
5) Start recording in order to check whether the paper is loaded correctly.
6) If the printing process fails to be initiated, the paper may have been loaded upside down. Try to reload the paper.



Install Recording Paper

CAUTION

- **Load paper carefully; otherwise the thermal print head may get damaged.**
- **During output by the recorder, it is not allowed to pull the record paper outward with force; otherwise the recorder may get damaged.**
- **Do not keep the recorder door open except for paper change or troubleshooting.**

20.8 Clear Jammed Paper

If the recorder makes any abnormal sound during operation or the record paper outputs abnormally, please check to see if any paper is jammed. If yes, please clear it according to the following steps:

1) Open the recorder door.
2) Take out the record paper, and cut off the crease part.
3) Reload the record paper, and close the recorder door.

20.9 Recorder Cleaning

After long-term use of the recorder, scraps of paper and impurities will be accumulated on the print head, which will affect the quality of recording and the service life of print head and roll shaft.

Cleaning:

1) Prior to cleaning, measures should be taken to prevent the device from being damaged by static electricity.
2) Open the recorder door; take out the record paper, and use a cotton ball to dip an appropriate amount of alcohol.
3) Gently wipe the surface of the thermal part of print head.
4) When the alcohol becomes completely dry, reload the record paper and close the recorder door.

NOTE

- **Do not use any materials (e.g., abrasive paper) that can damage the thermal part.**
- **Do not squeeze the thermal print head with force.**

Chapter 21 Print

21.1 Printer

The Monitor can output patient reports through USB cable connected printer or networked printer. Currently, the monitor supports the following types of printers that complied with IEC 60950-1 and relevant safety standards.

Specification of reports printed by the printer:

- Paper: A4
- Resolution: 300dpi
- Single/double-sided: Support both single and double-sided printing, if supported by the printer.

NOTE

- **For instructions on the printer, please see the documentation accompanied with the printer. This monitor may support more printers with the upgrade of the product, for which no prior notice will be provided. If you have any question about your printer, please feel free to contact us.**

21.2 Set the Printer Type

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key;
2) Click **[Print]** tab;
3) Set **[Printer Type]** to:
   - **[USB]**: to print reports through USB cable connected printer directly; or
   - **[NET]**: to print reports after setting the printer properties (refer to "***Section 21.3 Set the Networked Printer***").

21.3 Set the Networked Printer

The reports stored on the Monitor can be printed through a networked printer. Follow the steps below to set the networked printer:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key;
2) Click **[Print]** tab;

3) Set the **[Printer IP Address]**: click the "" button on the far right of the printer IP address input box; on the pop-up page, enter the IP of any printer in the LAN as the printer of the Monitor;
4) Set the **[Paper Size]**.

21.4 Manual Printing

21.4.1 Start Printing on the Current Page

To print the real-time report, click **[Realtime Print]** quick key or go to the **[Normal Report]** page to click **[Realtime Report]** (refer to "*Section 21.4.2 Print Normal Reports*").

21.4.2 Print Normal Reports

Normal reports include:

- ECG Report;
- Real-time Report;
- Tabular Trends Report;
- Graphic Trends Report.

Follow the steps below to print normal reports:

1) Click **[Main Menu]** quick key → **[Report]** → **[Normal Report]**.
2) Select the report tab to be printed.
3) Check the print settings.
4) Click **[Print]**.

21.5 Automatic Printing

1) Follow any path described below to select a parameter alarm tab, such as **[Alarm]** tab:

- Click **[Alarm Setup]** quick key;
- Click the corresponding parameter tile or waveform tile and then select an alarm tab; or
- Click **[Main Menu]** quick key → **[Parameters]** → **[Setup]**, select the desired parameter and then select an alarm tab.

2) Enable the desired parameter and the **[Alarm Output]** option.

When any alarm occurs to such parameter, the printer will be started automatically to print the waveform data of such parameter.

21.6 Set the Printed Report

21.6.1 Set the ECG Report

1) Click **[Main Menu]** quick key → **[Report]** → **[Normal Report]**.
2) Click **[ECG Report]**.
3) Set the desired menu items.

21.6.2 Set the Realtime Report;

1) Click **[Main Menu]** quick key → **[Report]** → **[Normal Report]**.
2) Click **[Realtime Report]**.
3) Set the desired menu items.

21.6.3 Set the Tabular Trends Report

1) Click **[Main Menu]** → **[Report]** → **[Normal Report]**.
2) Click **[Tabular Trends Report]**.
3) Set the desired menu items.

21.6.4 Set the Graphic Trends Report

1) Click **[Main Menu]** → **[Report]** → **[Normal Report]**.
2) Click **[Graphic Trends Report]**.
3) Set the desired menu items.

21.6.5 set the NIBP List Report

1) Click **[Main Menu]** → **[Report]** → **[Normal Report]**.
2) Click **[NIBP List Report]**.
3) Set the desired menu items.

21.6.6 Printer Out of Paper

When the printer is out of paper, no response will be given to the print request sent; when there are too many tasks without response, printer abnormality may be caused. At this moment, please properly load paper into the printer and resend the print request; when necessary, restart the printer.

Therefore, please make sure there is enough paper in the printer before sending a print request.

Chapter 22 Battery

22.1 Overview

The monitor is equipped with a built-in rechargeable battery. When AC power supply is connected, the battery can be charged automatically till full no matter whether the device is turned on or not. In the event of unexpected power outage, the system will automatically use the battery to supply voltage, thus to avoid interruption of device operation. After AC power supply is cut off, the battery indicator light blinks, indicating the battery is being used to supply voltage, and device operation will not be affected.

The Battery icon shown on the screen indicates the current battery status;

 indicates battery level is full.

 indicates battery level is not full.

 indicates the battery is being charged.

 indicates absence or damage of the battery.

WARNING

- **Improper replacement of the lithium battery will result in unacceptable risks.**
- **Replacement of the lithium battery by unprofessional personnel may result in risks.**
- **Battery electrolyte is hazardous. In case that battery electrolyte comes into contact with your skin or enters your eyes, please wash with clean water immediately and seek medical advice.**
- **Please keep the battery out of the reach of children.**
- **When the battery is used for operation, the monitor will power off automatically when the battery level is low.**

NOTE

- **If the battery is to be left unused for a long period of time (More than 3 months), please remove the battery and keep it properly.**
- **If the device is provided with a built-in battery, the battery must be charged after each use to ensure sufficient battery reserve.**

22.2 Install Battery

The Monitor's battery must be installed and replaced by the maintenance personnel trained and authorized by us.

⚠ WARNING

- **Only use battery designated by the manufacturer.**
- **Do not remove the battery when the device is working.**

22.3 Optimize and Check Battery Performance

22.3.1 Optimize Battery Performance

The battery must undergo at least two complete optimization cycles before first use. The battery's performance will gradually decrease as the time of use increases. It is recommended that you optimize the battery every three months. If it is not optimized during a long time, the displayed battery voltage level may not be accurate.

When optimizing the battery, please ensure the following:

1) Completely disconnect the monitor from the patient and stop all monitoring and measurement.
2) Put the battery for optimization in the battery case of the device.
3) Please ensure that the battery is charged uninterruptedly till it is fully charged.
4) Disconnect AC power supply, and use the battery to supply voltage to the monitor till the monitor shuts down automatically.
5) Battery optimization is finished.

22.3.2 Check Battery Performance

The battery life varies with the storage and operation environments, frequency of battery discharging and use time. The battery performance will degrade gradually even if the battery is not used. A battery performance check must be performed every three months. When you suspect a battery fault, you will also need to perform a battery performance check.

For the battery performance check procedure, see steps 1 to 4 in "*Section 22.3.1 Optimize Battery Performance*". The length of discharge time reflects the performance of the battery. If the battery's power supply time is significantly lower than the time stated in the Specifications, the battery should be replaced.

NOTE

- **In order to prolong the service life of the rechargeable battery, if the battery is stored for a long period of time, it is suggested that the battery should be charged every three months to prevent excessive discharging.**
- **The voltage supply time of the battery depends on the configuration and operation of the device. For example, frequent NIBP measurement will reduce the voltage supply time of the battery.**

22.4 Battery Recycling

If the battery is obviously damaged or runs out, it should be replaced. Waste batteries should be properly recycled in accordance with applicable laws and regulations or the rules of the hospital.

WARNING

- **Do not disassemble or short-circuit the battery or place it in fire; otherwise battery fire, explosion, leakage of hazardous gas or other hazards may be caused.**

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Chapter 23 Cleaning and Disinfection

Only materials and methods listed in this chapter that are accepted by the Company can be used for cleaning or disinfection of the device. For any damage arising from use of unaccepted materials or methods, the Company will not provide any warranty.

The Company will not assume any liability for the effectiveness of listed chemicals or methods when they are used as infection control means. For infection control methods, please consult the Infection Prevention Department or an epidemiologist in your hospital. Besides, please refer to local policies that apply to your hospital and country.

23.1 Overview

This chapter describes the cleaning and disinfection methods of the monitor, plug-in box and some accessories. The cleaning and disinfection methods for other non-disposable accessories refer to the corresponding files attached with the accessories.

Please keep the device and its accessories dustless. After cleaning, please check the device carefully. If there is any evidence of ageing or damage, please stop using it immediately. If it is necessary to send back the device to Comen for repair, first clean it. Please observe the following precautions:

⚠ WARNING

- **Only use detergents and disinfectants recommended in this Instruction Manual; use of other detergents and disinfectants will result in damage to the device or safety risks.**
- **Never soak the device in any liquid.**
- **Never pour any liquid onto any part or accessory of the device.**
- **Never allow any liquid to flow into the housing.**
- **Please dilute detergent and disinfectant as specified by the manufacturer.**
- **Before cleaning the monitor, please power it off and disconnect it from the AC power supply.**
- **Never leave any disinfectant on any surface and accessory of the monitor; please use a wet cloth to clean it immediately.**
- **It is not allowed to use detergent mixture; otherwise it will be dangerous.**
- **This chapter only introduces the methods for cleaning reusable accessories. Disposable accessories should not be reused after cleaning and disinfection to avoid cross infection.**
- **To protect the environment, disposable accessories must be recycled or dealt with properly.**
- **Never soak the sensor or connector in any solution for cleaning or disinfection.**
- **DO NOT touch the metal connectors for avoiding corrosion when cleaning and disinfecting the device**

and its accessories.

- After cleaning, if the sensor cable is damaged or shows any evidence of ageing, it should be replaced with a new cable.
- High-temperature sterilization of the monitor and all accessories is not allowed.
- Never use EtO (ethylene oxide) to disinfect the monitor.
- Do not use any frictional material, bleaching powder or strong solvent (e.g., acetone or detergent containing acetone).
- In order to prevent the entry of cleaning solution and dust into the ISA gas analyzer via LEGI port, the Nomoline sampling line should always be connected when cleaning the ISA analyzer. Never soak the ISA sidestream gas analyzer in any liquid for disinfection.
- The Nomoline sampling line is not a sterile device. In order to avoid damage, please do not sterilize any part of the sampling line under high pressure.
- Before cleaning the IRMA sensor, please remove the disposable IRMA airway adapter. Never disinfect the IRMA sensor or soak it in any liquid.
- The IRMA O_2 battery and the IRMA airway adapter are not sterile devices. In order to avoid damage, do not sterilize the device under high pressure.

⚠ CAUTION

- If you carelessly pour any liquid onto the device or any accessory, please contact the maintenance personnel or our Company immediately.
- If the device gets damped accidentally, put it in a ventilated place and then contact maintenance personnel or our company immediately.

23.2 Cleaning of Monitor and Modules

The monitor and modules should be kept clean. It is suggested that the external surface of the housing should be cleaned frequently; especially in environments with tough conditions or very windy and dusty places, the cleaning frequency should be increased. Prior to cleaning, please first consult or understand relevant rules of your hospital on device cleaning. Detergents recommended: water, alcohol (75%).

Cleaning steps:

1) Power the device off, and unplug the power cord.
2) Use a soft cloth with a proper amount of detergent to wipe outside shells of the device and plug-in box. Take care of not touching their connectors and metal parts.
3) Use a soft cloth dipped with an appropriate amount of detergent to wipe the display screen of the device.
4) Use a soft, dry cloth to remove residual detergent.
5) Put the device in a cool, well-ventilated environment to air-dry it.

23.3 Disinfection of Monitor and Modules

The device and modules are disinfected only when it is considered necessary in the hospital's maintenance plan. Please clean them before disinfection.

Disinfectants recommended: OPA (5.5g/L), 70% isopropanol, 70% n-propanol, 2% glutaraldehyde, 3% hydrogen peroxide, 0.5% sodium hypochlorite solution.

23.4 Cleaning and Disinfection of Accessories

Prior to cleaning, please first consult or understand relevant rules of your hospital on device cleaning. The accessories are disinfected only when it is considered necessary in the hospital's maintenance plan. Please clean accessories before disinfection.

23.4.1 Cleaning and Disinfection of BP Cuff

Detergents recommended: water, alcohol (75%)

Disinfectants recommended: OPA (5.5g/L), 70% isopropanol, 70% n-propanol, 3% hydrogen peroxide, 0.5 % sodium hypochlorite solution.

- Prior to cleaning, the gasbag must be taken out.
- The cuff can be washed by machine or hand with detergent, whereas hand wash can prolong its service time. The gasbag can be cleaned using a wet cloth dipped with clean water. Naturally air-dry it after cleaning.
- The cuff can be disinfected using a wet cloth dipped with detergent. Long-term use of disinfectants may result in color fading or discoloration of the cuff.

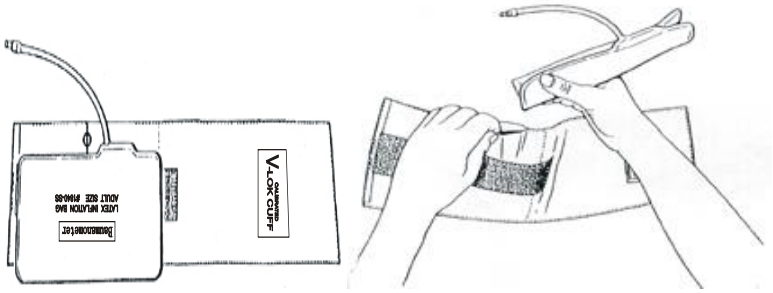
WARNING

- **Do not squeeze the rubber tube on the cuff.**
- **During cleaning, only wipe the external surface of the connector socket; never wipe its internal surface.**
- **When cleaning the gasbag, care should be taken not to allow any liquid to flow into the gasbag.**
- **It is forbidden to dry-clean the cuff.**
- **The disposable cuff can be cleaned with soap to control infection.**

After cleaning, please reinstall the gasbag into the cuff according to the following steps.

1) To reinstall the gasbag into the cuff, first put the gasbag at the head of the cuff so that the rubber tube can line up with the big opening of the long end of the cuff;

2) Then vertically curl up the gasbag and insert it into the big opening of the cuff; hold the rubber tube and the cuff, and shake the entire cuff till the gasbag is in position.
3) Lead the rubber tube into the cuff, and run it through the liner via the small hole. See the figure below:



23.4.2 Cleaning and Disinfection of other accessories

23.4.2.1 Cleaning of accessories

Cleaning steps:

1) Use a soft cloth dipped with an appropriate amount of detergent to wipe the accessories.
2) You can use a soft, dry cloth to remove residual detergent.
3) Put the accessories in a cool, well-ventilated environment to air-dry it.

See the table below for detergents recommended:

Part for Cleaning	Detergent
ECG cable, Temp sensor, IBP cable, CO_2 extended cable, C.O. cable, Comen SpO_2 sensor	water, alcohol (75%)
Masimo SpO_2 sensor, Nellcor SpO_2 sensor, Comen SpO_2 sensor, and relative cables	water, alcohol (75%)
NIBP airway tube	water, alcohol (75%)

23.4.2.2 Disinfection of accessories

See the table below for disinfectants recommended:

Part for Disinfection	Disinfectant
ECG cable, Temp sensor, IBP cable, CO_2 extended cable, C.O. cable, Comen SpO_2 sensor	OPA (5.5g/L), 70% isopropanol, 70% n-propanol, 2% glutaraldehyde, 3% hydrogen peroxide, 0.5% sodium hypochlorite solution
Masimo SpO_2 sensor, Nellcor SpO_2 sensor, Comen SpO_2 sensor, and relative cables	OPA (5.5g/L), 70% isopropanol, 70% n-propanol, 2% glutaraldehyde, 3% hydrogen peroxide, 0.5% sodium hypochlorite solution
NIBP airway tube	OPA (5.5g/L), 70% isopropanol, 70% n-propanol, 2% glutaraldehyde, 3% hydrogen peroxide, 0.5% sodium hypochlorite solution

23.5 Sterilization

DO NOT sterilize the monitor, supporting products and accessories unless otherwise stated in the accompanying instructions.

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Chapter 24 Maintenance

24.1 Maintenance Checks

Before use of the monitor, or every 6-12 months or after each maintenance or upgrade, a comprehensive check, including functional safety check, of the device should be carried out by qualified technical maintenance personnel having received training.

If there is any evidence of functional failure of the device, it is not allowed to use this monitor for patient monitoring. Please contact our company or a biomedical engineer of your hospital.

All safety checks or maintenance work requiring disassembly of the device should be performed by professional maintenance personnel; operation by unprofessional personnel may result in malfunction of the device or safety hazards, and may also endanger personal safety.

Upon request by the user, Comen will conditionally provide relevant circuit diagrams to help the user to repair user-serviceable components of the device by appropriate and qualified technicians.

⚠ WARNING

- **The hospital or organization using this monitor should establish a sound maintenance plan; failure to do so may result in malfunction of the device and unpredictable consequences, and may also endanger personal safety.**
- **DO NOT use the monitor when finding its outer shell crack for preventing electric shock caused by leakage current. Contact maintenance personnel to deal with it.**
- **DO NOT refit the device without permission.**
- **No parts on the device can be repaired by the user. Contact maintenance personnel if needed.**
- **All safety checks or maintenance work requiring disassembly of the device should be performed by professional maintenance personnel; operation by unprofessional personnel may result in malfunction of the device or safety hazards, and may also endanger personal safety.**
- **DO NOT disassemble the battery, short circuit it, place it in an environment above 60°C or burn it. These operations may cause the battery to burn, explode, leak or become hot, resulting in personal injury.**
- **The maintenance personnel should have certified qualifications and be familiar with the device.**

24.2 Maintenance Plan

The following tasks can be fulfilled only by professional maintenance personnel recognized by the Company. If the following maintenance is needed, please timely contact the maintenance personnel. Prior to test or maintenance, the device must be cleaned and disinfected.

Test and Maintenance Items		Frequency
Visual inspection and performance inspection		
Visual inspection		Before first use every day
Parameter module performance inspection and calibration		1. When measurement inaccuracy is suspected 2. When the relative module is maintained or replaced. 3. At least once every year for CO_2 module and AG module 4. At least once every two years for other modules
Analog output test		When the malfunction of analog output is suspected
Defibrillation Synchronization test		When the malfunction of Defibrillation Synchronization is suspected
Nurse Call test		When the malfunction of nurse call is suspected
Safety inspection		
Perform safety inspection according to GB9706.1/IEC 60601-1		1. When the power module is maintained or replaced 2. When the monitor drops down 3. At least once every two years or as needed
Other inspections		
When the device starts		Before use every time
Recorder test		Before first use When the recorder is maintained or replaced
Network printing test		After the initial installation When the printer is maintained or replaced
System integrated test		1. After the initial installation 2. When the integrated device is maintained or replaced
Battery inspection	Function test	1. After the initial installation 2. After the battery is replaced
	Performance test	Every three months or the battery running time is shortened noticeably.
NIBP leakage test		At least once every two years or as needed.
NIBP verification		At least once every two years or as needed.
ECG calibration		At least once every two years or as needed.
IBP calibration		At least once every two years or as needed.
Mainstream and sidestream CO_2 calibration and performance check		At least once every two years or when measurement inaccuracy is suspected of.
Battery		Refer to the battery-related chapter in this manual.

24.3 Service life of Reusable accessories

Name	Service life
ECG lead cable	2years
Comen SpO_2 sensor	2 years
Nellcor/Masimo SpO_2 sensor	4380 hours
Reusable BP cuff	18 months
Temp sensor	2 years
CO_2 module, CO_2 sensor,AG module	5 years
C.O. (cardiac output) cable	2 years
Injection temp sensor	2 years
IBP cable	2 years

24.4 Version information

Click **[Main Menu]** quick key → **[System]** → **[Version]** to view the system software information.

To view more version information as follows:

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and hit the Enter key.
2) Select **[Version]** tab. You can view the information of system software version, module software version, hardware version and fixed version.

24.5 Testing methods and steps

All tests and maintenance work can be fulfilled only by professional maintenance personnel recognized by the Company except the follow tasks.

- General inspection, including visual inspection and startup inspection
- Printer and recorder test
- Battery inspection

If other maintenance is needed, please timely contact the maintenance personnel.

24.5.1 Visual inspection

Perform a visual inspection of the device appearance before the first use every day. If any damage or malfunction occurs, stop use the device immediately and contact the hospital's equipment engineer or our maintenance personnel.

Visual inspection items:

- The environment and power supply meet the requirements.

- No dirt on the outer shell of the device; no crack or damage on the panel or screen.
- Power cord is not worn out and has a good insulation performance.
- The connector, plug and cable are not damaged or entangled.
- Cables are well connected with the device and modules.

24.5.2 Startup inspection

The monitor will perform a self-inspection after startup. The inspection items are listed as follows:

- The monitor can boot normally
- The alarm system works normally
- The screen displays normally

24.5.3 Recorder test

- Enable a record print task to print the waveform and report.
- Check whether the paper is fed normally
- Check whether the waveform and texts are displayed clearly and completely.

24.5.4 Network printer test

- Start the printer to print the real-time waveform and report.
- Check if the printer is connected well and working properly
- Check whether the waveform and texts printed are clearly and completely.

24.5.5 Battery inspection

Refer to *"Section 22.3 Optimize and Check Battery Performance"*.

24.5.6 Monitor disposal

When the monitor reaches the end of its service life, dispose it and its accessories according to local laws and regulations.

WARNING

- **Local regulations on the disposal of hospital waste can be followed when there is no corresponding regulation for the disposal of components and accessories.**

24.6 NIBP leakage test

The test is used to ensure the airtightness of NIBP gas circuit by detecting whether the NIBP measurement pump is leaking. NIBP leakage test should be performed once every two years or the readings seem not correct. NIBP leakage test shall be performed by the maintenance personnel.

24.7 NIBP Verify

NIBP verify should be performed once every two years or the reading displayed seems not correct. NIBP leakage test shall be performed by the maintenance personnel.

24.8 ECG Cable Test

It is recommended to conduct an ECG cable test once a year.

Test tool: ECG simulator

Specific test steps are as follows:

1. Switch to monitoring mode. If a 12-lead ECG cable is being tested, enter the 12-lead screen.
2. Connect the ECG cable to the defibrillator/monitor and connect the ECG lead wire to the ECG simulator.
3. Start the ECG simulator and select a normal ECG rhythm
4. After several seconds, check that there is a normal ECG waveform displayed and there is no **[ECG Lead Off]** technical alarm. For a 12-lead ECG cable, press the button to print a 12-lead real-time waveform and confirm the output waveforms of all leads are normal.

24.9 ECG Calibration

During the use of the monitor, ECG calibration is required when the ECG signal is inaccurate. ECG calibration should be conducted by the service personnel approved by Comen at least once a year or when you doubt any measured values.

Specific steps are as follows:

1) Enter **[Main Menu]** quick key → select **[Maintence]** from **[System]** column → enter password.
2) Select **[Module]** tab →press **[ECG Calibration]** to enter calibrating state, and button change into **[Stop ECG Calibration]**.
3) select **[Stop ECG Calibration]** to stop the calibration.
4) The monitor cannot be used to monitor the patient when ECG calibration is being performed. The prompt “ECG Calibrating” is also display on the lower left corner of the device screen.

24.10 IBP calibration

IBP calibration should be performed once every two years or the reading displayed seems not correct. IBP calibration shall be performed by the maintenance personnel.

Chapter 25 Other Functions

25.1 Safety Information

WARNING

- Use only secure Local Area Network connection. Make sure your hospital's firewall software is configured correctly, thus blocking incoming connection requests from the Internet. Improper use of network connection may cause virus infections of the Windows system and eventually malfunctions may occur.
- The following changes to the IT network require additional analysis:
  - Changes in network configuration
  - Connection and disconnection with other devices
  - Device updates and upgrades

NOTE

- Additional network security features may be established by the local security policy.
- Connection of the monitor to an IT NETWORK that includes other medical equipment could result in previously unidentified risks to the patient, operators or other function units.
- Personnel responsible for connecting this system should identify, analyze, evaluate and control these risks and be liable to verify if the system complies with IEC 60601-1. If you have any questions, please contact us.
- When you change the IT network configuration; like adding connection of other items to the IT NETWORK; or disconnecting items from the IT NETWORK; you shall follow the regulation of Local Area Network connection, and the user manual of CMS.
- If the following changes occur on the IT NETWORK, please communicate with our professional service personnel:
  - update of equipment connected to the IT NETWORK; and
  - upgrade of equipment connected to the IT NETWORK.
- The system has been verified for compatibility, and compliance for connection to a local area network (LAN) which complies with IT safety standard of IEC 60950-1/IEC 62368-1.
- The hospital LAN must be equipped with antivirus software and a firewall to supervise, defend and clean up viruses and malware.

25.2 Set Network Type

1) Select **[Main Menu]** → **[System]** → **[Maintenance]** → input Maintenance password → click Enter
2) Select **[Network Setup]** tab → **[Network Type]** → **[Network Protocol]**
   - **[CMS]**： connects Comen's Central Monitoring System.
   - **[OEM]**： connects MEDICALSYSTEM's OEM
3) Set **[Monitor]** to **[LAN1 IP]** or **[WLAN]**.

25.3 Set Wired Network

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and click the Enter key.
2) Select **[Network Setup]** tab → **[LAN1 IP]** tab.
3) Select **[Obtain IP Address Automatically]**. Or select **[Use the Following Address]**, and set **[IP Address]**, **[Subnet Mask]**, **[Gateway]**.

25.4 Set Wireless Network

1) Click **[Main Menu]** hot key → **[System]** → **[Maintenance]**, enter the maintenance password and click the Enter key.
2) Select **[Network Setup]** tab → **[WLAN]** tab.
3) Select **[Add WLAN]** tab, add your desired WLAN, and complete the settings.
4) Select **[WLAN]** and set **[SSID]**, **[Security]** and **[Password]**.
5) Select **[WLAN IP]**, input **[IP Address]**, **[Subnet Mask]** and **[Gateway]** manually.

25.5 Connect to Hospital's Information System by HL7 Protocol

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and click the Enter key.
2) Select **[Network Setup]** tab → **[HL7 Configuration]** tab.
3) Turn on the switch of **[Send Data]**, **[Send Waveforms]**, and **[Send Alarms]**as required.
4) Select **[Destination IP]** and **[Port]** to set the IP address and port of the server that receives real-time data and waveforms.
5) Set **[Data Interval]**.

Users can view the server connection status through this page.

25.6 Connect to Central Monitoring System

1) Click **[Main Menu]** quick key → **[System]** → **[Maintenance]**, enter the maintenance password and click the Enter key.
2) Set network protocol to **[CMS]** according to "*25.2. Set Network Type*".
3) Set **[Network Type]** as **[LAN 1]** or **[WLAN]** according to "*25.2. Set Network Type*".
4) Set **[Net Bed]**, **[Service IP]**, **[Modify Server Port]**.
5) Refer to Comen Central Monitoring System Instructions Manual for detailed function descriptions when the connection to the central monitoring system is established.

NOTE

- **When the WiFi is on, the wired network is not available.**
- **The Net Bed on the monitor must be unique to avoid conflicts with other Net Beds connecting to the central monitoring system.**
- **Refer to the instruction manual of our central monitoring system for details.**
- **[Time Setup] on the monitor will turn grey and cannot be operated when it is connected to the central monitoring system.**
- **The alarm delay time from alarm signal generation on the monitor to the alarm signal generation on the remote equipment is ≤3 seconds, measured at the monitor signal output connector and the input of communicator of the CMS. And alarm delay time on the monitor is about 1s.**

25.7 Remote View

Remote view means that the monitor can observe all the measured parameters on another monitor in the same network. It can observe up to 12 net beds simultaneously.

Enter **[Remote View]** screen in any of the ways listed below:

- Press **[Remote view]** quick key.
- Select **[Screen Setup]** quick key → **[Primary Screen]** tab or **[Secondary Screen]** tab (as needed) → select **[Choose Screen]** tab → **[Remote View].**

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Appendix I Accessories

Here we recommend the following accessories for the Monitor.

WARNING

- **Use the accessories of designated types only, or the Monitor may be damaged.**
- **To prevent reduced performance and cross infections, please do not reuse any disposable accessory.**
- **Check the package of accessory before using. If the package or accessory itself is damaged, please do not use.**
- **The expired or damaged accessories, if disposed of at will, will cause environment pollution and therefore must be disposed of in accordance with local laws or hospital regulations.**
- **Refer to the User Manual of accessory when use it and the working temperature must be considered.**
- **Disposable accessories must be used in the period of validity.**
- **Accessories equipped with this Monitor have been tested to verify their compliance with the Monitor in accordance with relative standards.**
- **Before monitoring patients, please check whether the accessory is compatible with the Monitor. Incompatible accessories will reduce the performance of the Monitor.**

1. ECG accessories

Name	Model/Specification	Manufacturer
ECG lead	98ME01AC458	Shenzhen Launch Electrical Co. Ltd.
ECG lead	98ME01AC457	
ECG lead	98ME01AB076	
ECG lead	98ME01EC681	
ECG lead	98ME01EC680	
ECG lead	98ME01EB075	
ECG lead	98ME01AD473	
ECG lead	98ME01AD474	
ECG lead	98ME01AD475	
ECG lead	98ME01EB477	
ECG lead	98ME01EB478	
ECG lead	98ME01EB479	
ECG lead	98ME01EB046	
ECG lead	98ME01AC658	
ECG lead	A6196-EL0	

Name	Model/Specification	Manufacturer
ECG lead	A6096-EL0	
ECG lead	A3105-EC1	APK Technology Co., Ltd
ECG lead	A5105-EC1	
ECG lead	A4020-EE1	
ECG lead	A3105-EC0	
ECG lead	A5105-EC0	
ECG lead	A4020-EE0	
ECG lead	A600C-EK2D	
ECG lead	A6196-EL1	
ECG lead	A6096-EL1	
ECG lead	CM-M01-001	Shenzhen Comen Medical Instruments Co., Ltd.
ECG lead	CM-M01-002	
ECG lead	CM-M01-003	
ECG lead	CM-M01-004	
ECG lead	CM-M01-005	
ECG lead	CM-M01-006	
ECG lead	CM-M01-007	
ECG lead	CM-M01-008	
ECG lead	CM-M01-017	
ECG lead	CM-M01-018	
ECG lead	CM-M01-019	
ECG lead	CM-M01-020	
ECG lead	CM-M01-031	
ECG lead	CM-M01-037	
ECG lead	CM-M01-033	
ECG lead	CM-M01-035	
ECG lead	CM-M01-036	
ECG lead	CM-M01-051	
ECG lead	CM-M01-052	
ECG lead	CM-M01-053	
ECG lead	CM-M01-054	
ECG lead	CM-M01-059	
ECG lead	CM-M01-060	
ECG lead	CM-M01-061	
ECG lead	CM-M01-062	
ECG lead	CM-M01-067	
ECG lead	CM-M01-068	

Name	Model/Specification	Manufacturer
ECG lead	CM-M01-069	
ECG lead	CM-M01-070	
ECG lead	CM-M01-071	
ECG lead	CM-M01-072	
ECG lead	CM-M01-073	
ECG lead	CM-M01-074	

2. SpO_2 accessories

Comen SpO_2				
Specifications	**Models**	**Part of body applied**	**Intended patient population**	**Remarks**
Comen SpO_2 probe (Adult use, finger clip type)	SAL104	Finger	Adult	Reusable
Comen SpO_2 probe (Adult use, finger clip type)	SAS104	Finger	Adult	Reusable
Comen SpO_2 probe (Pediatric use, bandage type)	SES104	Foot /Toe/Finger	Pediatric	Reusable
Comen SpO_2 cable extender	SLZ122	/	/	Reusable
Comen SpO_2 probe (Adult use, finger clip type)	A0816-SA105PV	Finger	Adult	Reusable
Comen SpO_2 probe (Adult use, finger clip type)	CM-M02-001	Finger	Adult	Reusable
Comen SpO_2 probe (Adult use, finger clip type)	CM-M02-003	Finger	Adult	Reusable
Comen SpO_2 probe (Pediatric use, finger clip type)	CM-M02-004	Finger	Pediatric	Reusable
Comen SpO_2 probe (Pediatric use, finger clip type)	CM-M02-006	Finger	Pediatric	Reusable
Comen SpO_2 probe (Adult use, finger wrap type)	CM-M02-007	Finger	Adult	Reusable

Comen SpO_2 probe (Adult use, finger wrap type)	CM-M02-009	Finger	Adult	Reusable
Comen SpO_2 probe (Pediatric use, finger wrap type)	CM-M02-010	Finger	Pediatric	Reusable
Comen SpO_2 probe (Pediatric use, finger wrap type)	CM-M02-012	Finger	Pediatric	Reusable
Comen SpO_2 probe (Adult/ pediatric/ neonate use, bandage type)	CM-M02-013	Finger/Sole	Adult/pediatric/ neonate	Reusable
Comen SpO_2 probe (Pediatric/ neonate use, bandage type)	CM-M02-014	Finger/Sole	Pediatric/ neonate	Reusable
Comen SpO_2 probe (Adult/pediatric use, ear clip type)	CM-M02-015	Ear	Adult/pediatric	Reusable
Comen SpO_2 probe (Adult/neonate use, bandage type)	CM-M02-020	Finger/Sole	Adult/neonate	Disposable
Comen SpO_2 probe (Adult use, bandage type)	CM-M02-021	Finger	Adult	Disposable
Comen SpO_2 probe (Pediatric use, bandage type)	CM-M02-022	Finger	Pediatric	Disposable
Comen SpO_2 probe (Infant use, bandage type)	CM-M02-023	Big toe	Infant	Disposable
Comen SpO_2 probe (Adult/ pediatric/ neonate use, adhesive type)	CM-M02-024	Finger/Sole	Adult/ neonate	Disposable
Comen SpO_2 probe (Adult use, adhesive type)	CM-M02-025	Finger	Adult	Disposable
Comen SpO_2 probe (pediatric use, adhesive type)	CM-M02-026	Finger	Pediatric	Disposable

Comen SpO_2 probe (Infant use, bandage type)	CM-M02-027	Big toe	Infant	Disposable
SpO_2 adapting cable	CM-M20-001	/	/	Reusable

Masimo SpO_2				
Specifications	**Models**	**Part of body applied**	**Intended patient population**	**Remarks**
Adult Reusable finger clip SpO_2 sensor	RD SET DCI	Toe/Finger	Adult/ Pediatric (>30 kg)	Reusable
Pediatric/Slender digit Reusable finger clip SpO_2 sensor	RD SET DCI-P	Toe/Finger	Adult/ Pediatric (10-50kg)	Reusable
Masimo SpO_2 sensor, Neonate use, Y- type)	RD SET YI	Foot	Neonate(<3 kg)	Reusable
Masimo Y-sheath	/	/	/	/
Masimo SpO_2 cable	CM12-RD-L	/	/	Reusable

Nellcor SpO_2				
Specifications	**Models**	**Part of body applied**	**Intended patient population**	**Remarks**
Nellcor SpO_2 probe (Adult use, finger clip type)	DS100A	Finger	Adult/ Pediatric (>40kg)	Reusable
Nellcor SpO_2 probe (Adult use, Y- type, bandage type)	D-YS	Foot /Toe/Finger	Adult/ Pediatric	Reusable
Nellcor SpO_2 cable	SLZ068	/	/	Reusable

3. Temp accessories

Description	**Models**	**Intended patient population**	**Manufacturer**
Temp sensor /Adult/pediatric/intracavity	TAE03-04	Adult/pediatric	Shenzhen LAUNCH Electrical Co. Ltd.
Temp sensor /Neonate/ intracavity	TPE03-01	Neonate	
Temp sensor /Neonate / body surface	TPS03-01	Neonate	

Temp sensor/Adult/Pediatric/body surface	TAS03-09	Adult/Pediatric	
Temp sensor/reusable / body surface	CM-M03-001	Adult	Shenzhen Comen Medical Instruments Co., Ltd.
Temp sensor/reusable / intracavity	CM-M03-002	Adult	
Temp sensor/disposable / body surface	CM-M03-005	Pediatric/ Neonate	
Temp sensor/disposable / intracavity	CM-M03-006	Pediatric/ Neonate	

4. NIBP cuff

Description	Models	Intended patient population	Remarks	Manufacturer
Blood pressure cuff	U1880S	Adults	25-35cm, Reusable	Unimed Medical Supplies. INC
Blood pressure cuff	U1881S	Pediatric	18-26cm, Reusable	
Blood pressure cuff	U1882S	Neonate	10-19cm, Reusable	
Blood pressure cuff	U1883S	Neonate	6-11cm, Reusable	
Blood pressure cuff	U1884S	Adult	46-66cm, Reusable	
Blood pressure cuff	U1885S	Small adult	20-28cm, Reusable	
Blood pressure cuff	U1869S	Large adult	33-47cm, Reusable	
Blood pressure cuff	U1889S	Large adult	33-47cm, Reusable	
Blood pressure cuff	U1681S	Neonate	3-6cm, Disposal	
Blood pressure cuff	U1682S	Neonate	4-8cm, Disposal	
Blood pressure cuff	U1683S	Neonate	6-11cm, Disposal	
Blood pressure cuff	U1684S	Neonate	7-13cm, Disposal	
Blood pressure cuff	U1685S	Neonate	8-15cm, Disposal	
Blood pressure cuff	CM-M04-001	Adult	46-66cm, reusable	Shenzhen Comen Medical Instruments Co., Ltd.
Blood pressure cuff	CM-M04-002	Adult	33-47cm, reusable	

Blood pressure cuff	CM-M04-003	Adult	25-35cm, reusable	
Blood pressure cuff	CM-M04-004	Pediatric	18-26cm, reusable	
Blood pressure cuff	CM-M04-005	Infant	10-19cm, reusable	
Blood pressure cuff	CM-M04-006	Infant	7-13cm, reusable	
Blood pressure cuff	CM-M04-007	Adult	46-66cm, reusable	
Blood pressure cuff	CM-M04-008	Adult	33-47cm, reusable	
Blood pressure cuff	CM-M04-009	Adult	33-47cm, reusable	
Blood pressure cuff	CM-M04-010	Adult	25-35cm, reusable	
Blood pressure cuff	CM-M04-011	Adult, reusable	25-35cm, reusable	
Blood pressure cuff	CM-M04-012	Pediatric	18-26cm, reusable	
Blood pressure cuff	CM-M04-013	Infant	10-19cm, reusable	
Blood pressure cuff	CM-M04-014	Infant	7-13cm, reusable	
Blood pressure cuff	CM-M04-015	Neonate	3 -6cm, disposable	
Blood pressure cuff	CM-M04-016	Neonate	4-8cm, disposable	
Blood pressure cuff	CM-M04-017	Neonate	6-11cm, disposable	
Blood pressure cuff	CM-M04-018	Neonate	7-13cm, disposable	
Blood pressure cuff	CM-M04-019	Neonate	8-15cm, disposable	

5. IBP accessories

Description	Models	Manufacturer
Abbott Invasive Blood Pressure Cable	MC06-141110-01	Shenzhen LAUNCH Electrical Co. Ltd.
Edwards Invasive Pressure Cable	MC06-141112-01	
Braun Invasive Pressure Cable	MC06-141115-01	
BD invasive pressure cable	MC06-141113-01	
Utah invasive pressure cable	MC06-141111-01	
Utah invasive pressure sensor	PT-1 1100	Copper Medical Technology CO.Ltd

Braun invasive pressure sensor	PT-1 1200	
BD invasive pressure sensor	PT-1 1300	
Edwards invasive pressure sensor	PT-1 1400	
Abbott invasive pressure sensor	PT-1 1500	

6. CO_2 accessories

Description	Models	Intended patient population/remarks
Masimo mainstream CO_2 module	4748	Masimo mainstream CO_2 module
Masimo CO_2/AG adapting cable	98ME07GC968	Masimo CO_2/AG adapting cable
Mainstream Airway adapter	CAT.NO.106220	Adult/pediatric
Mainstream Airway adapter	CAT.NO.106260	Infant
Sidestream CO_2/AG Sampling tube	3827	Adult
Sidestream CO_2/AG Sampling tube	3828	Pediatric
Sampling tube	4367	Neonate
Sidestream CO_2/AG Sampling tube	3830	Adult
Sidestream CO_2/AG Sampling tube	3831	Pediatric
Sidestream CO_2/AG Sampling tube	3832	Neonate
Sidestream CO_2/AG Sampling tube	3833	Adult
Sidestream CO_2/AG Sampling tube	3834	Pediatric
Sidestream CO_2/AG Sampling tube	3835	Adult
Sidestream CO_2/AG Sampling tube	3836	Pediatric
Sidestream CO_2/AG Sampling tube	3837	Adult
Sidestream CO_2/AG Sampling tube	3838	Pediatric
Sidestream CO_2/AG Sampling tube	3839	Adult
Comen mainstream CO_2 module	M-01	Mainstream
Sidestream CO_2 filter tube	CM-M05-001	Sidestream

Sidestream CO_2 Sampling tube	CM-M05-002	Sidestream
Sidestream CO_2 Sampling tube	CM-M05-003	Sidestream
Sidestream CO_2 Dehumidification Tube	CM-M05-004	Sidestream
Sidestream CO_2/AG Sampling tube	CM-M05-005	Adult
Sidestream CO_2/AG Sampling tube	CM-M05-006	Pediatric
Sidestream CO_2/AG Sampling tube	CM-M05-007	Neonate
Mainstream Airway adapter	CM-M05-008	Adult
Mainstream Airway adapter	CM-M05-009	Pediatric
Sidestream CO_2/AG Sampling tube	CM-M05-010	/
Respironics mainstream CO_2 module	1015928	Mainstream
Mainstream adults airway adapter	6063-00	Adult
Mainstream neonates airway adapter	6312-00	Neonate
CO_2 adapting cable	98ME07GC067	/
Sidestream Airway adapter	3473Adu-00	Adult/pediatric
Sampling tube	1103408	Adult
Sampling tube	1103409	Pediatric
Sampling tube	1103410	Neonate
Respironics CO_2 filter tube	1103416	/
Respironics CO_2 Drying tube	1103417	/
Sampling tube	1103414	Large
Sampling tube	1103415	Small

7. C.O. accessories

Description	Models	Manufacturer
C.O. cable	CM10-2P4-L30	Shenzhen LAUNCH Electrical Co. Ltd.

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1) Monitor Type

Classified by	Type
Protection against electric shock	Class I; defibrillation-proof devices with internal power supply;
Degree of protection against electrical shock	Defibrillation-proof type CF: ECG, Resp, Temp, SpO_2, NIBP, IBP, C.O; Defibrillation-proof type BF: CO_2.
Operation mode	Continuous operation equipment.
Mobile level	Portable
Protection against ingress of liquid	Main Unit: IPX1; SpO_2: IPX2
The degree of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide or within an oxygen-rich environment	Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide or within an oxygen-rich environment.

2) Environmental Specifications

Item	Specification	
Operating condition	Ambient temperature	0℃-40℃
	Relative humidity	15% -95%, non-condensing
	Barometric pressure	57.0~107.4kPa
Transportation	Protect the device against violent impact, vibration, rain and snow during transportation.	
Storage	The packaged monitor shall be kept in a well-ventilated environment free of corrosive gas with certain ambient temperature (-20℃-+60℃), relative humidity (10%-95%), non-condensing.	
Shock & Vibration (robustness)	Conform to standards of IEC 80601-2-30:2018, ISO 80601-2-55:2018, ISO80601-2-61:2017	

3) Power Supply

Item	Specification
AC input voltage	100-240V~
AC input frequency	50/60Hz
Input power	1.0-0.5A
Battery specification	This monitor is equipped with 1 lithium-ion battery. Standard battery: 10.8V ⎓ 2500mAh; Optional battery: 10.8V ⎓ 5000mAh
Battery operation time	Full battery, NIBP measurement with an interval of 15 min, environmental temperature(25±5℃), connected with 5-lead ECG cable and SpO_2 sensor, no built-in printing, and screen brightness set as 1 (lowest level): a) Standard battery (10.8V ⎓ 2500mAh): ND10/ND10A/ND10C/ND10S/ND12/ND12A/ND12C/ND12S: no less than 4 hours, ND15/ND15A/ND15C/ND15S: no less than 2.5 hours b) Single battery (10.8V ⎓ 5000mAh): ND10/ND10A/ND10C/ND10S/ND12/ND12A/ND12C/ND12S: no less than 8 hours; ND15/ND15A/ND15C/ND15S: no less than 6 hours,
Battery charging time	a) In power-off state: 10.8V ⎓ 2500mAh: about 2.5h to charge the exhausted battery to 90% of its capacity, and about 3h to 100% of its capacity. b) In power-on state: 10.8V ⎓ 2500mAh: about 4.5h to charge the exhausted battery to 90% of its capacity, and about 5h to 100% of its capacity. c) In power-off state: 10.8V ⎓ 5000mAh: about 5h to charge the exhausted battery to 90% of its capacity, and about 6h to 100% of its capacity. d) In power-on state: 10.8V ⎓ 5000mAh: about 8h to charge the exhausted battery to 90% of its capacity, and about 9h to 100% of its capacity.

4) General Specifications

Item	Specification
Dimension	ND15/ND15A/ND15C/ND15S：about 394mm×280mm×189mm ND12/ND12A/ND12C/ND12S：about 340mm×236mm×185mm ND10/ND10A/ND10C/ND10S：about 300mm×210mm×177mm
Main unit weight	ND15/ND15A/ND15C/ND15S: ≦5kg

	ND12/ND12A/ND12C/ND12S: ≦4kg ND10/ND10A/ND10C/ND10S: ≦3.5kg
Display screen	ND15/ND15A/ND15C/ND15S: size: 15 inch; Resolution: 1024×768; up to 13 waveforms can be performed. ND12/ND12A/ND12C/ND12S: size: 12.1 inch; Resolution: 800×600; up to 13 waveforms can be performed. ND10/ND10A/ND10C/ND10S: size: 10.4 inch; Resolution: 800×600; up to 13 waveforms can be performed.

5) Data Storage specifications

Name	Specifications
Trend data	240h (minimum resolution 1 second); 2400h(minimum resolution 10 minutes)
NIBP measurement	3500 groups
Alarm Event	2500groups
Waveform length	72h(for one waveform)
Arrhythmia Statistics	48h
OxyCRG events	400 events
12-lead ECG analysis	20 groups
ST review	120h

6) Record specifications

Name	Specification
Record Paper Width	50mm
Print width	48mm
Paper speed	12.5mm/s, 25 mm/s, 50mm/s
Record time	8s, 16s, 32s, Continual
No. of Waveform	Up to 3 curves
Timed Record Interval	10min, 20min, 30min, 40min, 50min, 1h, 2h, 3h, 4h and Off

7) ECG specifications

Name	Specification
Standard;	IEC 60601-2-27/IEC 60601-2-25
Lead Type	3-Lead; 5-Lead; 6-Lead, 12-Lead and Auto; Auto identification of ECG lead type is available for the monitor.
Overload Protection	Loaded with differential input-circuit voltages of 1 V peak-to-valley, no damage

Lead off detection and noise suppression current	Measurement electrode: <0.1μA Driven electrode: <900nA	
Trigger amplitude	200μV (lead II)	
Input dynamic range	Input signal amplitude	±8mV
	RTI	320mV/s
	DC offset voltage	±850mV
	Output signal variation	±10%
	Attenuation before no-display	Not lower than 50%
System noise	≤25μV (Vpp)	
Gain	1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/mV (×4) or Auto, error: <±5%. Variation range of sensitivity (when ±850mVd.c. offset voltage is applied): ±5%.	
	Gain change per minute	≤0.66%/min
	Gain change per hour	No more than ±10%
Frequency response	a) In Surgery mode: 1 Hz-20 Hz (-3.0dB~+0.4dB); b) In Monitor mode: 0.5Hz-40 Hz (-3.0dB~+0.4dB); c) In Diagnosis mode: 0.05Hz-150 Hz (-3.0dB~+0.4dB); d) In ST mode: 0.05Hz-40Hz (-3.0dB~+0.4dB).	
Sweep speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s; error: no more than ±10%	
Calibration signal	1mV; error: ±5%	
Common mode rejection	a) In Diagnosis mode: >90dB; b) In Monitor mode: >106dB; c) In Surgery mode: >106dB; d) In ST mode: >106dB.	
Pacemaker pulse rejection without overshoot	Amplitude: ±2mV~±700mV; width: 0.1ms~2.0ms; overshoot is less than $0.05a_q$, stabilization period is less than 5μs; the rise time and fall time of pulse not exceed 100μs; the pulse is applied preceding 40ms or less the QRS wave onset; the atrial pacemaker pulse precedes a ventricular pacemaker pulse by 150ms to 250 ms.	
Pacemaker pulse rejection of fast ECG signals	Min. input slew rate: 2.2V/s±15%RTI (pacer mode)	
Pacing pulse indication	ECG displays when: Amplitude: ±2mV~±700mV; width: 0.5ms~2.0ms; maximum rise time: 100μS;	No less than 0.2mV referred to input

	pulses: 100/min	
Arrhythmia types	Asystole, Vfib/Vtac, PVCs/min too high, R on T, VT>2, Run PVCs, Couplet, PVC, Bigeminy, Trigeminy, Tachy, Brady, Extreme Tachy, Extreme Brady, Missed beats, multiform PVC, V-Tach, Non-sustain V-Tach, Ventricular Rhythm, Pause, Pauses/min high, Irregular HR, Ventricular Brady, A-Fib, Pacer Not Capture, Pacer Not Pacing, Irregular HR End and A-Fib End, SVCs/min High, SVT, PAC Bigeminy , PAC Trigeminy , IPVC, VEB, Nonsus S-Tach, Atrial Rhythm, RUN SVCs, PAC Couplet, Wide QRS Tachy.	
Electrosurgery interference protection	Cut mode: 300 W; Coagulation mode: 100 W Resume normal operation mode within 10s. In compliance with the requirements in clause 202.6.2.101 of IEC 60601-2-27	
Notch Filter	a) Power frequency interference rejection ≥ 20dB; b) In Monitor/Surgery mode: 50Hz or 60 Hz notch filter; c) In Diagnosis mode: 50Hz or 60 Hz notch filter; select Strong or Weak notch filter manually.	
Differential input impedance	≥5MΩ	
Input signal	±10 mV (peak-to-peak value)	
Input offset current	≤0.1μA	
Sync defibrillation signal	Output impendence ≤100Ω Max. delay time ≤35ms (Pulse rising edge relative to R wave peak); Amplitude high level: 3.5V~5V; Pulse width: 100ms±10; Rise/Fall time ≤1ms.	
ECG analogy output signal	a. The outputs signals amplified by a factor of 1: 1000 with an error of ± 5%. b. Band width: Diagnosis mode: 0.05Hz-150 Hz; Monitor mode: 0.5Hz-40 Hz; Surgery mode: 1 Hz-20 Hz; ST mode: 0.05Hz-40Hz c. Max. delay time ≤35ms d. Gain (reference frequency 10Hz): 1V/mV (±5%)e. If **[PACE]** is turned on, pace enhancement signal provided: signal amplitude: Voh≥2.5V; pulse width: 10ms± 5%; signal rise and fall time: ≤100μs there is no pulse output; if not, pulses will be output with waveforms.	
QT/QTc Analysis	Measurement range	200ms - 800ms
	QT-HR	15 bpm-150bpm (Adu); 15bpm-180bpm (Ped, Neo);
	Measurement accuracy	QT: ±30ms QTc: not defined
	QT Measurement Time Step	4ms
HR measurement range	Adu	Range: 15~300 bpm
	Neo/Ped	Range: 15~350 bpm

and accuracy	Accuracy	±1% or ±1 bpm, whichever is greater.
	Resolution	1bpm
HR Alarm Range and Step	Alarm limit	Upper limit: 17bpm～295 bpm Lower limit: 16bpm～290 bpm Extreme Tachy: 60 bpm～300 bpm Extreme Brady: 15bpm～120 bpm
	Step	1 bpm for the range of 15bpm~40bpm, 5 bpm for 41bpm～300bpm
ST Measurement	Range	-2.5mV-+2.5mV (-25.0 mm～+25.0 mm)
	Accuracy	Within range: -0.8mV～+0.8mV; measurement error: ±0.02mV or ±10%, whichever is greater; Other range: not defined
	Resolution	0.01 mV (0.1 mm)
	Alarm limit	Upper limit: (lower limit+0.1mV) ~2.5mV; Lower limit: -2.5~(upper limit-0.1mV)
	Alarm Step	0.05mV
	ST Segment	ST Segment Could be Saved
Tall T-wave rejection	1.2mV	
Average HR calculation	As required in Section 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, the average HR is calculated as follows. If all of the last 3 RR intervals are longer than 1200ms, the average of the last 4 RR intervals is the HR. In other cases, the average of the last 12 RR intervals (with the longest interval and shortest interval excluded) is the HR.	
Heart rate accuracy and response to arrhythmia	As required in Section 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the HR is displayed as follows after the 20s stable segment: Figure 3 a) (bigeminy): 80±1bpm Figure 3 b) (slowly varying bigeminy): 60±1bpm Figure 3 c) (quickly varying bigeminy): 120±1bpm Figure 3 d) (two-way contraction): 90±2bpm	
Response time for HR changes	As required in Section 201.7.9.2.9.101 b) 5) of IEC 60601-2-27: the response time for a HR change, whether from 80bpm to 120bpm or from 80bpm to 40bpm, is less than 10s.	
Time to alarm for Tachycardia	As required in Section 201.7.9.2.9.101 b) 6) of IEC 60601-2-27, the waveform: Figure 4 a) 1 - range: 10s Figure 4 a) 0.5 - range: 10s Figure 4 a) 2 - range: 10s Figure 4 b) 1 - range: 10s Figure 4 b) 0.5 - range: 10s Figure 4 b) 2 - range: 10s	
QRS wave amplitude and	Amplitude (p-v RTI) range	0.5mV~5mV

interval range	Width range (Adu)	70ms~120ms
	Width range (Neo/Ped)	40ms~120ms
	No response for the signals below:	a) Signals with amplitude (p-v RTI) ≤ 0.15mV (except Ped mode); b) Signals with 1mV amplitude and 10ms width (except Neo/Ped mode).
Power frequency tolerance	>100μV (p-v)	
Drift tolerance	Triangle wave amplitude (p-v RTI)	4mV
	QRS wave amplitude (p-v RTI)	0.5 mV
	QRS wave amplitude width	100ms
	QRS wave repetition-rate	80bpm
Multichannel crosstalk	<5%	
Output display	Channel width	Min. 30mm
	Aspect ratio	0.4s/mV
Accuracy of signal reproduction	Total error: ±20%or ±100μV, whichever is greater Frequency response established by method A and D	
Baseline control and stability	Recovery time after reset	3s
	Drift rate within 10s	10μV/s
	Baseline drift within 1h	No more than 500μV
	Baseline drift under normal operating temperature	No more than 50μV/℃
HR measurement min. signal	HR measurement trigger threshold level: 200μV	
Alarm delay for cardiac standstill (asystole) and high/low HR	<10s	
Resting 12-lead ECG interpretation		
Method	Multiple lead- ECG analysis	
ECG sampling and amplitude quantisation	ECG sampling rate	500 Hz
	Skew vetween channels	Less than 100μs
	Amplitude quantisation	≤5μV/LSB
ECG report output	Heart rate(bpm), PR interval (ms), QRS duration (ms), QT/QTC interval (ms), P/QRS/T axes(°), RV5/SV1, RV5+SV1, RV6/SV2.	

8) Impedance Respiratory specification

Name	Specification
Method	Chest impedance method
Measurement lead	I, II, and Auto

Respiratory excitation waveform	<300 μA RMS, 56.9kHz (±10%)	
Resp measurement range and accuracy	Range	0 rpm-200rpm
	Accuracy	0 rpm-120 rpm: ±1rpm; 121 rpm-200 rpm: ±2rpm
Resp Alarm Range and Step	Range	Step
	Upper alarm limit: (lower limit + step) ~200rpm; Lower alarm limit: 0rpm~(upper limit - step).	0～20rpm, step size: 1rpm 21～200rpm, step size: 5rpm
No breaths time range and step	Adu mode: 10s-60s; Ped/Neo mode: 10s-40s	
	Step	5s
Cardiovascular artifact (CVA) Identification	When the HR rate is consistent with Resp rate, the monitor should generate an alarm and display a corresponding alarm message.	

9) SpO_2 specifications

Comen, Masimo and Nellcor SpO_2 module

Name	Specification
Meets the requirements of ISO 80601-2-61	
Displayed measurements	Pulse waveform; %SpO_2 and PR
Display resolution	1%
Data update period	1s
SpO_2 Measurement range	◆ Comen SpO_2: 0% ～ 100% ◆ Masimo SpO_2: 1% ～ 100% ◆ Nellcor SpO_2: 0% ～ 100%
SpO_2 Measurement accuracy	◆ Comen SpO_2: within range 70% ～ 100%: ±2% in Adu./Ped. mode (non-motion), ±3% in Neo. mode (non-motion); within range 0% ～ 69%: not defined. ◆ Masimo SpO_2: with range 70% ～ 100%: ±2% in Adu./Ped. Mode (non-motion), ±3% in Adu./Ped. mode (during motion), ±3% in Neo. mode (motion and non-motion); within range 1% ～ 69%: not defined. ◆ Nellcor SpO_2: within range 70% ～100%: ±2% in Adu./Ped. mode (non-motion), ±3% in Neo. mode (non-motion); within range 0% ～ 69%: not defined.
SpO_2 Alarm limit setting	◆ Comen SpO_2

	Upper alarm limit: (lower limit+2%) ～ 100%; Lower alarm limit: (extreme low limit+2%) ～ (upper limit-2%); Extreme low alarm limit: 0% ～ (lower limit-2%) ◆ Masimo SpO_2 Upper alarm limit: (lower limit+2%) - 100%; Lower alarm limit: (extreme low limit+2%) ～ (upper limit-2%); Extreme low alarm limit: 1% ～ (lower limit-2%) ◆ Nellcor SpO_2 Upper alarm limit: (lower limit+2%) - 100%; Lower alarm limit: When lower alarm limit ≥18 :(extreme low limit+2%) ～ (upper limit-2%); When lower alarm limit ≥18: 20% ～ (upper limit-2%); Extreme low alarm limit: 0% ～ (lower limit-2%)
	Step: 1%.
Perfusion Index (PI)	PI measurement range and accuracy ◆ Comen SpO_2 range: 0.05 ～20%; accuracy: not defined; ◆ Masimo SpO_2: 0.02% ～20%; accuracy: not defined;
	PI Resolution ◆ Comen SpO_2: 0.05%～9.99%, resolution: 0.01%, 10.0% ～20.0%, resolution: 0.1%. ◆ Masimo SpO_2: 0.02% ～9.99%, resolution: 0.01%. 10.0%～20.0%, resolution: 0.1%.

10) PR specifications

Item	Specification
Measurement range and accuracy	◆ Comen SpO_2: Measurement range: 20bpm-300bpm; resolution: 1bpm; measurement error: ±2bpm. ◆ Masimo SpO_2: Measurement range: 25bpm-240bpm; resolution: 1bpm; measurement error: ±3bpm (non-motion) or ±5bpm (during motion). ◆ Nellcor SpO_2 Measurement range: 20bpm-300bpm; resolution: 1bpm; measurement error: ±3bpm in 20bpm~250bpm range; 251 bpm～300 bpm: not defined ◆ Comen NIBP: Measurement range: 30bpm-300bpm; resolution: 1bpm; measurement error: ±3bpm or ±3%, whichever is greater.

	◆ IBP Measurement range: 20bpm-350bpm; resolution: 1bpm; measurement error: ±1bpm or ±1%, whichever is greater.
PR Resolution	1bpm
PR alarm settings	◆ Adu mode: Upper limit: (lower limit + step size) bpm~300bpm; lower limit: 15bpm~ (upper limit-step size) bpm. ◆ Ped/Neo mode: Upper limit: (lower limit + step size) bpm~350bpm; lower limit: 15bpm~(upper limit-step size)bpm.
	Step: 15～40 bpm: 1bpm; 41～300bpm: 5bpm

11) Temperature specifications

Name	Specification	
The body temperature measurement meets the requirements of ISO 80601-2-56:2017+A1:2018		
Measurement range and accuracy	Measurement range	0℃～50℃ (32℉～122℉)
	Measurement error	±0.2℃ (±0.4℉) (with sensorsMain unit)
Alarm setup	Alarm limits	Upper limit: (lower limit+0.1) ℃～50.0℃ Lower limit: 0℃～(upper limit-0.1) ℃
	ΔT upper alarm limit	0.1℃～50.0℃
Display resolution	0.1℃ (0.2℉)	
Channel number	2 channels	
Temperature sensor type	CY, YSI	
The monitor should be able to display the difference in temperature values between the two temperature probes (ΔT).		

12) CO_2 Specifications

Name	Specification	
Meets the requirements of ISO 80601-2-55		
Masimo $EtCO_2$ module (Mainstream)		Masimo $EtCO_2$ module(Sidestream)
$EtCO_2$ Measurement range	0～190mmHg 0～25.0% (at 760mmHg)	0～190mmHg 0～25.0% (at 760mmHg)
Resolution	1mmHg or 0.1kPa or 0.1%;	1mmHg or 0.1kPa or 0.1%;
CO_2 Accuracy	Under all conditions: 0～114mmHg: ± (2.25mmHg +4% of reading); not defined in the range of 115 mmHg - 190 mmHg	Under all conditions: Masimo sidestream: 0～114mmHg: ± (2.25mmHg +4% of reading); not defined in the range of 115 - 190 mmHg
Sampling rate	/	50ml/min

Sampling rate accuracy	/	±10ml/min
Data sampling rate	/	20Hz/channel
Total system response time	≤1.5s	<5s (using a 2m Airway Adapter Set sampling line)
CO_2 Stability	Short-term drift: more than 6 hours of work, the maximum drift does not exceed 1mmHg	Short-term drift: more than 6 hours of work, the maximum drift does not exceed 1mmHg
10% to 90% Rise time	/	<250ms
Warm-up time	<10s	<10s (Note: use after min. storage temperature, the warm-up time is 10 min.)
ET Calculation	$EtCO_2$ is displayed after one breath and have a continually updated breath average. The following methods are used to calculate end-tidal (ET) values The highest concentration of CO_2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. $EtCO_2$ within specification for all respiratory rates up to 150 bpm. ET will typically decrease below nominal value when respiration rate exceeds 80 bpm The maximum decrease is described by the formula ET=80*ETnom/RR. $EtCO_2$ will be within specification for all respiration rates up to 150 bpm	$EtCO_2$ is displayed after one breath and have a continually updated breath average. The following methods are used to calculate end-tidal (ET) values: The highest concentration of CO_2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. $EtCO_2$ within specification for all respiratory rates up to 150 bpm. ET will typically decrease below nominal values (ETnom) when respiratory rate (RR) exceeds the RR threshold (RRth) according to the following formulas: ET=ETnom*(125/RR) for RRth>125
$EtCO_2$ alarm limit setting	0～190mmhg: Upper limit: (lower limit + 2mmHg) ~ 190mmHg; Lower limit: 0mmHg ~ (upper limit – 2mmHg). Step: 1mmHg	
awRR measurement range	0 - 150rpm	0-150rpm
awRR measurement accuracy:	±1rpm	±1rpm
awRR alarm limit setting	Upper limit: (lower limit + step) ~ 150rpm; Lower limit: 0 rpm ~ (upper limit - step). Step: 0rpm ~20rpm: 1rpm; 21rpm ~ 150rpm: 5rpm	

$FiCO_2$ alarm limit setting	Upper limit: 0mmHg - 99mmHg; Lower limit: N/A Step: 1mmHg	
Breath detection	Adaptive threshold, minimum 1% change in CO_2 concentration	
Comen/Respironics $EtCO_2$ (Mainstream)		**Comen/Respironics $EtCO_2$ (Sidestream)**
CO_2 Measurement Range	0 ~150 mmHg, 0% ~ 19.7%, 0 ~20.0kPa (at 760mmHg)	Comen: 0 ~ 150 mmHg, 0% ~ 19.7%: 0 ~ 20.0kPa (at 760mmHg) Respironics CapnoTrak: 0mmHg ~ 99.0 mmHg, 0%~ 13.03%, 0kPa ~ 13.20kPa (at 760mmHg)
CO_2 Accuracy	a) 0 ~ 40 mmHg: ±2mmHg b) 41 ~70mmHg: ±5% of reading; c) 71 ~ 100mmHg: ±8% of reading; d) 101 ~ 150 mmHg: ±10% of reading;	Comen: a) 0 ~ 40 mmHg: ±2mmHg b) 41 ~70mmHg: ±5% of reading; c) 71 ~100mmHg: ±8% of reading; d) 101 ~ 150 mmHg: ±10% of reading; Respironics Capno-Trak: a) 0 ~ 38 mmHg: ±2mmHg of actual; b) 39 ~99.0 mmHg: ±10% of reading
Sampling Rate	/	50 ml/min
Sampling rate accuracy	/	±10 ml/min
Total system response time	Comen: <1.5s Respironics: <1s	<5s (using a 2m Airway Adapter Set sampling line)
Data sampling rate	/	100Hz
CO_2 Stability	Short-term drift: more than 6 hours of work, the maximum drift does not exceed 1mmHg	Short-term drift: more than 6 hours of work, the maximum drift does not exceed 1mmHg
10% to 90% Rise time	/	a) Comen sidestream: <500ms b) Comen Cpano: <550ms c) Respironics: <450ms
Warm-up time	Waveform perform: <15s; full accuracy specifications: ≤2min (at 25℃)	a) Respironics: Waveform perform: <10s; full accuracy specifications: ≤3min (at 25℃) b) Comen: Waveform perform: <20s; full accuracy specifications: ≤2min (at 25℃)
$EtCO_2$ alarm limit setting	Upper limit: (lower limit + 2mmHg) ~ 150mmHg; Lower limit: 0mmHg ~ (upper limit - 2mmHg). Step: 1mmHg	

awRR measurement range	Comen: 0 - 150rpm Respironics: 0rpm, 2rpm ~150rpm	Comen: 0 ~150rpm Respironics Capno Trak: 0rpm, 2rpm ~100rpm
awRR measurement accuracy	±1 rpm	
awRR alarm limit setting	Upper limit: (lower limit + 2rpm) ~ 150rpm; Lower limit: 0rpm ~ (upper limit - 2rpm). Step: 0rpm - 20rpm: 1rpm; 21rpm - 150rpm: 5rpm	
$FiCO_2$ alarm limit setting	Upper limit: 0mmHg ~ 76mmHg; Lower limit: N/A Step: 1mmHg	
No Breath time range and step	Comen and Respironics : For Adu.: 10s~60s; For Neo. /Ped.: 10s~40s. Masimo: For Adu: 15s~60s; For Neo/Ped.: 15s~40s.	
	Step	5s
I:E Ratio Effects	a) I:E ratios <2:1 have no effect on stated $EtCO_2$ accuracy stated above. b) For I:E ratios >2:1 the $EtCO_2$ accuracy specification is as follows: ◆ IE2:1: -7% + -4% for every 10BPM over 40 ◆ IE3:1: -7% + -5% for every 10BPM over 30 ◆ IE4:1: -12% + -6% for every 10BPM over 30	

13) NIBP specifications

Name	Specification		
Meets the requirement of IEC 80601-2-30			
Measurement method	Oscillation method		
Displayed measurement	Systole pressure (SYS), Diastolic pressure (DIA), Mean pressure (MAP) Pulse Rate (PR) in NIBP list		
NIBP measurement range	Measurement range in Adu mode	SYS	25mmHg ~290mmHg (3.3kPa~38.7kPa)
		MAP	15mmHg ~ 260mmHg (2.0kPa~34.7kPa)
		DIA	10mmHg ~250mmHg (1.3kPa~33.3kPa)
	Measurement range in Ped mode	SYS	25mmHg ~240mmHg (3.3kPa~32.0kPa)
		MAP	15mmHg ~ 215mmHg (2.0kPa~28.7kPa)
		DIA	10mmHg ~ 200mmHg (1.3kPa~26.7kPa)
	Measurement range in Neo mode	SYS	25mmHg ~ 140mmHg (3.3kPa~18.7kPa)
		MAP	15mmHg ~ 125mmHg (2.0kPa~16.7kPa)

<table>
<tr><td></td><td colspan="2"></td><td>DIA</td><td>10mmHg ~ 115mmHg (1.3kPa~15.3kPa)</td></tr>
<tr><td>NIBP Measurement Error</td><td colspan="4">Max. mean difference: ±5mmHg
Max. standard deviation: 8mmHg</td></tr>
<tr><td>Static pressure measurement range and accuracy</td><td colspan="4">Measurement range: 0mmHg ~ 300mmHg (0 kPa ~ 40.0 kPa);
Measurement accuracy: ±3mmHg (±0.4 kPa)</td></tr>
<tr><td rowspan="3">Software Over pressure protection range and accuracy</td><td colspan="2">Adu mode</td><td colspan="2">297mmHg ±3mmHg (39.6kPa±0.4kPa)</td></tr>
<tr><td colspan="2">Ped mode</td><td colspan="2">297mmHg ±3mmHg (39.6kPa±0.4kPa)</td></tr>
<tr><td colspan="2">Neo mode</td><td colspan="2">147mmHg ±3mmHg (19.6kPa±0.4kPa)</td></tr>
<tr><td>Maximum pressure for neonatal blood pressure measurement under normal operation</td><td colspan="4">143mmHg±3mmHg</td></tr>
<tr><td rowspan="6">NIBP alarm limit setting</td><td colspan="4">Alarm setting rules:
a) 4 types of alarm limits, including extreme high alarm limit, upper alarm limit, lower alarm limit, and extreme low alarm limit.
b) Step:
10mmHg ~50mmHg: 1mmHg.
51mmHg ~290mmHg: 5mmHg</td></tr>
<tr><td rowspan="3">Adu</td><td>SYS</td><td colspan="2">Extreme high alarm limit set range: 28mmHg~290mmHg
Upper alarm limit set range: 27mmHg ~ 285mmHg
Lower alarm limit set range: 26mmHg ~ 280mmHg
Extreme low alarm limit set range: 25mmHg ~275mmHg</td></tr>
<tr><td>DIA</td><td colspan="2">Extreme high alarm limit set range: 13mmHg ~ 250mmHg
Upper alarm limit set range: 12mmHg ~ 245mmHg
Lower alarm limit set range: 11mmHg ~ 240mmHg
Extreme low alarm limit set range: 10mmHg ~ 235mmHg</td></tr>
<tr><td>MAP</td><td colspan="2">Extreme high alarm limit set range: 18mmHg ~ 260mmHg
Upper alarm limit set range: 17mmHg ~ 255mmHg
Lower alarm limit set range: 16mmHg ~ 250mmHg
Extreme low alarm limit set range: 15mmHg ~ 245mmHg</td></tr>
<tr><td rowspan="2">Ped</td><td>SYS</td><td colspan="2">Extreme high alarm limit set range: 28mmHg ~ 240mmHg
Upper alarm limit set range: 27mmHg ~ 235mmHg
Lower alarm limit set range: 26mmHg ~ 230mmHg
Extreme low alarm limit set range: 25mmHg ~ 225mmHg</td></tr>
<tr><td>DIA</td><td colspan="2">Extreme high alarm limit set range: 13mmHg ~ 200mmHg</td></tr>
</table>

			Upper alarm limit set range: 12mmHg ~ 195mmHg Lower alarm limit set range: 11mmHg ~ 190mmHg Extreme low alarm limit set range: 10mmHg ~ 185mmHg
		MAP	Extreme high alarm limit set range: 18mmHg ~ 215mmHg Upper alarm limit set range: 17mmHg ~ 210mmHg Lower alarm limit set range: 16mmHg ~ 205mmHg Extreme low alarm limit set range: 15mmHg ~ 200mmHg
	Neo	SYS	Extreme high alarm limit set range: 28mmHg ~ 140mmHg Upper alarm limit set range: 27mmHg ~ 135mmHg Lower alarm limit set range:26mmHg ~ 130 mmHg Extreme low alarm limit set range: 25mmHg ~ 125mmHg
		DIA	Extreme high alarm limit set range: 13mmHg ~ 115mmHg Upper alarm limit set range: 12mmHg ~ 110mmHg Lower alarm limit set range: 11mmHg ~ 105mmHg Extreme low alarm limit set range: 10mmHg ~ 100mmHg
		MAP	Extreme high alarm limit set range: 18mmHg~ 125mmHg Upper alarm limit set range: 17 mmHg ~ 120 mmHg Lower alarm limit set range: 16mmHg ~115 mmHg Extreme low alarm limit set range: 15mmHg ~110mmHg
Blood measurement mode	Manual, auto (periodic), sequence, hourly and continuous mode		
	Measuring interval in auto mode		1min, 2min, 2.5min, 3min, 4 min, 5 min, 10 min, 15 min, 30 min, 1h, 1.5h, 2h, 3h, 4h, 8h, 12h
	Continuous mode cycling time		5 min.
Initial inflation pressure range	a) In Adu. mode: 80mmHg - 290mmHg (10.7kPa - 38.7kPa); b) In Ped. mode: 80mmHg - 240mmHg (10.7kPa - 32.0kPa); c) In Neo. mode: 60mmHg - 140mmHg (8.0kPa - 18.7kPa);		
Max. measuring period	120s in Adu./Ped. mode; 85s in Neo. mode		
Max. venipuncture time	125s in Adu/Ped. Mode; 87s in Neo. mode		

14) IBP specifications

Name	Specifications	
Meet the requirements of IEC 60601-2-34		
IBP channel number	2channels	
Airway pressure includes	ART (Arterial pressure), PA (Pulmonary artery pressure), CVP (Central venous pressure), RAP (Right atrial pressure), LAP (Left atrial pressure), ICP (Intracranial pressure), AO(Aortic pressure), UAP(Umbilical artery pressure), BAP(Brachial artery pressure), FAP (Femoral artery pressure), UVP (Umbilical vein pressure), LV (Left ventricular pressure), P1, P2, and other channels (expansion pressure is determined by the number of IBP channels). IAP (Intra-abdominal pressure), CPP (Cerebral perfusion pressure)	
Pressure detection range	ART:	0mmHg~370mmHg (0kPa~49.3kPa)
	PA	-6mmHg~120mmHg (-0.8kPa~16kPa).
	CVP	-10mmHg-40mmHg(-1.3kPa-5.3kPa)
	RAP	-10mmHg~40mmHg(-1.3kPa~5.3kPa)
	LAP	-10mmHg~40mmHg(-1.3kPa~5.3kPa)
	ICP	-10mmHg-40mmHg(-1.3kPa-5.3kPa)
	P1， P2 and other Expend channels	-50mmHg~370mmHg(-6.6kPa~49.3kPa)
	LV	0mmHg~370mmHg(0kPa~49.3kPa)
	AO	0mmHg~370mmHg(0kPa~49.3kPa)
	UAP	0mmHg~370mmHg(0kPa~49.3kPa)
	BAP	0mmHg~370mmHg(0kPa~49.3kPa)
	FAP	0mmHg~370mmHg(0kPa~49.3kPa)
	UVP	-10mmHg~40mmHg(-1.3kPa~5.3kPa)
	IAP	-10mmHg~40mmHg(-1.3kPa~5.3kPa)
	CPP	0mmHg~370mmHg(0kPa~49.3kPa)
Pressure measurement range	-50mmHg~+370mmHg (-6.6kPa~+49.3kPa), resolution: 0.1kPa or 1mmHg	
Pressure measurement accuracy	±1mmHg or ±2%, whichever is greater (sensor error excluded); the accuracy of CPP: not defined.	
IBP alarm limits	Alarm limit rules: a) ART has four alarm limits, namely Extreme high alarm limit, Upper limit, Lower limit and Extreme low alarm limit, while other pressure has two, namely Upper limit and Lower limit; b) adjusting step: -50mmHg~50mmHg, step: 1mmHg 51mmHg~370mmHg, step : 5mmHg	
	ART	extreme upper alarm limit: (upper limit + step）～ 370mmHg upper alarm limit：(lower limit + step）～ (extreme upper limit －step)

		Range for lower alarm limit: (extreme lower limit + step)～（upper limit － step) extreme lower alarm limit: 0mmHg～（lower limit － step)
	AO, UAP, BAP, FAP, LV, PA, CVP, RAP, LAP, ICP, UVP, IAP, Expend pressure (P1, P2)	upper alarm limit：(lower limit + step）～ Maximum limit lower alarm limit: Minimum limit～（upper limit - step)
Pressure Zeroing	Each channel should have the pressure zeroing function with an accuracy of ±1mmHg (±0.1kPa).	
PPV/SPV measurement	PPV measurement range: 0%-50%; resolution: 1% SPV measurement range: 0 mmHg-50mmHg; resolution: 1mmHg	
IBP analog output signal	IBP Dual-channel analog output is supported. Band width: (-3dB, reference 1Hz): 0-40Hz; Delay time: ≤30ms; Gain (reference 1Hz): 1V/100mmHg; error: ±5%	

15) C.O. specifications

Name	Specification	
C.O. measurement range	C.O.	0.1~20L/min
	BT	23~43℃
	IT	0~27℃
Accuracy	C.O.	±5% or ±0.1L/min, whichever is greater
	BT	±0.1℃ (with main unit)
	IT	±0.1℃ (sensor excluded)
BT Alarm limits	BT upper limit	(lower limit+0.1)~43.0℃
	BT lower limit	23.0~(upper limit-0.1) ℃
	Resolution	0.1℃

16) Alarm system

Name	Specification
The alarm system meets the requirements of IEC 60601-1-8.	

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Appendix III System Alarm Messages

Here we list some of the most important physiological and technical alarm messages.

If the problem still exists after you implement the relevant solution provided below, please contact our maintenance engineers.

Technical alarm types: A fully clearable, B the alarm sound and light are clearable or C Not clearable.

The level of each technical alarm is not adjustable (Except for ECG and SpO_2).

1) Physiological Alarm Messages:

1.1) General Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
XX Too High	Configurable for High and Med alarms	The corresponding measured parameter value exceeds the alarm upper limit.	Check the patient's condition, and confirm that the patient type and alarm limits are appropriate to the patient.
XX Too Low	Configurable for High and Med alarms	The corresponding measured parameter value goes below the alarm lower limit.	

Note: "XX" represents the label of physiological parameter such as HR, ST-I, ST-II, ST-III, ST-aVR, ST-aVL, ST-aVF, ST-V1, ST-V2, ST-V3, ST-V4, ST-V5, ST-V6, RR, T1, T2, △T, SpO_2, PR, etc.

1.2) Arrhythmia Alarm

Alarm Message	Alarm Level	Cause	Solution
Asystole	High	The patient develops an arrhythmia.	Check the patient's condition, electrodes, power cables and lead wires.
V-Fib/V-Tach	High		
V-Tach	High		
Extreme Tachy	High		
Extreme Brady	High		
Vent Brady	High		
R on T	Med		
Bigeminy	Med		
Trigeminy	Med		
Brady	Med		

Tachy	Med		
PVCs/min High	Med		
SVCs/min High	Med		
SVT	Med		
PAC Bigeminy	Med		
PAC Trigeminy	Med		
Nonsus S-Tach	Med		
Atrial Rhythm	Med		
RUN SVCs	Med		
PAC Couplet	Med		
Wide QRS Tachy	Med		
Multiform PVC	Med		
Nonsus V-Tach	Med		
Vent Rhythm	Med		
Pauses/min Too High	Med		
VT>2	Low		
Heart Pause	Low		
Pacer Not Capture	Prompt		
Pacer Not Pacing	Prompt		
Missed Beats	Prompt		
Couplet	Prompt		
PVC	Prompt		
A-Fib	Prompt		
Irr Rhythm	Prompt		
Irr Rhythm End	Prompt		
A-Fib End	Prompt		
IPVC	Prompt		
VEB	Prompt		

1.3) ECG Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
ST-Single Change Larger	Med	ST-single change exceeds the alarm limit	Check the patient's condition and confirm that the patient type and alarm limits are appropriate to the patient.
ST-Dual Change Larger	Med	ST-dual change exceeds the alarm limits	
QTc Too High	Med	QTc exceeds the alarm upper limit	
ΔQTc Too High	Med	ΔQTc exceeds the alarm upper limit	

1.4) Resp Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
No Breath	High	The patient has no breath or the patient's respiratory signal is too weak to be analyzed by the system.	Check the patient's condition. Check whether the electrode is placed correctly and the electrode, power cables and lead wires are firmly connected.
Resp Artifact	High	The patient's respiratory rate cannot be measured due to disturbance by the heartbeat.	Check the patient's condition and the connection of electrodes, power cables and lead wires.

1.5) SpO_2 Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
SpO_2 Extreme Low	High	The value of patient's SpO_2 is below the alarm lower limit.	Check the patient's condition. Confirm that the patient type and alarm limits are appropriate to the patient.
ΔSpO_2 Too High	High or medium	ΔSpO_2 exceeds alarm limits	Check the patient's condition and confirm whether the alarm settings are appropriate to this patient.

1.6) NIBP Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
NIBP-S/NIBP-D/NIBP-M Extreme High	High	The value of patient's NIBP exceeds the alarm upper limit.	Check the patient's condition. Confirm that the patient type and alarm limits are appropriate to the patient.
NIBP-S/NIBP-D/NIBP-M Extreme Low	High	The value of patient's NIBP is below the alarm lower limit.	

1.7) IBP Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
Art-S/Art-D/Art-M Extreme High	High	The value of patient's IBP exceeds the alarm upper limit.	Check the patient's condition. Confirm that the patient type and alarm limits are appropriate to the patient.
Art-S/Art-D/Art-M Extreme Low	High	The value of patient's IBP is below the alarm lower limit.	

1.8) PR Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
SpO_2/Art//PA/Ao/UAP/ BAP/FAP/LV/P1/P2 No Pulse	High	Pulse is too weak to be detected.	Check the patient's condition, and the SpO_2 or IBP sensor and sensor's application site.

1.9) CO_2 Physiological Alarm

Alarm Message	Alarm Level	Cause	Solution
No Breath	High	Respiratory rate cannot be measured due to no breaths or weak respiratory signal.	Check the patient's condition; Ensure electrodes, power cables and lead wires are well connected.

2) Technical Alarm

Major technical alarms are listed here, including their alarm levels, methods of alarm clearing, and the corresponding causes and solutions.

Technical alarms respond differently when the alarm system is reset. For easy clarification, in this section the technical alarms are classified into three categories according to the responses when the alarm system is reset:

Fully clearable: the technical alarms will be completely cleared.

Partially clearable (the alarm sound and light can be cleared): these technical alarms can have the audio silenced and LED alarms turned off, but a text message remains on screen indicating an alarm has occurred.

Not clearable: the audio reminder of a technical alarm will be muted, and the text message will be displayed with a "√" in front of the message to indicate that this alarm has been checked and confirmed, and the LED alarms keep flashing.

2.1) General Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
XX Module Comm Stop	High	Not clearable	XX module cannot communicate with the main system.	Contact the manufacturer for maintenance.
XX Module Comm Err	High	Fully clearable	XX module cannot communicate normally with the main system.	
ZZ Overrange	Low	Not clearable	The measured value of XX parameter exceeds the allowed measuring range of the system.	

Note:

"XX" represents a module name, such as ECG,etc.

"ZZ" represents a label name of physiological parameter, such as HR, ST-I, ST-II, ST-III, ST-AVR, ST-AVL, ST-AVF, ST-V1, ST-V2, ST-V3, ST-V4, ST-V5, ST-V6, RR, etc.

2.2) ECG Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
ECG Lead Off	High/Med/Low	The alarm sound and light are clearable	The ECG lead wire is not or poorly connected	Check the connection of ECG electrodes, lead wire or cable wires.
ECG XX Lead Off	High/Med/Low	The alarm sound and light are clearable	Electrode is not or poorly connected to the patient, thus causing lead off..	
ECG Noise	Low	Fully clearable	The ECG signal contains strong interfering signal.	Check if the ECG lead is connected properly and if the patient performs any major movement.
ECG Relearn	Prompt	/	Relearn is triggered manually or automatically.	/

ECG Pacer Reject	Prompt	Not clearable	The pacemaker is turned on while the pacer inhibition switch is also turned on.	/
ECG XX Overload	Low	Fully clearable	Patient's skin impedance is too high.	Check the position where the electrode is placed.

Note: "XX" represents a module name, such as I, II, III, RA, LA, LL, V, V1, V2, V3, V4, V5, V6, etc.

2.3) Temp Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
T1 Sensor Off	Low	Fully clearable	The Temp sensor is connected unreliably.	Check if the Temp sensor is connected properly.
T2 Sensor Off	Low	Fully clearable		
T1 Overrange	Low	Not clearable	The measured value exceeds the allowed measuring range of the system.	/
T2 Overrange	Low	Not clearable		

2.4) SpO_2 Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
SpO_2 Sensor Not Connected	Low	Fully clearable	SpO_2 main cable is disconnected from the module, or the SpO_2 sensor is not firmly connected with the SpO_2 main cable.	Ensure the sensor and main cables of SpO_2 are well connected. If the alarm still cannot be cleared, please contact the manufacturer for maintenance.
SpO_2 Nellcor Fault. Resetting	Low	Not clearable	There is a Nellcor module error. The system is resetting.	If system resetting fails, or the error still exists after you restart the Monitor, contact the manufacturer for maintenance.
SpO_2 Search Pulse	Prompt	/	The SpO_2 sensor is searching pulse.	Check the patient's condition and if the SpO_2 sensor is connected properly.

SPO_2 Low Perfusion	Low	Not clearable	The SpO_2 sensor is not placed properly or the patient's PI is too low.	1. Connect the SpO_2 sensor correctly. 2. Change the sensor to another measurement site.
SPO_2 Interference Detected	Low	Not clearable	Patient's excessive movement or electromagnetic interference such as electrotome.	Ensure there is no interference around the sensor; check the connection of SpO_2 lead wire; check the patient's condition and whether a big body movement is made.
SpO_2 Too Ambient Much Light	Low	Not clearable	The ambient light is too strong around the SpO_2 sensor.	Place the sensor in an environment with weak light or cover the sensor end to reduce light interference.
SPO_2 Unknown Sensor	Low	Not clearable	SpO_2 module cannot recognize the sensor.	Check and replace the sensor; if the error still exists, contact the manufacturer for maintenance.
SpO_2 Poor Signal Quality	Low	Not clearable	SpO_2 sensor is connected improperly	Check the connection of SpO_2 sensor.
SPO_2 Module Error	Low	Not clearable	The module fails	Contact the manufacturer for maintenance.
SPO_2 Diagnostic Failed	Low	Not clearable	The diagnosis fails	Reinsert the module.
SPO_2 No Cable	Low	Fully clearable	The Power cable is not connected.	Ensure the cable is well connected; if the error still exists, please replace the sensor.
SpO_2 Incompatible Cable	Low	Not clearable	An incompatible cable is used.	Check the cable, and replace it with a proper one.
SpO_2 Unknown Cable	Low	Not clearable	An unknown cable is used.	
SpO_2 Cable Failure	Low	Not clearable	A defective cable is used.	

SpO_2 Cable Expired	Low	Not clearable	An expired cable is used.	
SpO_2 Incompatible Sensor	Low	Not clearable	An improper sensor is used.	Check the sensor and replace it with a proper one if needed.
SpO_2 Sensor Failure	Low	Not clearable	A defective sensor is used.	
SpO_2 Sensor Expired	Low	Not clearable	An expired sensor is used.	
Check the Default SpO_2 Cable and Sensor	Prompt	/	Check the default SpO_2 Cable and Sensor	/
SpO_2 Cable Near Expired	Prompt	/	Cable Near Expiration is prompted.	/
SpO_2 Sensor Near Expired	Prompt	/	Sensor Near Expiration is prompted.	/
Check SpO_2 Sensor Connection	Low	Not clearable	It needs to check the connection of SpO_2 sensor.	Please check the connection of SpO_2 sensor.
SpO_2 Sensor Initializing	Prompt	/	SpO_2 Sensor Initializing is prompted.	/
Only SpO_2 Reliable	Low	Not clearable	Only SpO_2 is reliable	/
SpO_2 Finger Sensor Off	High/Med,/Low	The alarm sound and light are clearable.	The SpO_2 Sensor is disconnected with the finger.	Check the condition of SpO_2 sensor.

2.5) NIBP Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
NIBP Selftest Error	Low	Fully clearable	An error occurs during NIBP initialization.	Restart the system; if the error still exists, contact the manufacturer for maintenance.
NIBP Pneumatic Leak	Low	Fully clearable	A leak exists in the NIBP gas circuit.	Check the connection of each part or replace the cuff with a new one. If the error still
NIBP Pressure Overrange	Low	Fully clearable	An error occurs during measuring	

			the curve, and the system cannot perform the measurement analysis calculation.	exists, contact the manufacturer for maintenance.
NIBP Air Leak	Low	Fully clearable	NIBP cuff is poorly connected, or a leak exists in the NIBP gas circuit.	
NIBP Air Pressure Error	Low	Fully clearable	An error occurs during measuring the curve, and the system cannot perform the measurement analysis calculation.	
NIBP Weak Signal	Low	Fully clearable	An error occurs during measuring the curve, and the system cannot perform the measurement analysis calculation.	Check whether the patient type is selected correctly; Check the connection of each part replace the cuff with a new one. If the error still exists, contact the manufacturer for maintenance.
NIBP Excessive Motion	Low	Fully clearable	The patient moves his/her arm.	Check the connection of each part and patient's condition, and measure again. If the error still exists, contact the manufacturer for maintenance.
NIBP Signal Saturated	Low	Fully clearable	An error occurs during measuring the curve, and the system cannot perform the measurement analysis calculation.	
NIBP System Failure	High	Fully clearable		
NIBP Measure Timeout	Low	Fully clearable		
NIBP OverPressure	Low	Fully clearable	The gas circuit may be folded or the module fails.	Check whether the gas circuit is blocked. Check the patient's condition. If the error still exists, contact the manufacturer for maintenance.
NIBP Block	Low	Fully clearable	The discharge valve may be blocked.	Check whether the airway tube is bent

				sharply or blocked; if the error still exists, contact the manufacturer for maintenance.
NIBP Need Calibration	Prompt	/	NIBP Need Calibration is prompted	/
NIBP Cuff Type Error	Low	Fully clearable	The cuff type may not match with the set patient type.	Check whether the patient type is selected correctly; Check the connection of each part or replace the cuff with a new one. If the error still exists, contact the manufacturer for maintenance.

2.6) IBP Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
XX Sensor Off	Med	The alarm sound and light are clearable	The IBP sensor is poorly connected.	Check or reinsert the IBP sensor; if the error still exists, contact the manufacturer for maintenance.
Zero Failed	Low	Not clearable	Zero IBP fails	Re-zero it.
Calibration Failed	Low	Not clearable	IBP Calib. Failed	Re-calibrate it.
Sensor Fault	Med	Not clearable	Sensor Fault	Check the sensor and replace it with a proper one.
XX Cable Shorted	Prompt	/	Remove the IBP cable and sensor from patient, or open the cross valve to atmosphere	Check the hydraulic connection. Confirm the cross valve open to patient's end. Replace the cable and sensor if zeroing fail again.

Note: XX represents a label name of IBP such as IBP: Art, IBP: PA, IBP: Ao, IBP: UAP, IBP: BAP, IBP: FAP, IBP: CVP, IBP: LAP, IBP: RAP, IBP: ICP, IBP: UVP, IBP: LV, IBP: IAP, IBP: P1, IBP: P2, IBP: P3, IBP: P4, etc.

2.7) CO_2 Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
CO_2 Standby	Prompt	/	CO_2 work mode is standby	Set CO_2 work mode to measuring mode.
CO_2 Sampling Line Clogged	Low	Not clearable	AG Sampling Line Clogged	Check and replace the sampling line; if the error still exists, contact the manufacturer for maintenance.
CO_2 No Sampling Line	Low	Fully clearable	The sampling line is not or poorly connected.	1. Ensure the sampling line is properly connected. 2. Check and replace the sampling line; if the error still exists, contact the manufacturer for maintenance.
CO_2 Replace Adapter	Low	Not clearable	The adapter malfunctions.	Check and replace the adapter; if the error still exists, contact the manufacturer for maintenance.
CO_2 No Adapter	Low	Fully clearable	The adapter is not or poorly connected.	
CO_2 Exceed Error Tolerance Range	Low	Not clearable	The measured value exceeds the nominal accuracy range.	Follow the nominal accuracy range specified by the manufacturer.
CO_2 Inner Temp Overrange	Low	Not clearable	The ambient temperature is too high or the module fails.	1. Decrease the ambient temperature. 2. Take out and reinsert the CO_2 module. 3. If the error still exists, the module may be inoperative. Contact the service personnel for maintenance.

CO_2 Factory Calibration Lost	Low	Not clearable	The factory calibration data of CO_2 module is lost.	Reinsert the module; If the error still exists, please contact the manufacturer for maintenance.
CO_2 Motor Speed Out Of Bounds	Low	Not clearable	The CO_2 motor speed exceeds the allowed range.	
CO_2 Atm Pressure Overrange	Low	Not clearable	The ambient pressure exceeds the allowed module working pressure range or the module fails.	1. Confirm the current ambient baropressure does not exceed the environmental specifications required by this monitor, and the baropressure is not affected by external interference sources. 2. Reinsert the CO_2 module. If the error still exists, contact the service personnel for maintenance.
CO_2 Zero Required	Low	Not clearable	CO_2 Zero is required.	Perform the CO_2 Zero in the interface of the CO_2 settings.
CO_2 Software Error	Low	Not clearable	A software error occurs in the CO_2 module.	Reinsert the module; If the error still exists, please contact the manufacturer for maintenance.
CO_2 Hardware Error	Low	Not clearable	A hardware error occurs in the CO_2 module.	
CO_2 Warming Up...	Prompt	/	Message when Respironics CO_2 module is warming up	/
CO_2 Calibrate Required	Low	Not clearable	CO_2 module calibration required	Return to themanufacturer for calibration.

2.8) C.O. Technical Alarm

Alarm Message	Alarm Level	Alarm Clearance Mode	Cause	Solution
C.O. IT Sensor Not Connected	Low	The alarm sound and light are clearable	The injection temperature sensor is not connected.	Check the sensor and connect it appropriately.
C.O. BT Sensor Not Connected	Low	The alarm sound and light are clearable	The blood temperature sensor is not connected.	Check the sensor and connect it with blood appropriately.
CO Baseline Move	Low	Not clearable	It may be disturbed by a high-frequency electrosurgical equipment.	The monitor and C.O. Sensor should not be placed in close proximity to a high-frequency electrosurgical equipment.
C.O. Baseline Big Noise	Low	Not clearable		
C.O. IT Overrange	Low	Not clearable	The injection temperature exceeds 30℃	Cool down the injection in a proper way. For example, place the catheter below the injection container in a vessel with ice water.
C.O. BT Overrange	Low	The alarm sound and light are clearable	The blood temperature exceeds the allowed range (25℃ - 43℃)	Lower the temperature of the patient before taking measurement.
C.O. Baseline Compute	Low	The alarm sound and light are clearable	The baseline temperature is not steady before the user clicks to start the test.	Start the test in conditions with a steady baseline temperature.
Multiple C.O. Peaks	Low	The alarm sound and light are clearable	The blood temperature fluctuates excessively.	Perform the injection with a steady speed.
C.O. Measure Timeout	Low	The alarm sound and light are clearable	The blood temperature has no change after Start Measure is clicked; or the injection time is too late.	Perform the injection with a quick and steady way after clicking Start Measure.

C.O. Module Fault	High	Not clearable	C.O. Module Failed.	Check and reconnect the C.O. module; if the error still exists, contact the service personnel for maintenance.

2.9) IT-Network Technical Alarm

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
CMS Disconnected	Low	The alarm sound and light are clearable	The connection between the monitor and CMS is disrupted.	Check the IT-Network connection.
CMS Network Conflict	Low	The alarm sound and light are clearable	There are monitors with the same IP connected to CMS.	Check the configuration of IP address,
Viewed Bed XX-YY-ZZ disconnected	Low	Fully clearable	The connection between the monitor and the viewed bed is disrupted.	Check the network connection.
Viewed by XX YY-ZZ, Connection Lost	Low	Fully clearable	The connection between monitor being viewed and the primary monitor is disrupted.	Check the network connection.
IP Conflict	Prompt	/	The IP address of monitors are the same.	Check the network connection.
MAC Conflict	Prompt	/	The MAC address of monitors are the same.	Check the network connection.

Note: XX represents the department; YY represents the room number; ZZ represents bed number. If the bed number is not entered, the network bed number will be displayed.

2.10) Power Supply Technical Alarm

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
Low Battery	Med	Not clearable	The battery capacity is low.	Connect to mains supply and charge the battery.

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
Battery is critically low	High	Not clearable	The battery is near depletion and would shut down.	Connect to mains supply and charge the battery.
Power Board Comm Stop	High	Not clearable	Power board failure.	Restart the monitor. If the error still exists, contact the service personnel for maintenance.

2.11) Recorder Technical Alarm

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
Recording…	Prompt	/	The recorder is printing.	/
Recorder Head Hot	Low	Not clearable	The recorder is printing for a long time.	Stop printing and wait until it cools down.
No Record Paper	Low	The alarm sound and light are clearable	There is no recorder paper or it is not installed well.	Reload the recorder paper.
No Recorder Connected	Prompt	/	No recorder connected.	Please insert the recorder module.

2.12) Technical Alarms of Printer

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
Printer No Connected	Prompt	/	The printer is not properly connected.	Check the printer is correctly connected.
No Paper	Prompt	/	The printer has no paper.	Load the printer paper.

2.13) Other Technical Alarm/information message

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
XX module conflict	Prompt	/	The number of same modules inserted exceeds the maximum configuration.	Remove the other modules.

Alarm Message	Alarm Priority	Alarm Clearance Mode	Possible cause	Solution
Storage Space Ful	High, Med or Low	The alarm sound and light are clearable	History profile has filled the available disk memory. Or admitted too many patients.	Usually the monitor will delete the history profile. If the alarm condition last long, please contact the service personnel for maintenance.
Storage Disk Error	/	Fully clearable	Storage disk failure or file corruption.	Restart the monitor and Format the storage disk. If the alarm condition remains, contact the service personnel for maintenance.
XX Measurement Closed	Prompt	/	The corresponding parameter module is closed.	If the module is needed, open it. For detailed instructions, see section *4.3.11 Set parameters On/Off*.

Appendix IV Default Configuration Information

1. Parameters Settings

1) ECG default settings

Name	Default setting	
Filter	Monitor	
QRS Volume	2	
Alarm Source	Auto	
Lead Set	Auto	
ECG1	II	
ECG2 (5-Lead, 6-Lead, 12-Lead)	I	
Va	V1	
Vb	V2	
Notch Filter	Weak	
Waveform Speed	25 mm/s	
ECG Gain	X1	
ECG2 Gain	X1	
Alarm On/Off	On	
Alarm Auto Print	Off	
Alarm Priority	Med	
Paced	No	
Pacer Reject	Off	
Smart Lead	Off	
HR Lower/Upper Alarm Limits	Adu	50-120
	Ped	75-160
	Neo	100-200
Extreme Tachy	Alarm On/Off	On
	Upper Alarm Limits	Adu: 160 Ped: 180 Neo: 220
	Alarm Priority	High
	Alarm Auto Print	Off
Extreme Brady	Alarm On/Off	On
	Upper Alarm Limits	Adu: 35 Ped: 50 Neo: 60
	Alarm Priority	High
	Alarm Auto Print	Off

2) Arrhythmia default settings

Arrhythmia Alarm default settings

Name	Alarm	Alarm Level	Alarm Outputs
R on T	Off	Med	Off
Bigeminy	Off	Med	Off
Trigeminy	Off	Med	Off
Nonsus V-Tach	Off	Med	Off
Vent Rhythm	Off	Med	Off
PVCs/min High	Off	Med	Off
Asystole	On	High	Off
V-Fib/V-Tach	On	High	Off
V-Tach	On	High	Off
Vent Brady	On	High	Off
Extreme Tachy	On	High	Off
Extreme Brady	On	High	Off
Run PVCs	Off	Low	Off
Couplet	Off	Prompt	Off
PVC	Off	Prompt	Off
Pacer Not Capture	Off	Prompt	Off
Pacer Not Pacing	Off	Prompt	Off
Missed Beats	Off	Prompt	Off
Irr Rhythm	Off	Prompt	Off
Tachy	Off	Med	Off
Brady	Off	Med	Off
Heart Pause	Off	Low	Off
Multiform PVC	Off	Med	Off
A-Fib	Off	Prompt	Off
Pauses/min High	Off	Med	Off
Irr Rhythm End	Off	Prompt	Off
A-Fib End	Off	Prompt	Off
SVCs/min High	Off	Med	Off
SVT	Off	Med	Off
PAC Bigeminy	Off	Med	Off
PAC Trigeminy	Off	Med	Off
IPVC	Off	Prompt	Off
VEB	Off	Prompt	Off
Nonsus S-Tach	Off	Med	Off
Atrial Rhythm	Off	Med	Off
RUN SVCs	Off	Med	Off
PAC Couplet	Off	Med	Off
Wide QRS Tachy	Off	Med	Off

Arrhythmia threshold default settings

Name	Patient type	Default settings
Asystole Delay (s)	Adu	5
	Ped	
	Neo	
Heart Pause (s)	Adu	2.0
	Ped	
	Neo	
Extreme Tachy (bpm)	Adu	160
	Ped	180
	Neo	220
Extreme Brady (bpm)	Adu	35
	Ped	50
	Neo	60
Tachy (The HR upper limit) (bpm)	Adu	120
	Ped	160
	Neo	200
Brady (The HR lower limit) (bpm)	Adu	50
	Ped	75
	Neo	100
Ventricular bradycardia Rate (bpm)	Adu	40
	Ped	
	Neo	
Ventricular bradycardia PVCs	Adu	5
	Ped	
	Neo	
V-Tac Rate (bpm)	Adu	130
	Ped	130
	Neo	160
V-Tac PVCs	Adu	6
	Ped	
	Neo	
Multi PVCs Window	Adu	15
	Ped	
	Neo	
PVCs/min	Adu	10
	Ped	
	Neo	
A-Fib/Irr Rhy End Time (s)	Adu	2
	Ped	
	Neo	
Pauses/min	Adu	8

	Ped	
	Neo	
Supraventricular SVCs(s)	Adu	5
	Ped	
	Neo	
Supraventricular Heart Rate (bpm)	Adu	180
	Ped	200
	Neo	210
SVCs/min High	Adu	10
	Ped	
	Neo	

3) ST default settings

Name	Default settings	
ST Alarm Mode	Real-time value	
ST-I, ST-II, ST-III, ST-aVR, ST-aVL, ST-aVF, ST-V1, ST-V2, ST-V3, ST-V4, ST-V5, ST-V6, ST-Va, ST-Vb (**[Alarm mode]** is set to **[Real-time value]**)	Alarm On/Off	Off
	Alarm Limits	(-0.2mV, 0.2mV)
	Alarm Priority	Med
	Alarm Auto Print	Off
Single ST Alarm; Multi ST Alarm (**[Alarm mode]** is set to **[Various]**)	Alarm On/Off	Off
	Alarm Limits	(-0.1mV, 0.1mV)
	Alarm Priority	Med
	Alarm Auto Print	Off
ST Segment Analysis	Off	
ST Segment	Auto	
Show Markers	Off	
ST Point	J+60ms	
ST Point Adjustment	On	
ISO Point	-80ms	
J Point	48ms	

4) QT/QTc default settings

Name	Default settings	
QTc	Alarm On/Off	Off
	Alarm Upper Limit (ms)	Adu: 500 Ped: 480 Neo: 460
	Alarm Priorityl	Med
	Alarm Auto Print	Off
△QTc	Alarm On/Off	Off
	Alarm Upper Limit (ms)	60
	Alarm Priority	Med

	Alarm Auto Print	Off
QT Analysis	Off	
QT Leads	All	

5) Resp default settings

Name	Default settings	
RR	Alarm On/Off	On
	Lower/Upper Alarm Limits (bpm)	Adu: 8~30 Ped: 8~30 Neo: 30~100
	Alarm Priority	Med
	Alarm Auto Print	Off
Apnea	Alarm On/Off	On
	Alarm Priority	High
	Alarm Auto Print	Off
Apnea Timeout	Adu: 20s Ped: 20s Neo: 15s	
RR Source	Auto	
Resp Lead	Adu: Auto Ped: Auto Neo: II	
Gain	X1	
Waveform Speed	12.5mm/s	
Filter	On	
Auto Threshold Detection	On	

6) SpO_2 default settings

Masimo, Nellcor and Comen SpO_2

Name	Default settings	
SpO_2	Alarm On/Off	On
	Alarm Limits (%SpO_2)	Adu: 90~100 Ped: 90~100 Neo: 90~100
	Alarm Priority	Med
	Alarm Auto Print	Off
SpO_2 Desat	Alarm On/Off	On
	Alarm Lower Limit (%)	80
	Alarm Priority	High
	Alarm Auto Print	Off
Sensitivity	Masimo SpO_2: Adu/Ped: normal; Neo: APOD Comen SpO_2: High	

Waveform Speed	25mm/s	
PI Display (Masimo and Comen SpO_2)	On	
Signal indicator (Masimo, Nellcor and Comen SpO_2)	Off	
NIBP Simul	Off	
Smart pulse tone (Masimo SpO_2)	On	
Average Time (Masimo and Comen SpO_2)	8s	
Fast Sat. (Masimo and Comen SpO_2)	Off	
SatSecond (Nellcor SpO_2)	Off	
PR	Alarm On/Off	On
	Alarm Limits (bpm)	Adu: 50~120; Ped: 75~160; Neo: 100~200
	Alarm Priority	Med
	Alarm Auto Print	Off
	Alarm Source	Auto
	PR Source	Auto
	Pulse volume	General, OR: 2 Other: 0

7) NIBP default settings

Name	Default settings	
NIBP-S	Alarm On/Off	On
	Alarm Limits (mmHg)	Adu: 90~160 Ped: 70~120 Neo: 50~90
	Alarm Priority	Med
	Alarm Auto Print	Off
NIBP-D	Alarm On/Off	On
	Alarm Limits (mmHg)	Adu: 50~90 Ped: 40~70 Neo: 30~60
	Alarm Priority	Med
	Alarm Auto Print	Off
NIBP-M	Alarm On/Off	On
	Alarm Limits (mmHg)	Adu: 60~110 Ped: 50~90 Neo: 35~70
	Alarm Priority	Med

	Alarm Auto Print	Off	
NIBP-S Extreme	Alarm On/Off	Off	
	Alarm Limits (mmHg)	Adu: 75~175 Ped: 60~130 Neo: 45~95	
	Alarm Level	High	
	Alarm Auto Print	Off	
NIBP-D Extreme	Alarm On/Off	Off	
	Alarm Limits (mmHg)	Adu: 35~105 Ped: 30~80 Neo: 25~65	
	Alarm Level	High	
	Alarm Auto Print	Off	
NIBP-M Extreme	Alarm On/Off	Off	
	Alarm Limits (mmHg)	Adu: 45~125 Ped: 40~100 Neo: 30~75	
	Alarm Level	High	
	Alarm Auto Print	Off	
Initial Pressure (mmHg)	Adu: 160 Ped: 120 Neo: 100		
Measurement Interval	Manual		
Start Mode	Clock		
NIBP End Tone	Off		
Venipuncture Pressure	Auto		
Display Alarm Limits	Off		
NIBP Timeout	Off		
Sequence	Phase A	Measurement Times	25
		Measurement Interval	5min
	Phase B	Measurement Times	27
		Measurement Interval	15min
	Phase C	Measurement Times	27
		Measurement Interval	1h
	Phase D	Measurement Times	STAT
		Measurement Interval	1.5h
	Phase E	Measurement Times	Off
		Measurement Interval	1.5h

8) TEMT default settings

Name	Default settings	
T1	Alarm On/Off	On
	Alarm Limits (℃)	36.0~39.0
	Alarm Priority	Med
	Alarm Auto Print	Off
T2	Alarm On/Off	On
	Alarm Limits (℃)	36.0~39.0
	Alarm Priority	Med
	Alarm Auto Print	Off
△T	Alarm On/Off	On
	Alarm Limits (℃)	2.0
	Alarm Priority	Med
	Alarm Auto Print	Off
△Display	On	

9) CO_2 default settings

Name	Default settings	
$EtCO_2$	Alarm On/Off	On
	Lower/Upper Alarm Limits (mmHg)	Adu: 25~50 Ped: 25~50 Neo: 30~45
	Alarm Priority	Med
	Alarm Outputs	Off
$FiCO_2$	Alarm On/Off	On
	Alarm Upper Limit (mmHg)	4
	Alarm Priority	Med
	Alarm Outputs	Off
Apnea Timeout	Adu: 20s Ped: 20s Neo: 15s	
Work Mode	Measurement	
O_2 Compensation (Respironics/Comen)	16%	
O_2 Compensation (Masimo)	Low	
N_2O Compensation (Masimo)	Off	
Waveform Speed	6.25mm/s	
Scale	50	
Waveform Type	Line	

Balance gas (Comen/ Respironics)	Room air
Altitude unit	m

10) IBP default settings

Name	Default settings	
IBP-S	Alarm On/Off	On
	Alarm Limits (mmHg)	Art/AO/UAP/BAP/FAP/LV/P1-P4 arterial pressure: Adu: 90~160; Ped: 70~120; Neo: 55~90 PA: Adu: 10~35; Ped: 24~60; Neo: 24~60
	Alarm Priority	Med
	Alarm Auto Print	Off
IBP-D	Alarm On/Off	On
	Alarm Limits (mmHg)	Art/AO/UAP/BAP/FAP/LV/P1-P4 arterial pressure: Adu: 50~90; Ped: 40~70 Neo: 10~60 PA: Adu: 0~16; Ped: -4~4; Neo: -4~4
	Alarm Priority	Med
	Alarm Auto Print	Off
IBP-M	Alarm On/Off	On
	Alarm Limits (mmHg)	Art/AO/UAP/BAP/FAP/LV/P1-P4 arterial pressure: Adu: 70~110; Ped: 50~90 Neo: 35~70 PA: Adu: 0~20; Ped: 12~26; Neo: 12~26 CVP/ICP/RAP/LAP/UVP/P1-P4 venous pressure: Adu: 0~10;

		Ped: 0~4 Neo: 0~4
	Alarm Priority	Med
	Alarm Auto Print	Off
Art-S Extreme	Alarm On/Off	Off
	Alarm Limits (mmHg)	Adu: 75~175 Ped: 60~130 Neo: 50~95
	Alarm Priority	High
	Alarm Auto Print	Off
Art-D Extreme	Alarm On/Off	Off
	Alarm Limits (mmHg)	Adu: 35~105 Ped: 30~80 Neo: 15~65
	Alarm Priority	High
	Alarm Auto Print	Off
Art-M Extreme	Alarm On/Off	Off
	Alarm Limits (mmHg)	Adu: 55~125 Ped: 40~100 Neo: 30~75
	Alarm Priority	High
	Alarm Auto Print	Off
CPP	Alarm On/Off	On
	Alarm Limits (mmHg)	Adu: 50~130 Ped: 40~100 Neo: 30~90
	Alarm Priority	Med
	Alarm Auto Print	Off
Measure (P1,P2,P3,P4)	P1, P2: All P3,P4: Mean Only	
Waveform Speed	25mm/s	
PPV Measure	Off	
Alarm Display	Off	
Filter type	Normal	
Scale	ART/AO/BAP/FAP/LV/P1/P2: 0~160 CVP/ICP/RAP/LAP/UVP/IAP: 0~20 UAP/P3/P4: 0~80 PA: 0~30	
PAWP Timeout	15min	

11) C.O. default settings

Name	Default settings	
BT	Alarm On/Off	On
	Lower/Upper Alarm Limits (℃)	36~39
	Alarm Priority	Med
	Alarm Outputs	Off
C.O. Coefficient	0.542	
Injection temperature (℃)	2.0	
Interval time (s)	5s	
Auto Measure	Off	
Auto T1	Off	
C.O. Timeout	15min	

2. General Settings

1) Alarm

Name	Default settings
Alarm audio volume	2
High priority alarm audio volume	Alarm Vol+2
Reminder Volume	2
Printing Duration On Alarm	20s
Minimum Alarm Volume	2
Alarm audio volume enhance	Off
Increase Volume Delay	30s
Alarm paused/ Alarm audio paused	Alarm paused
Passed time	2 min
Pause 5 min	On
Pause 10 min	On
Pause 15 min	On
Alarm Light	On When Reset
Alarm Reset Reminder	On
Alarm Off Reminder	On
Reminder interval	1 min
ECG Lead Off	Low
SpO_2 Sensor Off	Low
IBP Sensor Off	Medium

Alarm Delay	6s
Lethal Arrythmia Alarm Off	Disabled
SpO_2 Desat. Alm Off	Disabled
Apnea Alarm Off	Disabled
Intubation Mode Duration	2min
Print Option	Printer

2) Review

Name	Default settings
Review window duration	8 h
Channel of waveform	5
Tubular trend time setting	5 min

3) Screen Setup

Name	Default settings	
Choose Screen	Normal Screen	
	Brightness	8
	Brightness On Battery	4
Night mode	Screen brightness	1
	Alarm audio volume	2
	QRS volume	1
	Key volume	0
	NIBP measurement complete volume	Off
	NIBP stop measurement reminder	Off
	Auto Night Mode	Off

4) Record

Name	Default setting
Record Wave1	II
Record Wave2	Off
Record Wave3	Off
Recording Speed	25mm/s
Record Time	8s
Timed Record Interval	Off

5) Print

Name	Default setting
Printer Type	NET
Printer IP Address	200.200.200.200
Paper Size	A4

6) Manage

Name	Default settings
Department	General monitoring
Default configuration	Load the Latest Configuration

7) Time

Name	Default settings
Date	YYYY-MM-DD
Time	Off

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Appendix V EMC

NOTE

- ND serial monitor complies with the applicable EMC requirements in IEC 60601-1-2, IEC 60601-2-25, IEC 606 01-2-27, IEC 80601-2-30, IEC 60601-2-34, ISO 80601-2-55, ISO 80601-2-56, ISO 80601-2-61.
- Please follow the EMC instructions in the User's Manual to install and use the Monitor.
- Portable and mobile RF communication equipment may affect the performance of the monitor ND10/ND10A/ND10C/ND10S//ND12/N1D2A/ND12C/ND12S/ND15/ND15A/ND15C/ND15S. To protect the Monitor against strong electromagnetic interference, please keep it away from mobile phones, microwave ovens, etc.
- Refer to the attached guidance and manufacturer's statement.

WARNING

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify the normal operation.
- Class-A equipment is intended to work in industrial environments. Considering this product's conduction disturbance and radiation disturbance, it may be difficult to ensure its EMC in non-industrial environments.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Accessory information:

The following cables shall be used in accordance with electromagnetic emission and immunity requirements:

Number	Name	Cable length (m)	With shielding	Remarks
1	ECG Cable	4.2	Yes	/
2	ECG Cable	4.2	Yes	/
3	ECG Cable	3.7	Yes	/
4	ECG Cable	4.2	Yes	/
5	ECG Cable	4.2	Yes	/
6	ECG Cable	3.7	Yes	Selected for test
7	ECG Cable	3.1	Yes	/

Number	Name	Cable length (m)	With shielding	Remarks
8	ECG Cable	3.1	Yes	/
9	ECG Cable	3.5	Yes	/
10	ECG Cable	3.1	Yes	/
11	ECG Cable	3.1	Yes	/
12	ECG Cable	3.5	Yes	/
13	ECG Cable	2.7	Yes	/
14	ECG Cable	2.7	Yes	/
15	ECG Cable	2.2	Yes	/
16	ECG Cable	2.7	Yes	/
17	ECG Cable	2.7	Yes	/
18	ECG Cable	2.2	Yes	/
19	ECG Cable	2.7	Yes	/
20	ECG Cable	2.7	Yes	/
21	ECG Cable	3.1	Yes	/
22	ECG Cable	1.3	Yes	/
23	ECG Cable	1.3	Yes	/
24	ECG Cable	1.3	Yes	/
25	ECG Cable	1.3	Yes	/
26	ECG Cable	3.0	Yes	/
27	ECG Cable	3.0	Yes	/
28	ECG Cable	3.0	Yes	/
29	ECG Cable	3.0	Yes	/
30	ECG Cable	3.0	Yes	/
31	ECG Cable	3.0	Yes	/
32	ECG Cable	3.0	Yes	/
33	ECG Cable	3.0	Yes	/
34	ECG Cable	3.4	Yes	/
35	ECG Cable	3.4	Yes	/
36	ECG Cable	3.4	Yes	/
37	ECG Cable	3.4	Yes	/
38	ECG Cable	3.0	Yes	/
39	ECG Cable	3.1	Yes	/
40	ECG Cable	3.0	Yes	/
41	ECG Cable	3.0	Yes	/
42	ECG Cable	3.0	Yes	/

Number	Name	Cable length (m)	With shielding	Remarks
43	ECG Cable	0.7	Yes	/
44	ECG Cable	0.7	Yes	/
45	ECG Cable	0.7	Yes	/
46	ECG Cable	0.7	Yes	/
47	ECG Cable	0.7	Yes	/
48	ECG Cable	0.7	Yes	/
49	ECG Cable	0.7	Yes	/
50	ECG Cable	0.7	Yes	/
51	ECG Cable	0.7	Yes	/
52	ECG Cable	0.7	Yes	/
53	ECG Cable	0.7	Yes	/
54	ECG Cable	0.7	Yes	/
55	ECG Cable	0.7	Yes	/
56	ECG Cable	0.7	Yes	/
57	ECG Cable	0.7	Yes	/
58	ECG Cable	0.7	Yes	/
59	Temp sensor cable	3.0	Yes	Selected for test
60	Temp sensor cable	1.0	Yes	/
61	Temp sensor cable	1.0	Yes	/
62	Temp sensor cable	2.5	Yes	/
63	Temp sensor cable	3.0	No	/
64	Temp sensor cable	3.0	No	/
65	Temp sensor cable	1.0	No	/
66	Temp sensor cable	3.0	No	/
67	SpO_2 sensor cable	1.0	Yes	/
68	SpO_2 sensor cable	3.0	Yes	/
69	SpO_2 sensor cable	1.0	Yes	/
70	SpO_2 sensor cable extender	3.0	Yes	/
71	SpO_2 sensor cable extender	1.0	Yes	/
72	Reusable SpO_2 sensor cable	1.0	Yes	/
73	SpO_2 sensor cable	1.0	Yes	/
74	SpO_2 sensor cable	1.0	Yes	/

Number	Name	Cable length (m)	With shielding	Remarks
75	Disposable SpO_2 sensor cable	0.9	Yes	/
76	Disposable SpO_2 sensor cable	0.5	Yes	/
77	Disposable SpO_2 sensor cable	0.5	Yes	/
78	Disposable SpO_2 sensor cable	0.9	Yes	/
79	Disposable SpO_2 sensor cable	0.9	Yes	/
80	Disposable SpO_2 sensor cable	0.5	Yes	/
81	Disposable SpO_2 sensor cable	0.5	Yes	/
82	Disposable SpO_2 sensor cable	0.9	Yes	/
83	SpO_2 sensor cable	0.9	Yes	/
84	SpO_2 sensor cable	0.9	Yes	Selected for test
85	SpO_2 sensor cable	0.9	Yes	/
86	SpO_2 sensor extender (main cable)	3.0	Yes	Selected for test
87	SpO_2 sensor cable	1.1	Yes	Selected for test
88	SpO_2 sensor cable	1.1	Yes	/
89	SpO_2 sensor extender (main cable)	3.0	Yes	Selected for test
90	Temp cable (surface)	3.0	Yes	/
91	Temp cable (surface)	3.0	Yes	/
92	Temp cable (intracavity)	3.0	Yes	/
93	Temp cable (intracavity)	3.0	Yes	Selected for test
94	Temp cable	3.0	Yes	/
95	Temp cable	3.0	Yes	Selected for test
96	Temp cable	3.0	Yes	/
97	Temp cable	3.0	Yes	/
98	Invasive Blood Pressure Cable	4.0	Yes	/

Number	Name	Cable length (m)	With shielding	Remarks
99	Invasive Blood Pressure Cable	4.0	Yes	Selected for test
100	Invasive Blood Pressure Cable	4.0	Yes	/
101	Invasive Blood Pressure Cable	4.0	Yes	/
102	Invasive Blood Pressure Cable	4.0	Yes	Selected for test
103	Comen mainstream CO_2 module cable	2.6	Yes	/
104	CO_2 module cable	0.3	Yes	/
105	Comen mainstream CO_2 module cable	3.0	Yes	Selected for test
106	Respironics CO_2 module cable	2.8	Yes	/
107	Respironics CO_2 module cable	0.3	Yes	/
108	C.O. (cardiac output) adapting cable	3.0	Yes	Selected for test
109	Power Cable	3.0	No	/
110	Ground cable	2.5	No	/

Essential Performance

under the normal condition or single fault condition, the monitor provided the essential performance listed below, or their failure is readily identifiable by the user.

1. Heart rate measurement accuracy/Impedance respiration rate measurement accuracy;
2. Pulse Oxygen Saturation Measurement Accuracy;
3. Pulse Rate Measurement Accuracy;
4. Body Temperature Measurement Accuracy;
5. NIBP Measurement Accuracy;
6. IBP Measurement Accuracy;
7. $EtCO_2$ Measurement Accuracy;
8. C.O. Measurement Accuracy;

Guidance and manufacturer's declaration –electromagnetic emission		
ND10/ND10A/ND10C/ND10S//ND12/N1D2A/ND12C/ND12S/ND15/ND15A/ND15C/ND15S patient monitor is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
Conducted and radiated RF emissions CISPR 11	Group 1	ND10/ND10A/ND10C/ND10S//ND12/N1D2A/ND12C/ND12S/ND15 /ND15A/ND15C patient monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted and radiated RF emissions CISPR 11	Class A	ND10/ND10A/ND10C/ND10S//ND12/N1D2A/ND12C/ND12S/ND15 /ND15A/ND15C patient monitor is suitable for use in all establishments other than domestic ones and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion emissions IEC 61000-3-2	Pass	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Pass	

Guide and Manufacturer's Statement – Electromagnetic Immunity			
ND10/ND10A/ND10C/ND10S//ND12/N1D2A/ND12C/ND12S/ND15/ND15A/ND15C/ND15S patient monitor is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	**IEC60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guide**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV, contact ±8 kV, air	±6 kV, contact ±8 kV, air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient burst (EFT/B) IEC 61000-4-4	± 2 kV for input AC and DC power input port ± 1 kV for SIP/SOP port 100 kHz repetition frequency	± 2 kV for input AC and DC power input port ± 1 kV for SIP/SOP port 100 kHz repetition frequency	Connect the equipment to supply mains of professional healthcare facility other than public supply mains

			SIP/SOPS whose maximum cable length is less than 3 m in length are excluded
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to ground	± 1 kV line to line ± 2 kV line to ground	Connect the equipment to supply mains of professional healthcare facility other than public supply mains
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T; 0.5 cycle (＞95 % dip in U_T) 40 % U_T; 5 cycle (60 % dip in U_T) 70 % U_T; 25cycle (30 % dip in U_T) <5% U_T; 5s (＞95 % dip in U_T)	<5 % U_T; 0.5 cycle (＞95 % dip in U_T) 40 % U_T; 5 cycle (60 % dip in U_T) 70 % U_T; 25cycle (30 % dip in U_T) <5% U_T; 5s (＞95 % dip in U_T)	The mains power supply should be of typical quality for commercial or hospital use. To ensure the continuously safe use running of the monitor, It is recommended to use an uninterruptable power supply or the battery power.
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m	30 A/m (50 /60Hz)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T refers to the AC voltage when the test voltage is not applied yet.			

Guide and Manufacturer's Statement – Electromagnetic Immunity			
ND10/ND10A/ND10C/ND10S//ND12/N1D2A/ND12C/ND12S/ND15/ND15A/ND15C/ND15S patient monitor is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity Test	**IEC60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guide**
	3 Vrms 0.15 MHz to 80 MHz	3 Vrms	Do not use any portable or mobile RF communication equipment within the recommended distance from any part of the monitor (including the cable).. Except as indicated on page V-11, such

RF conduction IEC 61000-4-6 RF radiation IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	recommended separation distance calculated from the equation according to the frequency of the transmitter. . Recommended separation distance: d = $1.2\sqrt{P}$ d = $1.2\sqrt{P}$ 80 MHz to 800 MHz d = $2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) The field intensity of fixed RF transmitters is measured by surveying[a] the electromagnetic field and should be lower than the compliance level in either frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency band was applied.

NOTE 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify essential performance. This equipment may cause radio interference or may disrupt the operation of nearby equipment. If anything abnormal occurs, it may be necessary to take mitigation measures, such as re-orienting or relocating the equipment or shielding the location.

b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Recommended Separation Distance between Portable and Mobile RF Communication Equipment and The Device

ND10/ND10A/ND10C/ND10S//ND12/N1D2A/ND12C/ND12S/ND15/ND15A/ND15C/ND15S patient monitor is intended to work in an electromagnetic environment with controlled RF radiation disturbance. The consumer or user of the monitor should prevent electromagnetic interference by maintaining the following recommended separation distance between the portable and mobile RF communication equipment (transmitters) and this product according to the maximum output power of the communications equipment except as indicated.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	80 MHz - 800 MHz $d = 1.2\sqrt{P}$	800 MHz- 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

In case of any maximum rated output power other than listed above, use the formula ("*P*" refers to the transmitter's maximum rated output power (W) learnt from the transmitter manufacturer) in the relevant transmitter frequency column to calculate the recommended isolation distance "d" (m).

Frequencies of portable and mobile transmitters for which the recommended separation distance is 30 cm (12 inches)

NOTE 1: At 80 MHz and 800 MHz, the higher frequency band was applied.

NOTE 2: These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2 Radio Management Compliance

RF Parameters

Parameters	IEEE 802.11b/g/n (2.4G)	IEEE 802.11a/n (5G)
Frequency	ETSI：2.4GHz ~2.483GHz FCC：2.4GHz ~2.483GHz MIC：2.4GHz ~2.495GHz SRRC:2.4 GHz ~2.483GHz	ETSI：5.15GHz ~5.35GHz，5.47GHz ~5.725GHz FCC：5.15GHz ~5.35GHz，5.725GHz ~5.82GHz MIC：5.15GHz ~5.35GHz，5.47GHz ~5.725GHz SRRC:5.15GHz ~5.35GHz，5.725GHz ~5.85GHz
Modulation	DSSS, OFDM	
Transmit power	≤20 dBm (Average) ≤33 dBm (Max)	

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Appendix VI **Glasgow 12-Lead ECG Analysis**

VI.1 Wave measurement

From the 12 average beats, a single combined function is formed and a provisional overall QRS onset and termination is determined by thresholding techniques. The provisional onset and termination are then used as starting points for a search for QRS onset and termination within each individual lead.

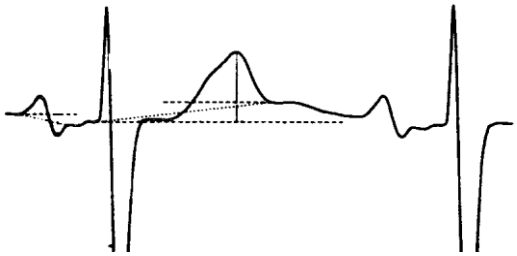

Figure 1 Varying choice of baselines.

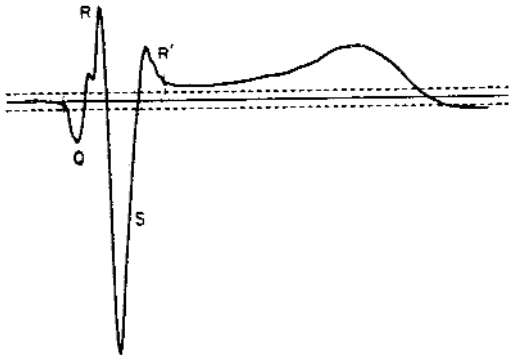

Figure 2 Baseline at the level of QRS onset as used by the Glasgow program.

In each individual lead, the QRS onset is taken as the baseline and hence Q, R, S, R' waves are measured with respect to the QRS onset as shown in the accompanying figures from the CSE paper.

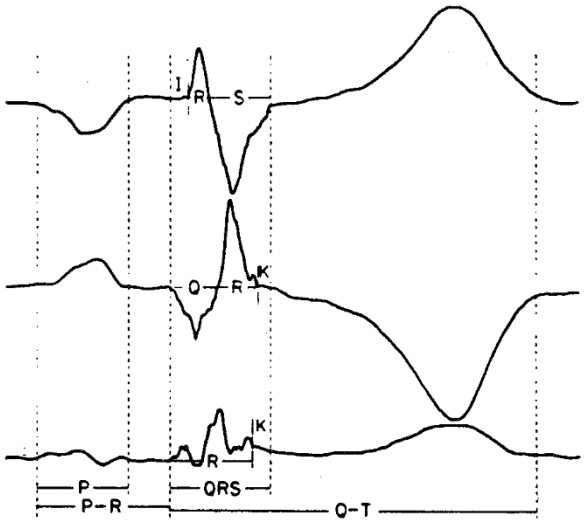

Figure 3 Illustration of isoelectric segments I and K.

Isoelectric segments at the beginning of a QRS complex, i.e. a flat segment between the provisional overall onset and the onset of an individual lead are excluded from the first component (Q or R) of the QRS complex as recommended by the CSE group. Similar considerations apply at the end of the QRS complex.

VI.2 ST Segment and Amplitude Measurement

ST segment (Figure 4) shows the ST onset as used in the diagnosis of ST elevation myocardial infarction. However, measurements are also made at equal intervals throughout the ST segment.

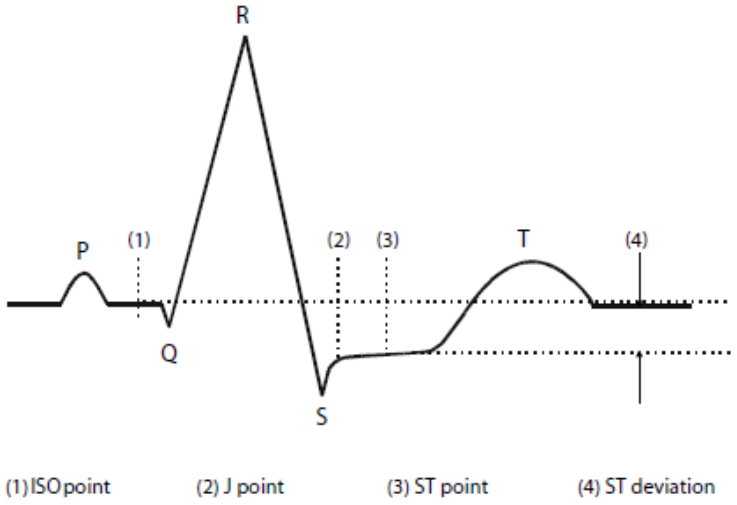

Figure 4 ST segment

P and T waves

A search for the P wave is made in the interval preceding the QRS complex. P wave amplitude is determined with respect to the same baseline as for Q, R, S amplitudes, namely the QRS onset. The global T end is derived in a similar fashion to the global QRS offset. The ST and T wave amplitudes, are also measured with respect to QRS onset. See the Figure 5 below:

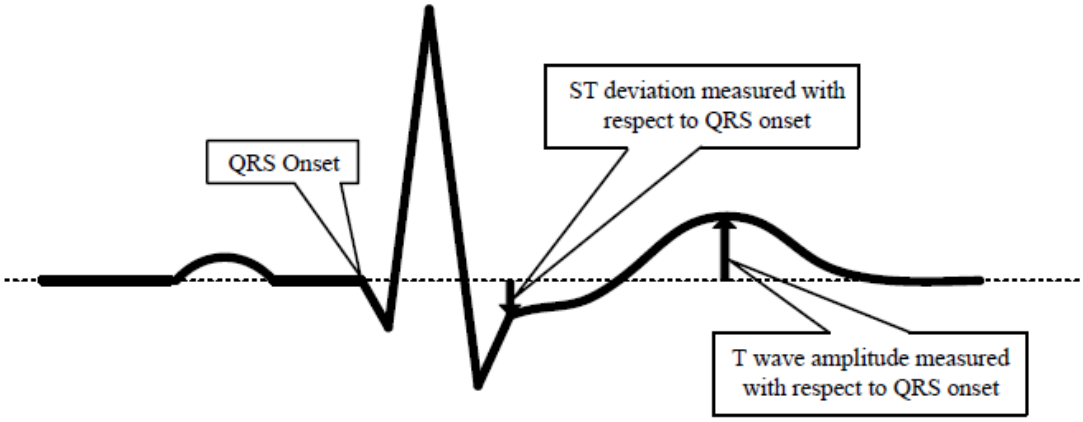

Figure 5 Components of the ECG waveform determination

VI.3 Interval Measurements

With respect to intervals, the global QT interval is measured from the global QRS onset to the global T end. On the other hand, because the P onset is taken as being simultaneous in all 12 leads, the global PR interval measurement is from the P onset to the global QRS onset.

VI.4 Stability of Measurements against Noise

Acceptance of minimum waves

The labelling of the QRS waveforms depends by definition (since Einthoven) on the first detected wave. A tiny positive wave at QRS beginning is called r or R and may mask a true, following Q wave. Therefore, the acceptance criteria of initial waveforms should be clearly defined and standardized。

the following rule for acceptance of minimum waves is used:

a) the signal part under consideration shows clearly two opposite slopes with at least one turning point in between;

b) the signal part under consideration deviates at least 30 μV from the reference level for a duration of at least 6 ms (see Figures 6 and GG);

c) this results in acceptance criteria for minimum waves with observable durations of about 12 ms and amplitudes ≥30 μV.

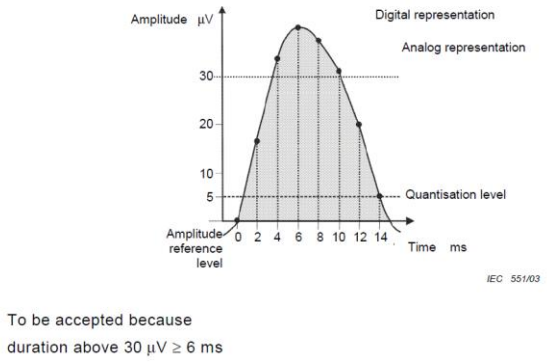

Figure 6 Detail of small accepted R-wave

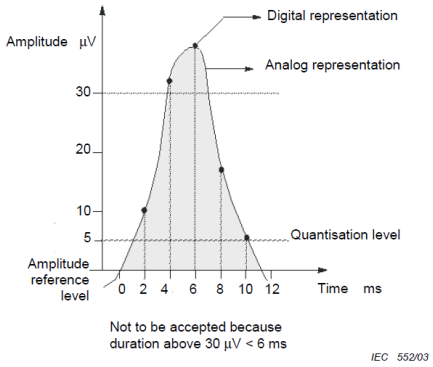

Figure 7 Detail of small rejected R-wave

Disclosure for changes of measurements caused by noise on ECGs according to Table HH.3

Global measurement	Type of added noise	Disclosed difference	
		Mean (ms)	Standard deviation (ms_
P-duration	High-frequency	1.2	2.62
P-duration	Line-frequency (50Hz)	-1.6	3.50
P-duration	Line-frequency (60Hz)	1.3	6.67
P-duration	Baseline	-0.8	5.73
QRS-duration	High-frequency	0.6	2.62
QRS-duration	Line-frequency (50Hz)	-3	7.757
QRS-duration	Line-frequency (60Hz)	-2.7	6.11
QRS-duration	Baseline	0.5	3.50
QT-interval	High-frequency	-0.7	3.38
QT-interval	Line-frequency (50Hz)	-2.4	4.57
QT-interval	Line-frequency (60Hz)	-2.7	6.58
QT-interval	Baseline	4.8	8.24

VI.5 Analyzing Electrocardiograph Intended Use

Diagnostic application

The Glasgow Program is intended to provide an interpretation of the resting 12 lead ECG in all situations, whether this be in a hospital or primary care setting. Analysis of the ECG signals is accomplished with

algorithms that provide measurements, graphical presentations and interpretations for review by the user. It is capable of diagnosing commonly recognized ECG abnormalities such as myocardial infarction (MI), including acute MI, ventricular hypertrophy, abnormal ST-T changes and common abnormalities of rhythm. Conduction defects and other abnormalities such as prolonged QT interval are also reported. It is not designed for interpretation of exercise electrocardiograms.

Intended population

The Glasgow 12-lead ECG analysis is intended for use in adults and children of any age from birth upwards. It makes significant use of the patient's age and gender and indeed operates at the level of days in the case of neonates.

Intended location

The monitor is intended to be used in hospital by trained professional healthcare.

Diagnostic accuracy

The Glasgow algorithm analysis has high sensitivity for detecting cardiac abnormalities as is evidenced by the results presented in the following section. In short, the algorithm aims for the highest sensitivity at a high specificity although there is always a tradeoff between one and the other.

Appendix VII **Units, Symbols and Abbreviations**

Abbreviation	In Full
Ω	ohm
μA	Microampere
μs	Microsecond
$AaDO_2$	Alveolar-arterial oxygen difference
AAP	American Academy of Pediatrics
AC	Alternating Current
ACCF	American College of Cardiology Foundation
AG	Anaesthesia Gas
AHA	American Heart Association
AM	Amplitude Modulation
AMI	Anterior myocardial infarction
Ao	Aortic Pressure
Art	Arterial Pressure
ATMP	Atmospheric Pressure
aVF	Left Foot Augmented Lead
aVL	Left Arm Augmented Lead
aVR	Right Arm Augmented Lead
awRR	Airway Respiratory Rate
BAP	Brachial Arterial Pressure
bpm	Beat Per Minute
BSA	Body Surface Area
BT	Blood Temperature
BTPS	Body Temperature and Pressure, Saturated
BUN	Blood urea nitrogen
CAA	Clinical Assistive Application
CaO_2	Arterial oxygen content
CCU	cardiac (coronary) care unit
CCHD	critical congenital heart disease
CCO_2	Capillary oxygen content
CH_20	Free water clearance
Clcr	Creatinine clearance rate
cm	centimeter
Cosm	Osmolar clearance
CPP	Cerebral perfusion pressure
Cr	Creatinine
CvO_2	Venous oxygen content
CVP	central venous pressure
DIA	diastolic

Abbreviation	In Full
DO_2	Oxygen transport
ECG	electrocardiograph
EDV	end-diastolic volume
EF	Ejection fraction
ESD	Electrostatic discharge
ESU	electrosurgical unit
$EtCO_2$	end-tidal carbon dioxide
EWS	Early warning system
FAP	femoral arterial pressure
FENa	Fractional excretion of sodium
$FiCO_2$	fraction of inspired carbon oxygen
FiO_2	fraction of inspired oxygen
FM	frequency modulation
GCS	Glasgow Coma Scale
GHz	gigahertz
Hb	hemoglobin
HR	heart rate
HRV	heart rate variability
Hz	hertz
IAP	Intra-abdominal pressure
IBP	invasive brood pressure
ICP	intracranial pressure
ICU	intensive care unit
IEC	International Electrotechnical Commission
IP	internet protocol
IT	injectate temperature
kg	kilogram
kPa	kilopascal
LA	left arm
LAP	left atrial pressure
LCW	left cardiac work
LCWI	left cardiac work index
LL	left leg
LVSW	left ventricular stroke work
LVSWI	left ventricular stroke work index
MAP	Artery mean pressure
MPAP	Pulmonary artery mean pressure
NIBP	noninvasive blood pressure
OR	operating room
PA	pulmonary artery
$PaCO_2$	Partial pressure of carbon dioxide in the arteries
PaO_2	Partial pressure of oxygen in the arteries

Abbreviation	In Full
PAWP	pulmonary artery wedge pressure
PCBA	Printed Circuit Board Assembly
$PeCO_2$	Partial pressure of mixed expiratory CO_2
PI	Perfusion index
Posm	Plasm osmolality
PPV	pulse pressure variation
PR	pulse rate
PVC	premature ventricular contraction
PvO_2	3+Partial pressure of oxygen in venous blood
PVR	pulmonary vascular resistance
PVRI	pulmonary vascular permeability index
qSOFA	quick SOFA, quick Sepsis-Related Organ Failure Assessment
RA	right arm
RAP	right atrial pressure
RCW	Right cardiac work
RCWI	Right cardiac work infex
RESP	respiration
RL	right leg
rpm	breaths per minute
RQ	respiratory quotient
RR	respiration rate
RVSW	Right ventricular stroke work
RVSWI	Right ventricular stroke work index
SACHDNC	Secretary's Advisory Committee on Heritable Disorders in Newborns and Children
SaO2	arterial oxygen saturation
SerNa	Serum sodium
SOFA	Sepsis-Related Organ Failure Assessment
SpO_2	arterial oxygen saturation from pulse oximetry
SSC	Surviving Sepsis Campaign
SV	stroke volume
SVI	stroke volume index
SvO_2	Venous oxygen saturation
SVR	systemic vascular resistance
SVRI	systemic vascular resistance index
SYS	systolic pressure
TD	temperature difference
Temp	temperature
TV	tidal volume
UAP	umbilical arterial pressure
Ucr	Urine creatinine
Uosm	Urine osmolality

Abbreviation	In Full
Urine	Urine
URK	Urine pstassium
URKEx	Urine potassium excretion
URNa	Urinary sodium
URNaEx	Urine sodium excretion
USB	universal serial bus
UVP	umbilical venous pressure
VA	Alveolar volume
Vd	Volume of physiological dead space
Vd/Vt	Physiologic dead space in percent of tidal volume
VO_2	oxygen consumption