Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 091264 0006 Rev. 02

Manufacturer:

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,
Pingshan District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF
CHINA

Product Category(ies): **Fetal Monitor, Fetal & Maternal Monitor, Ultrasonic Pocket Doppler, Patient Monitor, Electrocardiograph, Central Monitoring System, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, PC ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Diagnostic Ultrasound System, Holter System, Telemetry Transmitter, Anaesthetic Workstation, Ventilator, Biofeedback and Stimulation System, Ambulatory Blood Pressure Monitor, SPO2 Sensor; Temperature Probe; Ultrasonic Transducer.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ1989104

Valid from: 2019-11-25
Valid until: 2022-09-17

Date, 2019-11-25

Christoph Dicks
Head of Certification/Notified Body

A4 / 07.17

TÜV SÜD · CERTIFICATE · ZERTIFIKAT · 認證證書 · СЕРТИФИКАТ · CERTIFICADO · CERTIFICAT

TÜV®

Product Service

Certificate

No. Q5 091264 0016 Rev. 01

Holder of Certificate: **Edan Instruments, Inc.**
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV
SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Transcranial Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Patient Monitor, Central Monitoring System, Ultrasonic Pocket Doppler, Electrocardiograph, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, STRESS ECG, PC ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Data Management Software, Trolley (for medical use), ECG Electrode, Holter System, Treadmill (for medical use), Diagnostic Ultrasound System, Ultrasonic Imaging Management System, Blood Gas and Chemistry Analysis System (including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge, Controls, External electronic simulator, capillary adaptor, Ampoule adaptor); Hematology analyzer; Reagents for Hematology Analyzer (including diluent, lyse, cleaner, bleach, hematology control, hematology calibrator); Video Colposcope; Ultrasonic Transducer, TOCO Transducer; SPO2 Sensor; Temperature Probe; ECG Cable, Telemetry Transmitter, NIBP Cuff, Anaesthetic Workstation, Ventilator, Specific Protein Immunoassay System (including Protein Assay kit, Assay buffer, Sample dilution buffer, Washing buffer, Protein Analyzer), Biofeedback and Stimulation System, EMG/ Stimulation sensor, Ambulatory Blood Pressure Monitor, Medical Air Compressor, NIBP Tube, Connection Cable, Water Trap, Needle Guide Bracket.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the

TÜV®

A4 / 07.17

Product Service

Certificate

No. Q5 091264 0016 Rev. 01

requirements of the listed standard(s). See also notes overleaf.

Report No.:	BJ1989104
Valid from:	2019-12-01
Valid until:	2022-11-30

Date, 2019-11-25

Christoph Dicks
Head of Certification/Notified Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 091264 0016 Rev. 01

Applied Standard(s):   EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):   Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,
Pingshan District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF
CHINA

.

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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EDAN

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iM8 Series
Entry-level Patient Monitors

Our Position

- Top 2 patient monitoring exporter
- All products with CE approval

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Our R&D Investments

- More than 300 R&D engineers
- 3 R&D centers distributed in China & US
- Industrial design associates in Germany

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Our Value Proposition

Bring innovation and value together to improve the human condition.

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EDAN products has presences in **156** countries

iM8 Series

iM8
12.1"
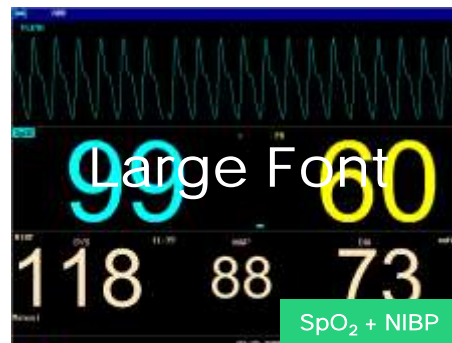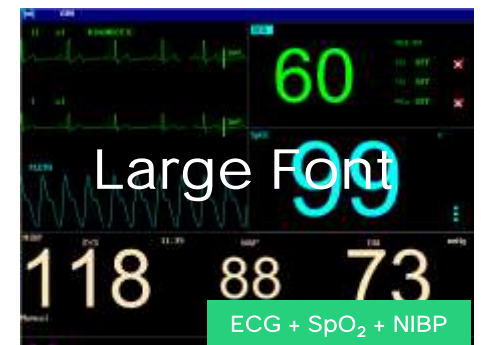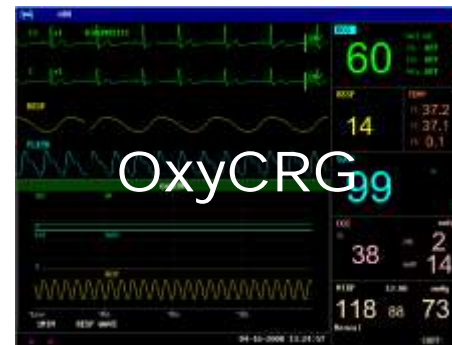
iM8A
10.4"

iM8B
10.1"

Critical
Cares

Emergency
Cares

General
Ward

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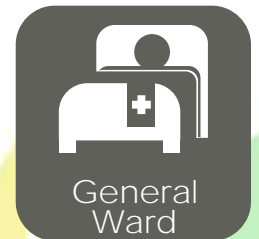
Multiple Display Modes

- Maximum 10 channels

- Maximum 11 waveforms

Standard

Trend Screen

OxyCRG

Large Font — ECG + SpO_2 + NIBP


Large Font — SpO_2 + NIBP

Large Font — SpO_2 Only

Standby Mode

Though named as "Standby", on this mode, background monitoring still continues while a clock displays, hiding patient's vital information for privacy protection purpose during family visits.

- Background monitoring continues

- Real-time monitoring data is still sending to central station/other systems.

- No physiological parameter or alarms will appear on the screen but on the central station

3-level Alarm System
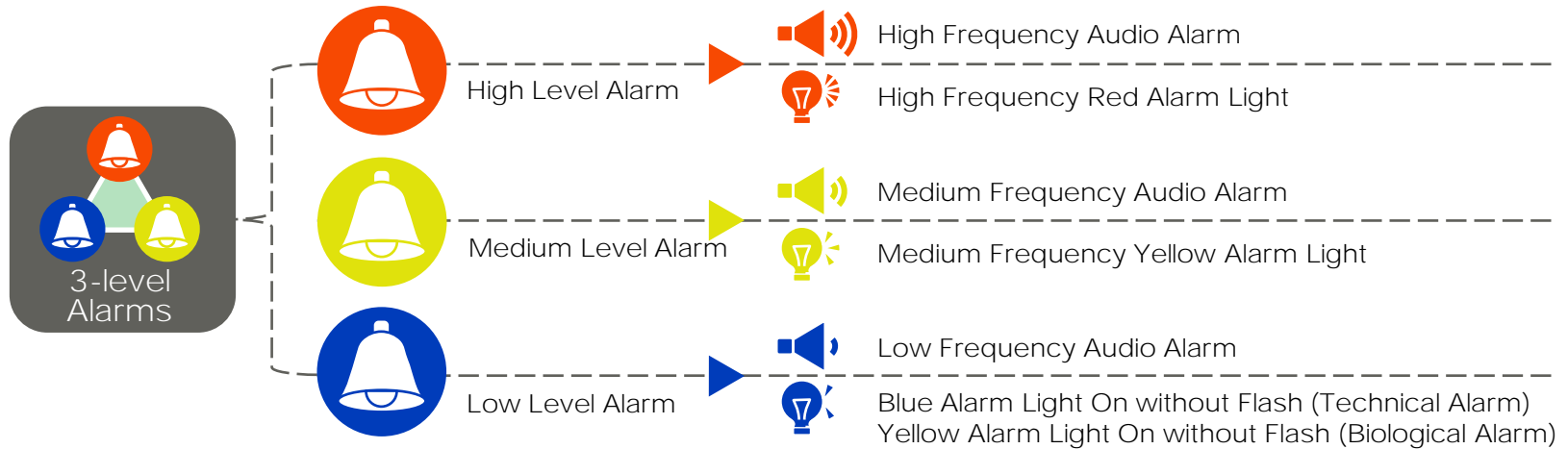
A customizable 3-level alarm management system is built in the monitors, presented with different audio & visual indications.

■ **High Level Alarm**
High priority alarms which requires immediate medical response.

■ **Medium Level Alarm**
Medium priority alarms which requires close attentions.

■ **Low Level Alarm**
Lowest priority alarms which is likely to result in discomfort of the patient.

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Essential Alarm Management

On EDAN monitors, alarms can be switched off as per user configuration. However, additional restrictions are put upon some essential alarms to control over possible lethal conditions.

- ## Cardiac Arrest
  Cardiac arrest alarm can never be switched off.
  Cardiac arrest alarm level is fixed as high.

- ## Apnea
  Apnea alarm can never be switched off.
  Apnea alarm level is fixed as high.
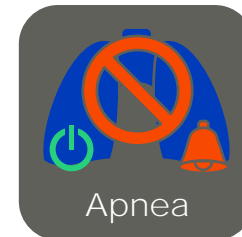
- ## Ventricular Fibrillation/Tarchycardia
  Ventricular fibrillation/tarchycardia alarm can can never be switched off.
  Ventricular fibrillation/tarchycardia alarm level is fixed as high.

- ## Most Biological Alarms
  Most biological alarms level can never be switched into low.

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Alarm Mute/Reset

The alarm reset on the setupmenu serves for the ongoing alarm.

- ■ Ongoing alarm mute

- ■ New alarm will break the mute status

Alarm Reset

The alarm mute silicone button serves for overall alarms

- ■ Click
  1/2/3 minutes mute of overall alarms
  New alarm will break the mute status

- ■ Long Press (3 seconds)
  Permanent mute of overall alarms
  New alarm will break the mute status

Alarm Mute

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Personalized Alarm Programs

Preconfigured alarm programs are built inside the machine, divided into adult, pediatric, and neonate.

At the same time, users may configure their own alarm settings according to different clinical requirements and save into the monitor. User may also edit the existed programs as new saves.

- **Adult Alarm Program**
  Activated when patient type is "Adult".

- **Pediatric Alarm Program**
  Activated when patient type is "Pediatric".

- **Neonatal Alarm Program**
  Activated when patient type is "Neonate".

- **User Configured Alarm Program**
  Activated when selected.

Factory
Alarm Set

User
Alarm Set

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Built-in Temporary Memory

The machine comes with built-in temporary memory with which you may easily review the monitoring history data.

Once reboot, the temporary memory will be lost.

- **Trend Review**
  120 hours of trend graph/trend table

- **Alarm Review**
  60 sets

- **Arrhythmia Review**
  60 sets

- **Frozen Waveform**
  720 seconds

- **NIBP Review**
  1200 sets

Trend Review

Alarm Review

Arrhythmia Review

Frozen Waveform
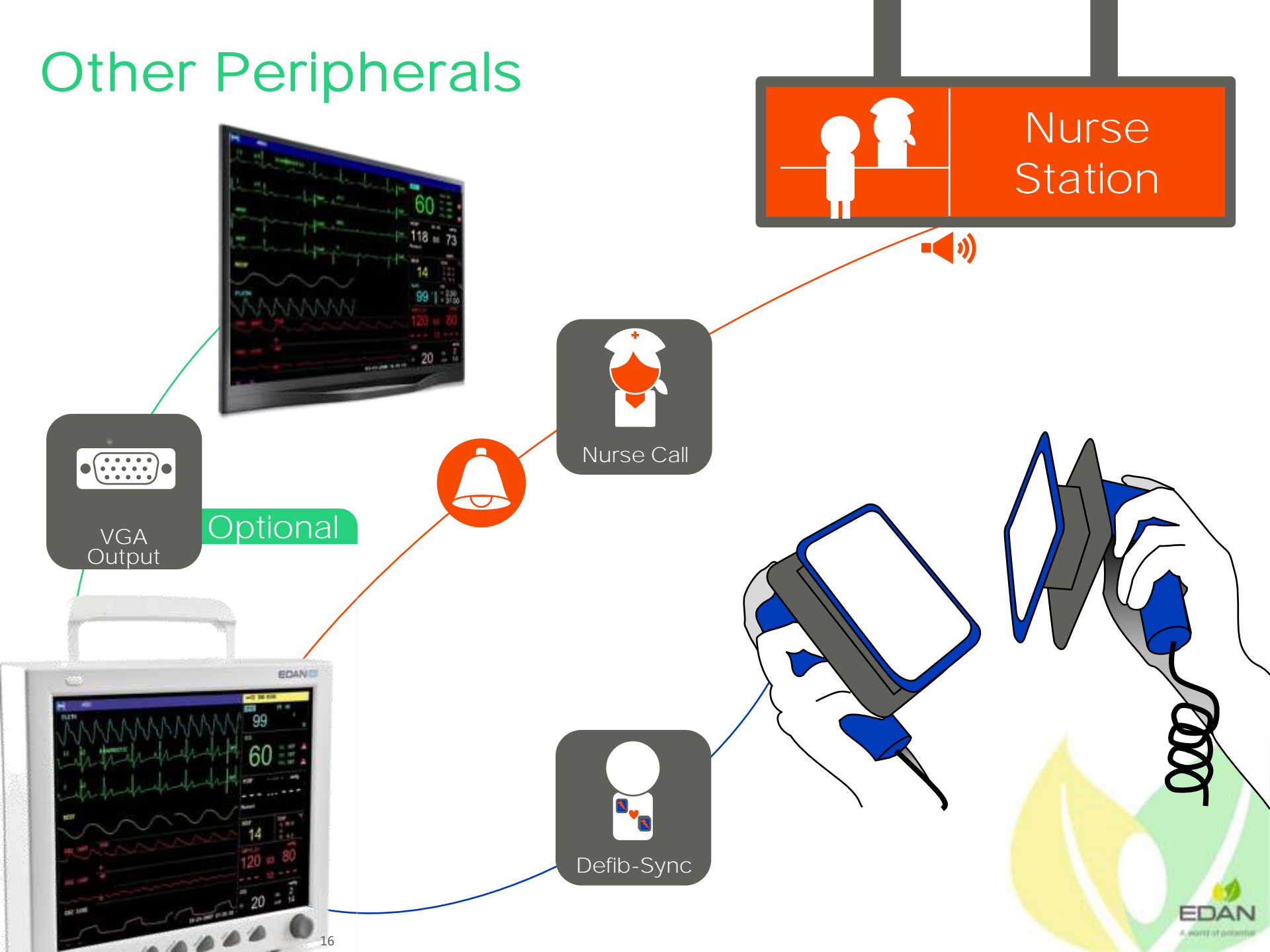

NIBP Review

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External Memory

Installed with an external USB flash disk, monitoring data can be stored permanently. You may either review these data on any EDAN monitor or on PatientCare Viewer PC software.

For each patient::

- **Trend Storage**
  96 hours of trend graph/trend table

- **Alarm Storage**
  60 sets

- **Arrhythmia Storage**
  60 sets

- **NIBP Storage**
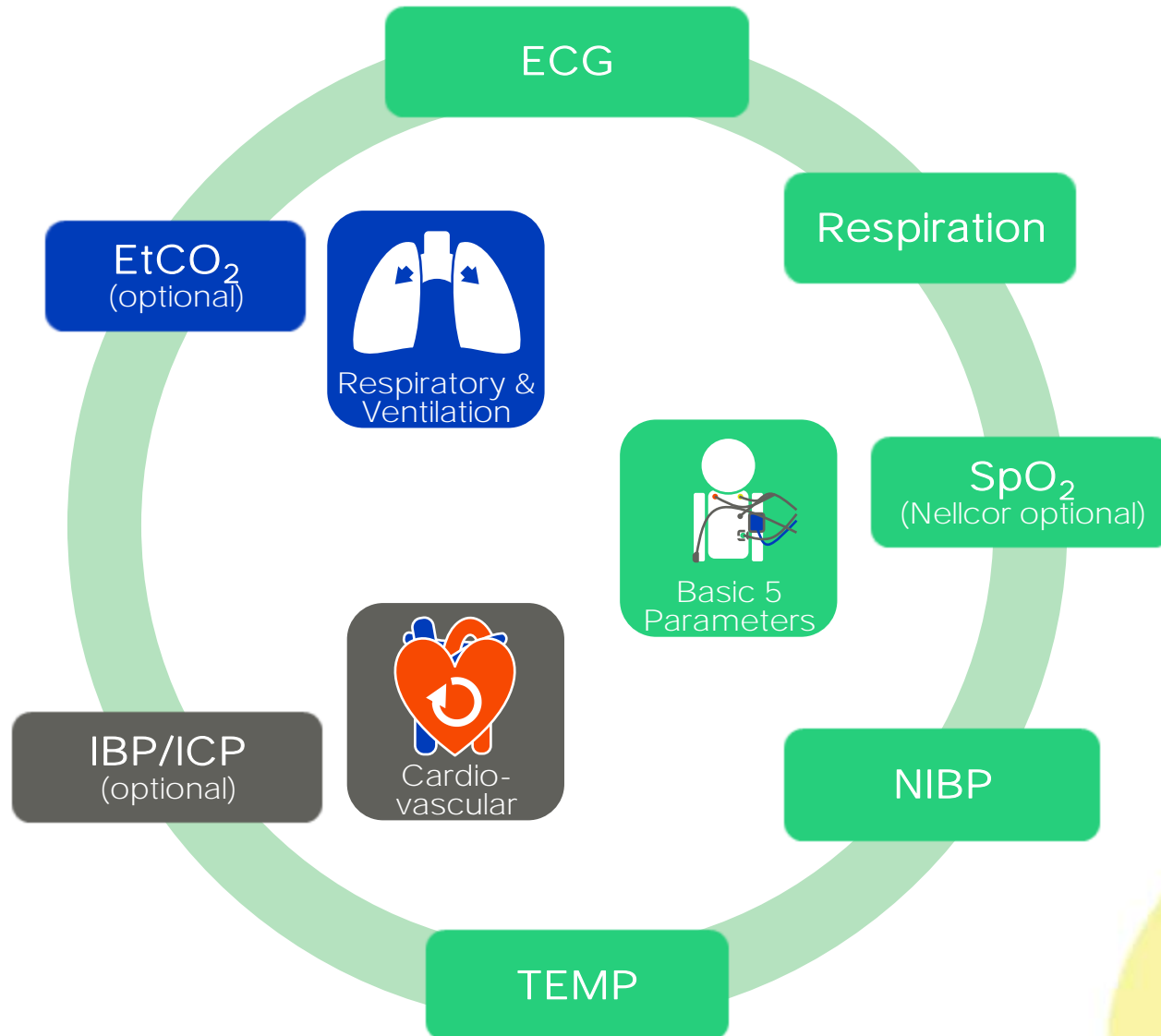 500 sets

- **Waveform Storage**
  120 seconds

Trend Review

Alarm Review
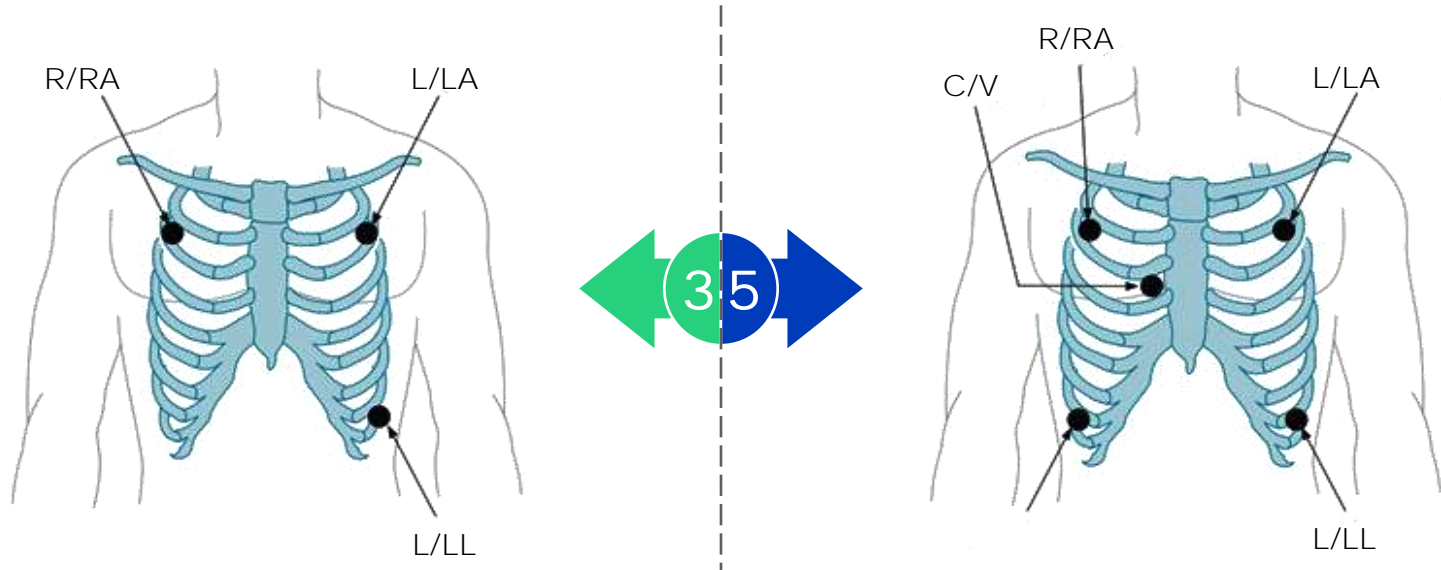
Arrhythmia Review

NIBP Review

Waveform

USB
Flash Disk

EDAN

Other Peripherals

Nurse Station

VGA Output

Optional

Nurse Call

Defib-Sync

16

EDAN

Mounting Solutions

- Rolling Stand

- Wall Mount

- Bedrail Hook

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Parameters

18

3/5-lead ECG Monitoring

R/RA L/LA

3 5

R/RA L/LA
C/V

L/LL L/LL

- **EDAN iSEAP™ algorithm optimized for arrhythmia detection, pacemaker detection, ST analysis, and HR measurement.**

- 16 types of arrhythmia events recording and alarms

- Pacemaker detection

- Defibrillator protection

- ESU protection

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EDAN iSEAP™ Monitoring Algorithm

Based on the experience of EDAN's last generation ECG algorithm, AKA "SEAP", a new generation algorithm iSEAP™ was introduced by April 2012. It shows outstanding performance with great improvement in Arrhythmia Detection, ST Analysis, Giant T Wave Differentiation, Pacemaker Detection, and Interference Resistance.

Heartbeat Detection

ARR Detection

ST Analysis

PACE Detection

iSEAP™

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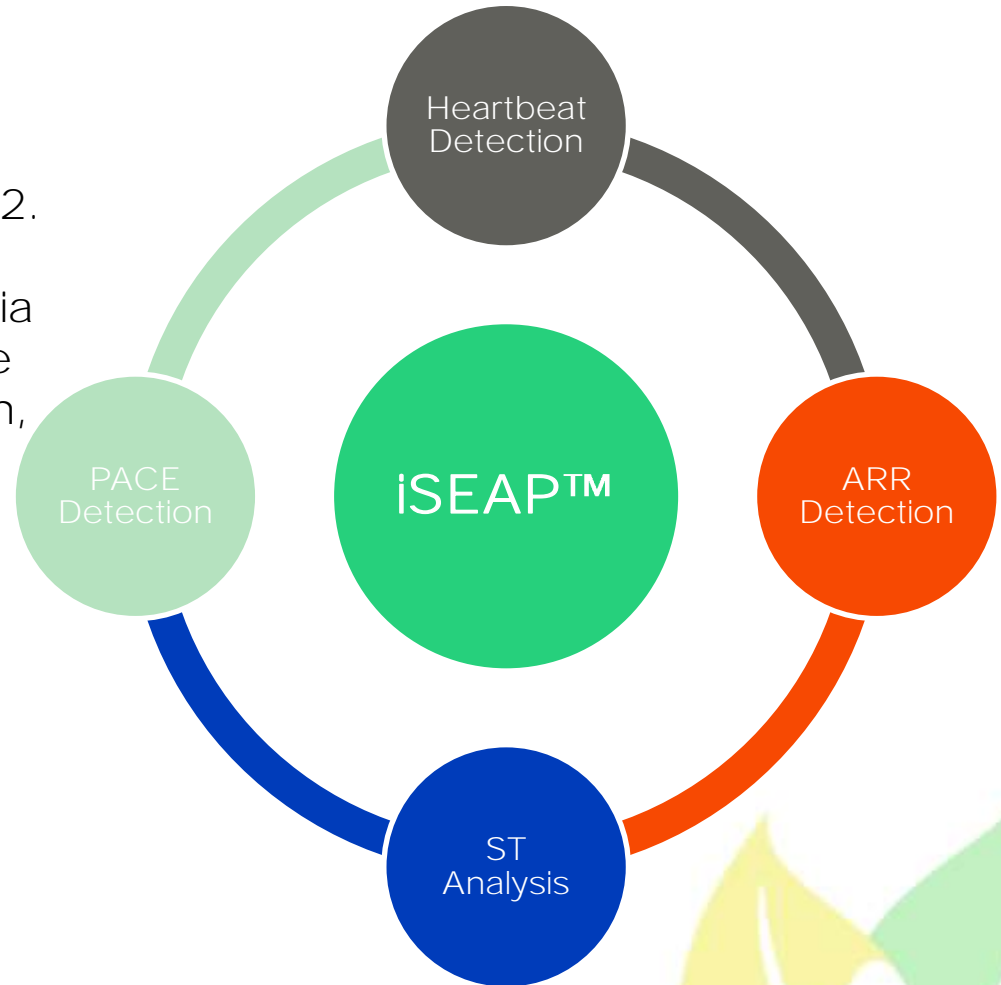
EDAN iSEAP™ Heartbeat Detection
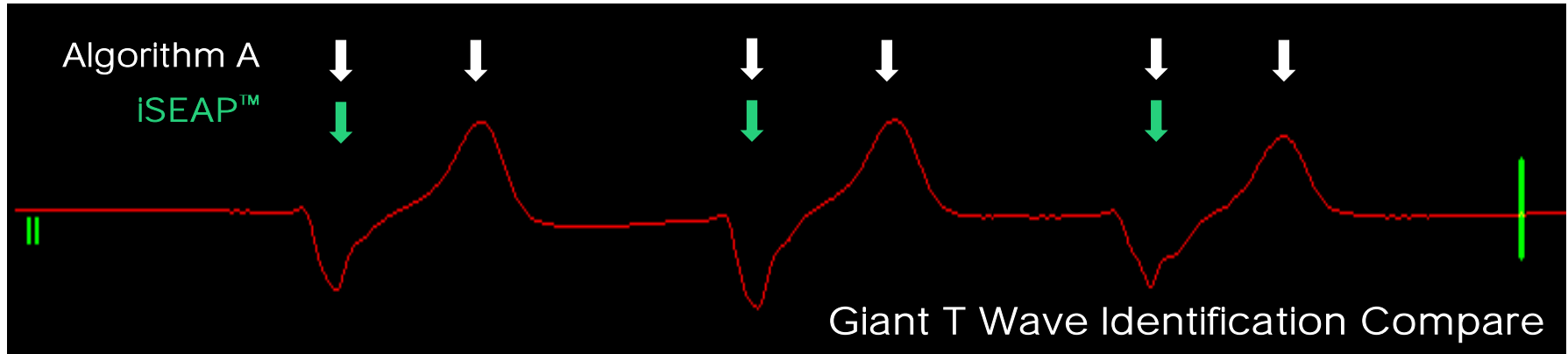
Algorithm A is another algorithm from market as a compare reference.

- iSEAP™ identifies giant T waves and avoids false heartbeat, providing accurate HR measurements for patients with ischemic T waves, myocarditis, hyperkaliemia, early repolarization syndrome, and so on.

- For patients with tachycardia, bradycardia, atrial flutter, etc., iSEAP™ makes sure the heart beat sound fits exactly as the real heart beat. You can even tell the heart rate with the heart beat sound alone.

- The heart beat sound detection algorithm is cognate with the heart rate detection algorithm. The two algorithms correct each other to ensure acute heart beat detections

EDAN iSEAP™ Heartbeat Sound Detection

- For patients with tachycardia, bradycardia, atrial flutter, etc., iSEAP™ makes sure the heart beat sound fits exactly as the real heart beat. You can even tell the heart rate with the heart beat sound alone.

- The heart beat sound detection algorithm is cognate with the heart rate detection algorithm. The two algorithms correct each other to ensure acute heart beat detections

- Patients with giant T waves could confuse the ECG monitoring and ends up with false heart beat sound and false HR readings. iSEAP™ differentiates the T waves and ensures the accuracy.
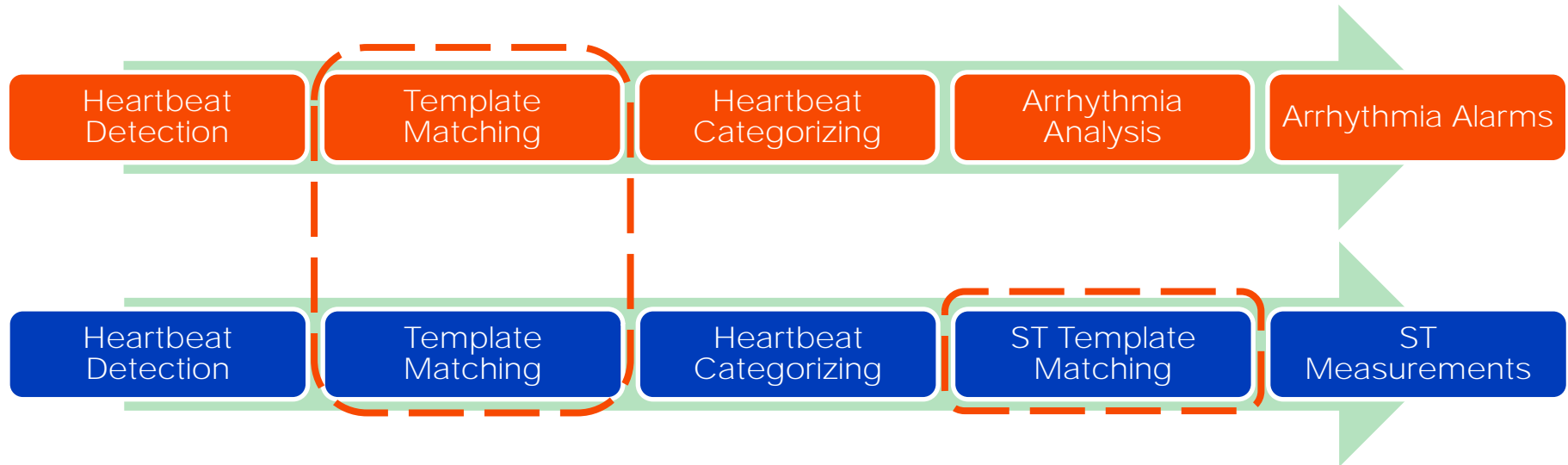
| Capture Heartbeat | Cognate with Detected HR | Heartbeat Sound Output |

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EDAN iSEAP™ Arrhythmia & ST Analysis

Heartbeat Detection	Template Matching	Heartbeat Categorizing	Arrhythmia Analysis	Arrhythmia Alarms

Heartbeat Detection	Template Matching	Heartbeat Categorizing	ST Template Matching	ST Measurements

iSEAP™ is designed with a special built-in template library, containing piles of ECG templates to help with analysis.

- It compares heartbeats with built-in template library to categorize them before analysis.

- It compares ST segments with built-in template library to assist ST analysis.

- External interference may bring false alarms as ventricular fibrillation, ventricular tachycardia, ventricular premature, cardiac arrest, and so on. iSEAP™ will differentiate the interferences and avoid the false alarms.

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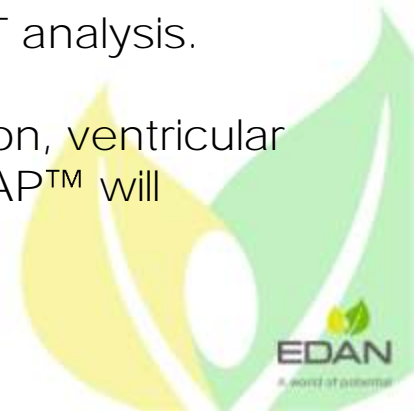
EDAN iSEAP™ Pacemaker Detection

| High Frequency Sampling	Locate the Pacemaker Signal	PACE Mark

- It rules out the external inferences and avoid false pacemaker detections.

- It picks accurate pacemaker signal immediately with a high sampling rate

EDAN

Respiration

EDAN monitors employs impedance method to monitor respiration rate.

- When patient breaths, the movement of chest causes impedance changes with which the machine may calculate the respiration rate.

- Monitored through ECG accessories, no extra accessory required.

- Monitor through lead I or lead II as per user selection.
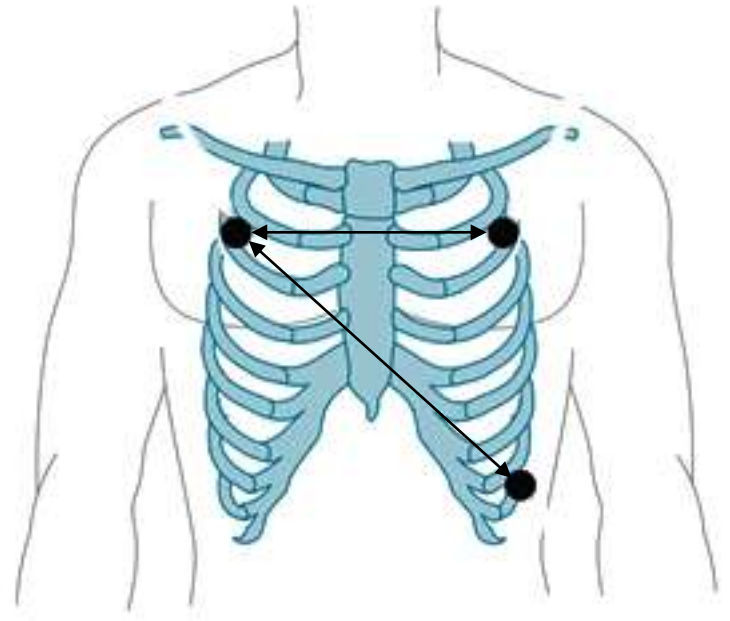
EDAN SpO$_2$

- **EDAN iMAT™ algorithm with outstanding motion resistance and low perfusion resistance performance**
  Must work with EDAN SpO2 sensor to ensure accurate readings.

- **Pitch Tone (Pulse-tone modulation)**
  9 types of different tones. Doctors can rely on it to identify SpO$_2$ changes without checking the readings.

- **PI (Perfusion Index)**
  Reference reading from 0 to 10 according to perfusion changes.

Light Shield

Unique shield design to block outside lights, avoiding light interference.

26

EDAN Anti-interference Oximetry

There are many factors which limit the performance of pulse oximetry. Two of the most common are high motion (such as occurs with patients' shivering and tremors) and low perfusion at the area of measurement.

In consideration of this, EDAN developed its anti-interference oximetry, the use of which can largely eliminate the interference even under harsh conditions of high motion and low perfusion. This technique addresses this issue on a combo of hardware and software designs:
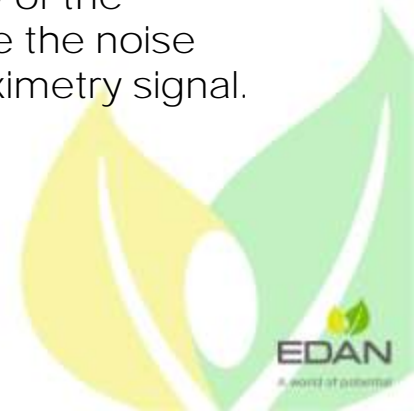
- ■ Hardware Design
  A high signal-to-noise ratio circuit with low-noise components is designed for the acquisition of a weak signal under low perfusion.
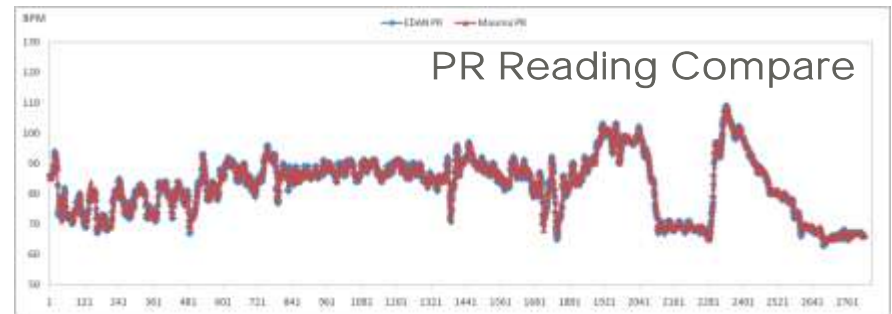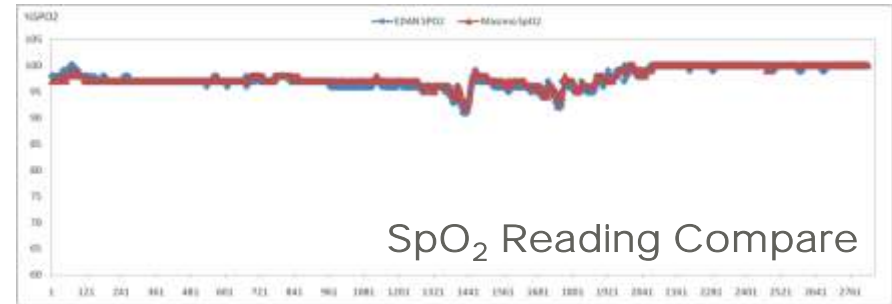
- ■ iMAT™ Algorithm
  A unique signal processing algorithm iMAT™ takes advantage of signal characteristics under high motion and low perfusion to improve the accuracy and stability of the measurement. This algorithm employs a special filtering process to reduce the noise caused by motion, as well as from other sources, and amplify the pulse oximetry signal.

EDAN SpO$_2$ Compare

■ **EDAN v.s. Nellcor**
Tested in NICU

NICU

SpO$_2$ Reading Compare

PR Reading Compare

SpO$_2$ Reading Compare

PR Reading Compare
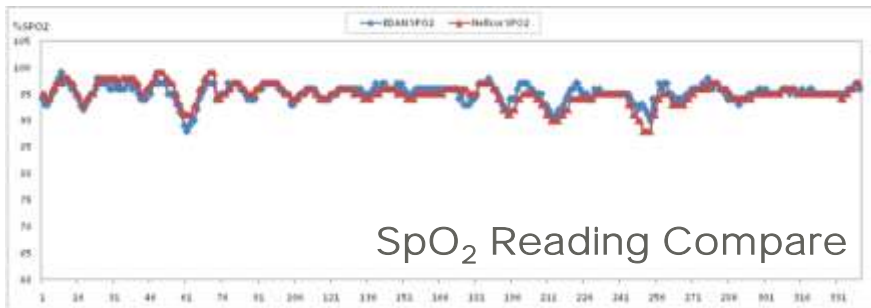
■ **EDAN v.s. MASIMO**
Tested in OT

Operation Theater

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Nellcor™ Oximax™ SpO$_2$

- **Built-in Nellcor™ Oximax™ Module**
  Must work with Nellcor™ SpO$_2$ sensor to ensure accurate readings.

- **Pitch Tone (Pulse-tone modulation)**

- **Reputable motion resistance & low perfusion resistance performance**

COVIDIEN

EDAN

EDAN NIBP

- **EDAN iCUFS™ NIBP algorithm optimized for cardiac patients, hypertensive patients, and neonatal patients**
  Must work with EDAN NIBP cuff to ensure accurate readings.
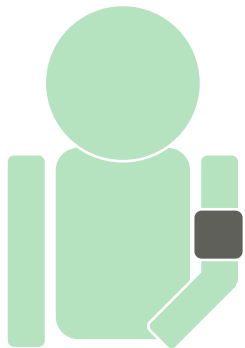
- **Measuring Mode**
  Auto, Manual, Continual (STAT mode as known in many other brands)

- **Low Noise**
  Environment friendly. Makes patient more comfortable.

- **Full Range of Optimized Cuff Sizes**
  9 different sizes of cuffs covering from neonates to large adults, from arm to thigh.
 Cuff sizes are optimized according to clinical researches.

EDAN iCUFS™ Smart Deflation

With the smart deflation technology used in EDAN iCUFS™, normal BP measuring time will be decreased by avoiding unnecessary deflation steps, ensuring BP measuring efficiency especially in emergency cares.

- **Time Reduced:**
  Around 5 seconds when there's re-inflation
  Around 2~3 seconds when there's no re-inflation
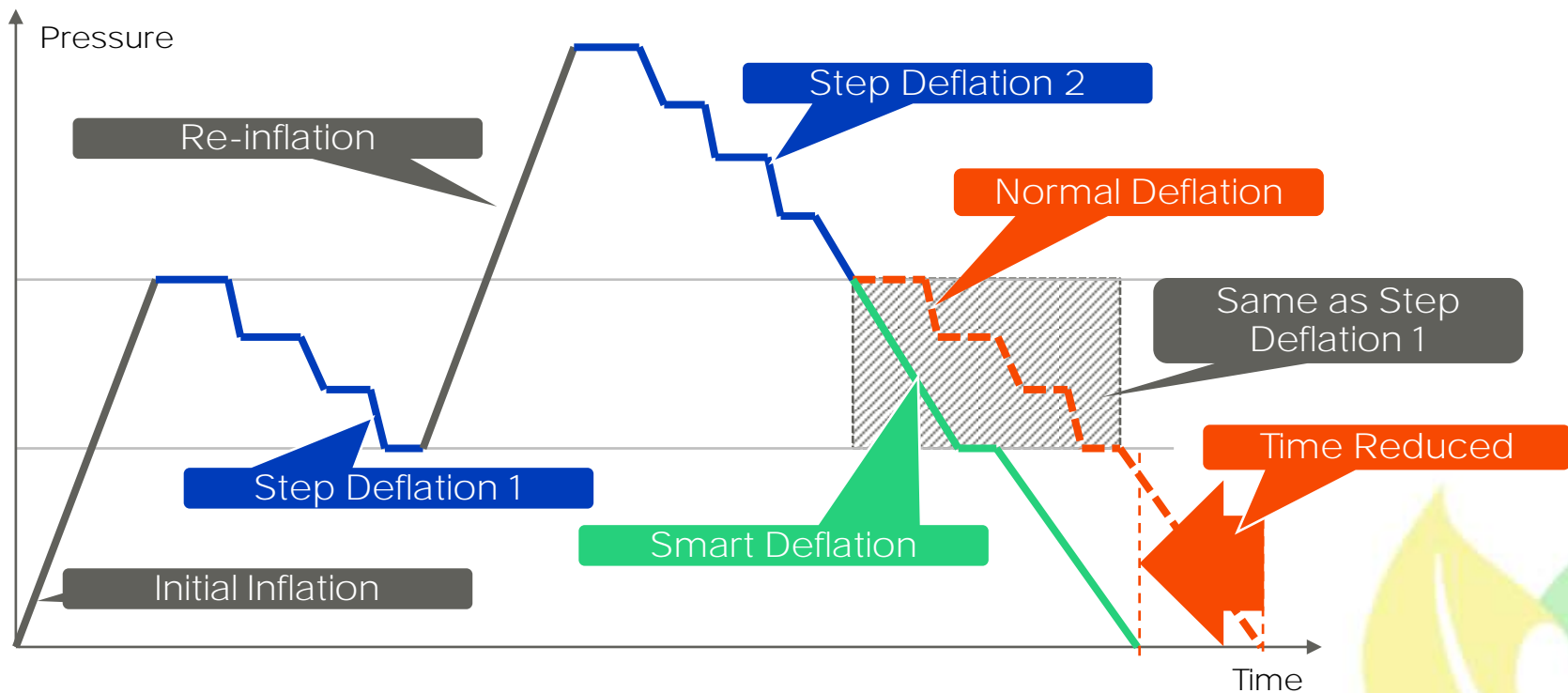
EDAN iCUFS™ Neonatal Cuff Verification

Sometimes during neonatal monitoring, patient type could be set as adult by mistake. In this case, iCUFS™ shall locate the mistake immediately by measuring the climb speed of cuff pressure and deflate right away. This will prevent unintentional harm brought to the neonatal patients.

Cuff Pressure

Wrong Climb Speed of Cuff Pressure

Immediate Deflation

Normal Inflation

Neonatal Cuff Verification

Time
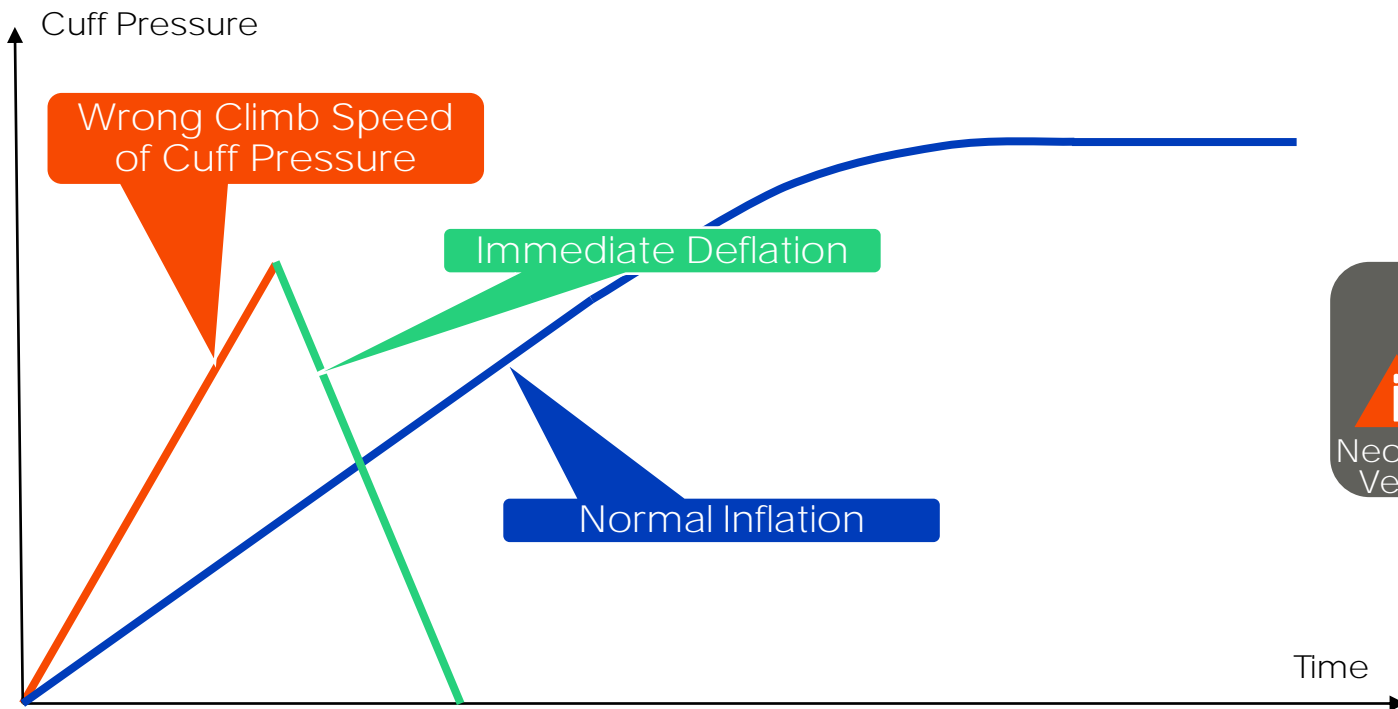
EDAN iCUFS™ Pulse Wave Calibration

Clinical Research » Pulse Wave Patterns

| Pulse Wave Detected | Pattern Recognition | Calibrate NIBP Measuring | NIBP Measurements |
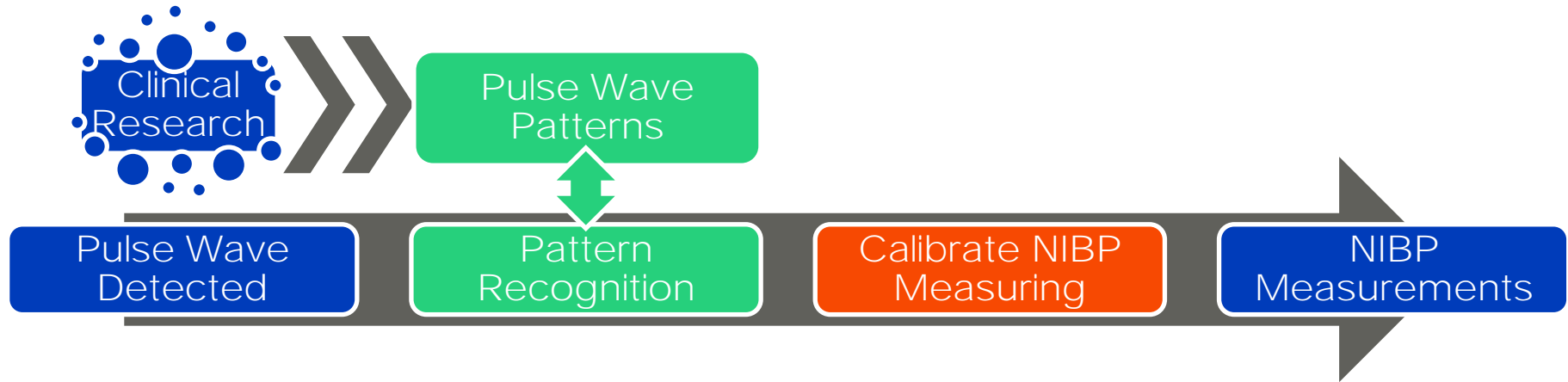
With thousands of clinical research data, iCUFS™ is equipped with pulse wave patterns got from different types of subjects, such as arrhythmia patients, restless patients, transport patients, etc. These patterns help iCUFS™ to generate correct NIBP measurements out of various interferences, especially in cardiac cares and emergency cares.

Road Type	Percentage of Measuring with Readings Come Out	Variation Compared to Resting BP in Non-Transport Status
Paving Road with Bends;Flat Unpaved/Gravel Road	100% with Readings	90% with less than 15 mmHg Variation
Rough Unpaved/Gravel Road; Road with 10 degree Slope; Road with Water/Ice/Snow	90% with Readings	80% with less than 15 mmHg Variation

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Temperature

- **2-channel Temperature monitoring**

- **Probes**
  Compatible with CY and YSI probes
  Compatible with 2.252 K/25°C & 10K/25°C probes

- **Measuring Positions**
  Skin, Oral & Rectal temperature measurements

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IBP

- **2-channel IBP monitoring**

- **Pressure Labels**
  ART, PA, CVP, RAP, LAP, ICP, Pl(User-defined), P2(User-defined)

- **Pressure Units**
  mmHg/kPa/cmH$_2$0
  (cmH$_2$0 is designed specially for venous pressure monitoring)

IBP Transducer

EDAN
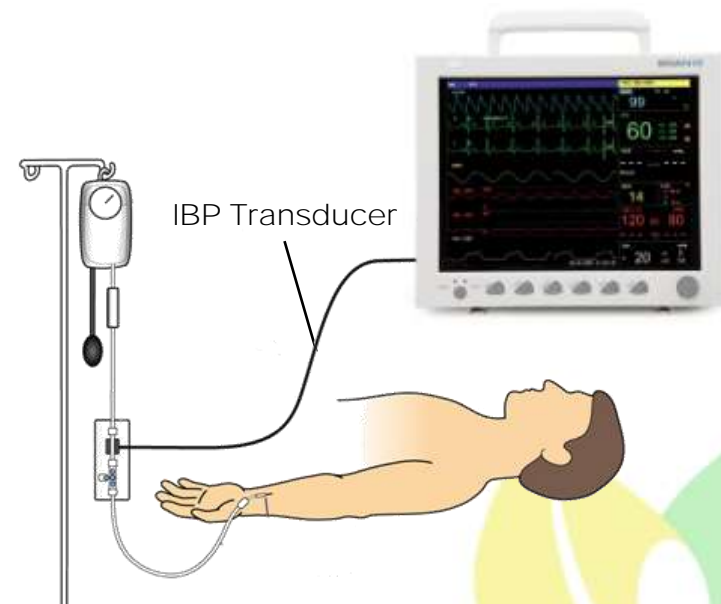
ICP

ICP monitoring uses a transducer, placed inside the head, which senses the pressure inside the skull and sends its measurements to patient monitor.

ICP monitoring can prevent the brain damage caused by increased intracranial pressure, and help to decrease the mortality.

Compatible Transducer

Gaeltec

ICT/B Transducer

ICP monitoring takes one IBP channel.

EDAN

EDAN G2 Sidestream CO_2

EDAN G2 CO_2 is designed as a sidestream CO_2 with dehumidification cup. Such design is most widely accepted and utilized in Capnography monitoring.

- **Built-in G2 CO_2 Module**
  Needs to work with G2 water trap

- **Superior Water Trap Design**
  Airway pressure fluctuation filter design to prevent possible CO2 pseudo wave.

- **iCARB™ CO_2 Algorithm**
  Unique algorithm with intelligent CO2 pseudo wave identification.

- **Instant Warm-up**
  Warm-up time < 4 seconds

- **Automatic Zeroing**
  No need for manual zeroing

- **Automatic Real-time Air Compensation**
  No need for manual compensation

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EDAN G2 Water Trap

Water cup design nowadays still faces two frequent technical problems. One is drainage failure of the water, which leads to air chamber damage; the other is false readings on lower sampling rate.To solve such problems, a few advanced technologies are developed in EDAN's G2 water trap

- **Dual-channel Pumping**
  With one channel connecting the air chamber, the second channel serves only for water drainage into the reservoir. Such design eliminates drainage failure and protects the module from water droplets.

- **Arc Dehumidification Channel**
  A thin arc style dehumidification channel is introduced to G2 water trap. Such design effectively reduced the dead spaces and improves the drainage capability.

- **One-way Channel Design**
  In order to achieve a lower sampling flow rate, some dehumidification cups introduce tee valve to control the flow rate of the second channel. However, the switch itself causes the air fluctuation and affects the measurement. On G2 water trap, instead of tee valve, a one-way structure design is employed on the second channel. It prevents the air backflow on inspiration and eliminates the affections of the tee valve.

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EDAN iCARB™ Pattern Recognition

Based on massive clinical data and analysis, pattern recognition is developed and applied in iCARB^{TM} as a core technology. Even in the most complex clinical cases with a lot of psuedo signals, EDAN iCARB™ still locates the real phases and the real CO2 values through comparing the Capnogram with the known patterns.
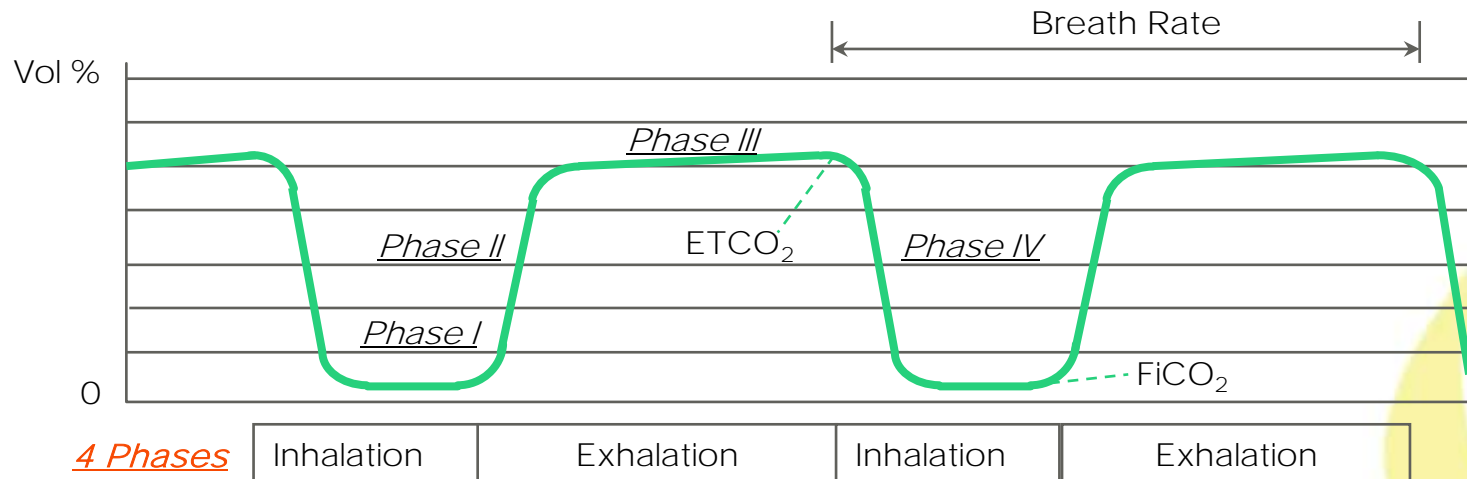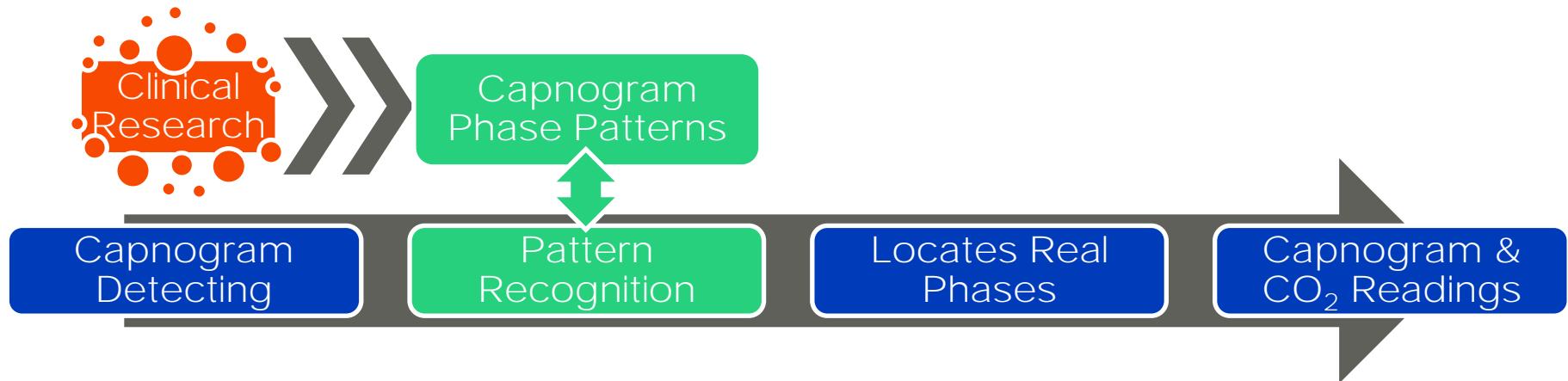
EDAN iCARB™ Cardiogenic Oscillation

Cardiogenic Oscillations are caused by the heart beating against lungs, which generally happens on pediatric patients. Under this circumstance, the Capnogram presents periodic multimodal structure on the inspiratory downstroke, which normal Capnography misleads to lower EtCO2 and critically high Respiration Rate.

With pattern recognition technology, iCARB™ recognizes cardiogenic oscillation, and generates accurate readings.

Real Breath Rate

Vol %

Fake Breath Rate

Real ETCO$_2$

Fake ETCO$_2$

0
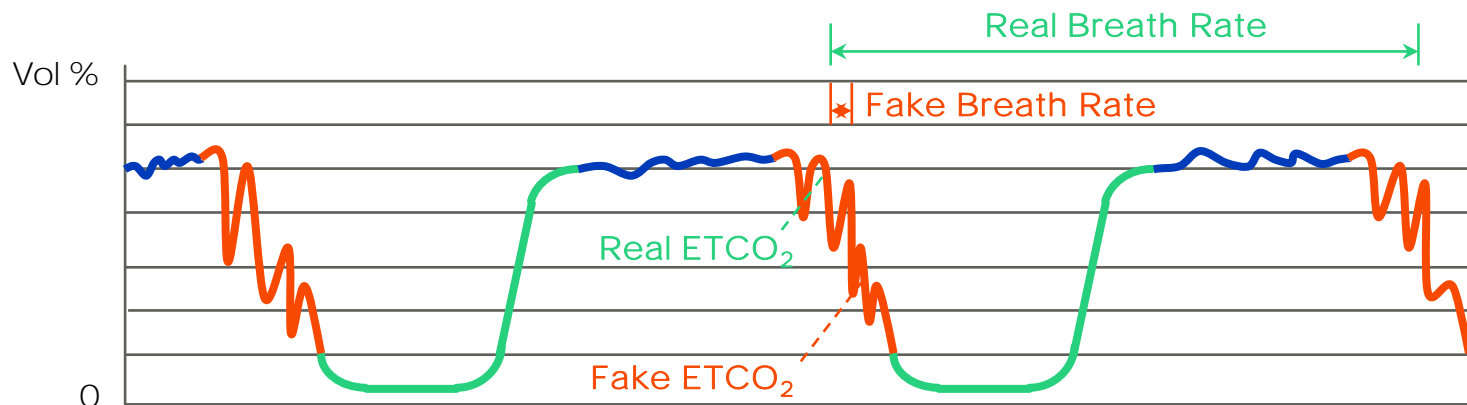
| Capnogram Detecting | Pattern Recognition | Cardiogenic Oscillation Recognized | Locates Real Phases | Capnogram & CO$_2$ Readings |

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EDAN iCARB™ Mechanical Ventilation

During mechanical ventilations, spontaneous breathing also happens from time to time. It always results in some small and narrow waveforms on the respiratory baseline. Normal Capnography may be confused and gives wrong readings of extreme low $EtCO_2$.

With pattern recognition technology, iCARB^{TM} recognizes spontaneous breaths, and generates accurate readings.
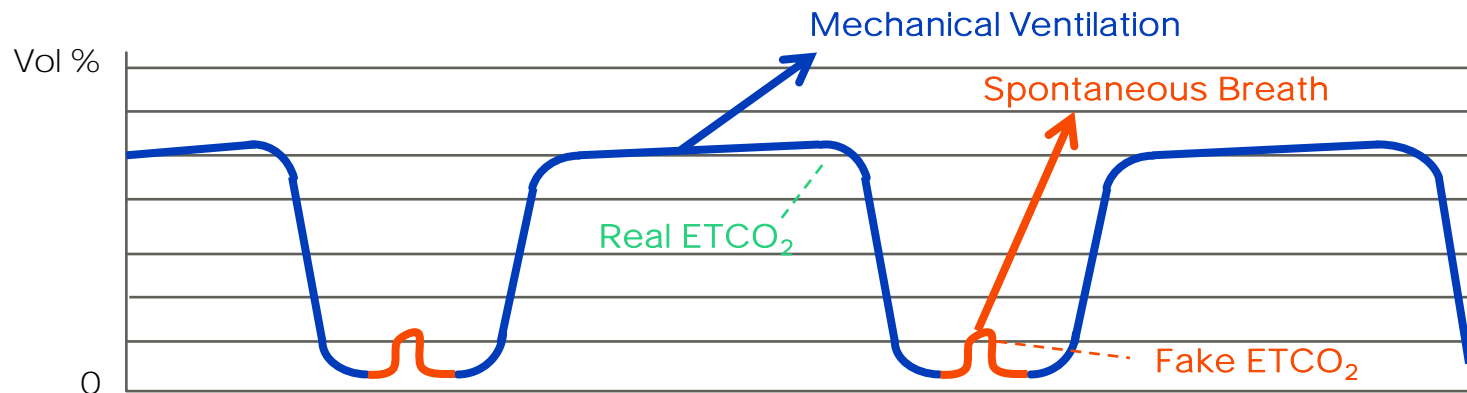
Capnogram Detecting	Pattern Recognition	Spontaneous Breath Recognized	Locates Real Phases	Capnogram & CO_2 Readings

EDAN iCARB™ Curare Cleft

While the anesthesia patients are regaining spontaneous breathings, curare clefts in the alveolar plateau will appear. Normal Capnography may give wrong readings of extreme FiCO2.

With pattern recognition technology, iCARB™ recognizes curare clefts, and generates accurate readings.

Curare Cleft

Vol %

Fake $FiCO_2$

Real $FiCO_2$

0
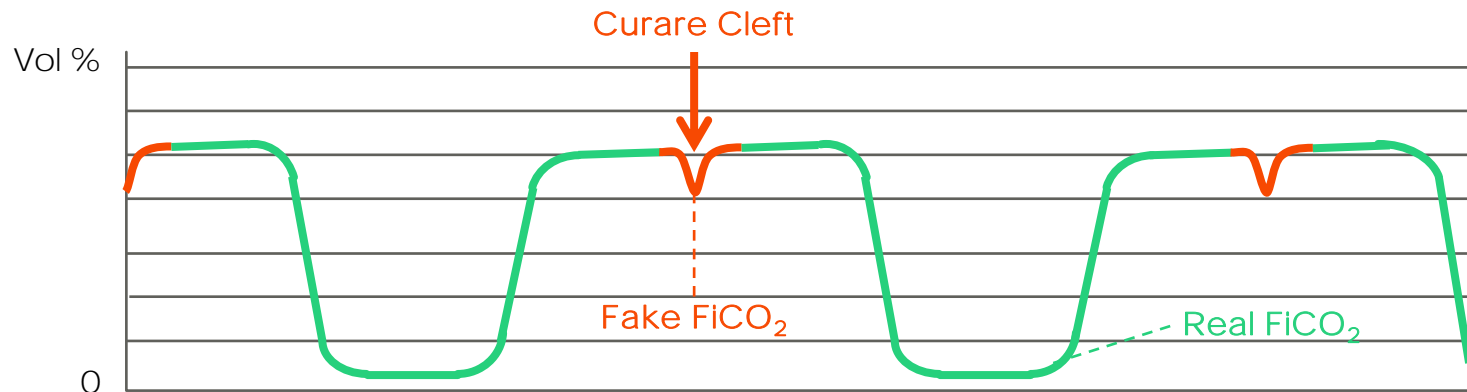
| Capnogram Detecting | Pattern Recognition | Curare Clefts Recognized | Locates Real Phases | Capnogram & CO_2 Readings |

EDAN

EDAN G2 Compare

	EDAN G2 CO_2	Company A
CO_2 Range	0~150 mmHg 0~20 Vol% (Wider range for critical pulmonary patients, such as chronic obstructive emphysema patients)	0~99 mmHg
Respiration Frequency Range	2~150 bpm	0~120 bpm
Automatic Zeroing	Yes (No need for manual operations)	No
Zeroing Time Cost	< 4s (Faster response to start measurement)	10~20s
Barometric Compensation	Auto	Manual

Company A is another brand as a compare reference.

AUT O
Automatic Zeroing

<4s
Fast Zeroing

BARO
Barometric Compensation

EDAN

Respironics LoFlo™ Sidestream CO_2

- **Plug & Play LoFlo™ CO_2 Module**
  Modular-like Design
  Needs to work with Respironics CO_2 sampling tubes

- **Short Warm-up Time**
  10~20 seconds

- **Water Trap**
  Dehumidification Tubing Design

- **Unique Sampling Chamber Design**
  Prevent contamination of the module

- **Low Flow Rate**
  50 ml/min to suit neonatal monitoring

Dehumidification Tube
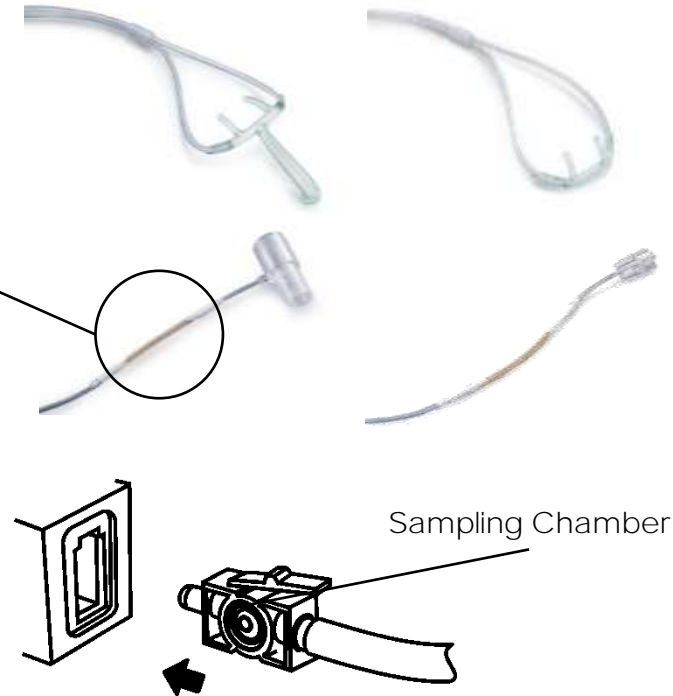
Sampling Chamber
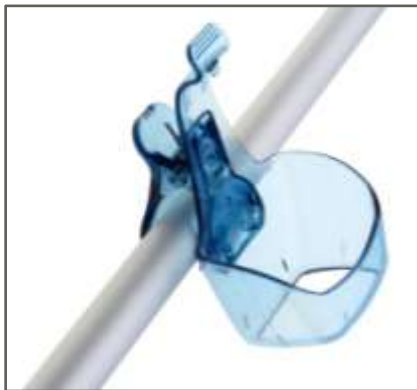
PHILIPS
RESPIRONICS

Plug & Play

50 ml/min
Flow Rate

EDAN
A world of potential
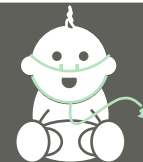
Respironics CAPNOSTAT® Mainstream CO_2
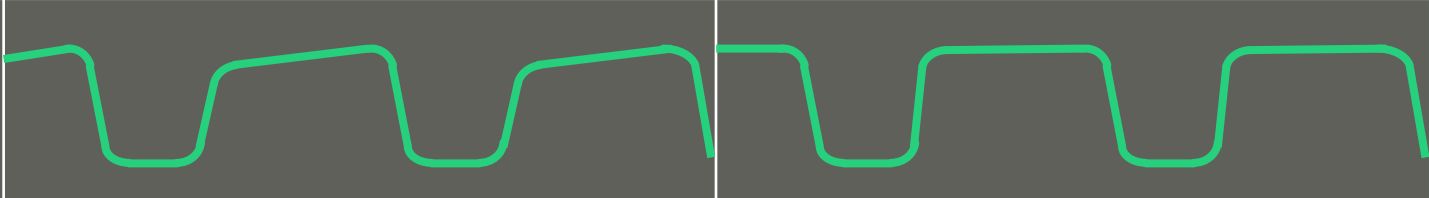
- **Plug & Play Mainstream CO_2 Module**
  Needs to work with a Respironics CAPNOSTAT® CO_2 sensor

- **No Water Trap**
  Installed directly on the airway.

- **Maintenance Free**
  No routine calibration needed

- **Fast Response**

PHILIPS
RESPIRONICS

Plug & Play

EDAN
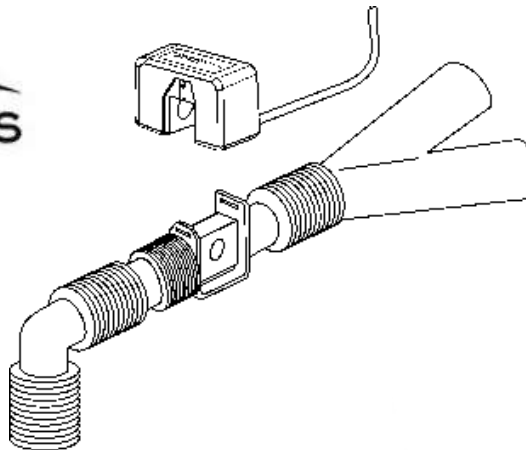
Sidestream v.s. Mainstream CO_2

	Sidestream CO_2	Mainstream CO_2
Waveform		
Patient Type	Non-intubated Patient Intubated Patient Patients with Mask	Intubated Patient Patient with Mask
Applications	Mostly used on non-intubated patients	Mostly used on intubated patients Perfect for intubation guide
Sensor Placement	Gases will be sampled to the sensor	On the airway
Response	2~3 seconds delay	Immediate response
Water Trap	Water cup （EDAN G2） Dehumidification tube （Loflo™）	No need

EDAN
A world of potential

Clinical Calculations

Drug dose calculation and hemodynamic calculation are introduced to provide related clinical guides.

Drug Dose

Hemo-dynamic

External AP

ASUS WL-330n

Wi Fi

External AP

iM8 Series connects to Ethernet network via either built-on LAN port or an external AP.

EDAN
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Central Monitoring Solution

Patient Info
EDAN FORMAT

Monitoring Data
EDAN FORMAT

Monitoring Data
ORU

Web Viewer

Web Viewer

Bi-directional Communication

Wi Fi   LAN
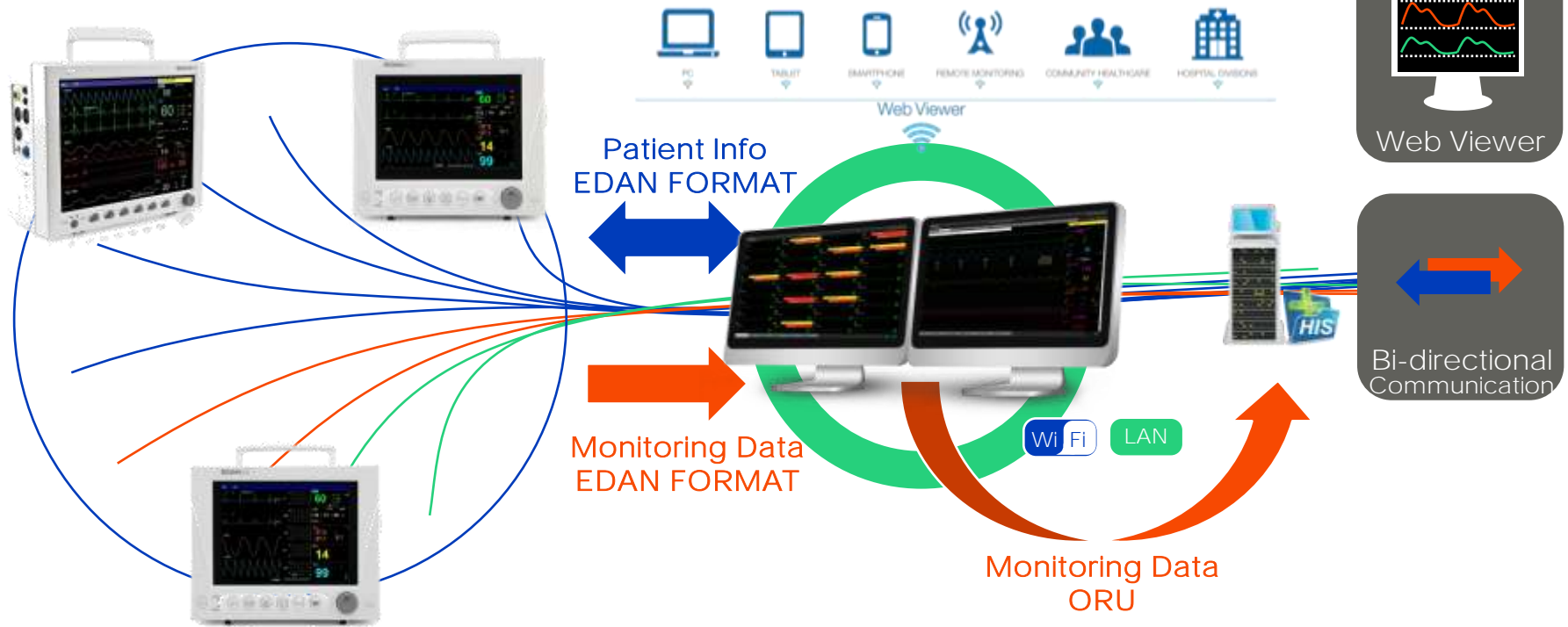
- **Central Monitoring Station**
  EDAN MFM-CMS central monitoring station may communicate with EDAN monitors on a bi-directional basis.

- **Web Viewer**
  You may log in from any device, anywhere.

- **HL7 Communication**
  Monitoring data could be transmitted to HIS via HL7 from MFM-CMS.

Remote Control

Time Synchronization

Remote NIBP Measurement

Remote Alarm Settings

Time Synchronize

Remote Control

Batch Management

Wi Fi   LAN
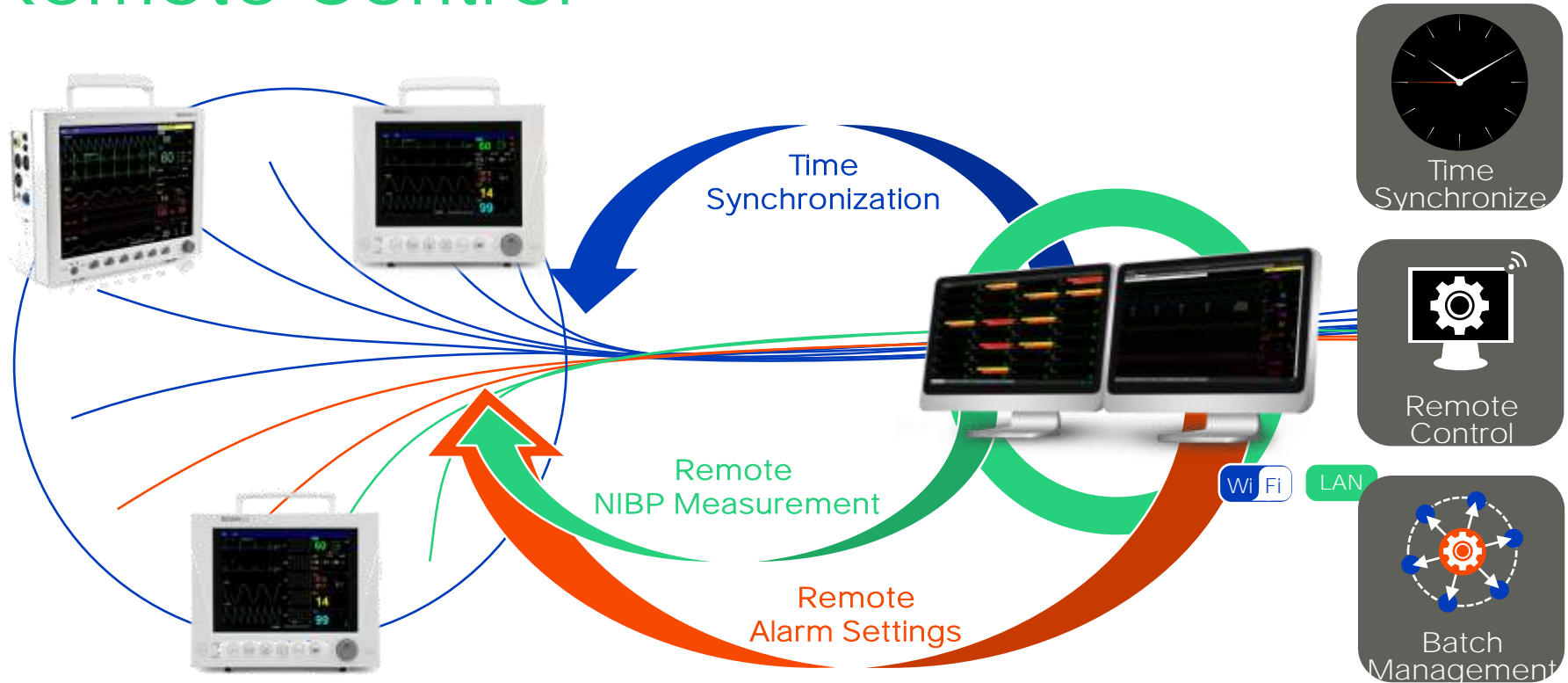
■ **Time Synchronization**
Time setup of each monitor synchronizes with MFM-CMS either automatically or manually.

■ **Remote NIBP Measurement**
NIBP measurement can be activated remotely from MFM-CMS.

■ **Remote Alarm Settings & Batch Management**
Alarm settings can be adjusted remotely from MFM-CMS.
Alarm configuration for single monitor can be obtained by the central monitoring system and applied into other patient monitors in same network.

EDAN
A world of potential

Central Statistics & Analysis

A regular central monitoring system could provide a large amount of physiological data gathered from long term monitoring of a large number of patients. And in most conditions, such data is not properly organized but only listed in trends. If doctors want to extract any valuable information from this ocean of data, they have to look up manually term by term.

In order to help with the diagnosis, an innovative central analysis technology is now introduced into the central monitoring system. As found in MFM-CMS, the central monitoring system developed by EDAN, central analysis function provides intuitive, easy-to-understand diagrams which focus on alarms, arrhythmias, trends and physiological measurements.

Data Statistics	Alarm Histogram	History Histogram
Total data amount and event amount during the whole monitoring period.	General view of the abnormal events with the amount & percentage of each event.	Measurement distribution diagram of each parameter.

EDAN
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HL7 Gateway Solution

Patient Info
EDAN FORMAT

Patient Info
ADT

Customizable
Protocol

HL7
Gateway

Wi Fi   LAN

Monitoring Data
EDAN FORMAT

Monitoring Data
ORU

Bi-directional
Communication
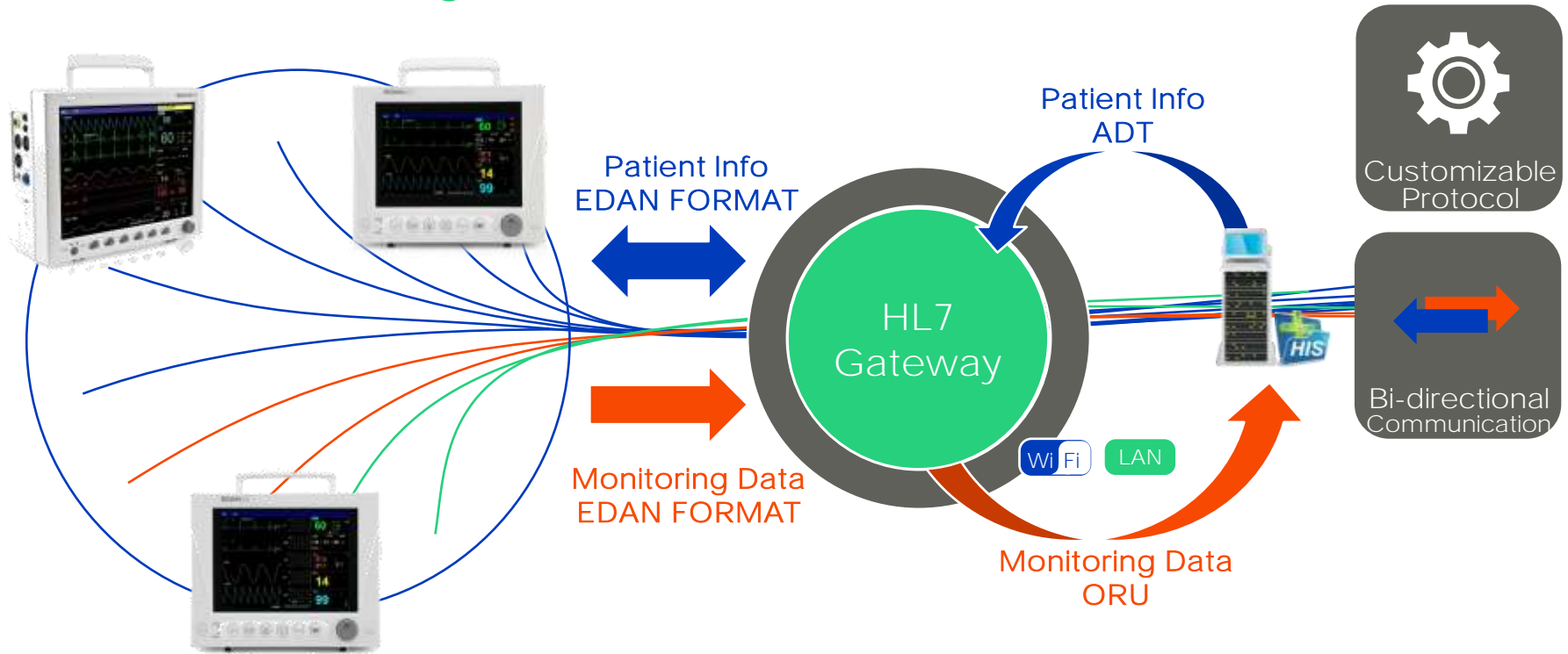
Installed on any device in the network, EDAN HL7 gateway brings machines and HIS together:

■ **Bi-directional Communication**
Barrier free transmission of patient info and monitoring data.

■ **Customizable Protocol**
You may customize the protocol according to actual needs without turning to 3-party software developers.

EDAN
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Critical Cares

Emergency Cares

General Ward

4 Display Mode

Standby Mode

3-level Alarms

User Alarm Set

USB Flash Disk

VGA Output

Nurse Call

Defib-Sync

Design Highlights

EDAN

Parameter Highlights

Web Viewer

Bi-directional Communication

Time Synchronize

Remote Control

Batch Management

Data Statistics

Alarm Histogram

History Histogram

MFM-CMS

Customizable Protocol

Bi-directional Communication

HL7 Gateway

External AP

Bed View

Network Highlights

EDAN

THANK YOU

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Jan 20, 2015

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EDAN Agile PLM Electronic Signature Information

--Signatures related to this document and performed in EDAN Agile PLM.

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iM8 M8 Series
Patient Monitor
Version 1.4

User Manual

CE 0123

About this Manual

P/N: 01.54.456009

MPN: 01.54.456009014

Release Date: January, 2018

Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which the manufacturer can not be held liable.

The manufacturer owns the copyrights of this manual. Without prior written consent of the manufacturer, any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.

Materials protected by the copyright law, including but not limited to confidential information such as technical information and patent information are contained in this manual, the user shall not disclose such information to any irrelevant third party.

The user shall understand that nothing in this manual grants him, expressly or implicitly, any right or license to use any of the intellectual properties of the manufacturer.

The manufacturer holds the rights to modify, update, and ultimately explain this manual.

Responsibility of the Manufacturer

The manufacturer only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by the manufacturer, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure

Table of Contents

Chapter 1 Intended Use and Safety Guidance

1.1 Intended Use/Indications for Use

iM8 Series: The Patient Monitor (hereinafter called monitor) is intended to be used for continuous monitoring of ECG, RESP, SpO$_2$, NIBP (Non-invasive Blood Pressure), dual-TEMP, dual-IBP and CO$_2$.

M8 Series: The Patient Monitor (hereinafter called monitor) is intended to be used for continuous monitoring of ECG, RESP, SpO$_2$, NIBP (Non-invasive Blood Pressure), dual-TEMP, dual-IBP and CO$_2$.

The monitor is intended to be used only under regular supervision of clinical personnel. It is applicable to adult, pediatric, and neonatal usage in a hospital environment and during patient transport inside a healthcare facility.

The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

1.2 Safety Guidance

1.2.1 Environment

Follow the instructions below to ensure a completely safe electrical installation. The environment where the monitor will be used should be reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so on. For a cabinet mounted installation, allow sufficient room at the front for operation and sufficient room at the rear for servicing with the cabinet access door open.

The monitor operates within specifications at ambient temperatures between 0 °C and 40 °C. Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5cms) clearance around the instrument for proper air circulation.

1.2.2 Power Source Requirements

Refer to *Appendix Ⅰ*.

1.2.3 Grounding the Monitor

To protect the patient and hospital personnel, the cabinet of the monitor must be grounded. Accordingly, the monitor is equipped with a 3-wire cable which grounds the instrument to the power line ground (protective earth) when plugged into an appropriate 3-wire receptacle. If a 3-wire receptacle is not available, consult the hospital electrician.

Connect the grounding wire to the equipotential grounding terminal in the main system. If it is not evident from the instrument specifications whether a particular instrument combination is hazardous or not, for example due to summation of leakage currents, the user should consult the

manufacturers concerned or an expert in the field, to ensure that the necessary safety of all instruments concerned will not be impaired by the proposed combination.

1.2.4 Equipotential Grounding

Protection class I instruments are already included in the protective grounding (protective earth) system of the room by way of grounding contacts in the power plug. For internal examinations on the heart or the brain, the monitor must have a separate connection to the equipotential grounding system. One end of the equipotential grounding cable (potential equalization conductor) is connected to the equipotential grounding terminal on the instrument rear panel and the other end to one point of the equipotential grounding system. The equipotential grounding system assumes the safety function of the protective grounding conductor if ever there is a break in the protective grounding system. Examinations in or on the heart (or brain) should only be carried out in medically used rooms incorporating an equipotential grounding system. Check each time before use that the instrument is in perfect working order. The cable connecting the patient to the instrument must be free of electrolyte.

WARNING

If the protective grounding (protective earth) system is doubtful, the monitor must be supplied by internal power only.

1.2.5 Condensation

Make sure that during operation, the instrument is free of condensation. Condensation can form when equipment is moved from one building to another, and thus being exposed to moisture and differences in temperature.

1.2.6 Safety Precautions

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the instrument.

WARNING

1   The monitor is provided for the use of qualified physicians or personnel professionally trained. They should be familiar with the contents of this user manual before operation.

2   Only qualified service engineers can install this equipment. And only service engineers authorized by the manufacturer can open the shell.

3   EXPLOSION HAZARD–Do not install the monitor in the presence of flammable anesthetics.

4   SHOCK HAZARD-The power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet.

WARNING

5   SHOCK HAZARD-Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.

6   Accessory equipments connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN60601-1. If in doubt, consult our technical service department or your local distributor.

7   If the monitor is accidentally damped, place it in the dry circumstance, and do not operate it until it is approved for further use. If liquid is inadvertently spilled on the monitor, contact the service personnel authorized by the manufacturer.

8   During monitoring, if the power supply is off and there is no battery for standby, the monitor will be off. The settings configured by the user can be stored, and settings not configured by user keep no change. That is, the last settings used will be recovered when the power is restored.

9   The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do not dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

10 The packaging is to be disposed of according to local or hospital's regulations; otherwise, it may cause environmental contamination. Place the packaging at the place which is inaccessible to children.

11 Only patient cable and other accessories supplied by the manufacturer can be used. The performance and electric shock protection can not be guaranteed, and the patient may be injured otherwise.

12 Before using the device, the equipment, patient cable and electrodes etc. should be checked. Replacement shall be taken if there is any evident defect or signs of aging which may impair the safety or performance.

13 Be sure that all electrodes have been connected to the patient correctly before operation.

14 Do not touch the patient and metal part of the monitor when operating the monitor.

15 Do not touch the patient, bed or instrument during defibrillation.

16 Please set the alarm according to the individual status of patient to avoid delaying treatment. Ensure there will be alarm audio prompt when alarming.

17 Devices connecting with monitor should be equipotential.

WARNING

18 When the monitor and electrosurgical device are used together, the user (physician or nurse) should guarantee the safety of patient.

19 This equipment is not intended for family usage.

20 Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

21 Without use of data store function, all data measured (including trend data, review data, alarm events and so on) are cleared either when the monitor is turned off or when the monitor is powered down in the process of monitoring.

22 Additional multiple socket-outlet or extension cord can't be connected to the system.

23 Only items that have been specified as part of the system or specified as being compatible with the system can be connected to the system.

24 SHOCK HAZARD - Don't connect electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.

25 SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.

26 Do not touch accessible parts of medical or non-medical electrical equipment in the patient environment and the patient simultaneously, such as USB connector, VGA connector or other signal input/output connectors.

27 Connecting any accessory (such as external printer) or other device (such as the computer) to this monitor makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:

   a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and

   b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

28 All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.

29 Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

30 The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you must check that normal operation is possible in the necessary configuration before you start monitoring patients.

WARNING

31 Portable and mobile RF communications equipment can affect medical electrical equipment, refer to the recommended separation distances provided in Appendix A2 EMC Information.

32 The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.

33 Do not service or maintain the monitor or any accessory which is in use with the patient.

34 Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.

35 The monitors are intended for use by trained healthcare professionals in hospital environments.

36 Operation of the equipment exceeding specified physiological signal or the operational specification may cause inaccurate results.

37 The appliance coupler or mains plug is used as isolation means from supply mains. Position the monitor in a location where the operator can easily access the disconnection device.

38 The equipment can provide protective means to prevent the patient from being burned when used with HF SURGICAL EQUIPMENT. The equipment can protect against the effects of the discharge of a defibrillator. Use only the accessories approved by the manufacturer.

39 After defibrillation, the ECG display recovers within 10 seconds if the correct electrodes are used and applied based on the manufacturers' instructions.

40 Only recommended batteries can be used for the monitor.

41 When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.

42 Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

43 To protect the monitor from damage during defibrillation, for accurate measurement information and to protect against noise and other interference, use only accessories specified by the manufacturer.

44 If several items of medical equipment are interconnected, pay attention to the sum of the leakage currents, otherwise it may cause shock hazard. Consult your service personnel.

WARNING

45 No modification of this 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.

46 The device must be connected to the ground to avoid signal interference.

47 The monitor is suitable for use in the presence of electrosurgery. When the monitor is used with HF surgical equipment, user (doctor or nurse) should be cautious about patient safety.

48 Make sure networking function is used in a secure network environment.

CAUTION

1 Federal laws (U.S.) restrict this device to sale, distribution and use by, or on the order of a physician.

2 Electromagnetic Interference - Ensure that the environment in which the patient monitor is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, microwaves, etc.

3 Keep the environment clean. Avoid vibration. Keep it far from corrosive medicine, dust area, high temperature and humid environment.

4 Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.

5 Do not use autoclave or gas to sterilize the monitor, recorder or any accessories.

6 The device and reusable accessories may be sent back to the manufacturer for recycling or proper disposal after their useful lives.

7 Remove a battery whose life cycle has expired from the monitor immediately.

8 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.

9 Avoid liquid splash and excessive temperature. The temperature must be kept between 0 °C and 40 °C while working. And it should be kept between -20 °C and 55 °C during transportation and storage.

10 A potential hazard may exist if different alarm presets are used for the same or similar equipment in any single area.

11 Protect the device against mechanical damage resulting from falls, impacts, and vibration.

12 A ventilated environment is required for monitor installation. Do not block up the ventilation grille at the back of the device.

13 Poor connection might be caused by frequently plugging and unplugging the power cord. Check the power cord regularly and replace it in time.

	CAUTION
14	Route all cables carefully to avoid possible entanglement, apnea, or electrical interference. For the device mounted over the patient, sufficient precautionary measures should be taken to prevent it from falling on the patient.

NOTE:

1   The monitor can only be used on one patient at a time.

2   If the monitor gets damp, put it in dry circumstance to dry it until it can work normally. If liquid pours on the monitor, please contact the service personnel of the manufacturer.

3   The manufacturer suggests that the lifetime of the monitor is 5 years.

4   This monitor is not a device for treatment purpose.

5   The pictures and interfaces in this manual are for reference only.

6   The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1: 2009.

7   If the device is discolored or damaged, then discontinue use of the device.

8   Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.

9   Use the wireless device recommended by the manufacturer, otherwise some exceptional situations such as frequent network disconnection may occur on the monitor.

10 When there's measurement beyond range, invalid measurement or no measurement value, it will display ---.

1.2.7 Explanation of Symbols on the Monitor

1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		DEFIBRILLATION-PROOF TYPE BF APPLIED PART
3		Caution
4		Operating instructions
5		Equipotential grounding
6		USB (Universal Serial Bus) Connection

7		Video output
8		Power Supply switch
9		Gas inlet
10		DO NOT REUSE
11	**SN**	SERIAL NUMBER
12	$C\epsilon_{0123}$	CE marking
13	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
14		Date of manufacture
15		MANUFACTURER
16	P/N	Part Number
17		General symbol for recovery/recyclable
18		Disposal method
19	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
20	IPX1	Ingress Protection IPX1 (Protected against vertically falling water drops)
21		Refer to User manual (Background: blue; Symbol :white)

22		Warning (Background: yellow; Symbol and outline: black)
23		Non-ionizing electromagnetic radiation
24		(This mark is optional.) Conforms to UL Std. 60601-1, IEC Std. 60601-2-27, IEC Std. 60601-2-30, IEC Std. 60601-2-34, IEC Std. 60601-2-49 Certified to CSA Std. C22.2 No 601.1, CSA Std. C22.2 No 60601-2-27, CSA Std. C22.2 No 60601-2-30, CSA Std. C22.2 No 60601-2-34, CSA Std. C22.2 No 60601-2-49

NOTE:

The user manual is printed in black and white.

Chapter 2 Installation of Monitor

Installation should be carried out by qualified service personnel, either by the hospital's biomedical department, or by the manufacturer Support.

For mechanical and electrical installation, you need technically qualified personnel with knowledge of English. Additionally, for monitor configuration, you need clinically qualified personnel with knowledge of the use environment.

NOTE:
1   The monitor configuration settings must be configured by authorized hospital personnel.
2   To ensure that the monitor works properly, please read *Chapter 1 Intended Use and Safety Guidance* and follow the steps before using the monitor.

2.1 Opening the Package and Checking

Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage. Open the package and take out the monitor and accessories carefully. Keep the package for possible future transportation or storage. Check the components according to the packing list.

◆   Check for any mechanical damage.
◆   Check all the functions, cables and accessories.

If there is any problem, contact the manufacturer or local representative immediately.

2.2 Connecting the Power Cable

Connection procedure of the AC power line:

◆   Make sure the AC power supply complies with the following specifications: 100 V-240 V~, 50 Hz/60 Hz.

◆   Connect the power cord provided with the monitor. Connect the power cord to connector of the monitor. Connect the other end of the power cord to a grounded power outlet.

NOTE:
Connect the power line to the jack special for hospital usage.

◆   Connect to the ground line if necessary. Refer to *Section 1.2 Safety Guidance* for details.

NOTE:
When the battery configuration is provided, after the device is transported or stored, the battery must be charged. Powering on without connecting AC power supply may cause the device to malfunction. Switching on AC power supply can charge the battery no matter if the monitor is powered on.

2.3 Powering on the Monitor

After you power on the monitor, LOGO information will be displayed on the screen.

WARNING

If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact biomedical engineer in the hospital or Customer Service Center immediately.

NOTE:
1   Check all the functions of the monitor and make sure that the monitor is in good status.
2   If rechargeable batteries are provided, charge them after using the device every time, to ensure the electric power is enough.
3   After long-time continuous running, please restart the monitor to ensure the monitor's steady performance and long lifespan.

2.4 Connecting Patient Sensors

Connect all the necessary patient sensors between the monitor and the patient.

NOTE:
For information on correct connection, refer to related chapters.

2.5 Checking the Recorder

If your monitor is equipped with a recorder, open the recorder's door to check if paper is properly installed in the slot. If no paper exists, refer to *Chapter 9 Recording* for details.

Chapter 3 Introduction

This user manual is based on the maximum configuration and therefore your monitor may not have all of the functions and options described in the manual. Also, illustrations in this manual serve as examples only and do not necessarily reflect the setup on your monitor. The content displayed on you monitor depends on the way it has been tailored for your hospital.

You may frequently use the follow functions:

◆ ECG monitoring (Refer to *Chapter 13 Monitoring ECG/RESP* for more information.)

◆ SpO$_2$ monitoring (Refer to *Chapter 14 Monitoring SpO$_2$* for more information.)

◆ TEMP monitoring (Refer to *Chapter 16 Monitoring TEMP* for details)

◆ NIBP monitoring (Refer to *Chapter 15 Monitoring NIBP fo*r more information.)

◆ Alarm (Refer to *Chapter 6 Alarms* for more information.)

3.1 General Information

The monitor integrates the functions of parameter measurement module, display, recording and output to compose a compact, portable device. Its built-in replaceable battery provides convenience for patient movement. On the high-resolution display screen, 7 waveforms and all the monitoring parameters can be displayed clearly.

The **POWER** switch is on the left of the front panel (Figure 3-1 ①). The **POWER** indicator lights when the monitor is powered on (Figure 3-1②). The CHARGE indicator shows the charging status (Figure 3-1). The ALARM indicator flashes when the alarm is triggered (Figure 3-1④). The sockets of various sensors are on the left panel. Other sockets and the power plug-in are on the rear panel. The recorder is on the right panel.

The monitor is a user-friendly device with operations conducted by a few buttons and a trim knob on the front panel (Figure 3-1⑤⑥). Refer to *Section 3.3 Button Functions*.
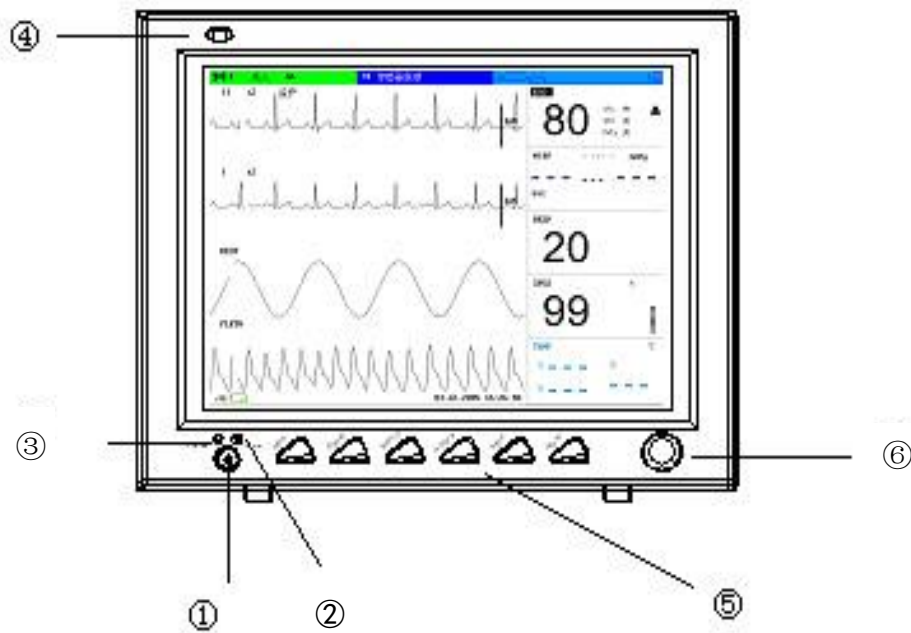
Figure 3-1 iM8/M8 Patient Monitor

The monitor has 6 models: M8, M8A, M8B, iM8, iM8A and iM8B.
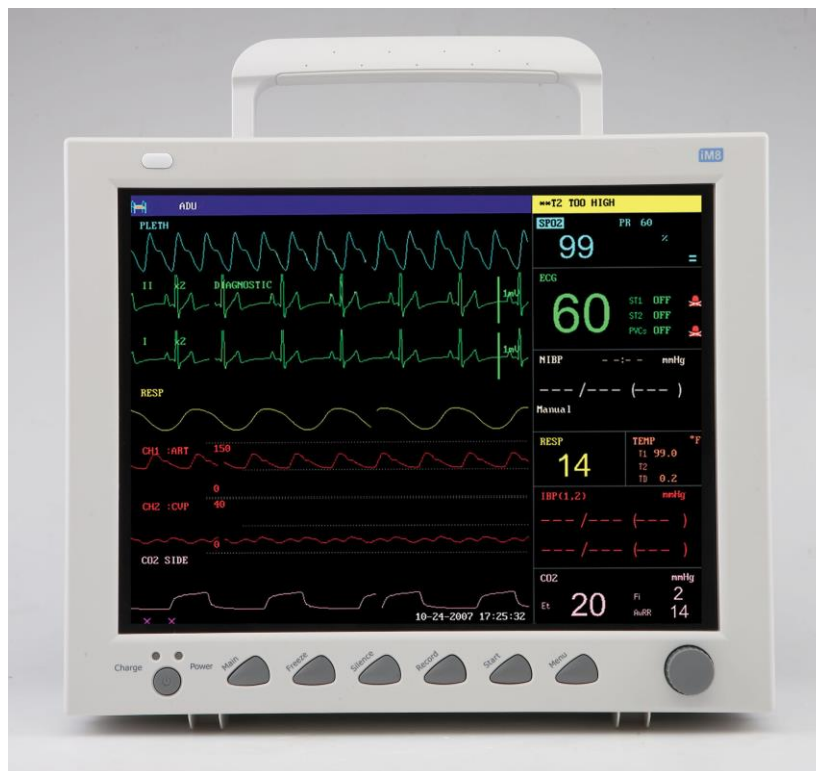
Figure 3-2 iM8/M8 Patient Monitor

Figure 3-3 iM8A/M8A Patient Monitor

Figure 3-4 iM8B/M8B Patient Monitor

The monitor can monitor the following parameters and waveforms:

ECG: Heart Rate (HR)

        Maximum 7-channel

        Arrhythmia and ST-segment analysis (optional)

RESP: Respiration Rate (RR)

Respiration Waveform

SpO$_2$:   Oxygen Saturation (SpO$_2$), Pulse Rate (PR)

SpO$_2$ Plethysmogram

NIBP: Systolic Pressure (SYS), Diastolic Pressure (DIA), Mean Pressure (MAP), PR (NIBP)

TEMP: Channel-1 Temperature (T1), Channel-2 Temperature (T2),

Temperature Difference between two channels (TD)

IBP: Channel-1 SYS, DIA, MAP

Channel-2 SYS, DIA, MAP

Dual-IBP waveforms

CO$_2$:   End Tidal CO$_2$ (EtCO$_2$)

Fraction of inspired carbon dioxide (FiCO$_2$)

Air Way Respiration Rate (AwRR)

CO$_2$ waveform

The monitor provides extensive functions such as visual and audible alarms, storage for trend data, NIBP measurements, alarm events, drug dose calculation, and so on.

3.2 Screen Display

The monitor is equipped with a high-resolution multicolor TFT LCD screen. The patient parameters, waveforms, alarm messages, bed number, time, monitor status and other data can be reflected from the screen.

The screen is divided into three areas:

1 Information Area ① ④;

2 Waveform Area ②;

3 Parameter Area ③.
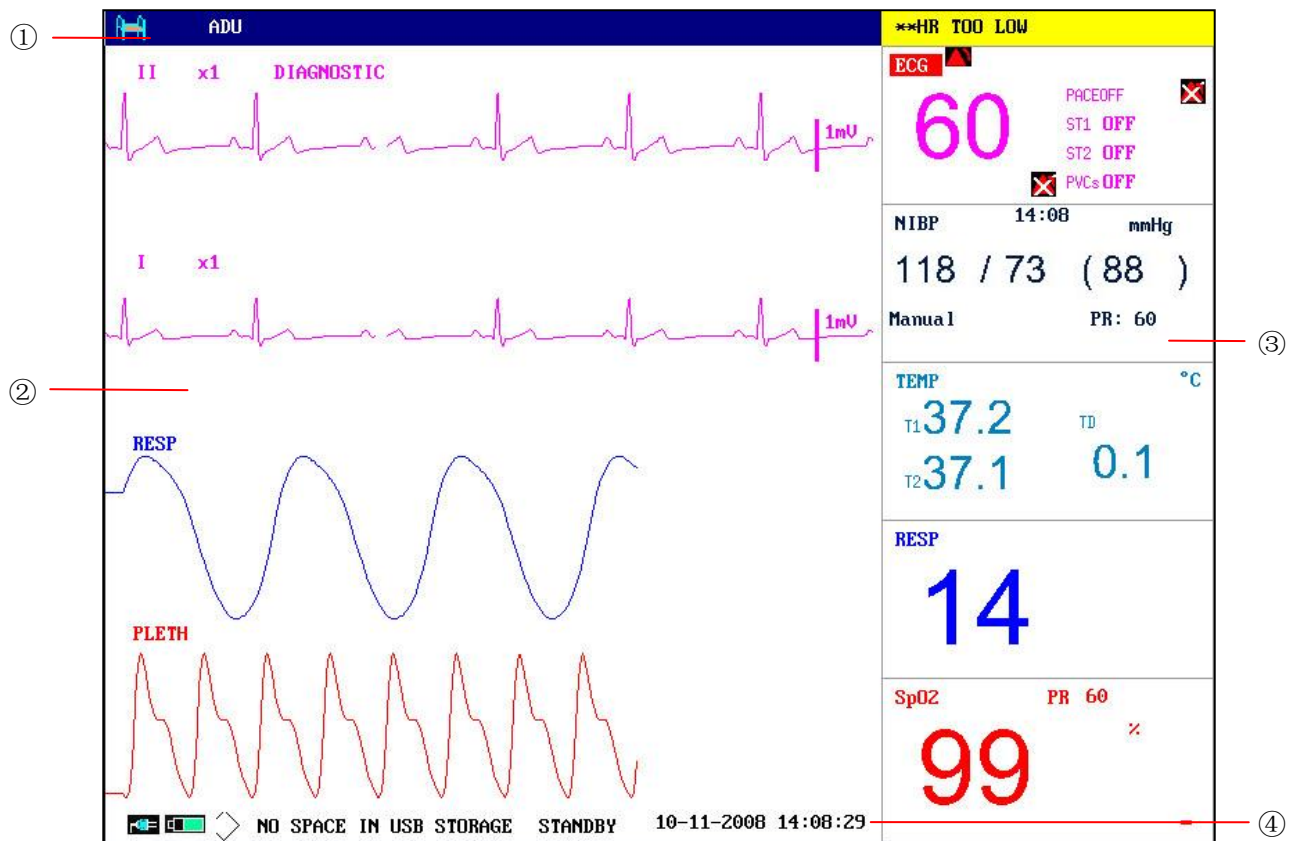
Figure 3-5 Main Display

Information Area（① ④）

The Information Area is at the top and bottom of the screen, displaying the operating state of the monitor and the status of the patient.

The information area contains the following data:

	Bed number of the monitored patient
ADU	Type of patient. Three options: Adult, Pediatric, Neonatal.
Name	Name of the monitored patient, when the user inputs patient name, this name will be displayed on the right side of the patient type. If the user doesn't input patient name, this position will be vacant.
10-11-2008	Current date
14: 08: 29	Current time
	Indicates the status of mains power supply
	means the mains power supply is on,
	means the mains power supply is off.
	Indicates the battery and its capacity;
	gives information about remaining battery charge, estimated

operating time and maintenance requirements;

 means there is no battery equipped in the monitor.

                    Indicates the audio alarm is turned off.

                    Indicates the audio alarm is paused.

                    Displays beside a parameter to indicate the alarm is turned off.

                    USB storage indicator

STANDBY   Select this item to enter Standby mode, the dialog pops up:
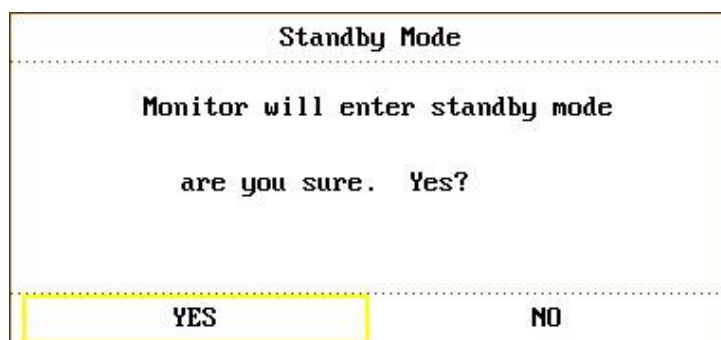
Figure 3-6 Standby Mode

Select **YES** to enter Standby mode and display the current time; if you select **NO**, the monitor will return to the main display.

Other information of the Information Area comes up only with respective monitoring status. They are:

◆ Signs indicating the operating status of the monitor and the sensors are displayed at the right side of patient name.

◆ Alarm message is displayed in the right most area.

◆ "**FREEZE**" appears when the waveforms are frozen.

Waveform Area (②)

Seven waveforms can be displayed at the same time. The sequence of waveforms can be adjusted. With the maximum configuration, the system can display 2 ECG waveforms, a SpO_2 waveform, a respiration waveform (can be from ECG module), 2 IBP waveforms and a CO_2 waveform.

In the **TRACE SETUP** menu, all the waveforms are listed. The user can select the waveform to be displayed, and adjust the display position. Refer to *Section 4.8 Tracing Waveforms Selection* for details.

The name of the waveform is displayed on the upper left part of the waveform. The name of ECG is user-selectable. Gain and filter way of this channel are displayed as well. A 1mV scale is marked on the right of ECG waveform. The IBP waveform scale can also be selected according

to the actual requirement. Its range is described in the part: IBP Monitoring. In the IBP waveform area, the waveform scale is displayed. The three dotted lines for each IBP waveform from up to down represent respectively the upper limit scale, reference scale and lower limit scale. The values of these three scales can be set. The specific method is given in the part: IBP Monitoring.

When a certain menu is displayed, some waveforms become invisible. Main display is restored when you exit the menu.

The user may set up the rate to refresh the waveform. The method to adjust the refreshing rate of each waveform is discussed in the setup description of each parameter.

Parameter Area（③）

Parameter area is on the right of Waveform area, and parameters are displayed corresponding to waveforms basically. They are:

ECG:
- —— Heart Rate (Unit: beats per minute, bpm)
- —— ST-segment analysis of Channel 1 & 2-ST1, ST2 (Unit: mV)
- —— PVCs (Premature Ventricular Contraction) events (Unit: event/min)

SpO_2:
- —— Oxygen Saturation SpO_2 (Unit: %)
- —— PR (Unit: BPM)

NIBP:
- —— Systolic pressure, Mean pressure, Diastolic pressure (Unit: mmHg or kPa)
- —— PR (NIBP) (Unit: BPM)

TEMP:
- —— Temperatures of channel 1, channel 2 and their temperature difference: T1, T2, TD (Unit:°C or °F)

RESP:
- —— Respiration Rate (Unit: breath/min)

IBP:
- —— The blood pressure of channel 1 and 2. From left to right, there are Systolic pressure, Mean pressure and Diastolic pressure (Unit: mmHg, kPa, or cmH_2O)

CO_2:
- —— $EtCO_2$ (Unit: %, mmHg or kPa)
- —— $FiCO_2$ (Unit: %, mmHg or kPa)
- —— AwRR (Unit: times/minute)

Alarm Indicator and Alarm Status

In normal status, the alarm indicator does not light.

When an alarm occurs, the alarm indicator will light or flash. The color of light represents the alarm level. Refer to *Chapter 6 Alarms* for details.

Refer to relative content of parameter for Alarm information and prompt.

Charge Indicator and Charge Status

To indicate the status of charging: When the battery is charged, the light color turns to orange.

3.3 Button Functions

All the operations to the monitor can be finished by several buttons and a knob. They are:
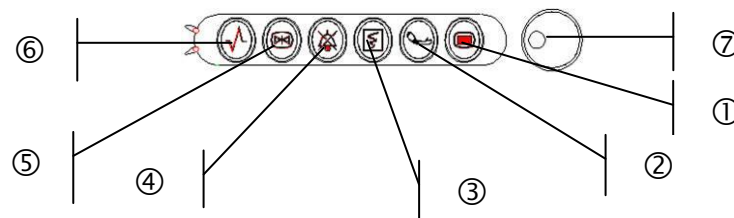
Figure 3-7 Buttons

① **Menu**	Press to call up the **SYSTEM MENU**. Refer to *Chapter 4 System Menu* and *Chapter10 Trend and Event* for details.
② **Start**	Press to fill air into cuff and start blood-measuring. During the measuring process, press the button to stop measure.
③ **Record**	Press to start a real-time recording. The recording time is set in **RT REC TIME** of **RECORD** submenu.
④ **Mute**	Press this button to pause or turn off the auditory alarm as needed.
⑤ **Freeze**	In normal mode, press this button to freeze all the waveforms on the screen. In **FREEZE** mode, press this button to restore the waveform refreshing.
⑥ **Main**	Press this button to return to the main interface.
⑦ **Trim Knob**	The user can use the trim knob to select the menu item and modify the setup. It can be rotated clockwise or anticlockwise and pressed. The user can use the knob to realize the operations on the screen, in the **SYSTEM MENU** and parameter menu.

Method to Use the Knob to Operate on the Screen:

The rectangular mark on the screen that moves with the rotation of the knob is called "cursor". Operation can be performed at any position at which the cursor can stay.

When the cursor is in the waveform area, the user may immediately modify the current setup. When the cursor is in the parameter area, the user may open the setup menu of the corresponding parameter module so as to set up the menu items of the module.

Operating method:

◆ Move the cursor to the item where the operation is required.

◆ Press the knob.

◆ One of the following four situations may appear:

1. The cursor with background color may become a frame without background color, which implies that the content in the frame can change with the rotation of the knob.

2. Menu or measuring window may appear on the screen, or the original menu is replaced by the new menu.

3. A check mark "√" appears at the position, indicating that the item is confirmed.

4. The system immediately executes a certain function.

3.4 Interfaces

For the convenience of operator, interfaces of different functions are in different sites of the monitor. There is a USB port on the panel for connecting USB storage.

Right Side of the Monitor

At the right side of the monitor, there are a bracket of water trap for CO_2 module (①) and the recorder's paper inlet cover (②).
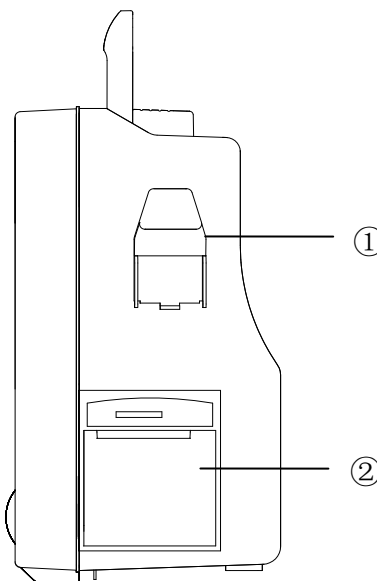
Figure 3-8 Right Panel

Left Side of the Monitor

Connectors for cables and sensors are as shown in the following figure.

1. CO_2 sensor connector
2. IBP1 transducer connector
3. ECG cable connector
4. NIBP cuff connector
5. TEMP1 probe connector

6. TEMP2 probe connector

7. IBP2 transducer connector

8. SpO_2 sensor connector
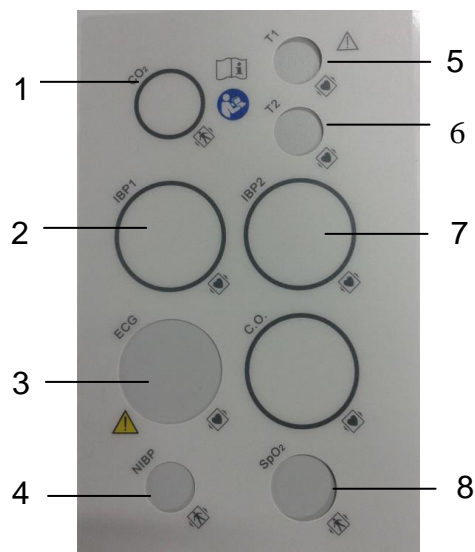
Figure 3-9 Left Panel

Rear Panel

Figure 3-10 Rear Panel

① Network Interface (reserved): Standard RJ45 Socket, for connecting to MFM-CMS of the manufacturer.

② VGA interface (optional)

③ USB port

④ Equipotential grounding terminal for connection with the hospital's grounding system.

⑤ Fuse box, in which fuses are put.

⑥ Power supply socket: 100 V-240 V~, 50 Hz/60 Hz.

NOTE:

The VGA function is optional.

3.5 Built-in Rechargeable Battery

3.5.1 Battery Safety Information

WARNING

1   Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.

2   Do not place battery in the monitor with the (+) and (-) in the wrong way around.

3   Do not connect the positive (+) and negative (-) terminals with metal objects, and do not put the battery together with metal object, which can result in short circuit.

4   Do not unplug the battery when monitoring.

5   Do not heat or throw battery into a fire.

6   Do not use, leave battery close to fire or other places where temperature may be above 60 °C.

7   Do not immerse, throw, or wet battery in water/seawater.

8   Do not destroy the battery: do not pierce battery with a sharp object such as a needle; Do not hit with a hammer, step on or throw or drop to cause strong shock; Do not disassemble or modify the battery.

9   The recommended battery can only be used for this monitor.

10   Do not solder the leading wire and the battery terminal directly.

11   If liquid leaking from the battery gets into your eyes, do not rub your eyes. Wash them well with clean water and go to see a doctor immediately. If liquid leaks of the battery splash onto your skin or clothes, wash well with fresh water immediately.

12   If leakage or foul odor is detected, ensure that there's no fire around.

13   Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.

14   Do not use a battery with serious scratch or deformation.

3.5.2 Battery Status on the Main Screen

The monitor is equipped with a built-in chargeable battery. When the AC power supply is switched on, the battery will be charged automatically until the electric energy becomes full. There is a sign "   " in the lower left corner of screen to show the charging status, and the color part is the electric energy of battery. When the monitor is not equipped with battery, the battery status will be shown as the sign "   ", which means no battery.

One battery can power the monitor. Under the cable connectors is the cover of battery compartment. See Battery compartment in the following figure.
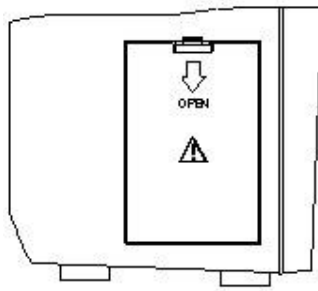
Figure 3-11 Battery Compartment

Battery status symbols show the status of battery and battery power remaining:

   Remaining battery power: 100%.

   Remaining battery power: 75%

   Remaining battery power: 50%

   Remaining battery power: 25%

   Batteries are almost depleted and need to recharge immediately.

3.5.3 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery maintenance as recommended here can help to slow down this process.

1. Disconnect the patient from the monitor and stop all monitoring and measurement.

2. Switch the monitor power on and charge the battery for more than 6 hours continuously.

3. Disconnect monitor from mains power and let the monitor run until there is no battery power left and the monitor shuts off.

4. The running time of the battery reflects the battery performance.

If the running time is obviously less than the specified time in the specification, please change the battery or contact the service personnel.

3.5.4 Replacing the Battery

To install or replace the battery, please follow the procedure:

1. Pull the battery door downwards to open it according to indication on it.

2. Pull the metal retainer until the battery can be removed.

3. Insert the new battery into the battery compartment.

4. Pull the metal retainer downward to fix the battery and close the battery door.

3.5.5 Recycling the Battery

When the battery no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly.

3.5.6 Maintaining the Battery

Batteries should be conditioned regularly to maintain their useful life.

Remove the batteries from the monitor if they are not used for a longer period of time. And recharge the batteries at a minimum of every 6 months when they are stored.

Discharge the battery completely once every month.

3.5.7 Battery Alarm Information

Technical Alarm:

Message	Cause	Alarm Level	What to do
Battery Low	Battery Low	High	Change the battery or charge the battery.

Chapter 4 System Menu

The **SYSTEM MENU** is introduced in this chapter.

The monitor features in flexible configurations. You can configure various aspects of the monitor, including the parameters to be monitored, sweeping speed of the waveforms, audio signal volume, and output content.

Press the **MENU** button on the front panel to call up **SYSTEM MENU**. You can perform the following operations in this menu.
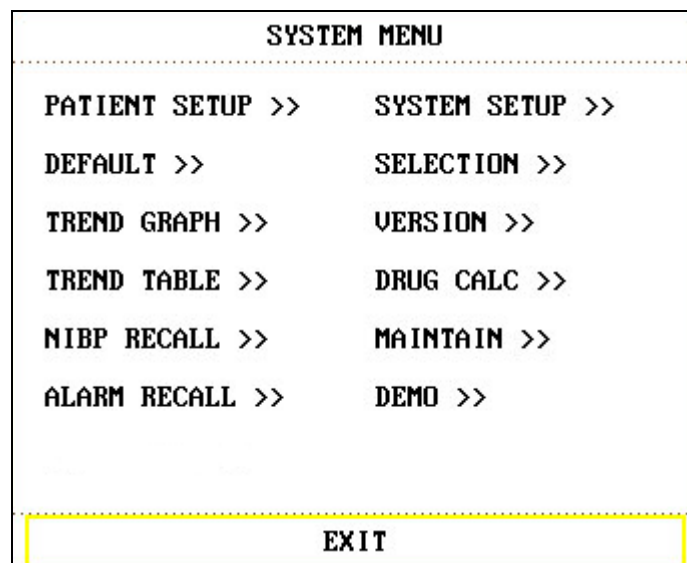
Figure 4-1 System Menu

Select **SYSTEM SETUP >>** to see the following menu:
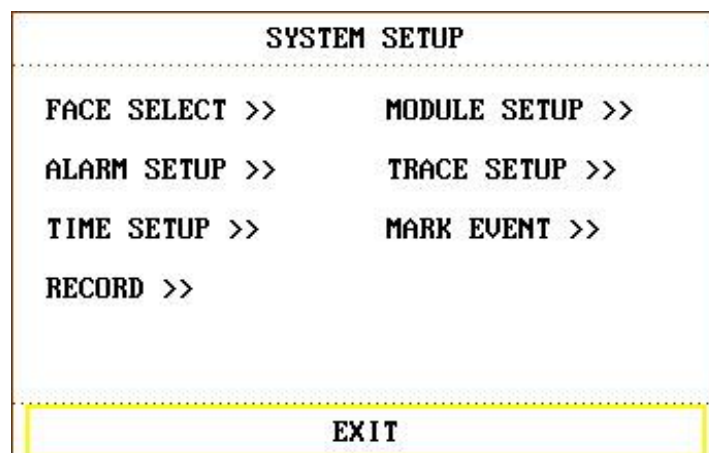
Figure 4-2 System Setup

Review of trend graphs/tables, NIBP measurements and alarm recall will be described in *Chapter10 Trend and Event*.

4.1 Patient Setup

Pick **PATIENT SETUP** in **SYSTEM MENU** to call up the following menu.

Figure 4-3 Patient Setup

You can set up the following patient information:

DEPT.	Department in which the patient receives treatment.
PAT NO	Patient Number
BED NO	Patient bed number (Range: 1 to 254)
DOCTOR	Name of the doctor.
NAME	Patient name (Valid characters: A to Z, 0 to 9; Maximum length: 12 characters)
SEX	Patient gender (Available options: "**F**" for Female, "**M**" for Male)
PAT TYPE	Patient type (Available options: **ADU**, **PED**, and **NEO**)
ADMIT	Hospitalization starting date (format: **year/month/day**)
BIRTH	Patient date of birth (format: **year/month/day**)
HEIGHT(cm/inch)	Patient height (Increase/decrease by 0.5 cm or 0.5 inch per switch)
WEIGHT(kg/lb)	Patient weight (Increase/decrease by 0.5 kg or 0.5 lb per switch)

BLOOD	Patient blood type (Pick **A**, **B**, **O**, **AB**, or **N**. **N** represents unknown blood type)
NEW PATIENT	Admission of new patient

Also in this menu, the user may select "**NEW PATIENT**" item to access "**CONFIRM TO UPDATE PATIENT**" dialog box as shown below, in which the user decides whether to monitor a new patient.
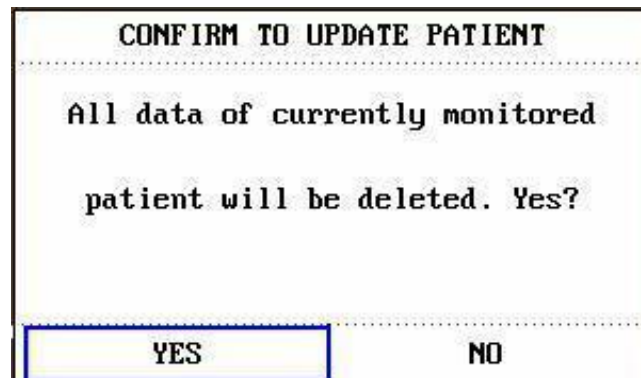
Figure 4-4 Confirm to Update Patient

Pick **YES** to delete all information of the patient being currently monitored and exit the menu.
Pick **NO** to give up updating the patient and the system will keep the information of the current patient and exit the menu.

NOTE:
Selecting **YES** will delete all information about the currently monitored patient.

4.2 Default Setup

NOTE:
Select any item in this sub-menu to cancel the current setup and use the selected default setup.
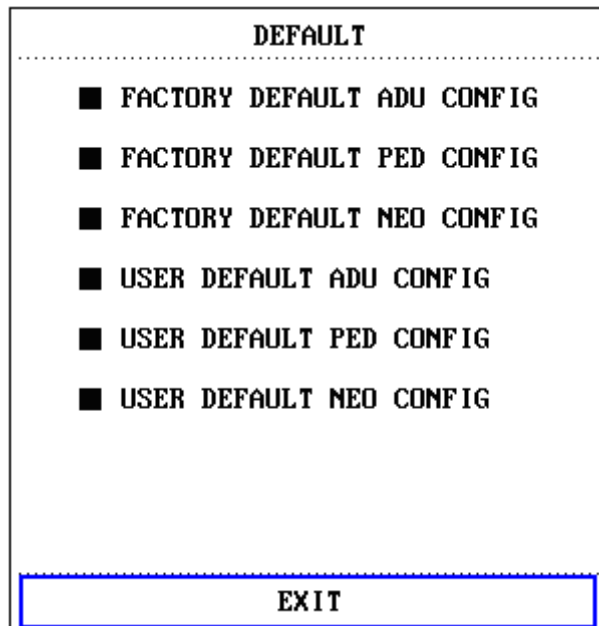
Figure 4-5 Default Menu

In this sub-menu, you can select the factory default or the user-defined default.

To check the configuration currently used, select **SYSTEM MENU** > **DEFAULT**. The one labeled with (■) is current configuration. If there's no labeled configuration, it means the currently used configuration is not one of them.

If factory default is same with user-defined default, though user-defined is applied, the label (■) will be displayed on factory default.

4.3 Mark Event

There are four types of event that you can define.

Select **MARK EVENT** item in **SYSTEM SETUP** to call up the following menu:
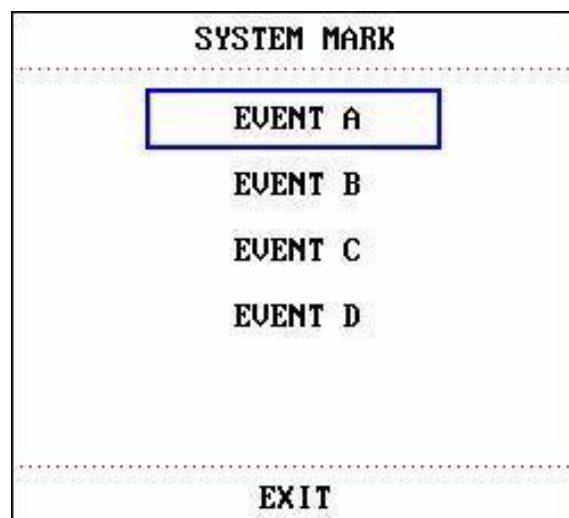
Figure 4-6 Mark Event

To mark the event: Use the trim knob to select one from event **A, B, C** and **D**. There is a "@" signal for the one selected. To cancel your selection, repress the knob at selected item. Press **EXIT** to return to the previous menu.

The point of using event function:

To differentiate the patient events that have impact on parameter monitoring, such as dose taking, injection, therapy status, etc.

The Event will be displayed on the **Trend Graph** and **Trend Table** to assist analyzing patient parameter of the time when the event happens.

4.4 Face Select

Select **FACE SELECT** item in **SYSTEM SETUP** menu to access **FACE SELECT** dialog box as shown below, in which four selections are available: **STANDARD SCREEN, TREND SCREEN, oxyCRG SCREEN** and **LARGE FONT SCREEN**. Only one selection can be chosen each time.
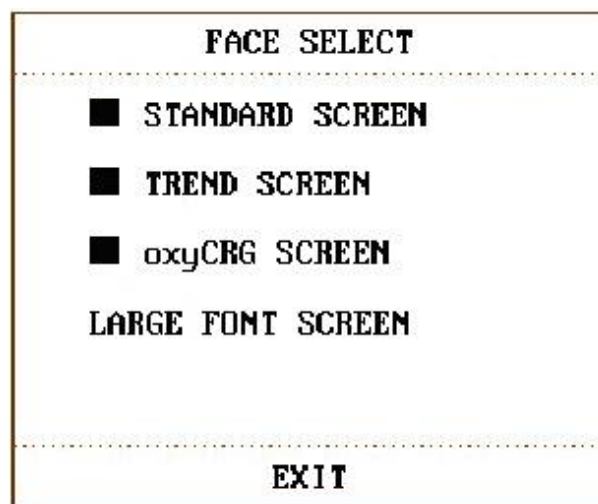
Figure 4-7 Face Select

After entering **LARGE FONT FACE SCREEN**, you can select three modes. See as follows:
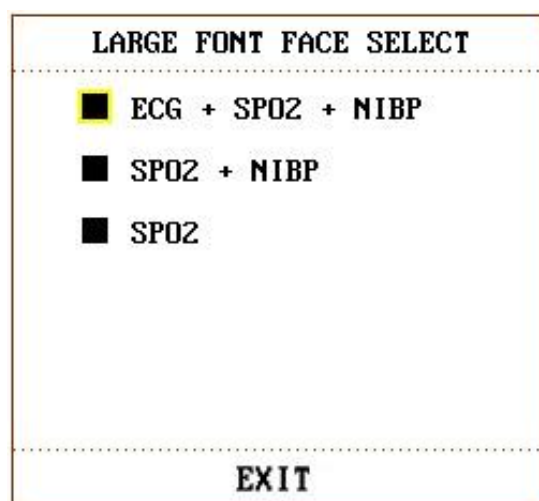
Figure 4-8 Large Font Face Select

4.5 Time Setup

Select **TIME SETUP** item in **SYSTEM SETUP** menu to access the sub-menu of **TIME SETUP** as shown below. System time is in the format of **MONTH-DAY-YEAR, DAY-MONTH-YEAR, YEAR-MONTH-DAY**. Pick the item and turn the knob to modify the items. Select **EXIT** item to return to the previous menu.

```
              TIME SETUP
..........................................................

    DATE:        11 - 10 - 2008

    TIME:        13 : 55 : 50

    DATE FORMAT: MONTH-DAY-YEAR

..........................................................
                  EXIT
```

Figure 4-9 Time Setup

4.6 Record Setup

Select **RECORD** in **SYSTEM SETUP** menu to call up the following menu:

```
                RECORD
..........................................................

    REC WAVE1          ECG1

    REC WAVE2          ECG2

    REC WAVE3          RESP

    RT REC TIME        CONTINUAL

    TIMING REC TIME    OFF

    REC RATE           25.0

            CLEAR REC TASK

..........................................................
                 EXIT
```

Figure 4-10 Record

In the sub-menu, the user may select the **REC WAVE1**, **REC WAVE2** or **REC WAVE3**, a maximum of 3 waveforms can be printed out.

The output waveforms can be selected for the following items:

ECG1, ECG2, ECG3	ECG1 waveform, ECG2 waveform and ECG3 waveform. (There will be 7 ECG waveforms on the screen in Full-Lead display mode). If no ECG waveform is currently displayed on the screen, this item cannot be picked.
SpO₂	SpO_2 Plethysmogram. (If no SpO_2 waveform is currently displayed on the screen, this item cannot be picked. In ECG Full-Lead display mode, this item can be picked, although no SpO_2 waveform is currently displayed on the screen.)
RESP	RESP waveform. (If no RESP waveform is currently displayed on the screen, this item cannot be picked. But in ECG Full-Lead display mode, this item can be picked, although no RESP waveform is currently displayed on the screen.)
IBP1, IBP2	IBP1 waveform and IBP2 waveform. (If no IBP waveform is currently displayed on the screen, this item cannot be picked. But in ECG Full-Lead display mode, this item can be picked, although no IBP waveform is currently displayed on the screen.)
CO₂	Display CO_2 module waveform. (If there is no CO_2 waveform on the screen, we cannot choose it. But in full screen multi-lead mode, we can choose it though we can not see it.)
OFF	No display for this channel.

◆ **RT REC TIME**: represents "**real-time recording time**", for which two selections are available: **CONTINUAL** and **8S** (8 seconds). "**CONTINUAL**" means once pressing the "**Record**" button on the front panel, the recorder will continuously print out the waveform or parameter until the "**Record**" button is pressed again.

◆ **TIMING REC TIME**: represents "**time interval between two times of timing recording**". 10 selections are available: "**OFF**, **10MIN**, **20MIN**, **30MIN**, **40MIN**, **50MIN**, **1HOUR**, **2HOURS**, **3HOURS** and **4HOURS**". It means that the system will trigger the recording operation according to the selected time interval. The recording time is fixed at 8 seconds.

NOTE:
RT REC TIME has the higher priority compared with **TIMING REC TIME**.

◆ **REC RATE**: **25.0 mm/s** or **50.0 mm/s**.

◆ **CLEAR REC TASK**: this item can be used to stop recorder from printing out too many tasks.

NOTE:
1   The recorder is an optional part.

2   If two same waveforms are selected, one of them will change to a different waveform automatically.
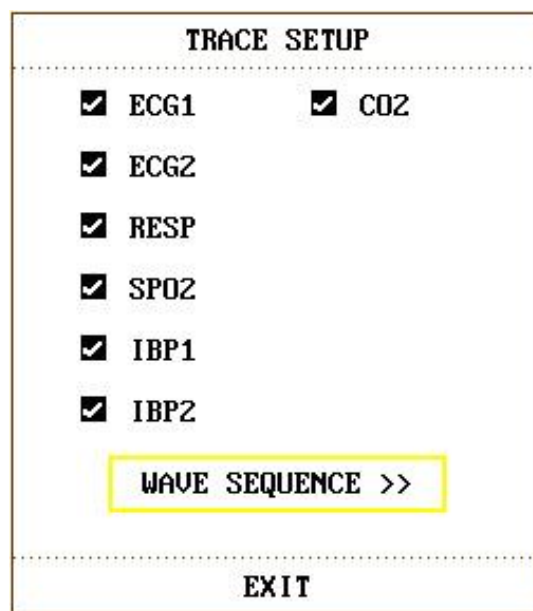
3   When ECG waveforms are selected for printing, with gain of ×1, ×0.5 or ×0.25, X0.125, a 3-channel waveform can be printed out; however, with gain of ×2, X4, only a 2-channel waveform can be printed out to avoid overlapping of waveforms, and the third waveform will be omitted.

4   The 3-channel waveform can be printed only in real-time recording, while it is not available in other recording modes, such as alarm review recording, and alarm triggered recording.

4.7 Module Setup

Select **MODULE SETUP** item in **SYSTEM SETUP** menu. You can choose the parameter you want to monitor from this menu, so that you can enhance the display efficiency, and avoid interference from other messages.

4.8 Tracing Waveforms Selection

Select **TRACE SETUP** item in **SYSTEM SETUP** menu to call up the following menu:

```
                    TRACE SETUP
        ☑ ECG1        ☑ CO2

        ☑ ECG2

        ☑ RESP

        ☑ SPO2

        ☑ IBP1

        ☑ IBP2

        ┌─────────────────────────┐
        │   WAVE SEQUENCE >>       │
        └─────────────────────────┘

                     EXIT
```

Figure 4-11 Trace Setup

You can define the traces displayed on the screen in this menu. The waveforms available for selection are those whose modules have been selected in **MODULE SETUP** menu.

4.9 Monitor Version

Pick **VERSION** to show the software version information of this monitor.

4.10 Alarm Volume

The system provides 10 levels of alarm volume and audio alarm off function. The system will give audio alarm prompt (except alarm sound) based on the selection.

The user may select different levels of volume as per clinical requirement. The method is listed below:

Press **ALARM SETUP** item in **SYSTEM SETUP** menu to call up **ALARM SETUP** sub-menu as shown below, in which the user may set up the alarm volume and other alarm information.

－ **ALARM VOL**: Set the alarm volume by turning the knob. The valid range is from 1 to 10.

－ **ALM REC TIME**: Set to 8 s, 16 s or 32 s.

－ **ALM Reset**: Reset the alarm by selecting this soft key.

You can also set alarm parameters in **MAINTAIN > USER MAINTAIN > ALARM SETUP**. Refer to *Chapter6 Alarm* for details.

4.11 Key Volume

Select **SELECTION** item in **SYSTEM MENU** to call up **SELECTION** sub-menu as shown below. Select **KEY VOL** item and set the volume. The selections are **OFF**, **LOW**, **MED**, **HIGH**.
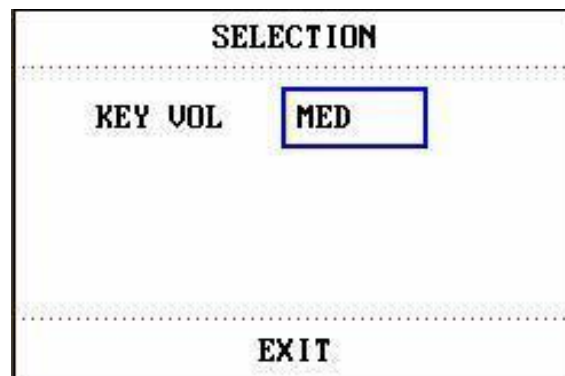
Figure 4-12 Selection

4.12 Drug Calculation

The monitor provides drug calculation and titration table display functions for fifteen different drugs. For details, please refer to the *Chapter11 Drug Calculation and Titration Table.*

4.13 Waveform Demonstration

Select **DEMO** item in **SYSTEM MENU** to call up **INPUT DEMO KEY**. After entering the password, the system enters the Demonstration Waveform status.

The purpose of waveform demonstration is only to demonstrate the machine performance and for training purposes. In clinical applications, this function is not recommended because the **DEMO** will mislead the hospital personnel to treat the waveform and parameter as actual data of the patient, which may result in delay of treatment or mistreatment.

4.14 Maintenance

Select **MAINTAIN** item in **SYSTEM MENU** to open the **ENTER MAINTAIN PASSWORD**

dialog box as shown below, in which you can enter password and then customize maintenance settings. Factory maintenance function is only available for the service engineers of the manufacturer or representatives authorized by the manufacturer.

```
┌──────────────────────────────────────────────────┐
│               ENTER MAINTAIN PASSWORD             │
│  ................................................ │
│                                                   │
│   USER KEY:                   FACTORY KEY:        │
│      ┌──────────────┐                             │
│      │_             │           ................  │
│      └──────────────┘                             │
│        CONFIRM                    CONFIRM          │
│                                                   │
│                                                   │
│   ┌─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┬─┐      │
│   │A│B│C│D│E│F│G│H│I│J│K│L│M│N│O│P│Q│R│S│T│U│      │
│   ├─┼─┼─┼─┼─┼─┼─┼─┼─┼─┼─┼─┼─┼─┼─┼─┼─┼──┬──┤      │
│   │V│W│X│Y│Z│0│1│2│3│4│5│6│7│8│9│ │ │DEL│ OK│      │
│   └─┴─┴─┴─┴─┴─┴─┴─┴─┴─┴─┴─┴─┴─┴─┴─┴─┴───┴───┘      │
│                                                   │
│  ................................................ │
│                      EXIT                         │
└──────────────────────────────────────────────────┘
```

Figure 4-13 Enter Maintain Password

User Maintain

Input the password **A B C** into the **ENTER MAINTAIN PASSWORD** box and press **CONFIRM**, then the **USER MAINTAIN** menu will pop up, in which you can set up the following items.

◆ **LANGUAGE**: You can set the language to be displayed on the interface.

NOTE:
Please restart the monitor after changing the language.

◆ **LEAD NAMING**: You can select **AHA** or **IEC**. To know the difference between these two styles, refer to *Chapter13 ECG/RESP Monitoring*.

◆ **LOCAL NET NO**: Physical Number of monitor.

◆ **ALARM SETUP>>**: You can set up parameters of alarm. For more details refer to *Chapter6 Alarm*.

◆ **OTHER SETUP >>**: You can set some other functions. See as follows:

```
                        OTHER SETUP
      ..............................................................

        HUM TYPE                    50HZ

        HUM STATUS                  ON

        RESP DRIFT FILTER           ON

        TEMP SENSOR                 CY-F1

        NURSE CALL                  ON


      ..............................................................
                          EXIT
```

Figure 4-14 Other Setup

  ✓ **NURSE CALL**: Turn on or off the nurse call. When a new alarm of physiological parameter occurs, it gives a 3-second **NURSE CALL** alarm; if the system alarm or the audio alarm is turned off, the **NURSE CALL** is unavailable. It is connected to RJ45 socket, the same port as connected to Ethernet. **NURSE CALL** occupies the 7th and 8th pins of RJ45. When the alarm occurs, the 7th and 8th pins are in short circuit: otherwise they are disconnected.

◆ **CO_2 MAINTAIN >>**:

Only applicable to EDAN $EtCO_2$ module.

In this menu, it displays **BARO PRESS**, **GAS CELL PRESSUR**E, **MODULE TEMP**. You can set standard **GAS TEMP** (25 °C is recommended) and CO_2 value for **CALIBRATE** operation. **ZERO CAL** operation has no need to set standard **GAS TEMP** and CO_2 value.

◆ **SELECT FONT**: You can set the displayed font on the main screen to **ARIAL** or **ARIALBOLD**. The default is **ARIALBOLD**.

◆ **NIBP MAINTAIN**: It is used to **RESET**, **CALIBRATE** and **LEAK TEST**.

◆ **SAVE CURRENT AS USER CONFIG**

In this sub-menu, you can save the current configuration as the user-defined default configuration. At this time, the system will automatically save all the setups in the parameter menu, ECG lead, gain and filter way as the user-defined default configuration according to the patient type. The dialog box as shown below will pop up.
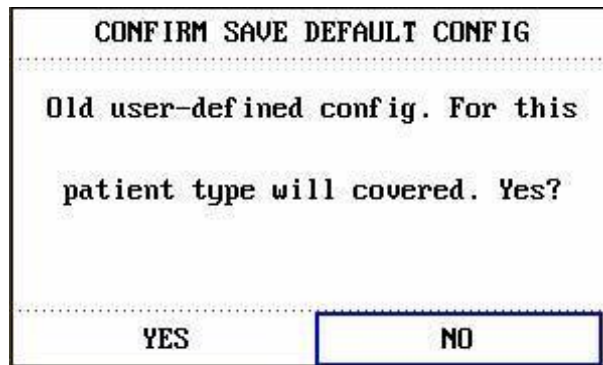
Figure 4-15 Confirm Save Default Configuration

Click on **YES** to save the current patient type configuration as the user default configuration.
Click on **NO** to give up the operation.

◆ **SERVER IP**: The default server IP is 202.114.4.119, it can be changed by the user according to the IP address of PC installed with MFM-CMS of the manufacturer.

◆ **SERVER PORT**: Set server port.

◆ **SELECT COLOR >>**: Users can set the displaying colours of waveforms by this item. 16 colours can be selected. Selecting **DEFAULT** can set the colour configuration to default setup.
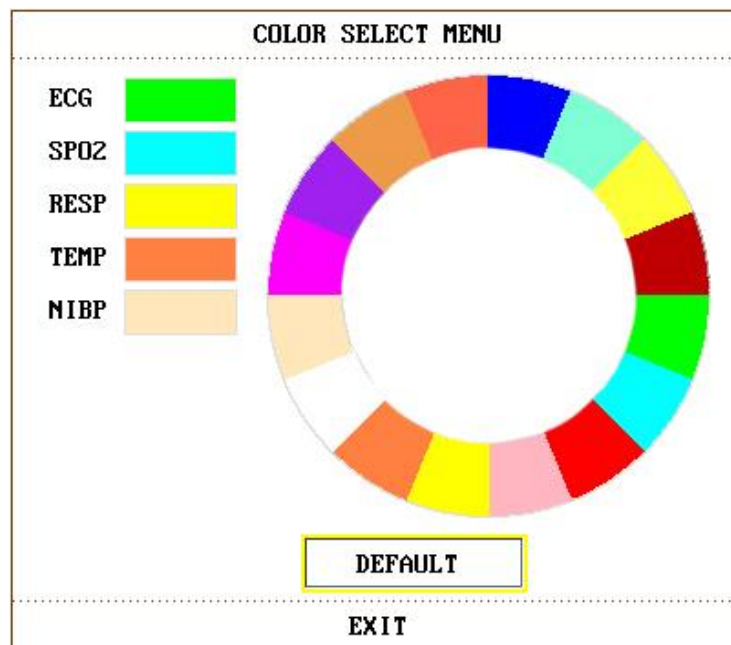
Figure 4-16 Colour Select Menu

Factory Maintain

Factory maintenance function is only available for the service engineers of the manufacturer or representatives authorized by the manufacturer.

4.15 Data Storing

Users can store the measured data into USB storage by Data store function, query or delete data in the menu.

The factory default of data store is in off status. If **DATA STORE** in **FACTORY MAINTAIN** is set to **ON**, user can select **DATA STORE** in **SYSTEM MENU** to call up the following dialog box:

NOTE:

The monitor may not be compatible with all models of USB disks, it is recommended to use Netac USB disk of 4G.

```
┌─────────────────────────────────────────┐
│            DATA STORE MENU               │
│··········································│
│                                          │
│  DATA STORE    ┌──────┐                  │
│                │ ON   │                  │
│                └──────┘                  │
│                                          │
│  SELECT DATA       DELETE USB            │
│                                          │
│                                          │
│                                          │
│··········································│
│                 EXIT                     │
└─────────────────────────────────────────┘
```
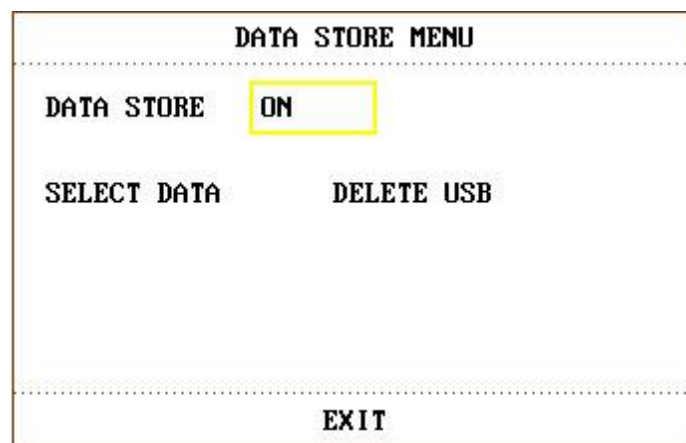
Figure 4-17 Data Store Menu

◆ **DATA STORE**: set this item to **ON** or **OFF** to turn on or off the data store function.

The data file will be stored into the folder of patient-data/patient ID in the USB storage; if the patient ID has not been set, the data will be stored into the default folder "**patient**" in USB storage.

Each data file is named by time, it can save 96-hour trend data with 1-min resolution, 1-hour trend data with 1-second resolution, 60 groups parameter alarm, 60 groups ARR data, 500 groups NIBP data, 720 seconds waveforms and patient information.

◆ **EXIT U DISK**: users should exit the U disk via the menu before dismounting it.

After selecting **EXIT U DISK**, if the data is being stored, it will indicate "**Transmitting…, Please Waiting**"; if the U disk is dismounted successfully, it will indicate **EXIT U DISK SUCCESS**. After the USB icon vanishes, remove the U disk.
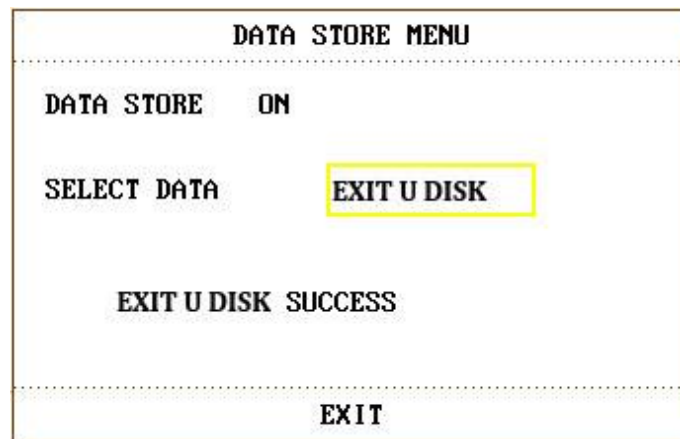
Figure 4-18 Delete USB success

◆ **SELECT DATA**: select this item to query data. The dialog box displays as follows:
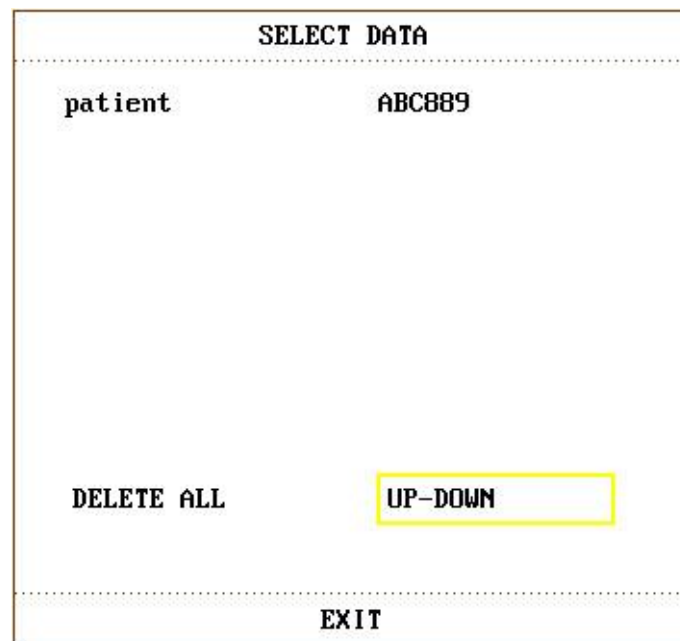
Figure 4-19 Select data

－ **DELETE ALL**: users can delete all the data of selected patient ID by this item.

－ **UP-DOWN**: users can page up or down by this item, patient ID can be displayed on few pages.

Select patient ID to enter the following dialog box for selecting the data:
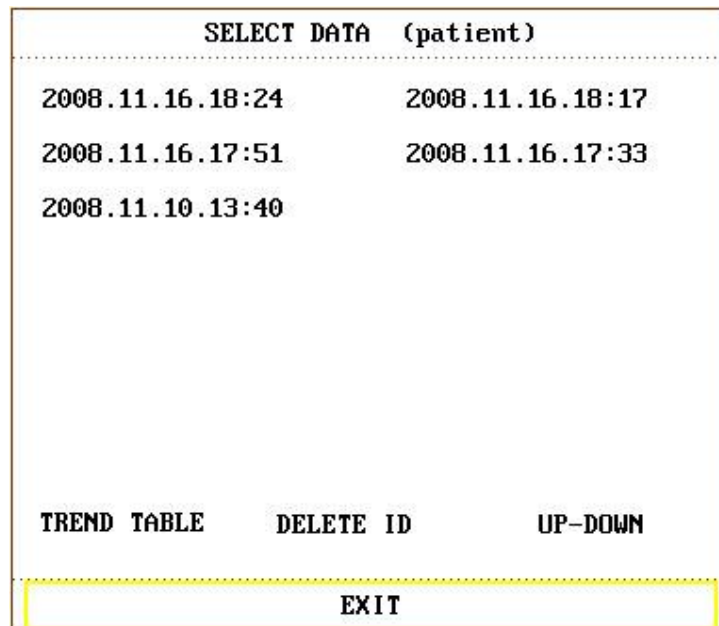
Figure 4-20 Select data

After selecting the time, the data will be imported from the USB storage to the monitor, it indicates as follows:
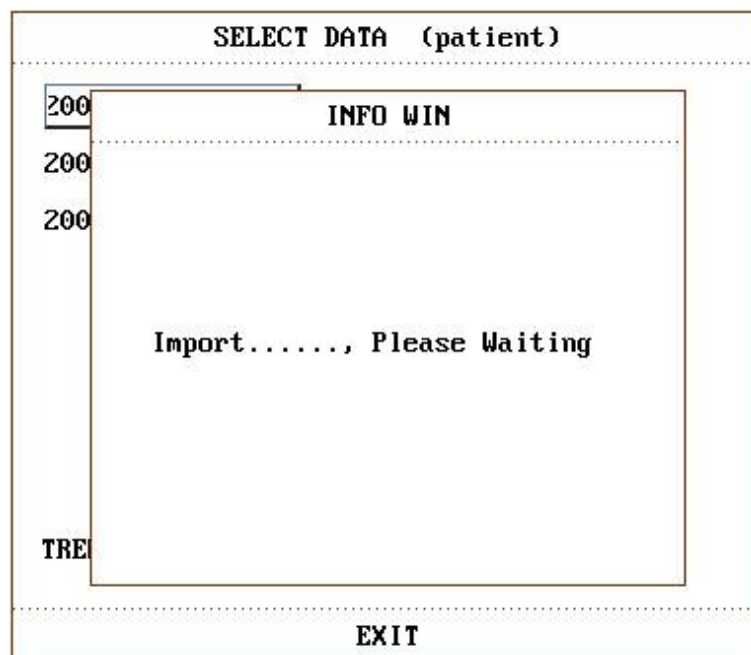
Figure 4-21 Importing data

－ **TREND TABLE**: users can select this item by trim knob after importing data, the real line box becomes broken line box, select the following contents to display: **TREND TABLE, TREND GRAPH, NIBP RECALL, PATIENT INFO, FREEZE RECALL, ARR RECALL** or **ALARM LIST.**

－ **DELETE ID**: users can delete all the data for current ID by this item. The dialog box displays:
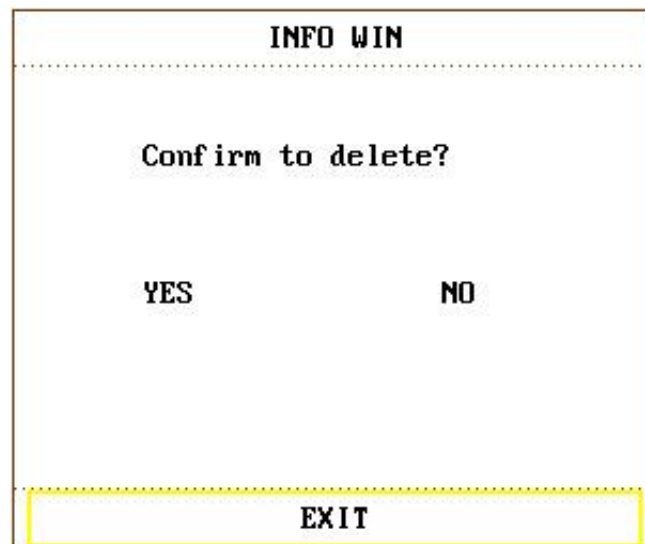
Figure 4-22 Confirm to delete

After deleting successfully, it indicates **DELETE SUCCESS!**

NOTE:

The data of the current monitoring patient ID can not be deleted.

If the data has not been saved successfully because of the power supply off or USB storage failure, when the users queries data by **SELECT DATA**, the prompt pops up "**INVALID DATA**".

If the user wants to query or delete data before selecting data, the prompt will pop up "**please choose data**"

If the USB storage is full, the monitor can't store data and it indicates **NO SPACE IN USB STORAGE** on the screen; the user needs to manually delete some data to continue.

NOTE:

1   Data store function can be set to on or off in **FACTORY MAINTAIN** by the manufacturer or the representative permitted by the manufacturer.

2   Remove USB disc before deleting may damage the USB storage or loss data.

Chapter 5 Face Select

This monitor has four different operating screens, which are **Standard Screen, Trend Screen, oxyCRG Screen and Large Font Screen**. Users can select different operating screens for necessary information as requested.

5.1 Selecting Operating Screen

In the **SYSTEM MENU**, select the **FACE SELECT** option in the **SYSTEM SETUP** menu to call up the dialog box as shown in the figure below. There are four options in this dialog box, which are **STANDARD SCREEN, TREND SCREEN, oxyCRG SCREEN** and **LARGE FONT SCREEN**. Only one item can be selected at a time.
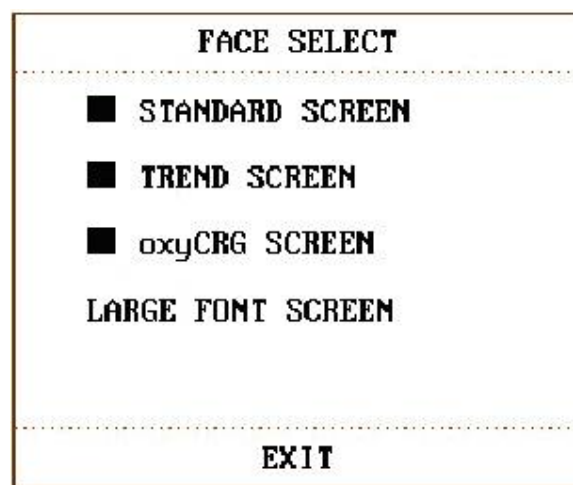
```
              FACE SELECT
      ........................................
      ■ STANDARD SCREEN

      ■ TREND SCREEN

      ■ oxyCRG SCREEN

      LARGE FONT SCREEN


      ........................................
                  EXIT
```
Figure 5-1 Face Select

5.2 Standard Screen

In the **FACE SELECT** menu, select the **STANDARD SCREEN** option to enter the Standard Screen. The Standard Screen displays to us the parameters in the Parameter area and the waveforms being monitored. This screen is the basic operating screen of the monitor.

5.3 Trend Screen

◆ Entering **TREND SCREEN**

In the **FACE SELECT** menu, select the **TREND SCREEN** option to enter the Trend Screen.

◆ Position of trend graph

Trend graph is located on the right of the corresponding waveform in the Waveform area. Its colour is the same as that of the corresponding parameter.

◆ Trend length

Dynamic trend length is 2 hours. On the trend graph, the scale of the right end of the X-axis is 0 hour while the left end is 2-hour.

◆ Select trend parameter

If multiple parameters are located at the same position on the trend graph, by selecting the corresponding hot key of a parameter on the trend graph, you can have the trend graph of this parameter displayed on the screen. For example, on ECG trend graph, you can select hot keys such as HR, ST or PVCs, and then the system will display their corresponding trend graphs respectively.

◆   Close trend screen

In the **FACE SELECT** menu, select options of other operating screens to close the **Trend Screen**.

5.4 oxyCRG Screen

◆   Enter **oxyCRG SCREEN**

In the **FACE SELECT** menu, select the **oxyCRG SCREEN** option to enter the oxyCRG Screen.

◆   Trend graph of oxyCRG screen

Located at the lower part of the screen, oxyCRG screen consists of three trends: HR Trend, SpO_2 Trend and RR Trend or Compressed Resp. Waveform.

◆   Select oxyCRG trend length

There are two hot keys at the bottom part of the oxyCRG Screen, which are **4MIN/2MIN/1MIN** and **RR/RESP WAVE**.
By using hot keys for trend time, you may select to display trend graphs of three different lengths, i.e., 1 min, 2 min and 4 min.

◆   Select RR trend or Compressed RESP Waveform

By using the hot keys for **RR/RESP WAVE**, you may select either RR trend graph or compressed Resp. Wave. They occupy the same position. Therefore, if you select **RR**, the position displays the dynamic trend of RR. If you select **RESP WAVE**, the position displays the compressed Resp. Wave.

◆   Close oxyCRG

In the **FACE SELECT** menu, select options of other operating screens to close the oxyCRG Screen.

NOTE:
This interface is always used in NICU because the SpO_2, HR and Resp of the neonate are different from those of adults.

5.5 Large Font Screen

Large Font Screen is a kind of operating screen, just like Standard Screen, Trend Screen and other operating screens. It is used by customers to meet different display requirements in monitoring.
◆   Enter Large Font Screen

Choose **LARGE FONT SCREEN** in **FACE SELECT** menu to enter **LARGE FONT FACE**

SELECT. There are three modes, see as follows:
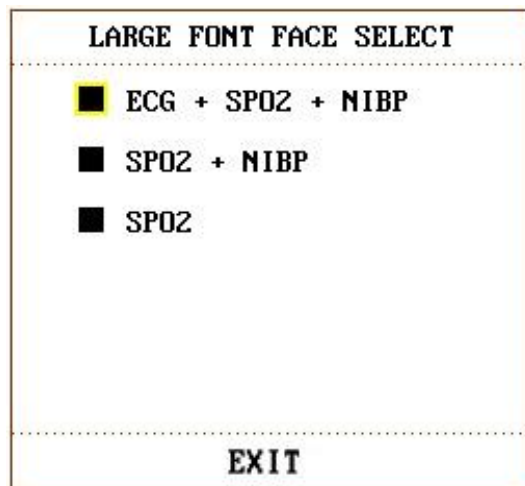
Figure 5-2 Large Font Face Select

◆ Three display modes

1. **ECG+SpO₂+NIBP** display mode:
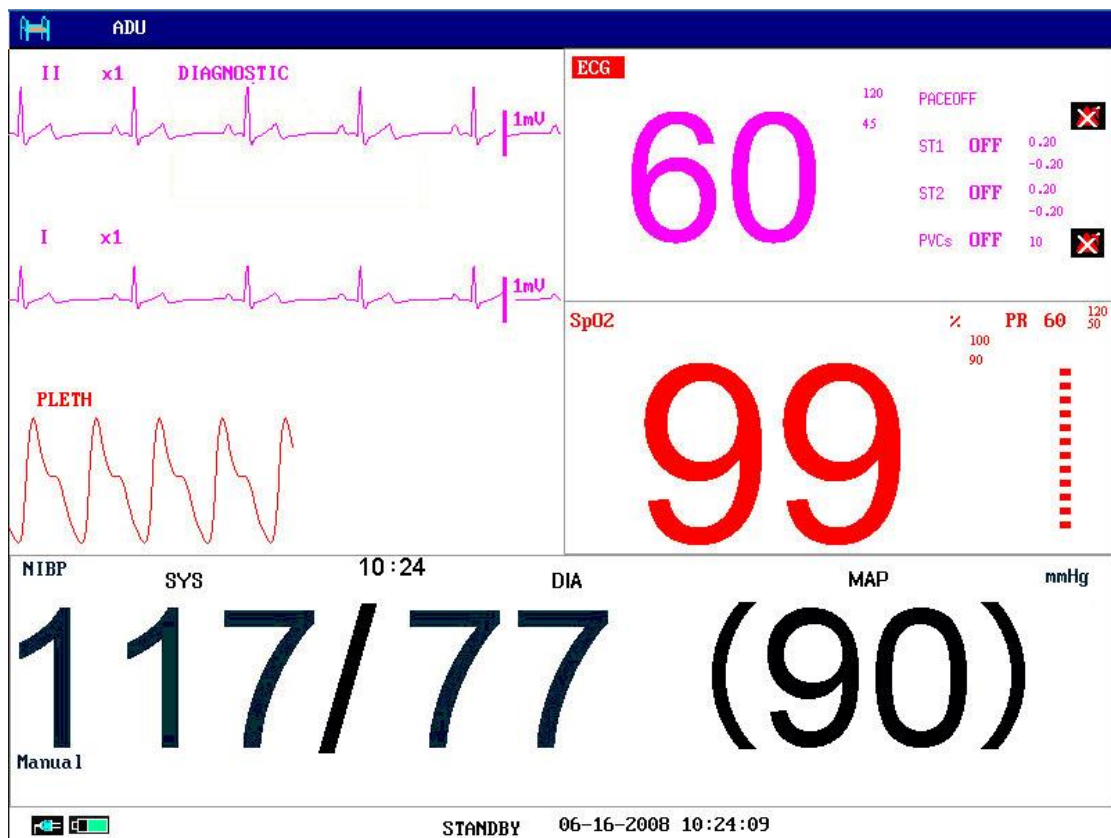
Figure 5-3 ECG+SpO₂+NIBP display mode

2. **SpO₂+NIBP** display mode:
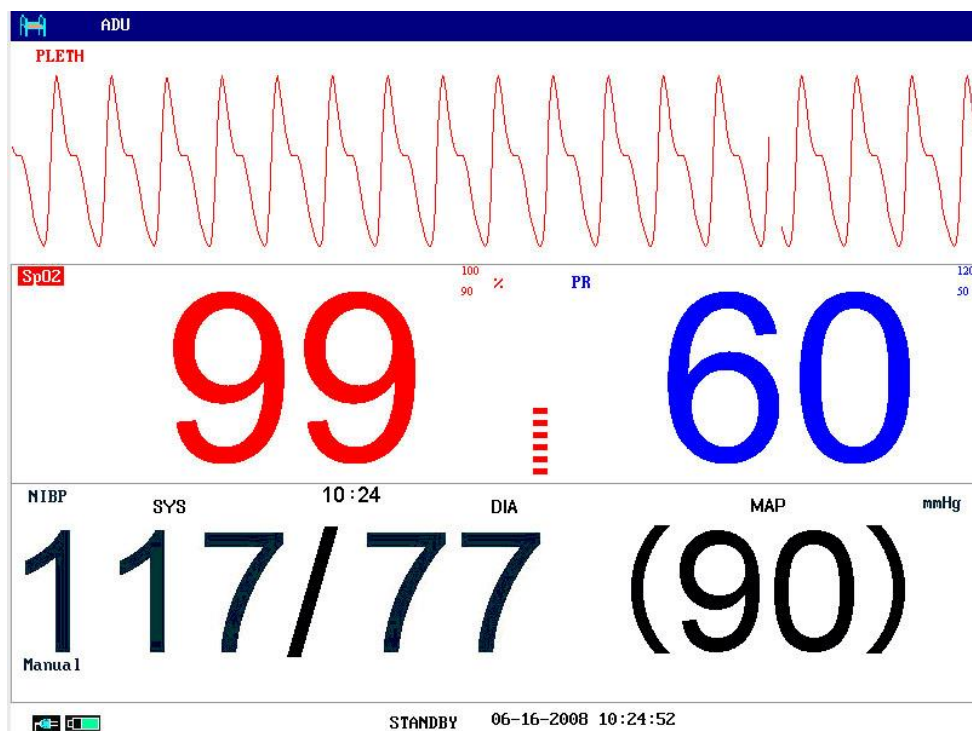
Figure 5-4 SpO₂+NIBP display mode

3. **SpO₂** display mode:
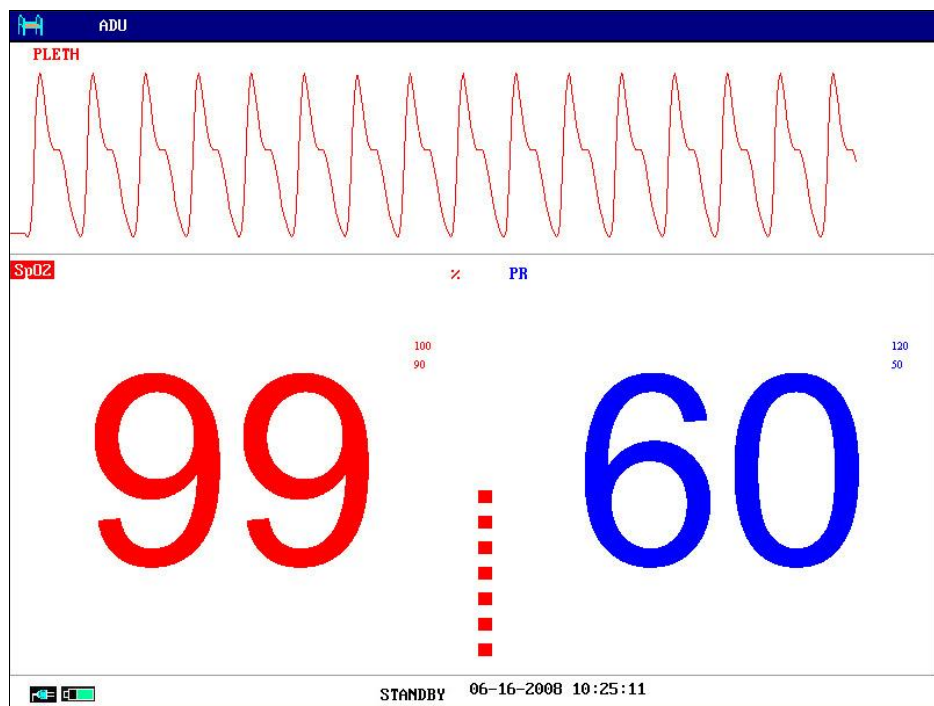
Figure 5-5 SpO₂ display mode

◆ Exit Large Font Screen

In the **LARGE FONT FACE SELECT** menu, choose **EXIT** to return to **FACE SELECT** screen.

Chapter 6 Alarms

This chapter gives general information about the alarm and measures to be taken accordingly. Alarm setup and prompt messages are provided in respective parameter setup sections.

WARNING

A potential 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 room.

6.1 Alarm Modes

6.1.1 Alarm Level

Each alarm, either technical or physiological, has its own level. For alarms of higher levels, when the alarm condition is active, the system will give an alarm prompt in various ways. Some alarm's level can be set by the user via software. Others can not be changed once defined by the system. Alarms in the monitor are divided into three levels, that is, high, medium and low.

A high-level alarm indicates the patient's life is in danger or the monitor in use has serious technical problems. It is the most serious alarm.

A medium-level alarm means a serious warning.

A low-level alarm is a general warning.

The monitor provides two types of alarm: physiological alarms and technical alarms. Also, the monitor provides prompts. Physiological alarms refer to those alarms triggered by patient's physiological situation which could be considered dangerous to his or her life. Technical alarms refer to system failure which can make certain monitoring process technically impossible or make monitoring result unbelievable. The monitor can give the character indication of monitoring process or other functions. And this character is called prompts.

All technical alarm levels and some of the physiological alarm levels are pre-set in the system and can not be changed by users.

6.1.2 Alarm Modes

When alarm condition is active, the monitor can raise the user's attention in at least three ways, which are audio prompt, visual prompt and description. Audio prompt is given by the speaker, and visual prompt is given by TFT display device and alarm indicator light. Description is displayed on the screen. Physiological alarm is displayed in the Physiological Alarm area. Most of technical alarms are displayed in the Technical Alarm area. Technical alarms related to NIBP measurement are displayed in the NIBP Technical Alarm area at the bottom of NIBP parameter area.

NOTE:

1 The Physiological Alarm area is on the upper right part of the screen. The Technical Alarm area is on the left side of the Physiological Alarm area.

2 If the monitor is connected to the external alarm prompt system (e.g. the alarm speaker and indicator are connected onto the rear panel of the monitor), when alarm condition is active, the external alarm prompt system responds in the same way as the monitor.

3 The concrete presentation of each alarm prompt is related to the alarm level.

How to indicate that the measured parameter has exceeded its alarm limits:

When physiological alarm of the monitored parameter exceeds the alarm limit, besides using the above-mentioned three ways to give the alarm prompt, the monitor also gives alarm by making the font or the background of monitored parameter flash in the frequency of 1Hz (refer to *Chapter 6.1.3 Alarm Setup*).

The icons for parameters exceeding the alarm limits:

Alarm level	Icon
High	
Medium	
Low	

Screen Display

When the measured parameter exceeds its alarm limits and triggers a physiological alarm, the corresponding parameter value will flash. "*" signal appears on the screen indicating the occurrence of an alarm. Red "***" indicates a high-level alarm, yellow "**" indicates a medium-level alarm, and yellow "*" indicates a low-level alarm. Technical alarms will not prompt "*" signal.

Lamp Light

The high/medium/low-level alarms are indicated by the system in following different visual ways:

Alarm level	Visual prompt
High	Alarm indicator flashes in red with high frequency.
Medium	Alarm indicator flashes in yellow with low frequency.
Low	Alarm indicator lights on in yellow.

Alarm Sound

The high/medium/low-level alarms are indicated by the system in following different audio ways:

Alarm level	Audio prompt
High	Mode is "DO-DO-DO------DO-DO, DO-DO-DO------DO-DO", which is triggered once every 10 seconds.
Medium	Mode is "DO-DO-DO", which is triggered once every 25 seconds.
Low	Mode is "DO-", which is triggered once every 30 seconds.

The sound pressure range for audible alarm signals is from 45 dB to 85 dB.

WARNING

1. Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

2. Ensure the volume is properly set up. When the sound pressure of audible alarm is below or equivalent to the ambient noise, it may be difficult for the operator to distinguish the audio alarm.

NOTE:
1　When alarms of different levels occur at the same time, the monitor prompts the one of the highest level.

2　If the monitor is powered off and then turned on, the alarm setup can resume to the setup which is set before the power-off.

6.1.3 Alarm Setup

Alarm setup in the ALARM SETUP menu

Press the **ALARM SETUP** button in the **SYSTEM SETUP** menu to call up **ALARM SETUP** menu (default menu) as shown below. In the **ALM SEL** item, the user may set up the information about common alarm setup and the alarm setup of each parameter.

◆ COMMON ALM SETUP

Select **COMMON ALM SETUP** option in **ALM SEL** item. This operation may call up the dialog box as the default one.

ALARM VOL: set the alarm volume by this item, the valid range is from **1** to **10**.

ALM REC TIME: this item can be set to **8 S, 16 S** and **32 S**.

ALM RESET: selecting this item can reset alarm.

◆ Alarm setup of each parameter

In the **ALARM SETUP** menu, select the **ALM SEL** item to set up the alarm information for the following parameters. They are **HR**, **ST**, **PVCs**, **SpO₂**, **NIBP**, **IBP (1**, **2**), **RESP**, **TEMP**, and **CO₂**. For example:

Method to set up HR alarm information:

Step 1: Select the **HR ALM SETUP** option in the **ALM SEL** item. Then the menu only displays HR setup items.

Step 2: You can set up five items in this menu, which are **HR ALM** (on/off of the alarm switch), **ALM LEV** (alarm level), **ALM REC** (alarm recording switch), **ALM HI** (higher limit of HR alarm), **ALM LO** (lower limit of HR alarm). You can move the cursor onto the item to be setup by using the knob and press the knob to make the setup.

The method for setting the alarm information of other parameters is the same as HR.

Alarm setup in the User Maintain menu

You can also set up alarm parameters in **SYSTEM MENU > MAINTAIN > USER MAINTAIN > ALARM SETUP**.

◆ **ALM SILENCE TIME**: Set up the duration of Alarm Pause status, it can be set to 1 minute, 2 minutes and 3 minutes.

◆ **Audio Alarm Off**: When it set to **ON**, hold the **Mute** button on the front panel for 3 seconds, and the alarm system will be silenced. Press this button again to turn on the alarm system.

◆ **ALARM TWINKLE**: Set it to **FONT FLASH** or **BK FLASH**. When the measured parameter exceeds the alarm limit, the monitor gives an alarm by font flash or background flash.

   FONT FLASH: When the measured parameter exceeds its alarm limits, the font of the parameter and the alarm limit flashes. For example, if the parameter exceeds high alarm limit, the parameter and the high alarm limit flash at the same time.

   BK FLASH: When the measured parameter exceeds its alarm limits, the background of the parameter and the alarm limit flash. For High alarm, the background flashes in red; for Medium alarm, and the background flashes in yellow; for Low alarm, the background displays in yellow without flash.

◆ **SENSOR OFF ALARM**: Turn on or off the sensor off alarm. When this item is set to **ON**, pressing the **Mute** button on the front panel can pause the audio alarm. Press again to resume the audio alarm; when the alarm is in pause state, it will give a visual alarm if sensor off alarm condition is active.

◆ **ALM LATCH**: Users can set it to **LATCH** or **UNLATCH**.

   When it is set to **LATCH**, the visual alarm indication is still displayed after the alarm condition ends; meanwhile, the alarm time is also displayed for the latched alarm for your reference. The indication lasts until you acknowledge the alarm. You can use **Alarm Reset** to acknowledge the latched alarm.

   When it is set to **UNLATCH**, alarm indications end when the alarm condition ends.

◆ **Disconnect Alarm**: Users can set it to **ON** or **OFF**.

NOTE:

1. When the monitor is connected with central monitoring system, you must set **Disconnect Alarm** to **On**.

2. If **Disconnect Alarm** occurs during audio alarm paused or audio alarm off status, the monitor will prompt a sounding alarm with information of **Network Disconnect**. During the network disconnected status, activating audio alarm paused or audio alarm off function can disable the audio alarm signal of **Disconnect Alarm**.

6.2 Alarm Cause

An alarm occurs when:

1. A physiological alarm is evoked;

2. An alarm for error of the system (technical alarm) is evoked;

3. A general alert occurs.

◆ **A. Conditions that activate the parameter alarms:**

The measurement value exceeds the alarm limit and the alarm is set to **ON**.

◆ **B. Conditions that activate the system alarms (technical alarm):**

Upon the system error, the monitor prompts an alarm immediately.

◆ **C. General alert**

In some circumstances, alerts will behave as physiological alarms. But in normal sense, we do not regard them as real patient health related items.

6.3 Audio Alarm Paused

To activate the audio alarm paused function, you can select **SYSTEM MENU** > **MAINTAIN** > **USER MAINTAIN** > **ALARM SETUP**, and set **ALM SILENCE TIME** to **1 MIN**, **2 MIN** or **3 MIN** (The default duration of auditory alarm pause is 2MIN), then press **Mute** button on the front panel to pause audio alarm. During the audio alarm paused status:

◆ In the information area, the monitor displays audio alarm off icon and **Audio Alarm Paused XXX S** with a red background.

◆ The audio alarm is paused, and no alarms are sounding.

◆ The visual alarm indications are still displayed.

◆ Other audible signals are not affected, including beat volume, key volume.

Auditory alarm will resume when you press **Mute** button again or the paused time terminates.

NOTE:

If a new alarm occurs during the audio alarm paused status, the new alarm will not be sounding.

6.4 Audio Alarm Off

To activate the audio alarm off function, you can select **SYSTEM MENU** > **MAINTAIN** > **USER MAINTAIN** > **ALARM SETUP**, and set **Audio Alarm Off** to **ON**, then press **Mute** button on the front panel and hold it for more than three seconds to turn off audio alarm. During the audio alarm off status,

◆ In the information area, the monitor displays the audio alarm off icon and **AUDIO ALARM OFF** with a red background.

◆ The audio alarm is turned off, and no alarms are sounding.

◆ The visual alarm indications are still displayed.

◆ Other audible signals are not affected, including beat volume, key volume.

Pressing **Mute** button again can resume the audio alarm.

When **Audio Alarm Off** is set to **OFF**, this function is inactivated. The monitor has no response if you press **Mute** button.

NOTE:

If a new alarm occurs during the audio alarm off period, the new alarm will not be sounding.

6.5 Alarm Reset

To reset the alarm, you can select **SYSTEM MENU** > **SYSTEM RESET** > **ALARM SETUP** > **Alarm Reset**. After resetting the alarm,

◆ The audio alarm is turned off, and no alarms are sounding.

◆ The visual alarm indications are still displayed.

◆ It will not influence the configuration of physiological alarm off, audio alarm paused and audio alarm off status.

NOTE:

If a new alarm occurs after the alarm is reset, the new alarm will be sounding.

6.6 Parameter Alarm

WARNING
1　Prior to monitoring, make sure that the alarm limit settings are appropriate for your patient.
2　Setting alarm limits to extreme values may cause the alarm system to become ineffective.

The setup for parameter alarms is in their menus. In the menu of a specific parameter, you can check and set the alarm limit and alarm status. The setup is isolated from each other. For iM8 and iM8A monitors, the alarm limit will be displayed beside each parameter. For iM8B, only alarm

limit of SpO_2 will be displayed beside the parameter.

When a parameter alarm is off, a symbol displays beside the parameter. If the alarms are turned off separately, they must be turned on separately.

For the parameters whose alarms are set to **ON**, the alarm will be triggered when at least one of them exceeds the alarm limits. The following actions take place:

1. Alarm message displays on the screen as described in alarm mode;

2. The monitor beeps in its corresponding alarm class and volume;

3. Alarm lamp flashes;

4. The icons for parameters exceeding the alarm limits will display beside parameters. The icon

    for Medium or Low alarm is , while for High alarm is .

6.7 When an Alarm Occurs

NOTE:
When an alarm occurs, you should always check the patient's condition first.

The alarm message appears on the top right side of the screen. You need to identify the alarm and act appropriately, according to the cause of the alarm.
1. Check the patient's condition.

2. Identify the cause of the alarm.

3. Identify which parameter is alarming or which alarm is happening.

4. When the cause of the alarm has been found out, check that the alarm is working properly.

You will find the alarm messages for the individual parameter in their appropriate parameter chapters of this manual.

6.8 Testing Alarms

When you switch the monitor on, a self-test is started with a "Di" tone. You must check that the alarm indicator lights and that you hear a single tone. This indicates that the visible and audible alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself or use a simulator. Adjust alarm limits and check that appropriate alarm behaviour is observed.

Chapter 7 Alarm Information

7.1 Physiological Alarm Information

WARNING
During monitoring, the physiological alarms including ASYSTOLE, VFIB/VTAC, RESP APNEA, SpO_2 No Pulse, CO_2 APNEA are preset to be on and cannot be turned off.

Message	Cause	Alarm Level
RR HIGH	RESP measuring value is above upper alarm limit.	User-selectable
RR LOW	RESP measuring value is below lower alarm limit.	User-selectable
RESP APNEA	RESP can not be measured within the set apnea alarm delay time.	High
SpO$_2$ HIGH	SpO$_2$ measuring value is above upper alarm limit.	User-selectable
SpO$_2$ LOW	SpO$_2$ measuring value is below lower alarm limit.	User-selectable
PR HIGH	PR measuring value is above upper alarm limit.	User-selectable
PR LOW	PR measuring value is below lower alarm limit.	User-selectable
SpO$_2$ No Pulse	The signal of the measurement site is too weak due to insufficient blood supply and environmental factors, so the monitor can't detect the pulse signal.	High
NS HIGH	NIBP SYS measuring value is above upper alarm limit.	User-selectable
NS LOW	NIBP SYS measuring value is below lower alarm limit.	User-selectable
ND HIGH	NIBP DIA measuring value is above upper alarm limit.	User-selectable
ND LOW	NIBP DIA measuring value is below lower alarm limit.	User-selectable
NM HIGN	NIBP MAP measuring value is above upper alarm limit.	User-selectable

NM LOW	NIBP MAP measuring value is below lower alarm limit.	User-selectable
PR (NIBP) High	PR measuring value from the NIBP module is above upper alarm limit.	User-selectable
PR (NIBP) Low	PR measuring value from the NIBP module is below lower alarm limit.	User-selectable
T1 HIGH	Measuring value of T1 channel is above upper alarm limit.	User-selectable
T1 LOW	Measuring value of T1 channel is below lower alarm limit.	User-selectable
T2 HIGH	Measuring value of T2 channel is above upper alarm limit.	User-selectable
T2 LOW	Measuring value of T2 channel is below lower alarm limit.	User-selectable
TD HIGH	Temperature difference of T1 and T2 is above upper temperature difference limit.	User-selectable
IS1 HIGH	SYS measuring value of channel 1 is above upper alarm limit.	User-selectable
IS1 LOW	SYS measuring value of channel 1 is below lower alarm limit.	User-selectable
ID1 HIGH	DIA measuring value of channel 1 is above upper alarm limit.	User-selectable
ID1 LOW	DIA measuring value of channel 1 is below lower alarm limit.	User-selectable
IM1 HIGH	MAP measuring value of channel 1 is above upper alarm limit.	User-selectable
IM1 LOW	MAP measuring value of channel 1 is below lower alarm limit.	User-selectable
IS2 HIGH	SYS measuring value of channel 2 is above upper alarm limit.	User-selectable
IS2 LOW	SYS measuring value of channel 2 is below lower alarm limit.	User-selectable
ID2 HIGH	DIA measuring value of channel 2 is above upper alarm limit.	User-selectable
ID2 LOW	DIA measuring value of channel 2 is below lower alarm limit.	User-selectable

IM2 HIGH	MAP measuring value of channel 2 is above upper alarm limit.	User-selectable
IM2 LOW	MAP measuring value of channel 2 is below lower alarm limit.	User-selectable
EtCO$_2$ HIGH	EtCO$_2$ measuring value is above upper alarm limit.	User-selectable
EtCO$_2$ LOW	EtCO$_2$ measuring value is below lower alarm limit.	User-selectable
FiCO$_2$ HIGH	FiCO$_2$ measuring value is above alarm limits.	User-selectable
AWRR HIGH	AwRR measuring value is above upper alarm limit.	User-selectable
AWRR LOW	AwRR measuring value is below lower alarm limit.	User-selectable
CO$_2$ APNEA	In the set apnea alarm delay time interval, no RESP can be detected using CO$_2$ module.	High
HR HIGH	HR measuring value is above the upper alarm limit.	User-selectable
HR LOW	HR measuring value is below the lower alarm limit.	User-selectable
ST1 HIGH	ST measuring value of channel 1 is above the upper alarm limit.	User-selectable
ST1 LOW	ST measuring value of channel 1 is below the lower alarm limit.	User-selectable
ST2 HIGH	ST measuring value of channel 2 is above the upper alarm limit.	User-selectable
ST2 LOW	ST measuring value of channel 2 is below the lower alarm limit.	User-selectable
PVCs HIGH	PVCs measuring value is above the upper alarm limit.	User-selectable

ARR physiological alarms:

Prompt	Applicable Patient Type	Occurring Condition	Alarm Level
ASYSTOLE	All patients	No QRS is detected for 4 consecutive seconds	High

Prompt	Applicable Patient Type	Occurring Condition	Alarm Level
VFIB/VTAC	Without pacemaker	4 consecutive seconds' fibrillation wave occurs, or each RR interval for 5 consecutive ventricular beats is less than 600 ms.	High
VT>2	Without pacemaker	$3 \leq$ the number of consecutive PVCs < 5	User-selectable
COUPLET	Without pacemaker	2 consecutive PVCs	User-selectable
BIGEMINY	Without pacemaker	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.	User-selectable
TRIGEMINY	Without pacemaker	A dominant rhythm of N, N, V, N, N,V	User-selectable
R ON T	Without pacemaker	A type of single PVC under the condition that HR<100bpm, R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable
PVC	Without pacemaker	Single PVC detected in normal heartbeats.	User-selectable
TACHY	All patients	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.	User-selectable
BRADY	All patients	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.	User-selectable
MISSED BEATS	Without pacemaker	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR $\geq$ 120 bpm, no beats are detected for one second.	User-selectable
IRR	Without pacemaker	Consistently irregular heart rhythm	User-selectable
PNC	With pacemaker	PACER NOT CAPTURE: no QRS complex detected in 300 ms after a pace pulse.	User-selectable

Prompt	Applicable Patient Type	Occurring Condition	Alarm Level
PNP	With pacemaker	PACER NOT PACED: no pace pulse detected in 1.75 times RR interval after a QRS complex.	User-selectable
VBRADY	Without pacemaker	VENTRICULAR BRADYCARDIA: Each RR interval for 5 consecutive ventricular beats > 1000 ms.	User-selectable
VENT	Without pacemaker	VENTRICULAR RHYTHM: Each RR interval for 5 consecutive ventricular beats ranges from 600 ms to 1000 ms.	User-selectable

7.2 Technical Alarm Information

NOTE:

The ECG alarm information listed in the below table describes the lead names in America. For the corresponding lead names in Europe, please refer to the section *Installing Electrodes.*

Technical alarms:

Message	Cause	Alarm level	What to do
RESP COMM STOP	RESP module failure or communication failure	High	Stop using measuring function of RESP module, notify biomedical engineer or the manufacturer's service staff.
RR Exceed	RR measuring value is out of the measure range.	Medium	Check whether interference to the respiratory signal exists. And check whether the patient is breathing normally; breathing too rapidly or too slowly may endanger patient's life.
RESP Cardiac Artifact	No RESP waveform can be detected due to apnea or shallow breathing of the patient.	High	Check whether the patient is breathing normally. Take measures to help the patient breathe normally when necessary. If the patient is breathing normally, try to adjust the electrode position on the patient in order to reduce the interference of cardiogenic artifact.

Message	Cause	Alarm level	What to do
RESP Noise	RR cannot be measured due to patient movement.	Low	Check whether the RESP leads are well connected. Keep the patient calm for better monitoring.
SpO₂ SENSOR OFF	SpO₂ sensor was not connected well, or the connection is loose.	Low	Make sure the sensor is well connected to the patient's finger or other parts.
SpO₂ NO SENSOR	SpO₂ sensor was not connected well, or the connection is loose.	Low	Make sure the monitor and sensor are well connected. Reconnect the sensor.
SpO₂ COMM STOP	SpO₂ module failure or communication failure	High	Stop using measuring function of SpO₂ module, notify biomedical engineer or Manufacturer's service staff.
SpO₂ Low Perfusion	The pulse signal is too weak or the perfusion of the measurement site is too low.	Low	Reconnect the SpO₂ sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff.
SpO₂ Noisy Signal	There is interference with SpO₂ measurement signals and the waveform is abnormal.	Low	Check the condition of patient and avoid patient movement; make sure the cable is well connected.
SpO₂ Light Interference	There is interference with SpO₂ measurement signals due to patient movement, ambient light, electrical interference or else.	Low	Reduce interference of the ambient light and avoid sensor's exposure to strong light.
SpO₂ Sensor Error	Malfunction in the SpO₂ sensor or in the extension cable.	Low	Replace the SpO₂ sensor or the extension cable.
NIBP COMM STOP	NIBP module failure or communication failure	High	Stop using measuring function of NIBP module, notify biomedical engineer or Manufacturer's service staff.
NIBP AIR LEAK	During the leakage test, the leakage ratio exceeds 6 mmHg/min.	Low	Check and replace the leaking parts, if required,

Message	Cause	Alarm level	What to do
			notify biomedical engineer or manufacturer's service staff.
NIBP OVER PRESSURE	Pressure has exceeded the specified upper safety limit.	Low	Measure again, if failure persists, stop using measuring function of NIBP module and notify biomedical engineer or manufacturer's service staff.
NIBP INIT PRESSURE HIGH	The initial pressure is too high during measuring	Low	
NIBP SECONDARY OVER PRESSURE	Secondary over pressure protection	High	Notify biomedical engineer or manufacturer's service staff.
NIBP TIME OUT	Measuring time has exceeded 120 seconds (adult) or 90 seconds (neonatal).	Low	Measure again or use other measuring method.
NIBP Self Test Error	When the monitor is powered on, NIBP module is detected to fail in calibration.	Low	Contact your service personnel.
NIBP Cuff Type Error	The cuff type used isn't consistent with the patient type.	Low	Confirm the patient type and change the cuff.
NIBP Pressure Error	Decline of air pressure is less than 2 mmHg after 6 deflations.	Low	Check whether the airway is occluded or pressure sensor works properly in pressure meter mode. If the problem still exists, contact your service personnel.
NIBP System Failure	Start up measurement, manometer and leakage test, and NIBP fail in calibration.	High	Contact your service personnel.
NIBP WEAK SIGNAL	Cuff is too loose or patient pulse is too weak.	Low	Use other method to measure blood pressure.
NIBP Interference	Due to motion, signal noise is too large or pulse rate is not	Low	Make sure that the patient under monitoring is motionless.

Message	Cause	Alarm level	What to do
	regular.		
NIBP Range Exceeded	Maybe the patient blood pressure value is beyond the measurement range.	High	Maybe the patient blood pressure value is beyond the measurement range.
NIBP Loose Cuff	Cuff is no properly wrapped or no cuff exists.	Low	Properly wrap the cuff.
T1 SENSOR OFF	Temperature cable of TEMP channe1 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected
T2 SENSOR OFF	Temperature cable of TEMP channe2 may be disconnected from the monitor.	Low	Make sure that the cable is properly connected.
T1 EXCEED	TEMP1 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
T2 EXCEED	TEMP2 measuring value is beyond measuring range.	High	Check sensor connection and patient condition
TEMP COMM STOP	TEMP module failure or communication failure	High	Stop using measuring function of TEMP module; notify biomedical engineer or Manufacturer's service staff.
T1 Calibration Failed	T1 Calibration Failed	High	Please check whether the module works properly.
T2 Calibration Failed	T2 Calibration Failed	High	Please check whether the module works properly.
IBP1 SENSOR OFF	IBP cable of channel 1 falls off from monitor.	Medium	Make sure that cable is properly connected.
IBP2 SENSOR OFF	IBP cable of channel 2 falls off from monitor.	Medium	Make sure that cable is properly connected.
IBP(1,2) COMM STOP	IBP module communication failure	High	Stop using measuring function of IBP module, notify biomedical engineer or Manufacturer's service staff.
IBP Catheter Off	IBP catheter falls off due to patient movement.	High	Check the catheter connection and reconnect it.

Message	Cause	Alarm level	What to do	
IBP Sensor Err	Malfunction in IBP sensor or in the extension cable.	Medium	Replace the IBP sensor or the extension cable.	
CO$_2$ SENSOR OFF	CO$_2$ sensor falls off	Low	Well connect the sensor	
CO$_2$ WATERTRAP OCCLUDE	Water trap of SideStream is occluded	High	Make sure the gas exhaust works well	
CO$_2$ COMM STOP	CO$_2$ module failure or communication failure	High	Stop using CO$_2$ alarm function, notify biomedical engineer or Manufacturer's service staff.	Applicable to EDAN EtCO$_2$ module and Respironics CO$_2$ Module
CO$_2$ Sensor Over Temp	CO$_2$ module exceeds the working temperature range.	High	Stop using measuring function of CO$_2$ module, notify biomedical engineer.	
CO$_2$ SENSOR FAULT	CO$_2$ module failure	High	Stop using measuring function of CO$_2$ module, notify biomedical engineer.	

Message	Cause	Alarm level	What to do	
CHECK ADAPTER	1) For the Respironics CO_2 module: The cannula is off or disconnected. 2) For the EDAN $EtCO_2$ module: The water trap is disconnected or not properly connected.	Low	1) For the Respironics CO_2 module: Check whether the adapter is properly connected or replace the adapter. 2) For the EDAN $EtCO_2$ module: Properly connect the water trap.	
CO_2 ADAPTER OCCLUDE	1) For the Respironics CO_2 module: The cannula/gas outlet is occluded. 2) For the EDAN $EtCO_2$ module: The water trap/ cannula/gas outlet is occluded.	High	1) For the Respironics CO_2 module: Replace the cannula; Check whether the gas outlet is occluded. 2) For the EDAN $EtCO_2$ module: Replace the water trap; Check whether the cannula is curved, or whether the gas outlet is occluded.	
CO_2 ZERO REQUIRED	Zero calibration failure	Low	Stop using CO_2 alarm function, notify biomedical engineer or Manufacturer's service staff.	Only applicable to Respironics CO_2 Module

Message	Cause	Alarm level	What to do	
CO₂ INIT ERR	CO_2 module failure	High	Stop using CO_2 alarm function; notify biomedical engineer or Manufacturer's service staff.	
CO₂ SYSTEM ROM ERR	CO_2 module failure	High		
CO₂ INT RAM ERR	CO_2 module failure	High		
NetWork Disconnect	The monitor and CMS network is disconnected	Low	Please check the network and reconnect it.	
ECG LEAD OFF	1) The drive electrode or more than one ECG limb electrode falls off the skin; 2) ECG cables fall off the monitor.	Low	Make sure that all electrodes, leads and patient cables are properly connected.	
ECG LL LEAD OFF	ECG electrode LL falls off the skin or the ECG cable LL falls off the monitor.	Low		
ECG LA LEAD OFF	ECG electrode LA falls off the skin or the ECG cable LA falls off the monitor.	Low		
ECG RA LEAD OFF	ECG electrode RA falls off the skin or the ECG cable RA falls off the monitor.	Low		
ECG V LEAD OFF	ECG electrode V falls off the skin or the ECG cable V falls off the monitor.	Low		
ECG SIGNAL EXCEED	ECG measuring signal is beyond measuring range.	Low	Check lead connection and patient condition	

Message	Cause	Alarm level	What to do
ECG COMM STOP	ECG module failure or communication failure	High	Stop using measuring function of ECG module; notify biomedical engineer or manufacturer's service staff.
ECG NOISE	ECG measuring signal is greatly interrupted.	Low	Check lead connection and patient condition

7.3 Prompts

Prompt message:

Message	Cause
Manual measuring…	It is in the process of measuring.
Continual Measuring	In continuous measuring mode.
Auto measuring…	It is in the process of automatic measuring.
Measurement over	Measurement is over.
Calibrating…	It is in the process of calibrating.
Calibration over	Calibration is over.
Pneum testing…	It is in the process of pneumatic testing.
Pneum test over	Pneumatic test is over.
Resetting...	NIBP module is resetting.
Please Start	NIBP module is in idle status.
CO_2 STANDBY STATUS	Turn from measuring mode to standby mode, making the module in energy-saving status.
CO_2 SENSOR WARMUP	The CO_2 module is at warm-up state
SpO_2 SEARCH PULSE	SpO_2 module is analyzing the patient signal and searching for the pulse to compute the saturation, when sensor is connected with patient.
ARR LEARNING	The QRS template building required for Arr. Analysis is in process.
CH1 ZERO FAIL!	IBP channel 1 sensor off during zeroing, or channel 1 pressure exceeds the zero range.

CH1 ZERO SUCCESS!	IBP channel 1 zero ok.
CH2 ZERO FAIL!	IBP channel 2 sensor off during zeroing, or channel 2 pressure exceeds the zero range.
CH2 ZERO SUCCESS!	IBP channel 2 zero ok.
CH1 CAL FAIL!	IBP channel 1 sensor off during calibration.
CH1 CAL SUCCESS!	IBP channel 1 calibration ok.
CH2 CAL FAIL!	IBP channel 2 sensor off during calibration.
CH2 CAL SUCCESS!	IBP channel 2 calibration ok.
CO_2 Zero Start	CO_2 module starts zero calibration.
CO_2 Zero OK	CO_2 module completes zero calibration.

7.4 Adjustable Range of Alarm Limits

ECG adjustable range of alarm limits are listed as follows (unit bpm):

	Patient Type	ALM HI	ALM LO
HR	ADU	300	15
	PED	350	15
	NEO	350	15

ST analysis adjustable range of alarm limits are listed as follows (unit mV):

	ALM HI	ALM LO
ST	2.0	-2.0

PVCs alarm upper limits are listed as follows:

	ALM HI
PVCs	10

RESP adjustable range of alarm limits are listed as follows (unit rpm):

Patient Type	ALM HI	ALM LO
ADU	120	6
PED	150	6
NEO	150	6

SpO$_2$ adjustable range of alarm limits are listed as follows (unit %):

	ALM HI	ALM LO
SpO$_2$	100	20

PR adjustable range of alarm limits are listed as follows (unit bpm):

	ALM HI	ALM LO
PR	300	30

NIBP adjustable range of alarm limits are listed as follows (unit: mmHg, kPa; 1 mmHg=0.133 kPa):

Patient Type		ALM HI	ALM LO
ADU	SYS	270	40
	DIA	215	10
	MAP	235	20
PED	SYS	230	40
	DIA	180	10
	MAP	195	20
NEO	SYS	135	40
	DIA	100	10
	MAP	110	20

TEMP adjustable range of alarm limits are listed as follows:

	ALM HI	ALM LO
T1	50 ℃ (122 ℉)	0 ℃ (32 ℉)
T2	50 ℃ (122 ℉)	0 ℃ (32 ℉)
TD	50 ℃ (90 ℉)	/

IBP adjustable range of alarm limits are listed as follows (unit mmHg):

	ALM HI	ALM LO
Art	300	0
RAP	40	-10
LAP	40	-10
ICP	40	-10
CVP	40	-10

PA	120	-6
P1	300	-50
P2	300	-50

CO_2 adjustable range of alarm limits are listed as follows:

	ALM HI	**ALM LO**
EtCO$_2$	150 mmHg	0 mmHg
FiCO$_2$	50 mmHg	0 mmHg
AwRR	150 rpm	2 rpm

Chapter 8 Freeze

8.1 General

When monitoring a patient, you may freeze the waveforms of interest so as to view them carefully. Generally you can review a frozen waveform of a maximum of 12 minutes. The Freeze function of this monitor has the following features:

◆ Freeze status can be activated on any operating screen;

◆ Once entering the Freeze status, the system exits all other operating menus. Besides, the system freezes all waveforms in the Waveform area of the Basic Screen, and also freezes Full Lead ECG waveforms and extra waveforms on the Full Lead ECG interface (if any). Nevertheless the Parameter area refreshes normally.

◆ The frozen waveforms can be reviewed and recorded.

8.2 Entering/Exiting Freeze Status

◆ **Enter Freeze Status**

In the Non-Freeze status, press the **FREEZE** button on the control panel of the monitor to let the system exit the Menu being currently displayed (if available), then enter the Freeze status and display the popup **FROZEN** menu. In the Freeze status, all other waveforms are frozen. In other words, the system will no longer refresh all other waveforms.

◆ **Exit Freeze Status**

In the Freeze status, executing any of the following operations will command the system to exit the Freeze status:

◆ Select the **EXIT** option in/from the **FROZEN** menu;

◆ Press the **FREEZE** button on the control panel again;

◆ Press the non-immediate-to-execute button (for example, once a button is pressed, a menu will pop up for you to further select an option) on the front panel and system buttons of Menu and Main;

◆ Execute any operation that may trigger the adjustment of the screen or the display of a new menu.

After exiting the Freeze status, the system will discharge the Freeze status, clear screen waveforms and resume display real-time waveforms. In the Screen Refresh mode, the system will sweep the waveforms from left to right in the Waveform Area.

8.3 FROZEN Menu

Press the **FREEZE** button on the control panel, and the **FROZEN** menu will appear on the bottom part of the screen. At the same time, the system enters the Freeze status.
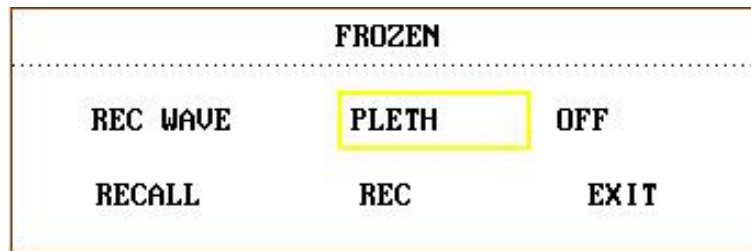
Figure 8-1 Frozen

◆ **REC WAVE**: it can be set to any waveform of 8s, such as **IBP1**, **CO₂**, **PLETH** etc. It can also be set to **OFF**.

◆ **RECALL**: Used to review frozen waveforms.

◆ **REC**: select this item to record the setting waveform in **REC WAVE**.

◆ **EXIT**: After this button is pressed, the system closes the **FROZEN** menu and exits the Freeze status.

NOTE:
Pressing the **FREEZE** button repeatedly in a short period of time may result in discontinuous waveforms displaying on the screen.

8.4 Reviewing Frozen Waveform

By moving the waveform, you may review a waveform of 12 minutes before it is frozen. For a waveform of less than 12 minutes, the remaining part is displayed as a straight line. Use the rotary snob on the control panel to move the cursor to the **RECALL** option in the **FROZEN** menu. Press the knob. By turning the knob left or right, frozen waveforms on the screen will move left or right correspondingly. There is an arrow indicating upward on the right side of the last waveform. There is also a time scale beside the arrow. "-0S" is used to mark the moment when waveforms are frozen. With waveforms moving right, this time mark will in turn change into -1S, -2S, -3S… These time marks are applied to all waveforms on the screen.

Chapter 9 Recording (Optional)

◆ General information on recording
◆ Instructions for configuring and recording
◆ Recording messages

9.1 General Information on Recording

A thermal dot matrices recorder with 48mm wide printout paper is used for the monitor.

Performance of the Recorder

◆ Waveform record is printed out at the rate of 25 mm/s or 50 mm/s.
◆ It can record up to three waveforms.
◆ English printout.
◆ User-selectable real-time recording time and waveform.
◆ Auto recording interval is set by the user, and the waveform is in accordance with the real time recording.

NOTE:
It is suggested that the user should not use the recorder when the low battery displays, or the monitor may be turned off automatically.

9.2 Recording Type

The monitor provides several types of stripe recording:
◆ Continual real-time recording
◆ 8 second real-time recording
◆ Automatic interval recording
◆ Physiological alarm recording
◆ Frozen waveform recording
◆ Trend graph/table review recording
◆ NIBP review recording
◆ Alarm event review recording
◆ Arrhythmia review recording
◆ Titration table recording

NOTE:
1   When ECG waveforms are selected for printing, with gain of ×1, ×0.5 or ×0.25, a 3-channel waveform can be printed out; however, with gain of ×2, only a 2-channel waveform can be printed out to avoid overlapping of waveforms, and the third waveform will be omitted.

2   The 3-channel waveform can be printed only in real-time recording, while it is not available in other recording modes, such as alarm review recording and alarm triggered recording.

Real-time Recording

Real-time recording starts as you press the **RECORD** button on the recorder.

The waveforms for continual real-time recording and continuous 8 second recording are automatically set by the monitor (usually the first three waveforms displayed on the screen). You can also configure it through the menu. Refer to related section for details.

In **RECORD** menu, the user can choose three waveforms to be printed out. The user can set up one or two waveforms to be off. Thus, the real time record will print out one or two waveforms. If three waveforms are off, the real time record will print out measure parameters only.

NOTE:
The system can start executing the next alarm recording task only when the current one is finished.

Auto Recording

The monitor starts the recorder for every 8 seconds according to the time interval set in the **TIMING REC TIME** of the **RECORD** menu. Refer to *Chapter9 Recording* Setup for details.

Alarm Recording

◆   Parameter Alarm

The monitor records waveforms 4, 8, or 16 seconds prior to and after the alarm (totally 8, 16 or 32 seconds) (which can be selected in **SYSTEM MENU**). All parameter values during the alarm will also be recorded.
When a parameter alarm occurs, two recorded waveforms can be printed out.
In order to avoid repeated printout of alarm waveforms:
① If more than two parameter alarms are switched on and triggered simultaneously, the recorder will print out that of the highest level. If they are of the same alarm level, the latest alarm will be printed out.
② If an alarm occurs during the alarm of another parameter, it will be printed out after the current recording is finished.
③ If many alarms occur at the same time, some of waveforms will be stored for printout in turn.

◆   ST Segment Alarm

The monitor records 2-channel ECG waveforms 4, 8, or 16 seconds prior to and after the alarm (totally 8, 16 or 32 seconds) (which can be selected in the **ECG SETUP** menu). All parameter values during the alarm will also be recorded.

◆   Arrhythmia Alarm

The monitor records 2-channel ECG waveforms 4, 8, or 16 seconds prior to and after the alarm (totally 8, 16 or 32 seconds). All measurement results during the alarm will also be recorded.

Titration Table

The monitor can print out the message in the current **TITRATION** window.

Notes on Recording

◆ Recording types:

   Real time Report

   Periodic Report

   Para Alarm Report

   Titration Table

   Arrhythmia Report

   Freeze Wave Report

   Trend graph

   Trend table

   Para Alarm Review

   NIBP Test Review

◆ Patient bed number, name, sex, height, weight, date of birth, admission date

◆ Parameter name and value

◆ Recording time

◆ Waveform name

◆ Waveform scale (for ECG waveform)

◆ ECG lead, scale, filter mode, (if there are ECG waveforms, they will be printed out within the first second or when changing the lead, gain and filter mode during real-time recording.)

◆ IBP scale (the first second of IBP waveform)

◆ CO_2 scale (the first second of CO_2 waveform)

◆ Date and time.

9.3 Recording Startup

You can start the recording in the following ways:

Continual real-time recording	Press the **RECORD** button to start/stop the recording.
8 second real-time recording	Press the **RECORD** button to start recording. It will automatically stop in 8 seconds.
Auto recording	Record the three waveforms selected in **RECORD** menu according to the setup time interval in **RECORD** menu. It will automatically stop in 8 seconds.
Alarm recording	When alarm recording is set to **ON**, it automatically starts when alarm occurs.
Trend graph recording	Access the **TREND GRAPH** menu, and then press the **RECORD** button to start recording.

Trend table recording	Access the **TREND TABLE** menu, then press the **RECORD** button to start recording.
Arrhythmia review recording	Enter the **ECG SETUP** menu via hot key, select **ARR ANALYSE** > **ARR RECALL**, then press the **RECORD** button to start recording.
Alarm review recording	Access the **ALARM RECALL** menu, then press the **RECORD** button to start recording.
NIBP review recording	Access the **NIBP RECALL** menu, then press the **RECORD** button to start recording.
Titration table recording	Access the **DRUG CALC** menu from the **SYSTEM MENU**. Pick the **TITRATION** button in the menu to access the **TITRATION** window. Pick the **REC** button to print out the titration currently displayed in the window.
Frozen waveform recording	8-second frozen waveform can be recorded, 2 waveforms are selectable.

NOTE:
You can press the **RECORD** button on the control panel to stop the current recording process.

Access the **RECORD** menu from the **SYSTEM SETUP** menu. Then pick the **CLEAR REC TASK** button to stop all recording tasks.

9.4 Recorder Operations and Status Messages

Record Paper Requirement

Only standard thermosensitive record paper can be used: otherwise the recorder may not function, the recording quality may be poor, and the thermosensitive printhead may be damaged.

Proper Operation

◆ When the recorder is working, the record paper goes out steadily. Do not pull the paper outward with force: otherwise the recorder may be damaged.

◆ Do not operate the recorder without record paper.

Paper Out

When **RECORDER OUT OF PAPER** alarm is displayed, the recorder cannot start. Please insert record paper properly.

Inserting Paper

◆ Pull outwards the upper arc part of the recorder casing to release the casing.

◆ Insert a new roll of paper into the paper cassette, printing side facing upwards.

◆ Ensure proper position and tidy margin.

◆ Pull about 2cm of the paper out, and close the recorder casing.

NOTE:
Be careful when inserting papers. Avoid damaging the thermo-sensitive print head. Unless when inserting papers or shooting troubles, do not leave the recorder catch open.

Removing Paper Jam

When the recorder functions or sounds improperly, you should open the recorder casing to check for a paper jam. Removing the paper jam in the following way:

◆ Cut the record paper from the feeding edge.

◆ Open the recorder casing.

◆ Re-insert the paper.

NOTE:
If the monitor is not installed with a recorder, it will indicate **NO RECORDER** after pressing the **RECORD** button.

9.5 Recorder Alarm Information

Technical Alarm:

Message	Cause	Alarm Level	What to do
Recorder Out Of Paper	Recorder Out Of Paper	Low	Please install the paper.
Recorder setup needed	The user presses the **RECORD** button when the monitor is not installed with a recorder.	Low	Notify the manufacturer's service staff to install and set the recorder.

Chapter 10 Trend and Event

The monitor provides 96-hour trend data of all parameters, storage of 500 NIBP measurement results and 60 alarm events. This chapter gives detailed instruction for review of all data.

10.1 Trend Graph

◆ The latest 1-hour trend is displayed every 1 or 5 seconds;
◆ The latest 96-hour trend is displayed every 1, 5 or 10 minutes;

Pick **TREND GRAPH** in the **SYSTEM MENU** to call up the following menu:
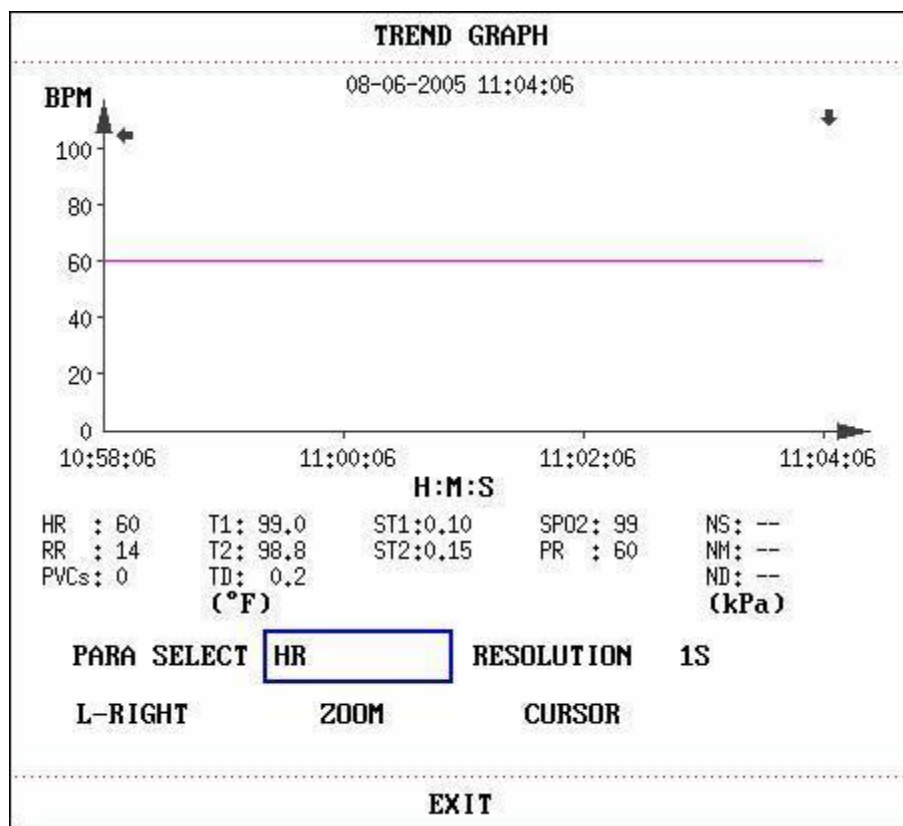
Figure 10-1 Trend Graph Menu

In the trend graph, the y-axis stands for the measured value and x-axis time. "↓" is the cursor of the trend graph, the parameter value of the position pointed by the cursor is displayed below the trend graph and the corresponding time is displayed above the trend graph. Other trends except NIBP trend are displayed as continuous curves. In NIBP trend graph, "▼" indicates systolic value, "▲" indicates diastolic value, and "*" indicates mean value.

To select trend graph of a specific parameter

Pick **PARA SELECT** item and select a requested parameter name by turning the knob.

To select 1-hour or 96-hour trend graph

Pick **RESOLUTION** item, choose 1 or 5 sec for 1-hour trend graph and 1, 5 or 10 min for 96-hour trend graph.

To view other trend curves

When " ➤ " appears on the right part of the screen, pick **L-RIGHT**, turn the knob clockwise to view later trend curves. When " ◀ " appears on the left part of the screen, pick the same item, turn the knob counterclockwise to view earlier trend curves.

To change the display scale

Pick the **ZOOM** button to adjust the y-axis scale and thus change the trend curve in proportion. The value beyond maximum value will be represented by the maximum value.

To obtain trend data of a specific time

The time to which the cursor points will change as the knob is turned. Parameter at this time is displayed below the x-axis. When " ➤ " appears on the right part of the screen, the trend graph pages down for later trend curves as the cursor moves here. When " ◀ " appears on the left part of the screen, the trend graph pages up for earlier trend curves as the cursor moves here.

Mark Event

If an event is marked **A**, **B**, **C**, or **D**, then the corresponding event type will display on the time axis of the trend graph，such as 🄰, 🄱, 🄲 or 🄳.

Operation Example

To view the NIBP trend graph of the last 1 hour:
◆ Pick the **Menu** button on the lower right of the screen.
◆ Pick **TREND GRAPH** item in the **SYSTEM MENU**.
◆ Select parameter: pick the **PARA** item and turn the knob until NIBP appears.
◆ Select **1S** or **5S** in the **RESOLUTION** item.
◆ Pick the **L-Right** button and turn the knob to view changes of the trend graph time and trend curve.
◆ Stop at requested trend time section for careful review. Pick the **ZOOM** button to adjust the display scale if necessary.
◆ For measurement result of a specific time, pick **CURSOR** to move the cursor to the point. Then the corresponding time and value will display above and below the waveform respectively.
◆ Pick **EXIT** to return to trend graph display.

10.2 Trend Table

◆ The latest 96-trend table data can be displayed every 1, 5, 10, 30, or 60 minutes.

Pick **TREND TABLE** in the **SYSTEM MENU** to call up the following menu:

Figure 10-2 Trend Table

Time corresponding to each group of trend data is displayed in the leftmost list with date in brackets. Marked event corresponds to marking time. Trend data of each parameter is divided into 8 groups.

HR, PVC

ST1, ST2

RR

T1, T2, TD

SpO_2, PR

NIBP NS/NM/ND

IBP1, IBP2

CO_2, $FiCO_2$, AWRR

The **IBP1, IBP CO_2, $FiCO_2$, AWRR** are optional according to the product models.

To choose a trend table of a different resolution

Pick the **RESOLUTION** item and turn the knob to change its content so as to change the time interval of trend data.

To view other trend data

When "⬆" appears on the upper part of the screen, pick **UP-DOWN** button and turn the knob counterclockwise to view later trend data. When "⬇ " appears on the lower part of the screen, pick the same item and turn the knob clockwise to view earlier trend data.

To obtain trend data of different parameters

Pick **L-RIGHT** to select one from the 8 groups of parameters. "➤" by the rightmost item indicates the next page available. "◀" by the leftmost item indicates the previous page available.

Mark Event

If an event is marked **A**, **B**, **C**, or **D**, the corresponding event type will display on the Time axis of the trend table.

Operation Example

To view a NIBP trend table:

◆ Pick the **Menu** button on the lower right of the screen to access **SYSTEM MENU**.

◆ Pick **TREND TABLE**.

◆ Pick **L-RIGHT** and switch to NIBP by turning the knob.

◆ Pick **RESOLUTION** to select requested time interval.

◆ Pick **UP-DOWN** and turn the knob to view NIBP trend data of different time.

◆ Pick **EXIT** to return to **SYSTEM MENU**.

10.3 NIBP Recall

The monitor can review the latest 500 NIBP measurement data.

Pick **NIBP RECALL** in the **SYSTEM MENU** to invoke the result and time of the latest 15 measurements, as shown in the figure below.

Figure 10-3 NIBP Recall

Data is listed chronologically from the latest to the earliest. 15 measurements can be displayed on one screen. Pick **UP-DOWN** to view up to 500 results of measurements. When you press the **RECORD** button, the recorder will print out the metrical data of current window.

NOTE:
When the user set the **NIBP SETUP > PR (NIBP)** to **ON**, the PR parameter will display in the menu of **NIBP RECALL**; if set it to **OFF**, the PR parameter area displays ─ ─.

10.4 Alarm Event Recall

The monitor can display the latest 60 alarm events.
Select **ALARM RECALL** in the **SYSTEM MENU** to access **ALARM RECALL CONDITION** menu as shown below.

Figure 10-4 ALARM RECALL CONDITION

In this menu, the user may select the conditions for alarm review, including:

1.   Start and End time of review:

The user may select the start time of review in the item of **START**.

Then the user may select the end time of review. Two selections are available: current time and the user-defined time.

For user-defined end time, the user can use the knob to select.

2.   ALARM RECALL EVENT

In the pull-down list of **ALARM RECALL EVENT**, the user can select the parameter whose alarm events he wants to review. The selections include **ALL** (alarm events of all parameters), ECG, REST, SpO_2, NIBP, PR(NIBP), IBP, TEMP, CO_2, HR_H>180 (the value of HR is above the upper alarm limit), HR_L<60 (the value of HR is below the lower alarm limit), SpO_2<90%, IBP_H>200 mmHg, IBP_L<40 mmHg, RR_H>40, RR_L<10, TEMP_H>40 ℃, TEMP_L<34 ℃.

After setting up all the review conditions, press the **ALARM RECALL** button to access **ALARM RECALL** window.

ALARM RECALL

The **ALARM RECALL** window is as shown below, in which the following data are displayed:

①   Time span (Format: month-day-year hour: minute-month-day-year hour: minute).

②   Event type.

③   Serial number (Format: NO. ××of ××).

④   The value at the time of alarm. NIBP result is with time.

⑤   Two 8/16/32-second waveforms.
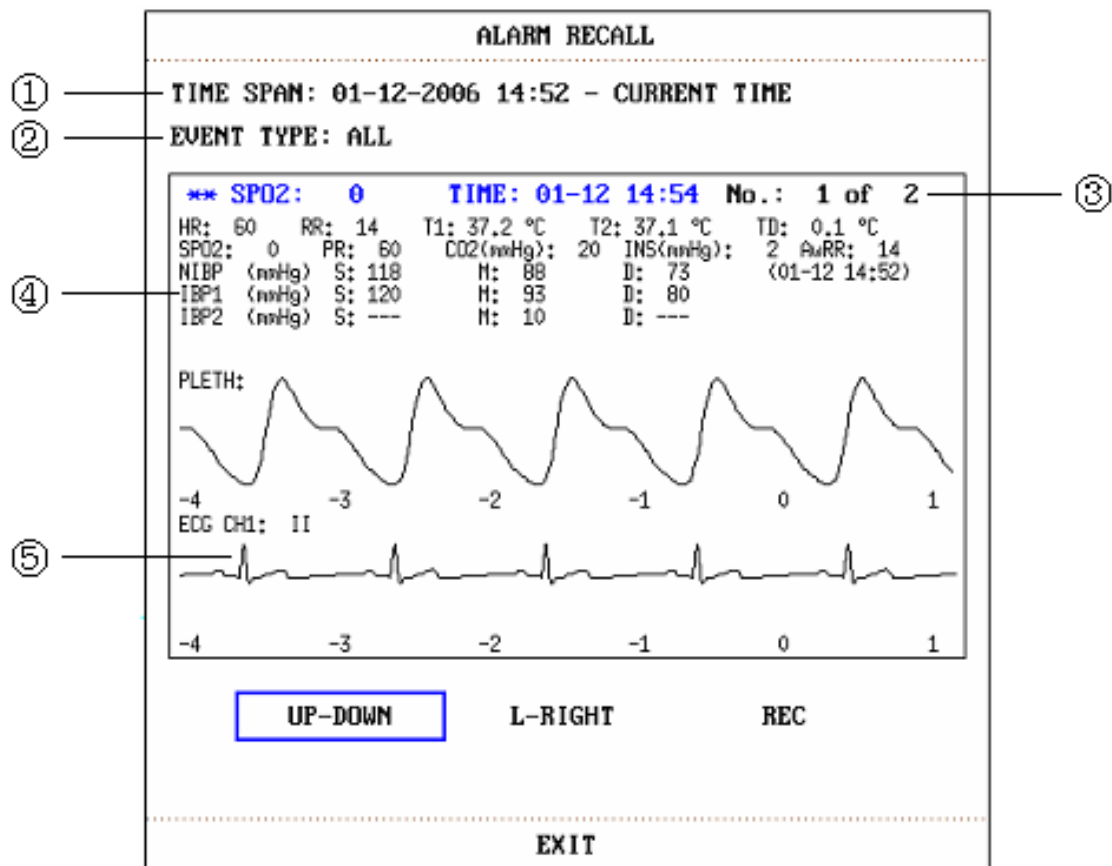
Figure 10-5 ALARM RECALL Menu

NOTE:
When the user set the **NIBP SETUP > PR (NIBP)** to **ON**, the **PR** parameter will display in the menu of **ALARM RECALL**; if the user set it to **OFF**, the **PR** parameter will not display.

To view all waveforms during the alarming process

Pick **L-RIGHT** and turn the knob to view all 8/16/32-second waveforms stored.

To view other alarm events

Events of up to 60 are listed chronologically from the latest to the earliest. Pick **UP-DOWN** button and turn the knob to view later or earlier events.

Recording

Pick **REC** to print out all data and waveforms of this event.

Chapter 11 Drug Calculation and Titration Table (Optional)

The patient monitor provides drug calculation and titration table display functions for fifteen drugs and outputs the content of titration table on the recorder.

11.1 Drug Calculation

The drug calculations that can be performed by the system are **AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN** and **PITOCIN. DRUG A, DRUG B, DRUG C, DRUG D** and **DRUG E** are also provided to flexibly replace any of the drugs.

By selecting **DRUG CALC** in **SYSTEM MENU**, the following **DRUG CALC** window appears:

```
                          DRUG CALC

    DRUG NAME   AMINOPHYLLINE    INF RATE   60.00    ml/hr

    WEIGHT      70.0      kg     DRIP RATE 20.00     GTT/min

    AMOUNT      500.00    mg     DROP SIZE 20.00     GTT/ml

    VOLUME      500.00    ml     DURATION  8.33      hr

    CONCENTRAT  1.00      mg/ml

    DOSE/min    1.00      mg     Please carefully verify

    DOSE/hr     60.00     mg     the input information!

    DOSE/kg/min 14.29     mcg

    DOSE/kg/hr  857.14    mcg    TITRATION >>


                          EXIT
```

Figure 11-1 DRUG CALC menu

The following formulas are applied to dose calculation:

Concentrate = Amount / Volume

INF Rate = DOSE / Concentrate

Duration = Amount / Dose

Dose = Rate $\times$ Concentrate

DRIP Rate = INF Rate / 60 $\times$ DROP Size

Operating Method:
In the Drug Calculation window, the operator should first select the name of the drug to be calculated, and then confirm the patient weight. Afterwards, the operator should also enter other known values.

Turn the knob to select the value of the item to be calculated. Turn the knob to change the value. When it is the required value, press the knob to view the calculation result. Each item has its calculation range. If the result exceeds the range, it displays "---.--".

NOTE:
1   For the drug calculation, the prerequisite is that the operator must first of all enter the patient weight and drug name. The system then gives a group of random initial values, which cannot be used by the operator as the calculation reference. Instead, he should enter a new group of values at the doctor's instruction.

2   Each drug has its fixed unit or unit series. Operator must select the proper unit at the doctor's instruction. If the result exceeds the system-defined range, it will display "---".

3   After entering a value, a prompt will appear in the menu warning the operator to confirm the correctness of the entered value. The correct value is the guarantee for the reliability and safety of the calculated results.

4   For each entered value, the system will always give a dialog box asking for the user's confirmation. You must be careful when answering each box. The calculated result is reliable only after the entered value is confirmed to be correct.

Select the Drug Name:
Turn the knob to pick the **DRUG NAME** item in **DRUG CALC** menu. The user may select the drug name in the pull-down list, including **AMINOPHYLLINE, DOBUTAMINE, DOPAMINE, EPINEPHRINE, HEPARIN, ISUPREL, LIDOCAINE, NIPRIDE, NITROGLYCERIN, PITOCIN, Drug A, Drug B, Drug C, Drug D** and **Drug E**. Calculation for only one type can be generated each time.

NOTE:
A, B, C, D or E is only code for drugs instead of their real names. The units for these five drugs are fixed. The operator may select the appropriate units according to the convention of using these drugs. The rules for expressing the units are:
— "mg" series units are fixedly used for drug A, B and C: g, mg, mcg.

— "unit" series units are fixedly used for drug D: unit, k unit, m unit.

— "mEq" is fixedly used for drug E.

Patient Weight:

After accessing the **DRUG CALC** window, the operator should enter the patient weight into the first or the second item. The entered weight will be used as the independent data only for the calculation of drug concentration.

NOTE:
This drug calculation function acts only as a calculator. That means the patient weight in Drug Calculation menu and it in Patient Information menu is independent from each other. Therefore if the Weight in Drug Calculation changes, it will not change in Patient Information. In this way, we can say, the Drug Calculation menu is independent from other menus in the system. Any change of it will not affect other information about the patient being currently monitored.

11.2 Titration Table

Access Titration Table:

Select **TITRATION** item in **DRUG CALC** menu to enter titration table display.
Titration table display for drug is as following:

```
                    TITRATION -- DRUG A
.................................................................
 AMOUNT       400.00   mg      VOLUME      250.00   ml

 DOSE/min    2500.00   mcg     INF RATE     93.75   ml/hr

 WEIGHT        70.00   kg      DRIP RATE    31.25   GTT/min

  ┌────────┬──────────┬────────┬──────────┬────────┬──────────┐
  │  DOSE  │ INF RATE │  DOSE  │ INF RATE │  DOSE  │ INF RATE │
  ├────────┼──────────┼────────┼──────────┼────────┼──────────┤
  │  0.00  │   0.00   │ 10.00  │   0.38   │ 20.00  │   0.75   │
  │  1.00  │   0.04   │ 11.00  │   0.41   │ 21.00  │   0.79   │
  │  2.00  │   0.08   │ 12.00  │   0.45   │ 22.00  │   0.83   │
  │  3.00  │   0.11   │ 13.00  │   0.49   │ 23.00  │   0.86   │
  │  4.00  │   0.15   │ 14.00  │   0.53   │ 24.00  │   0.90   │
  │  5.00  │   0.19   │ 15.00  │   0.56   │ 25.00  │   0.94   │
  │  6.00  │   0.23   │ 16.00  │   0.60   │ 26.00  │   0.98   │
  │  7.00  │   0.26   │ 17.00  │   0.64   │ 27.00  │   1.01   │
  │  8.00  │   0.30   │ 18.00  │   0.68   │ 28.00  │   1.05   │
  │  9.00  │   0.34   │ 19.00  │   0.71   │ 29.00  │   1.09   │
  └────────┴──────────┴────────┴──────────┴────────┴──────────┘

 BASIC  [DOSE         ]    STEP  1    DOSE TYPE  DOSE/min

          UP-DOWN                          REC
.................................................................
                          EXIT
```

Figure 11-2 TITRATION

- Method to operate the titration table:

1. In the **TITRATION** table, turn the knob to pick **BASIC** item. Press and turn the knob to select **INF RATE**, **DOSE** or **DRIP RATE**.

2. Then turn the knob to pick **STEP** item. Select step by pressing the knob. 1 to 10 are available for selection with the increments of 1.

3. Turn the knob to pick **DOSE TYPE** item. Press and turn the knob to select the unit in the pull-down list.

4. Use **UP-DOWN** item in the table to view the data in previous or next pages.

5. Turn the knob to pick **REC** item. After pressing the knob, the recorder prints out the data displayed in the current titration table.

6. Turn the knob to pick **EXIT** to return to **DRUG CALC** menu.

Total amount, dose, volume, INF rate, drip rate, patient weight and drug name are displayed on the top of the titration table. The meaning of each English identifier is:

AMOUNT: drug amount	**VOLUME**: liquid volume
DOSE/min: drug dose	**INF RATE**: flow rate
DRIP RATE: drop rate	**WEIGHT**: patient weigh

Chapter 12 Maintenance/Cleaning

<div style="border:1px solid">

WARNING

1   Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

2   If you discover a problem with any of the equipment, contact your service personnel, or your authorized supplier.

</div>

12.1 Inspecting

The overall check of the monitor, including the safety check, should be performed only by qualified personnel every 24 months, and each time after fix up.

The following items should be checked:

●   If the environment condition and power supply meet requirement.

●   If the power supply cord has damage and insulativity meets requirement.

●   If the device and accessories have damage.

●   Specified accessories.

●   If the alarm system can work properly.

●   If the recorder can work properly and the paper meets the requirement.

●   Battery performance

●   If all monitoring functions are in good conditions.

●   If the grounding resistance and leakage current meet requirement.

If any damage or abnormality is found, please don't use the monitor and contact local Customer Service Center.

12.2 Maintenance Task and Test Schedule

Maintenance shall be carried out at least once every two years, or as specified by local laws. The following tasks are for the manufacturer's qualified service professionals only. Contact a qualified service provider by the manufacturer if your monitor needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Maintenance and Test Schedule	Frequency
Safety checks. Selected tests on the basis of IEC60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped.

Maintenance and Test Schedule	Frequency
Check all monitoring functions and measuring functions	At least once every two years, or as needed.

12.3 Care and Cleaning

Use only the manufacturer's approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

The manufacturer has validated the cleaning and disinfection instructions included in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection

12.3.1 General Points

Keep your monitor, cables and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

● Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.

● Always dilute according to the manufacturer's instructions.

● Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.

● Do not pour liquid onto the system.

● Do not allow liquid to enter the case.

● Never use abrasive material (such as steel wool or silver polish).

● Inspect the monitor and reusable accessories after they are cleaned and disinfected.

CAUTION

If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or the manufacturer service engineer.

12.3.2 Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor and reusable accessories are:

● Mild near neutral detergent

- Ethanol (75%)

- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

12.3.2.1 Cleaning the Monitor

WARNING

Before cleaning the monitor, make sure that the monitor is switched off and disconnected from the power line.

To surface-clean the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.

2. Wipe the entire exterior surface, including the screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain..

3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

4. Dry the monitor in a ventilated and cool place.

12.2.3.2 Cleaning the Reusable Accessories

■ Cleaning the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the cleaning solution until no visible contaminants remain.

2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.

3. Wipe off residual moisture with a dry cloth.

4. Leave the cable assembly to air dry.

■ Cleaning the Blood Pressure Cuff

Cleaning the Cuff:

1. Take out the air bladder before cleaning.

2. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution. until no visible contaminants remain

3. Rinse the cuff and wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.

5. Wipe off residual moisture with a dry cloth.

4. Air dry the cuff thoroughly after cleaning.

Replacing the Air Bladder:

After cleaning, replace the air bladder into the cuff following the steps below:

1.   Roll the bladder lengthwise and insert it into the cuff from the large opening at one end of the cuff.

2.   Thread the hose from within the cuff and out through the small hole at the top of the cuff.

3.   Adjust the bladder until it is in position.

■ Cleaning the SpO$_2$ Sensor

1.   Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.

2.   Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution. until no visible contaminants remain

3.   Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.

4.   Wipe off with a dry cloth to remove residual moisture.

5.   Leave the sensor to air dry.

■ Cleaning the IBP Cable

1.   Wipe the cables with a soft cloth dampened with the cleaning solution until no visible contaminants remain.

2.   Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.

3.   Wipe off with a dry cloth to remove residual moisture.

4.   Leave the cables to air dry.

■ Cleaning the TEMP Sensor

1.   Wipe the patient contact area with a soft cloth dampened with the cleaning solution until no visible contaminants remain.

2.   Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.

3.   Wipe off with a dry cloth to remove residual moisture.

4.   Leave the sensor to air dry.

12.3.2.3 Cleaning the Dust-proof Filter Assembly

The dust-proof filter system consists of two parts, one is the filter base near the battery door of device (as left picture shown), and another is the dust proof filter assembly (as right picture shown) between the front housing and rear housing. Through filtering the dust in air and the

abnormal objects during deflation, the dust proof filter system can extend the pump's lifetime and improve measurement accuracy.

The recommended cleaning frequency is once every month, if the environment is dusty, the frequency may be twice every month, if the sound during inflation is noisier than usual, user needs to clean the dust-proof filter assembly according to the real condition.
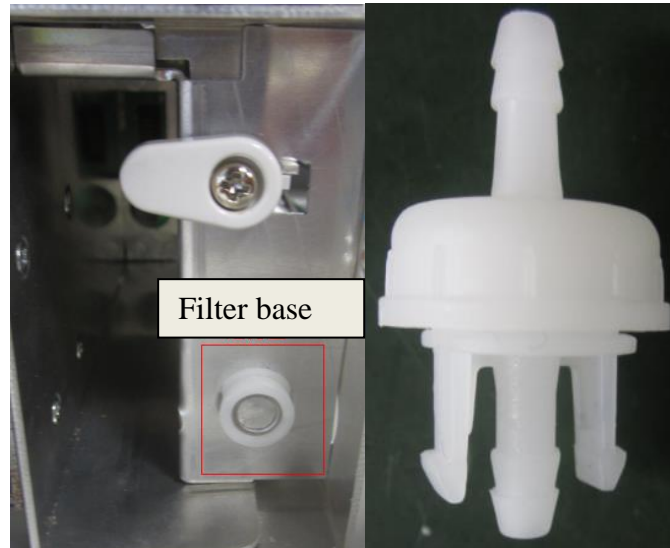
Filter base

To clean the filter base, follow these steps:

1. Switch off the monitor and disconnect it from the power line, open the battery door and take out battery;

2. Put one A6 size paper under the assembly, use a clean and dry cotton swab to clean the filter base, until it is clean;

3. Recycle the paper with dust.

NOTE:

1 Don't use wet cotton swab to clean the filter base.

2 Disassembling the filter base is prohibited.

3 If you need to replace the filter base, please contact the manufacturer's service personnel.

To clean the filter assembly, follow these steps:

1. Turn on the monitor, and set patient type as Adult;

2. Disconnect the extend cable and NIBP cuff ;

3. Press the **Start** button on front panel to inflate, the abnormal objects in the dust proof filter assembly will be blown out, if there is still abnormal object, press **Start** button again to repeat.

NOTE:

1 The dust proof filter assembly is designed in the device, users can't disassemble the device to clean.

2 If you need to replace the dust proof filter assembly, please contact the manufacturer's service personnel.

12.3.3 Disinfection

For devices or accessories that have been in contact mucosal surface, High Level disinfection must occur, for all other accessories, low level disinfection is appropriate. Clean the monitor and reusable accessories before they are disinfected. The validated disinfectants for cleaning the monitor and reusable accessories are:

● Ethanol (75%)

● Isopropanol (70%)

● Cidex OPA (High level disinfection of intracavitary temperature probe only)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

WARNING
The monitor and reusable accessories shall be disinfected to avoid patient cross infection.

12.3.3.1 Disinfecting the Monitor

WARNING
Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.

To disinfect the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.

2. Wipe the display screen using a soft, clean cloth dampened with the disinfectant solution.

3. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.

4. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.

5. Dry the monitor for at least 30 minutes in a ventilated and cool place.

12.3.3.2 Disinfecting the Reusable Accessories

■ Disinfecting the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the disinfectant solution.

2. Wipe off the disinfectant solution with a dry cloth after disinfection.

3. Leave the cable assembly to air dry for at least 30 minutes.

■   Disinfecting the Blood Pressure Cuff

Disinfecting the Cuff:

1.   Take out the air bladder before disinfection.

2.   Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.

3.   Leave the cuff and air bladder to air dry for at least 30 minutes.

Replacing the Air Bladder:

After disinfection, replace the air bladder into the cuff. Refer to Section *12.2.3.2* for more information.

NOTE:

Prolonged use of disinfectant may cause discoloration of the cuff.

■   Disinfecting the SpO$_2$ Sensor

1.   Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.

2.   Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.

3.   Wipe off the disinfection solution with a dry cloth after disinfection.

4.   Leave the sensor to air dry for at least 30 minutes.

■   Disinfecting the IBP Cable

1.   Wipe the cables with a soft cloth dampened with the disinfectant solution.

2.   Wipe off the disinfectant solution with a dry cloth after disinfection.

3.   Leave the cables to air dry for at least 30 minutes.

■   Disinfecting the TEMP sensor

The intracavitary TEMP sensors should be reprocessed by high-level disinfection before and after use on each new patient. Cidex OPA is the validated agent for high level disinfection. Refer to the instructions of the disinfectant for the methods of disinfection. High level disinfection has been validated with a 12 minute soak. Rinse and dry according to the labeled instructions of Cidex OPA. Do not dampen the sensor connector.

For the skin TEMP sensors, disinfect them as follows using ethanol or isopropanol only:

1.   Wipe the patient contact area with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).

2.   Wipe off the disinfectant solution with a dry cloth after disinfection.

3.   Leave the sensor to air dry.

12.3.4 Cleaning and Disinfecting Other Accessories

For cleaning and disinfecting other accessories, refer to the instructions delivered with the accessories. If the accessories are not accompanied by instructions, refer to this manual for the methods of cleaning and disinfecting the monitor.

12.4 Replacement of Fuse

Unscrew the fuse cap anticlockwise, replace the fuse (protector tube) and screw down the fuse cap clockwise. Fuse size: Φ5×20, Rated value: T3.15 AH250 VP.

NOTE:
Switch off the power switch of the patient monitor before examining the fuse.

12.5 Cleaning Battery and Battery Compartment Cover

Use only non-caustic detergents such as soap and warm water (40 °C /104 ℉ maximum) to clean the battery. Do not use strong solvent to clean battery, and do not dip the battery in liquid.

Chapter 13 Monitoring ECG/RESP

13.1 Overview

Monitoring the ECG produces a continuous waveform of the patient's cardiac electric activity to enable an accurate assessment of his current physiological state. Only proper connection of the ECG cables can ensure satisfactory measurement. On the Normal Display, the monitor provides display of 2-channel ECG waveforms.

◆ The patient cable consists of 2 parts

   The cable connects to the monitor

   The lead set connects to the patient

◆ Use a 3-lead or 5-lead set to monitor the ECG.

◆ The monitor displays the Heart Rate (HR), ST segment and Arrhythmia analysis.

   All of the parameters above can be set as alarm parameters.

◆ Lead off detecting: detect all the electrodes, indicate the broken off leads.

◆ Anti-electrotome function: if the monitor works with high-frequency electrotome, it will not be deadlock or restarting.

◆ Every ECG channel has Pacing impulse rejection and Bandpass filter circuit.

◆ Defibrillation protection (needs 1K resistance ECG cables in series) and hardware clamp function.

NOTE:

1   In the default settings of the monitor, the ECG waveforms are the first two waveforms from top in the Waveform Area.

2   The defibrillator cables should be used in the ECG monitoring that can prevent the cables from being burned by high frequency.

13.2 ECG Safety Information

<div align="center"><u>WARNING</u></div>

1   Do not come into contact with the patient, table, or the monitor during defibrillation.

2   Only use the ECG leads supplied by the manufacturer when using the monitor for ECG monitoring.

3   When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient but not the conductive part or ground.

4   The electrodes should be made of the same metal materials.

WARNING

5   Place the electrode carefully and ensure a good contact. Check every day whether there is skin irritation resulted from the ECG electrodes. If yes, replace electrodes every 24 hours or change their sites.

6   Store the electrodes in room temperature. Open the electrode package immediately prior to use. Never mix electrode types or brands. This may lead to problem due to impedance difference. When applying the electrodes, avoid bones close to skin, obvious layers of fat, and major muscles. Muscle movement can result in electrical interference. Applying electrodes on major muscles, for example on muscles of thorax, may lead to erroneous arrhythmia alarm due to excessive muscle movement.

7   For patients with pacemakers, the pacing impulse analysis function must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected.

8   PACEMAKER PATIENTS—Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance.

9   ECG accessories are not suitable for DIRECT CARDIAC APPLICATION (Refer to IEC60601-1 for more information about the definition of DIRECT CARDIAC APPLICATION).

10 Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. When the electrode or lead is loose or fallen, the monitor is easily affected by the transient response of certain types of insulation monitors. The transient monitor signal produced by poor insulation of the line may be very similar to the actual heart waveform, which will prevent the monitor from prompting a heart rate alarm. In order to avoid this, user should check lead wires for damage and ensure good skin contact prior to and during use. Always use fresh electrodes and follow proper skin preparation techniques.

11 The monitor can only be used on one patient at a time. Monitoring more than one patient simultaneously may result in hazards to the patient.

12 Pacemaker Failure: During a complete cardiac block or when pacemaker is unable to pacing/capture, high P-wave (greater than 1/5 of the average height of the R-wave) may be incorrectly counted by the monitor, which leads to a missing asystole.

13 To protect the monitor from damage during defibrillation, for accurate ECG information and to protect against noise and other interference, use only ECG electrodes and cables specified by the manufacturer.

NOTE:

1   Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

2   IEC/EN60601-1-2 (protection against radiation is 3 v/m) specifies that the electrical field density exceeding 3 v/m may cause measurement error in various frequencies.

It is accordingly suggested that do not use equipment generating electrical radiation near ECG/RESP monitoring devices.

3   The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.

4   If the pacemaker signals are beyond the claimed range, the heart rate may be calculated incorrectly.

5   In the default settings of the monitor, the ECG waveforms are the first two waveforms from top in the waveform area.

6   For measurements in or near the heart we recommend connecting the monitor to the potential equalization system.

7   For protecting environment, the used electrodes must be recycled or disposed of properly.

8   The patients can't be monitored during ECG calibration.

13.3 Monitoring Procedure

13.3.1 Preparation

1. Prepare the patient's skin prior to placing the electrodes.

    ◆ The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

    ◆ Shave hair from sites, if necessary.

    ◆ Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).

    ◆ Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

2. Attach clip or snap to electrodes prior to placement.

3. Put the electrodes on the patient. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not electrolyte self-supplied.

4. Connect the electrode lead to the patient's cable.

5. Make sure the monitor is ready with power supply.

WARNING
1   Placed the electrode carefully and ensure a good contact.
2   Check every day whether there is skin irritation resulted from the ECG electrodes. If yes, replace electrodes every 24 hours or change their sites.
3   Check if the lead connection is correct before monitoring. If you unplug the ECG cable from the socket, the screen will display the error message "ECG LEAD OFF" and the audible alarm is activated.

NOTE:

For protecting environment, the used electrodes must be recycled or disposed of properly.

13.3.2 Placing Electrodes for ECG Monitoring

NOTE:

The following table gives the corresponding lead names used in Europe and America respectively. (Lead names are represented by R, L, F, N, C, C1-C6 in Europe, whose corresponding lead names in America are RA, LA, LL, RL, V, V1-V6.)

AHA (America Standard)		IEC (Europe Standard)	
Lead Mode	Color	Lead Mode	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White
V1	Brown/ Red	C1	White/ Red
V2	Brown/ Yellow	C2	White/ Yellow
V3	Brown/ Green	C3	White/ Green
V4	Brown/Blue	C4	White/ Brown
V5	Brown/Orange	C5	White/ Black
V6	Brown/Purple	C6	White/ Purple

Electrode placement for 3-lead set

Take the American standard for example, see Figure 13-1:

◆ Red (R) electrode - Be placed near the right shoulder, directly below the clavicle.

◆ Yellow (L) electrode - Be placed near the left shoulder, directly below the clavicle.

◆ Green (F) electrode - Be placed on the left hypogastrium.
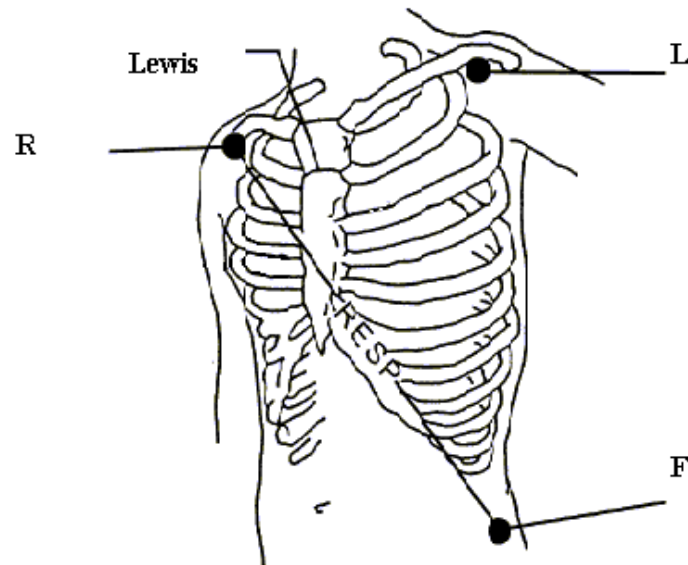
Figure 13-1 Electrode Placement for 3-lead Set

Electrode placement for 5-lead set

Take the American standard for example, see Figure 13-2:

◆ Red (R) electrode - Be placed near the right shoulder, directly below the clavicle.
◆ Yellow (L) electrode - Be placed near the left shoulder, directly below the clavicle.
◆ Black (N) electrode - Be placed on the right hypogastrium.
◆ Green (F) electrode - Be placed on the left hypogastrium.
◆ White (C) electrode - Be placed on the chest as illustrated in the Figure 13-2.
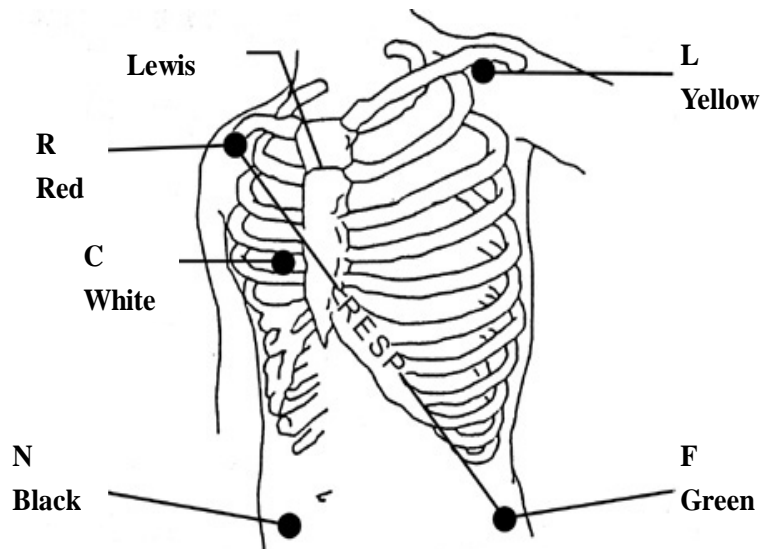
Figure 13-2 Electrode Placement for 5-lead Set

NOTE:
To ensure patient safety, all leads must be attached to the patient.

For 5-lead set, attach the C (V)-electrode to one of the indicated positions as below (Figure 13-3):

◆ V1   On the 4th intercostal space at the right sterna margin.
◆ V2   On the 4th intercostal space at the left sterna margin.
◆ V3   Midway between V2 and V4 electrodes.
◆ V4   On the 5th intercostal space at the left clavicular line.
◆ V5   On the left anterior axillary line, horizontal with V4 electrode.
◆ V6   On the left middle axillary line, horizontal with V4 electrode.
◆ V3R-V7R   On the right side of the chest in positions corresponding to those on the left.
◆ VE   Over the xiphoid position.
◆ V7   On the 5th intercostal space at the left posterior axillary line of back.
◆ V7R   On the 5th intercostal space at the right posterior axillary line of back.
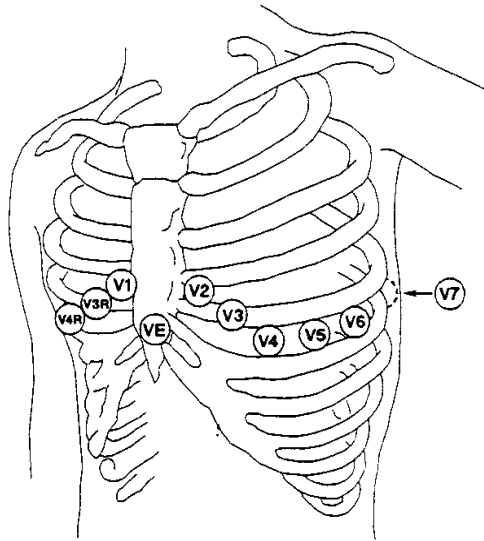
Figure13-3 C-Electrode Placement for 5-lead Set

Recommended ECG Lead Placement for Surgical Patients

WARNING

When using Electrosurgery (ES) equipment, leads should be placed in a position in equal distance from Electrosurgery electrotome and the ES grounding plate to avoid cautery. Electrosurgery equipment wire and ECG cable must not be tangled up.

Monitoring ECG leads are mainly used for monitoring the patient's vital signs. When using the patient monitor with other Electrosurgery equipment, it is advised to use the counteracting defibrillation ECG lead.

The placement of the ECG leads will depend on the type of surgery that is being performed. For example, in an open chest surgery the electrodes may be placed laterally on the chest or on the back. In the operating room, artifacts may affect the ECG waveform due to the use of ES (Electrosurgery) equipment. To help reduce this you can place the electrodes on the right and left shoulders, the right and left sides near the abdomen, and the chest lead on the left side at mid-chest. Avoid placing the electrodes on the upper arms. Otherwise the ECG waveform will be too small.

WARNING

ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use defibrillator-proof ECG lead to avoid burn.

Using 5-lead ECG Set

You can set the leads on ECG CH1 and ECG CH2 according to your needs. The lead label is displayed on the upper left part of the waveform. You can set them corresponding to any two from I, II, III, AVR, AVL, AVF and V1 to V6. If you set both to the same value, one of them will be adjusted to another option automatically. (Figure 13-5)
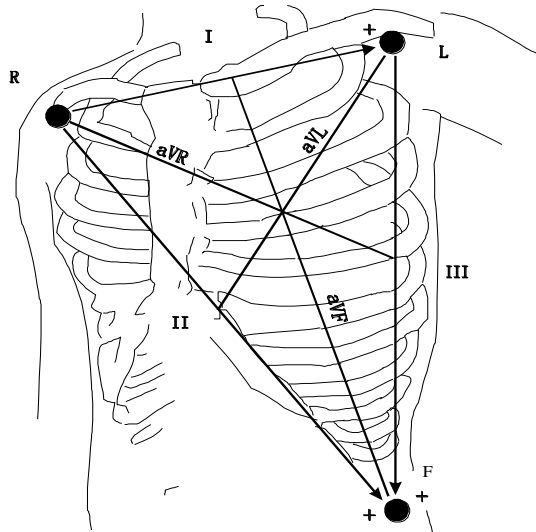
Figure13-4 ECG Lead

WARNING

In 5-lead mode, Pace detection ±2 mV to ±700 mV; In 3-lead mode, for Pace detection, it is recommended to set as II, ±2 mV to ±700 mV.

NOTE:
If an ECG waveform is not accurate, while the electrodes are tightly attached, try to change the lead.

Normal QRS complex should be:

◆ Tall and narrow with no notches.
◆ With tall R-wave completely above or below the baseline.
◆ With pacemaker spike no higher than R-wave height.
◆ With T-wave less than one-third of the R-wave height.
◆ With P-wave much smaller than the T-wave.
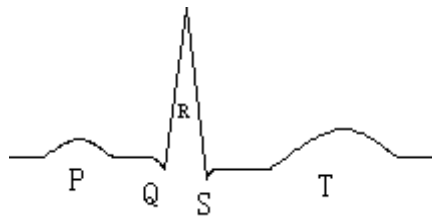
Figure 13-5 Standard ECG Waveform

13.4 ECG Screen Hot Keys

Figure 13-6 Hot Key for ECG

[1]. Leads of channel 1:

I, II, III, AVR, AVL, AVF, V1 to V6 are available.

Leads on the ECG wave must not have the same name. Otherwise, the system will automatically change the ECG waveform name that has the same name as the waveform being currently adjusted to another name.

[2]. Waveform gain of channel 1: used to adjust the size of ECG waveforms

Signal amplification and collection of Channel 1 ECG, it can collect gain value for each channel setting as ×**0.125, ×0.25, ×0.5, ×1, ×2, ×4** or **AUTO** mode. In **AUTO** mode, the monitor chooses an appropriate level automatically. A 1mV scale displays on each ECG channel's right side. The height of 1mV bar is directly proportional to the waveform amplitude.

NOTE:

When the input signals are too strong, the peak of the waveform may not be able to be displayed. In this case the user may manually change the setup method of ECG waveform according to the actual waveform so as to avoid the occurrence of the unfavorable phenomena.

[3]. Filter method: used for displaying clearer and more detailed waveforms

There are three filter modes for selection: **DIAGNOSTIC**, **MONITOR** and **SURGERY** modes. **SURGERY** mode may reduce perturbance and interference from Electrosurgery equipment. The filter method is the item applicable for both channels, which is always displayed at the waveform place of the channel 1 ECG waveform.

NOTE:

Only in Diagnosis mode, the system can provide non-processed real signals. In Monitor or Sugery mode, ECG waveforms may be distorted to different extents. In either of the latter two modes, the system can only show the basic ECG and the results of ST analysis may also be greatly affected. In Surgery mode, results of ARR analysis may be somewhat affected. Therefore, it is suggested that in the environment where relatively small interference exists, you'd better monitor a patient in Diagnosis mode.

[4]. Leads of channel 2: refer to [1] for detailed information.

[5]. Waveform gain of channel 2: refer to [2] for detailed information.

NOTE:

Pacemaker signal detection is marked by a "|" above the ECG waveform.

13.5 ECG Menu

13.5.1 ECG SETUP

Pick the ECG hot key on the screen, and the following menu will pop up.


```
                        ECG SETUP

  HR ALM      ON        HR CHANNEL   CH1

  ALM LEV     MED       LEAD TYPE    5 LEADS

  ALM REC     OFF       ECG DISPLAY    NORMAL DISPLAY

  ALM HI      120       ST ANALYSIS >>

  ALM LO      50        ARR ANALYSIS >>

  HR FROM     ECG       OTHER SETUP >>

  SWEEP       25.0


                        EXIT
```

Figure 13-7 ECG Setup

◆ **ECG Alarm Setting**

HR ALM: pick **ON** to enable prompt message and data record during the ECG alarm; pick

OFF to disable the alarm function, and there will be a [X] beside **ECG**.

<div align="center"><u>WARNING</u></div>

In order to avoid endangering the patient's life, the user should use this function cautiously.

ALM LEV: selectable from **HIGH, MED**. Level **HIGH** represents the most serious case.

ALM REC: pick **ON** to enable report printing upon ECG alarm.

ALM HI: used to set up the upper limit of ECG alarm.

ALM LO: used to set up the lower limit of ECG alarm.

ECG alarm is activated when the heart beat exceeds set **ALM HI** value or falls below **ALM LO** value.

NOTE:
Please set the alarm limits according to the clinical conditions of individual patients. The upper limit shall not be 20 beats per min higher than the patient's heart rate.

◆ HR FROM

ECG, SpO$_2$, AUTO and **BOTH** may detect heart rate. **AUTO** distinguishes the heart rate source according to the quality of signal. When the qualities of ECG signal and SpO$_2$ signal are the same, ECG takes priority over SpO$_2$. By picking ECG, the monitor prompts HR and activates HR beep. By picking SpO$_2$, the monitor prompts **PULSE** and activates pulse beep.

When SpO$_2$ is selected, the alarms for HR or PR are available, and the alarm prompt will display in information area, but the alarm limit and alarm flashes are different for them.

BOTH mode displays HR and PR simultaneously. When this item is picked, PR parameter is displayed to the right side of SpO$_2$. As for the sound of HR or PR in **BOTH** mode, HR is given the priority, i.e., if HR is available, the HR sound will be sent out, but if HR is not available, then the sound will be for PR.

◆ SWEEP

Available options for **ECG SWEEP** are 6.25, 12.5, 25.0 and 50.0 mm/s.

◆ HR CHANNEL

"**CH1**" to count the heart rate by CH 1 waveform
"**CH2**" to count the heart rate by CH 2 waveform

◆ LEAD TYPE

Users can select either **3 LEADS** or **5 LEADS** for this item.

◆ ECG DISPLAY: it varies according to **LEAD TYPE**.

When **LEAD TYPE** is set to **3 LEADS, ECG DISPLAY** can be set to **NORMAL DISPLAY**, it can display one ECG waveform on the main screen.

When **LEAD TYPE** is set to **5 LEADS, ECG DISPLAY** can be set to **NORMAL DISPLAY**, **MULTI-LEADS DISPLAY** and **HALF-SCN MULTI-LEADS DISPLAY**. Select **NORMAL DISPLAY** to display two ECG waveforms on the main screen; Select **MULTI-LEADS DISPLAY** to display seven ECG waveforms which occupying the area of seven waveforms on the main screen; Select **HALF-SCN MULTI-LEADS DISPLAY** to display seven ECG waveforms on the screen, occupying the area of four waveforms.

NOTE:
If **3 LEADS** is selected in the **ECG SETUP** menu, only **NORMAL DISPLAY** can be selected for **ECG DISPLAY** item in the sub-menu.

◆ **ST ANALYSE**

Pick this item to access **ST ANALYSE**. Please refer to *Section 13.6 ST Segment Monitoring* for details.

◆ **ARR ANALYSE**

Pick this item to access **ARR ANALYSE**. Please refer to *Chapter 13.7 Arr. Monitoring* for details.

◆ **OTHER SETUP**

Pick this item to access **OTHER SETUP** as shown below:

```
                    OTHER SETUP
..............................................................
SMART LEAD OFF   ON

BEAT VOL       2        ECG CAL

PACE         OFF        ADJUST WAVE POS >>

CASCADE      OFF        DEFAULT >>



..............................................................
                      EXIT
```

Figure 13-8 Other Setup menu

Users can access the following functions:

◆ **SMART LEAD OFF**: in **5 LEADS** mode, if the **CH1** and **CH2** can not measure because of the lead off or other reasons, it can shift to other **LEADS** to collect an ECG waveform.

◆ **BEAT VOL**

Six selections are available: **0, 1, 2, 3, 4, 5**. "**5**" indicates maximum volume. "**0**" indicates no sound. Beat frequency has positive correlation with measurement value.

◆ **PACE**

ON   detected signal will be marked by a "|" above the ECG waveform

OFF   for non-paced patient.

NOTE:

When monitoring a patient with a pacemaker, set "**PACE**" to **ON**. If monitoring a patient without a pacemaker, set "**PACE**" to **OFF**.

◆ **CASCADE**: turn on or off **CASCADE** display. When it is set to **ON**, the ECG waveform is display in 2 channels. This function is available only for the **NORMAL DISPLAY** in **ECG DISPLAY**.

◆ **ECG CAL**

Pick this item to start ECG calibrating process. Picking this item again can finish calibrating process.

Users can turn on or off the Power frequency filter of 50Hz or 60Hz in **DIAGNOSTIC** mode. It can use standardized voltage to set the display width for 1mV signal. For example X1 is for 10mm, X2 is for 20mm.

◆ **ADJUST WAVE POS**

Used to adjust the position of ECG waveform on the screen, pick this item to call up the **ADJUST WAVE POS** dialog box. The user may use **CH NAME** item to select the channel to be adjusted, **UP-DOWN** to adjust the position of the selected channel on the screen, **BACK TO DEFAULT** to let the waveform go back to the default position on the screen.

```
┌─────────────────────────────────┐
│        ADJUST WAVE POS          │
│ ................................│
│                                 │
│   CH NAME   CH1                 │
│                                 │
│   UP&DOWN                       │
│                                 │
│   BACK TO DEFAULT               │
│                                 │
│                                 │
│  ┌───────────────────────────┐  │
│  │          EXIT             │  │
│  └───────────────────────────┘  │
└─────────────────────────────────┘
```
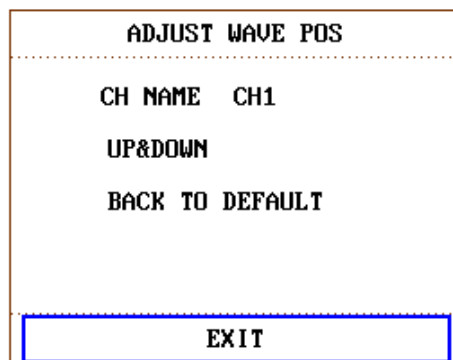
Figure 13-9 ADJUST WAVE POS Menu

◆ **DEFAULT**

Pick the **DEFAULT** item to call up the **ECG DEFAULT CONFIG** dialog box, in which you can select the **FACTORY DEFAULT CONFIG** or the **USER DEFAULT CONFIG** item. After selecting any of the items and exiting the dialog box, the system will pop up a dialog box asking for your confirmation.

WARNING

For patients with pacemakers, the pacing impulse analysis function must be switched **ON**. Otherwise, the pacing impulse may be counted as normal QRS complex, which results in failure of **ECG LOST** error detection.

NOTE:
When **PACE** Switch is **ON**, the Arrhythmia events related to **PVCs** will not be monitored. At the same time, the ST analysis will not be performed either.
If the monitor can do ST segment monitoring and Arrhythmia monitoring, please refer to *Section 13.6* and *13.7*.

13.6 ST Segment Monitoring (Optional)

◆ ST segment monitoring function is shut off by default. You can switch it to **ON** when necessary. When using the ST analysis function, the ST analysis results will be displayed on the right of the main screen, please refer to Figure13-15.

NOTE:

1   **ST ANALYSE** only can be used only in **ADU** mode, and is not clinically validated for use with neonatal and pediatric patients.

2   When setting **ST ANALYSE** on, the monitor should in **DIAGNOSTIC** mode.

3   ECG/RESP monitoring should select **DIAGNOSTIC** mode.

1   ST analysis is always performed using a dedicated filter which ensures diagnostic quality. If you are monitoring ECG using an ECG filter mode other than **Diagnosis**, the ST segment of the ECG wave may look different from the ST segment of the ST template for the same wave. For diagnostic evaluation of the ST segment, always set the filter to **Diagnosis** or use the ST template.

2   Reliable ST monitoring may be influenced in following situations:

    ● You are unable to get a lead with low noise

    ● If there is arrhythmia such as atrial fibrillation/flutter, the ECG baseline may be irregular.

    ● The patient is continually performing ventricular paced.

    ● The patient can not get the leading template for a long time.

    ● The patient has left bundle branch block.

    When any of above situations happens, ST monitoring should be switched off.

3   If you use ST analysis, you must adjust the ST measurement point when you start the monitor. If the patient's heart rate or ECG waveform changes significantly, this will affect the size of the QT interval, so the ST point must be placed. If the equipotential or ST points are not set correctly, the ST fragments of the artifacts may be depressed or raised. Always ensure that the ST measurement point is suitable for your patient.

4   ST values may be affected by such factors as some drugs or metabolic and conduction disturbances.

5   ST is calculated with a fixed delay from the R position. Changes in heart rate or the width of QRS may affect ST.

◆   It is available to measure the variance of ST segment with ST analysis at the waveform tracks for selected lead. The corresponding ST measurement result displays numerically at ST1 and ST2 in the Parameter Area. The trend can be viewed in table or graphic form.

◆   Measurement unit of ST segment: mV.

◆   Measurement symbol of ST segment: "+" = elevating, "-" = depressing.

◆   Measurement range of ST segment: -2.0 mV to + 2.0 mV.

Pick the **ST ANALYSE** item in the **ECG SETUP** menu to access the **ST ANALYSE** sub-menu as shown below.

ST ANALYSE Menu

Figure 13-10 ST Analyse menu

ST Analysis Alarm Setting

◆ **ST ANALYSE**: the switch for ST analysis. Set it to **ON** to activate the ST analysis or **OFF** to disable the ST analysis.

◆ **ST ALM**: pick **ON** to enable prompt message and data record during the ST analysis alarm; pick **OFF** to disable the alarm function, and there will be a [icon] beside ST. ST alarm is activated when the result exceeds set **ST HI** value or falls below **ST LO** value.

WARNING

In order to avoid endangering the patient's life, the user should use this function cautiously.

◆ **ALM LEV**: used to set up the ST alarm level. There are three selections: **HIGH, MED** and **LOW**.

◆ **ALM REC**: pick **ON** to enable report printing upon ST analysis alarm.

◆ **ALM LIMIT SETUP**: used to set up the upper limit and lower limit of ST alarm. The **ALM HI** can be set to 0.2 mV to 2.0 mV, and the **ALM LO** can be set to –2.0 mV to 0. 2 mV. The setup **ALM HI** should be higher than the **ALM LO**.

◆ **DEF POINT**: pick this item to access the **DEF POINT** window, in which the position of ISO and ST point can be set up.

    □ **ISO**   Base point. Default is 80 ms.

    □ **ST**   Measurement point. Default is 108 ms.
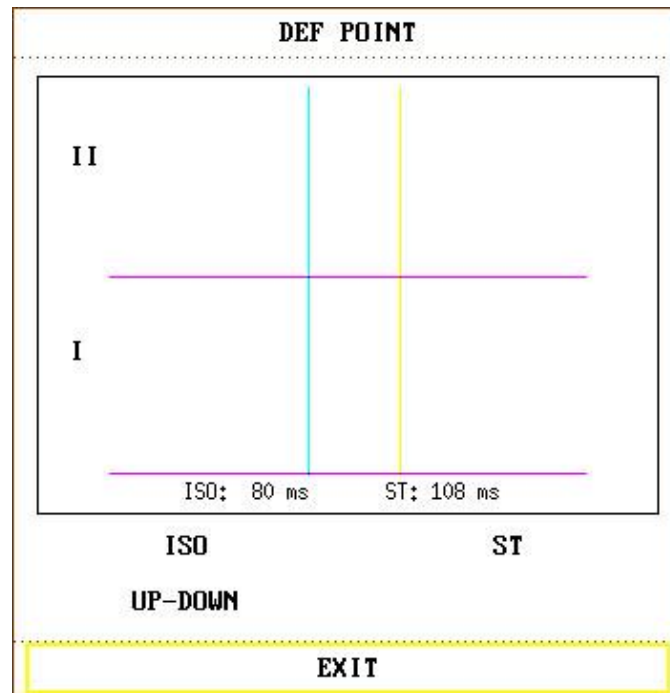
Figure 13-11 DEF POINT Window

The operator can adjust the position of both ISO and ST measurement points.
Set the reference point of ST measurement point to be peak point of R-wave.
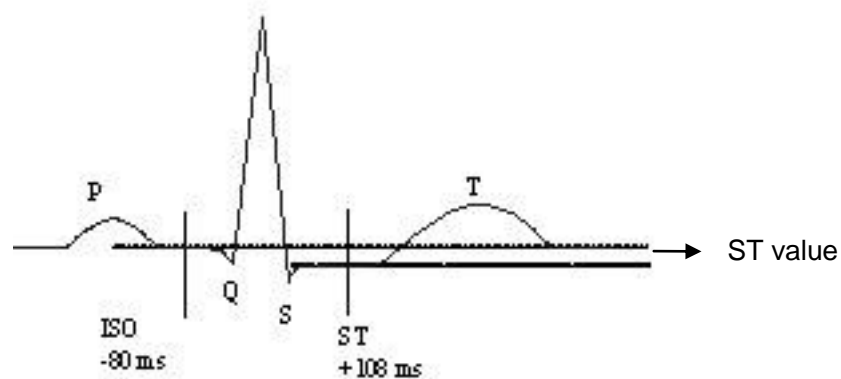
Figure 13-12 DEF POINT

The ST measurement for each beat complex is the vertical difference between the two measurement points.

NOTE:
1 The ST measurement point should be adjusted if the patient's HR or ECG morphology changes significantly.
2 The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.

Adjusting ISO, ST:

These two points can be adjusted by turning the knob.
When adjusting ST measurement point, the system will show the ST Measurement Point Window.

The system displays the QRS complex template in the window. It is adjustable for the highlight bar in the window. You may select ISO or ST, switch the knob left or right to move the cursor line. When the cursor is at the required position, you may select the base point or the measurement point.

NOTE:
Abnormal QRS complex is not considered in ST segment analysis.

ST Alarm Message

NOTE:
The alarm limits for two ST measurements are identical. No setting of alarm limits can be made only for one channel.

If the ST values are too high or too low, the monitor will give alarms for these parameters of ST value.

Lead Type	Parameters of ST Vaules
3-lead	ST-Ⅰ, ST-Ⅱ, ST-Ⅲ
5-lead	ST-Ⅰ, ST-Ⅱ, ST-Ⅲ, ST-AVR, ST-AVL, ST-AVF, ST-V

13.7 Arr. Monitoring (Optional)

Arrhythmia Analysis

The arrhythmia algorithm is used to monitor ECG of adult patients in clinical, detect the change of heart rate and ventricular rhythm, and also save arrhythmia events and generate alarming information. The arrhythmia analysis is not clinically validated for use with neonatal and pediatric patients. Arrhythmia algorithm can monitor paced and non-paced patients. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and decide the treatment. Besides detecting change of ECG, arrhythmia algorithm can also monitor patients and give proper alarm for arrhythmia.

◆ The arrhythmia monitoring is shut off by default. You can enable it when necessary.

◆ This function can call up the doctor's attention to the patient's heart rate by measuring and classifying the arrhythmia and abnormal heart beat and triggering the alarm.

◆ The monitor can conduct up to 16 different arrhythmia analyses.

   Pick the item **ARR ANALYSE** in **ECG SETUP** menu to access the **ARR ANALYSE** sub-menu.

◆ The monitor has a Pacing impulse detection circuit (select one from I, II, III, AVR, AVL, AVF and V).

Every ECG channel has a Pacing impulse rejection and a Band pass filter circuit. Pacing rate > 320mV/s (RTT).

WARNING

This device is not intended for treatment.

NOTE:
ECG/RESP monitoring should select **DIAGNOSTIC** mode.
Selecting an ECG lead for Arrhythmia:

In arrhythmia monitoring, it is important to select the appropriate lead.

For non-paced patients, the guidelines are:

- QRS should be tall and narrow (recommended amplitude> 0.5 mV)

- R wave should be above or below the baseline (but not biphasic)

- T wave should be smaller than 1/3 of the R wave height

- P wave should be smaller than 1/5 of the R wave height.

For paced patients, in addition to above guidelines, the pacemaker should also:

- not wider than normal QRS

- The QRS complexes should be at least twice the height of the pacing pulse

- large enough to be detected, without repolarization signal

According to Standard ISO60601-2-27, the minimum detection level of the QRS complex is set to 0.15 mV, to prevent the detection of P-wave or baseline noise as QRS complexes. Adjusting ECG displayed waveform size (gain adjustment) won't influence ECG signals which are used for arrhythmia analysis. If the ECG signal is too small, a false asystole alarm may occur.

Aberrantly-Conducted Beats:

As not recognizing the P waves, the monitoring system is difficult to distinguish between aberrantly-conducted beats and ventricular heartbeat. If the aberrantly-conducted beat is similar to ventricular tachycardia, it may be classified as ventricular. Make sure to select such a lead, the aberrantly-conducted beats have an R wave that is as narrow as possible to minimize the incorrect calls. The ventricular should have a different appearance from "normal heartbeat". Physicians should be more alert to these patients.

Intermittent bundle branch block: bundle branch block or other bundle obstruction phenomenon is a challenge for arrhythmia algorithm. If the QRS wave during the block has a considerable change in morphology compared to the normal QRS of learning, the blocked heartbeat may be misclassified as ventricular tachycardia, resulting in an incorrect chamber alarm. Make sure to select such a lead, which blocks the heartbeat of the R wave as narrow as possible to minimize the wrong classification. Ventricular heartbeat should have a different appearance from "normal heartbeat". Physicians should be more alert to these patients.

NOTE:

1   Heart rate reading may be affected by cardiac arrhythmias. Do not rely entirely on heart rate alarms when monitoring patients with arrhythmia. Always keep these patients under close surveillance.

2   Since the arrhythmia detection algorithm sensitivity and specificity is less than 100%, sometimes there may be some false arrhythmias detected and also some true arrhythmia events may not be detected. This is especially true when the signal is noisy.

ARR ANALYSE Menu

Figure 13-13 ARR ANALYSE

◆ **ARR ANALYSE**: Pick **ON** during monitoring. It is set to **OFF** by default.

◆ **PVCs ALM**: Pick **ON** to enable prompt message when alarm occurs; pick **OFF** to disable the alarm function, and there will be a [X] beside **PVCs**.

WARNING

In order to avoid endangering the patient's life, the user should use this function cautiously.

◆ **ALM LEV**: Selectable from **HIGH, MED, LOW**. Level **HIGH** represents the most serious case.

◆ **ALM REC**: pick **ON** to enable report printing upon PVCs alarm.

◆ PVCs alarm is activated when the PVCs exceeds the set **PVCs ALM HI** value.

◆ **ARR RELEARN** Pick this item to start a learning procedure.

◆ **ARR ALARM**   Pick this item to access the **ARR ALARM** dialog box to set arrhythmia alarm parameters.

You can pick **ALL ALM ON** to enable the alarm function of all arrhythmia types and pick **ALL ALM OFF** to disable this function. Likewise, you can pick **ALL REC ON** to enable the recording function of all arrhythmia types and pick **ALL REC OFF** to disable this function. Changing the **ALM LEV** can reset the alarm level of all arrhythmia types to the same value.

◆ **ARR RECALL**   Pick this item to review and edit the ARR analysis result.

The latest arrhythmia events (up to 60) are displayed.
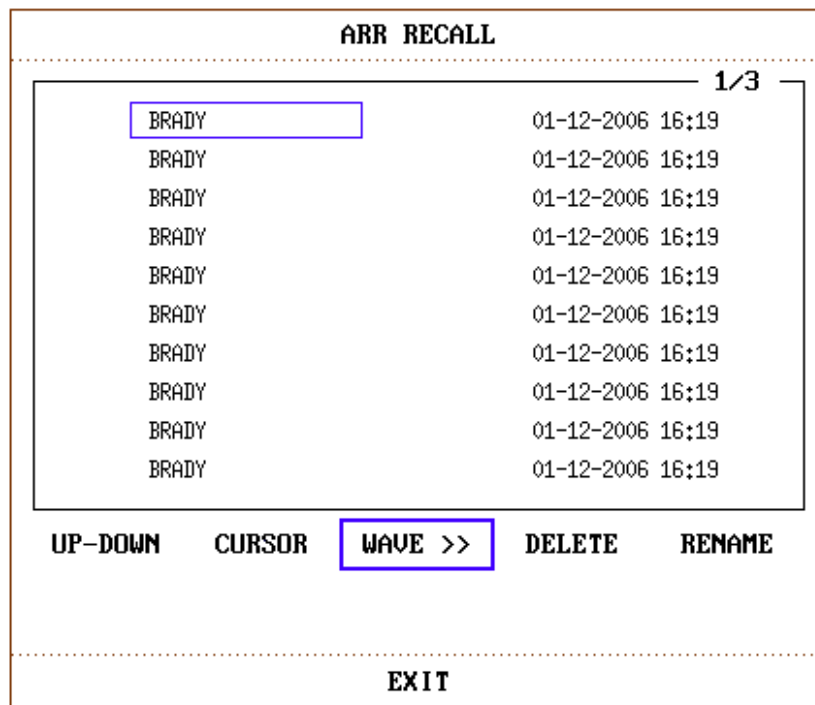
Figure 13-14 ARR RECALL

- □ **UP-DOWN**   Observe the event lists on other pages.
- □ **CURSOR**   Select the Arr. event, whose name is displayed in a protruding frame.
- □ **DELETE**   Delete the selected Arr. event.
- □ **RENAME**   Rename the selected Arr. Event displayed in a sunken frame.

    Switch the knob until the name you want appears.

- □ **WAVE**   Display the Arrhythmia waveform, time and parameter value.
    - ❍ **UP-DOWN**   To observe the waveforms of other Arrhythmia events.
    - ❍ **L_RIGHT**   To observe the 8-second waveform of the Arrhythmia events.
    - ❍ **REC**   To print out the displayed Arrhythmia event.
    - ❍ **EXIT**   To return to **ARR RECALL** menu of Arrhythmia event.

Patient type:

All patients: refers to performing Arr.analysis on patients either with pacemakers or without pacemakers.

Without pacemaker: refers to performing Arr. Analysis only on the patients without pacemakers.

With pacemaker: refers to performing Arr. Analysis only on the patients with pacemakers.

NOTE:

1   Arrhythmia name displays in the Alarm Message Area.

2   During the relearning phase of the algorithm, arrhythmia detection may not be available. So you should closely monitored the patient condition during and for several minutes after the learning phase to allow the algorithm to reach optimal detection performance.

3   Take care to initiate ARR selflearning only during periods of predominantly normal rhythm and when ECG signal is relatively noise-free. If ARR selflearning takes place during arrhythmia, the ectopics may be incorrectly learned as normal QRS complex. This may result in missed detection of subsequent events of arrhythmia.

4   If ARR selflearning is performed during ventricular rhythm, ventricular heartbeats may be erroneously identified as normal QRS complexes. This may lead to missed ventricular tachycardia and ventricular fibrillation events.

    Due to this reason, you should:

    1) Take care that ARR selflearning may start automatically;

    2) Response to lead off information;

    3) Always check the correctness of arrhythmia alarm.

13.8 Measuring RESP

WARNING

1   Respiration measurements can not detect all underexposure sudden events, nor can they distinguish between central, obstructive and mixed respiratory asphyxial events. It only prompts alarm in a predetermined time if the last breath is detected and the next breath is not detected, so it can not be used for diagnostic purposes.

2   If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3 V/m), field strengths above 3 V/m may cause erroneous measurements at various frequencies. Therefore it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.

3   Cardiogenic artifact in impedance respiration monitoring may make it difficult to detect breaths or may otherwise be counted as breaths. In some instances, the breath rate may also correspond to the heart rate making it difficult to determine if the signal is due to breathing or the cardiac cycle. Do not rely on RESP monitoring as the sole method for detecting cessation of breathing. Follow hospital guidelines and best clinical practices for apnea detection including monitoring additional parameters that indicate the patient's oxygenation status, such as $etCO_2$ and SpO_2.

4   For the diagnosis of apnea, especially in premature infants and infants, the safety and effectiveness of respiration measurements have not been validated.

5   To monitor the respiration, only non-ESU-proof accessories can be used. This is because the internal impedance of the ESU-proof accessories are required to be used for electrosurgical operation is too large.

6   Some implantable pacemakers can adjust their triggering frequency according to the "minute ventilation rate." Impedance respiration measurements may cause these pacemakers to react incorrectly. To prevent this, turn off the respiration measurement.

WARNING

7   In manual detection mode, after changing the gain of the respiration wave, be sure to check the setting of hold high and hold low.

8   When ECG electrode is placed on patient's limb, the impedance respiration may be unreliable.

9   Respiration measurement cannot be performed when ESU is used.

13.8.1 How to Measure RESP

The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

13.8.2 Setting up RESP Measurement

For RESP monitoring, it is not necessary for additional electrodes, however, it is very important to attach the electrodes to the correct positions.

Some patients, due to their clinical condition, expand their chest laterally, causing a negative intrathoracic pressure. In these cases it is better to place the two RESP electrodes laterally in the right axillary and left lateral chest areas at the maximum point of breathing movement to optimize the respiratory waveform.

NOTE:

The RESP monitoring is not recommended to be used on patients who are very active, as this can cause false alarms.

Checklist for RESP Monitoring

1.   Prepare the patient's skin prior to placing the electrodes.

2.   Attach snap or clip to the electrodes and attach the electrodes to the patient as described below.

3.   Switch on the monitor.

13.8.3 Installing Electrode for RESP Measurement

Placing the Electrodes for Respiratory Monitoring
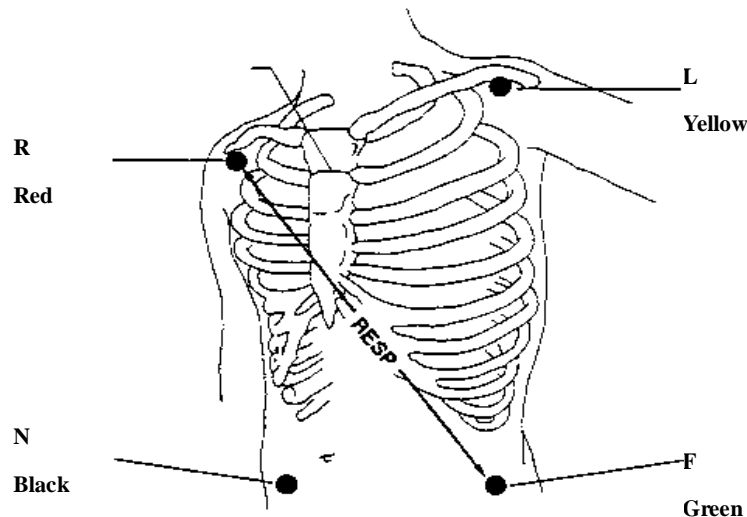
Figure 13-15 Electrodes Placement (5-lead)

NOTE:
1. Place the red and green electrodes diagonally to optimize the respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes so as to avoid cardiac overlay or artifacts from pulsating blood flow. This is particularly important for neonates.

2. Some patients, especially neonates, expand their chests laterally. In these cases it is best to place the two respiratory electrodes in the right midaxillary and left lateral chest areas at the patient's maximum point of breathing movement to optimize the respiratory wave.

13.8.4 RESP SETUP

Pick RESP hot key on the screen to call up the following menu:

Figure 13-16 RESP Setup

RESP alarm setting

◆ **ALM**: pick **ON** to enable prompt message during the RESP alarm; pick **OFF** to disable the alarm function, and there will be a ![x icon] besides "**RESP**".

WARNING

In order to avoid endangering the patient's life, the user should use this function cautiously.

◆ **ALM LEV**: selectable from **HIGH, MED** and **LOW**. Level **HIGH** represents the most serious case.

◆ **ALM REC**: pick **ON** to enable report printing upon RESP alarm.

◆ **ALM HI**: used to set up the upper alarm limit.

◆ **ALM LO**: used to set up the lower alarm limit.

RESP alarm is activated when the respiration rate exceeds set **ALM HI** value or falls below **ALM LO** value.

◆ **APNEA ALM**: to set the standard of judging an apnea case. It ranges from 10 to 40 seconds, and increases/decreases by 5.

◆ **RESP LEAD**: set the lead type to lead Ⅰ or Lead Ⅱ for respiration.

   Lead Ⅰ : Placing the leads on **R-L** (RA-LA) can measure the thoracic breathing.

   Lead Ⅱ : Placing the leads on **R-F** (RA-LL) can measure the abdominal breathing.
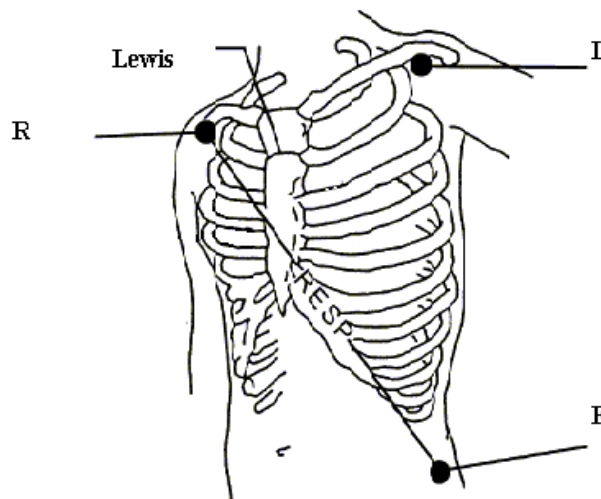
Figure 13-17 Install RESP leads

◆ **SWEEP**: Available options for **RESP SWEEP** are 6.25, 12.5, 25.0 and 50.0 mm/s.

◆ **WAVE AMP**: The user may set up the displaying amplitude of the RESP waveform. The selections are **0.25/0.5/1/2/3/4/5**.

◆ **HOLD TYPE**: can be set to **AUTO** or **MANUAL**. When it is set to **AUTO** mode, the **HOLD HI** and **HOLD LO** are unavailable, and the monitor can calculate the respiration rate automatically. When it is set to **MANUAL** mode, you can adjust the broken lines in RESP area by the **HOLD HI** and **HOLD LO** items.

◆ **HOLD HI/LO**: when the **HOLD TYPE** is **MANUAL**, you can adjust the broken lines for higher or lower limit of the respiration rate.

◆ **DEFAULT**: pick this item to access the **RESP DEFAULT CONFIG** dialog box, in which the user may select whether the **FACTORY DEFAULT CONFIG** or the **USER DEFAULT CONFIG** is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.

Figure 13-18 RESP default configuration

WARNING

The respiration sensitivity will descend after using the defibrillation cable, and the "**4**" mode is recommended in the **WAVE AMP**.

Chapter 14 Monitoring SpO$_2$

14.1 Overview

SpO$_2$ is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO$_2$ measuring unit. SpO$_2$ Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. The SpO$_2$ parameter can also provide a pulse rate (PR) and a plethysmogram wave (Pleth).

14.2 SpO$_2$ Safety Information

WARNING

1   Do not use the SpO$_2$ sensors if the packaging or the sensor is damaged and return them to the vendor.

2   If the SpO$_2$ sensor can not work properly, please reconnect the sensor or change a new one.

3   Use only the manufacturer's permitted sensors and extension cables with the monitor. Other sensors or extension cables may cause improper monitor performance and/or minor personal injury.

4   High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the high limit alarm off.

5   When serious arrhythmia is present, the SpO$_2$ pulse rate may differ from ECG heart rate but this does not indicate an inaccurate PR (SpO$_2$) value.

6   Correct and proper sensor application: if the sensor is too loose, it might compromise the optical alignment, and even cause the sensor to fall off. If the sensor is too tight, (such as the application site is too large or becomes too large due to edema), excessive pressure and local tissue ischemia, hypoxia and lack of nutrition may occur on the application site. Prolonged and continuous monitoring may increase the risk of Skin irritations or lacerations. To avoid these damages, users should periodically check surrounding skin of application site according to the patient's condition and pressure sensor, inspect if there is sign of stress-related damage in surrounding tissue, and regularly change the application site. For the patients whose fluid is easy to transfer and/or the patients with systemic or localized edema, users should inspect the skin and change application site more frequently.

NOTE:

1   SpO$_2$ value always displays at the same position. Pulse Rate will display when **HR FROM** is set to "**SpO$_2$**", No ECG signal when **HR FROM** is set to AUTO.

2   Avoid placing the sensor on extremities with an arterial catheter, or intravascular

venous infusion line.

3   When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.

4   SpO$_2$ waveform is not directly proportional to the pulse volume.

5   The device is calibrated to display functional oxygen saturation.

6   Functional tester or simulator can not be used to assess the SpO$_2$ accuracy.

7   The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1: 2009.

14.3 Monitoring Procedure

1. Switch on the monitor.
2. Attach the sensor to the appropriate site of the patient finger.
3. Plug the connector of the sensor extension cable into the SpO$_2$ socket on the monitor.
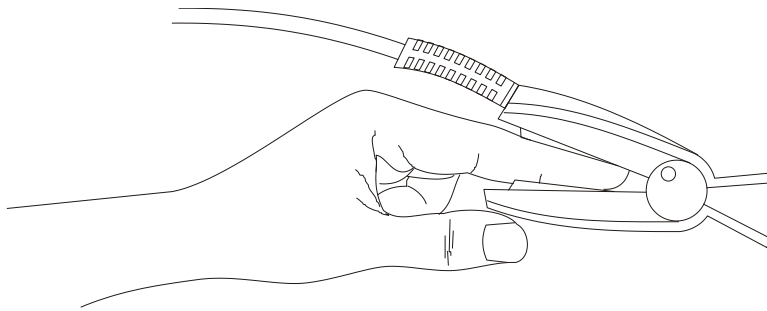
Figure 14-1 Mounting of the Sensor

WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours. For neonate, change the measuring site every 20 minutes.

NOTE:

1. Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.

2. Inspect the sensor to ensure that the light emitter and receiver are aligned with each other and there is no gap between the sensor and the finger. All the light emitted by the light emitter must pass through the patient's tissue. The sensor cable should be placed on the back of the hand.

3. Clean and remove any substances such as nail polish from the application site.

14.4 Measurement Limitations

Certain patient conditions can affect the measurements and cause the loss of the pulse signal.

Inaccurate measurements can be caused but not limited by:

- incorrect sensor application

- high levels of ambient light sources, such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight

- failure to cover the sensor with opaque material in high levels of ambient light conditions

- dysfunctional hemoglobins

- low peripheral perfusion

- excessive or violent patient movement

- venous pulsations

- intravascular dyes, such as indocyanine green or methylene blue

- externally applied coloring agents (nail polish, dye, pigmented cream)

- defibrillation

- placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

- electromagnetic interference

Loss of pulse signal can occur for the following reasons:

- the sensor is applied too tightly

- a blood pressure cuff is inflated on the same extremity as the one with the sensor attached

- there is arterial occlusion proximal to the sensor

- low peripheral perfusion

14.5 Assessing the Validity of a SpO$_2$ Reading

You can check the quality of the pleth wave and the stability of the SpO$_2$ values to assess whether the sensor functions properly and whether the SpO$_2$ readings are valid. Always use these two indications simultaneously to assess the validity of a SpO$_2$ reading.

Generally, the quality of the SpO$_2$ pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO$_2$ values also reflects the signal quality. Different from varying SpO$_2$ readings caused by physiological factors, unstable SpO$_2$ readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO$_2$ readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

NOTE:

1. The SpO$_2$ accuracy has been validated in controlled human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies composed of local healthy men and women from age 19 to 37, with various skin pigmentations. Note that the study population was healthy adults and not in the actual intended use population.

2. The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).

14.6 SpO$_2$ Alarm Delays

There is a delay between a physiological event at the measurement site and the corresponding alarm at the monitor. This delay has two components:

1. The time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing time and the sensitivity. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.

2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the monitor. This delay is the combination of the configured alarm delay time plus the general system delay time.

14.7 Perfusion Index (PI)

PI, a numeric value indicating perfusion level, reflects the pulse strength at the monitoring site.

As the measurement of SpO$_2$ is based on the pulsation caused by the blood flow through the vessel, PI is in relation to the strength of the pulse. Also, you can use PI as a signal quality indicator for the measurement of SpO$_2$.

It is indicated by a value ranging from 0 to 10. The bigger the value is, the stronger the signal is. The signal quality is at a maximum when the value reaches 10. When PI is below 2, it indicates the weak pulse at the monitoring site; you need to reposition the sensor or find a better site.

The PI value will be displayed in the SpO$_2$ waveform area.

14.8 SpO$_2$ SETUP

Pick the SpO$_2$ hot key on the main screen to open the **SpO$_2$ SETUP**.

WARNING
Setting the SpO$_2$ upper alarm limit to 100% is equivalent to switching off the alarm on upper limit. High oxygen levels may predispose a premature infant to retrolental fibroplasia. Therefore, the upper alarm limit for oxygen saturation must be carefully selected in accordance with commonly accepted clinical practices.

SpO$_2$ Alarm Setting

◆ **ALM**: pick **ON** to enable prompt message during the SpO$_2$ alarm; pick **OFF** to disable the alarm function, and there will be a besides "**SpO$_2$**".

WARNING

In order to avoid endangering the patient's life, the user should use this function cautiously.

◆ **ALM LEV**: used to set up alarm level, selectable from **HIGH, MED. HIGH** represents the most serious case.

◆ **ALM REC**: pick **ON** to enable report printing upon SpO$_2$ alarm.

◆ SpO$_2$ alarm is activated when the result exceeds **SpO$_2$ ALM HI** value or falls below **SpO$_2$ ALM LO** value. Use the knob to pick the **SpO$_2$ ALM HI** or **SpO$_2$ ALM LOW** item and turn the knob to select the desired alarm limit.

◆ PR alarm is activated when the pulse rate exceeds **PR ALM HI** value or falls below **PR ALM LO** value. Use the knob to pick the **PR ALM HI** or **PR ALM LOW** item and turn the knob to select the desired alarm limit.

◆ **SWEEP**

Available options for **SpO$_2$ SWEEP** are **6.25, 12.5**, **25.0** and **50.0mm/s**.

◆ **PR SOUND**

It indicates the Pulse beep volume. Options are "0 - 5". Pulse frequency has positive correlation with measurement value.

◆ **PITCH TONE**

When **ON** is enabled, the system will provide prompt sound with different tone for clinic under complex monitoring environment, based on the variance of SpO$_2$ value.

◆ **DEFAULT**

Pick this item to access the **SpO$_2$ DEFAULT CONFIG** dialog box, in which the user may select whether the **FACTORY DEFAULT CONFIG** or the **USER DEFAULT CONFIG** is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.
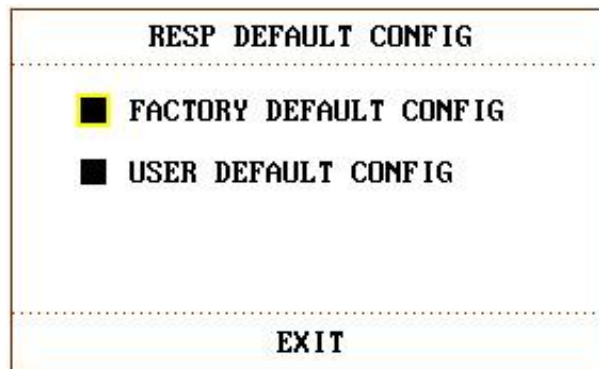
Chapter 15 Monitoring NIBP

15.1 Overview

This monitor uses the oscillometric method for measuring NIBP. It can be used for adult, pediatric and neonatal patients. It is also intended for use with pregnant, including pre-eclamptic patients.

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI/ISO 81060-2:2013) in relation to mean error and standard deviation.

15.2 NIBP Safety Information

WARNING
1   Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
2   Do not measure NIBP on the arm of the same side with a mastectomy.
3   Use clinical judgment to decide whether to perform frequent blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
4   Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
5   Do not attach the cuff to a limb being used for IV infusions as the cuff inflation can block the infusion, potentially causing harm to patient.
6   Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.
7   Ensure that the correct patient type is selected before performing measurements. Do not apply the higher adult inflation, overpressure limits and measurement duration for neonatal patients. Not using the neonate mode on a neonatal patient can block the blood flow, potentially causing harm to the patient.
8   Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
9   Measuring of blood pressure can temporarily cause malfunctioning of other medical monitoring devices on the same limb.

WARNING
10 NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.
11 Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.
12 Verifying the calibration is only applicable for adults, and it can not be operated in automatic measuring interval. Continuous measuring can not be operated in automatic measuring interval either.

NOTE:

1   It is suggested that the user should not start NIBP measuring when the low battery displays, or the monitor may be turned off automatically.

2   Please confirm the result by referring to patients' condition if the measurement fails or if the measurements are questionable.

3   Once the measurement limits are exceeded or patients' condition deteriorates, you may check if the tube is twisted or is blocked.

4   If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel.

5   Continuous use of the automatic measuring mode for short intervals may lead to the discomfort of patient. Continuous measuring and automatic measuring in neonatal or pediatric mode may result in tissue damage or ischemia to the patient.

6   NIBP measurement can be affected by extremes of temperature, humidity and altitude.

7   NIBP measurement value should be explained by qualified professionals.

8   The pulse rate based on the NIBP measurement may differ from the heart rate based on the ECG waveform. NIBP measures the number of peripheral pulse pulsations, and the heart rate is measured by the electrical signal of the heart. When the electrical signals of the heart occasionally fail to cause the peripheral blood vessels to pulse or the patient's peripheral perfusion is poor, the difference happens.

15.3 Measurement Limitations

Measurements are impossible with pulse rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible in the following situations:

● A regular arterial pressure pulse is hard to detect.

● Patients with cardiac arrhythmias.

● Patients with excessive and continuous movement such as shivering or convulsions.

● Patients with rapid blood pressure changes.

● Patients with severe shock or hypothermia that reduces blood flow to the peripheries.

● Patients with obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.

● Patients on an edematous extremity.

15.4 Measurement Methods

There are three methods of measuring NIBP:

● Manual - measurement on demand.

● Auto - continually repeated measurements (between 1 and 480 minute adjustable interval). After the first measurement starts manually, the monitor will automatically measure NIBP as preset interval.

● Sequence - the measurement will run consecutively in five minutes, then the monitor enters manual mode.

WARNING

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

15.5 Measurement Procedures

To obtain accurate measurements, the following operating steps need to be observed:

1. Ensure the patient position in normal use, including

◆ Comfortably seated (or lie flat on back), legs uncrossed;

◆ Feet flat on the floor;

◆ Back and arm supported;

◆ Middle of the cuff at the level of the right atrium of the heart

◆ During the measurement, relax as much as possible, neither talking nor applying external pressure against the cuff.

2. Plug in the air hose and switch on the system.

Apply the blood pressure cuff to the patient's arm or leg following the instructions below:
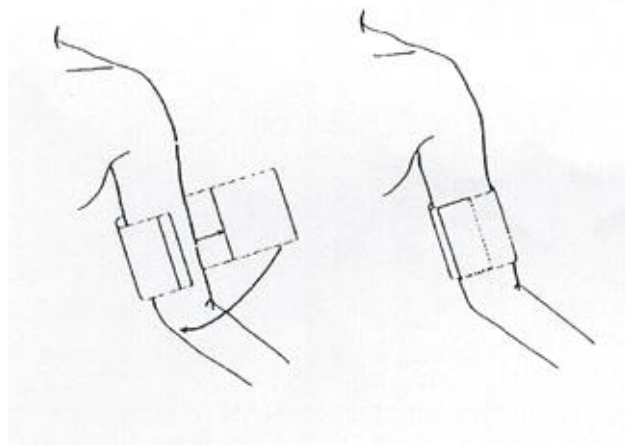
Cuff Usage

◆ Ensure that the cuff is completely deflated.

◆ Apply the appropriate size cuff to the patient. (About the cuff size selection, please refer to Section *NIBP Accessories*). And make sure that the symbol "Φ" is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremity.

◆ Make sure that the cuff edge falls within the range of the mark <->. If it does not, use a larger or smaller cuff that fits better.

3. Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible you should apply the following corrections to the measured values:

◆ If the cuff is not level with the heart, add 0.75 mmHg (0.10 kPa) to the displayed reading for each inch of elevation above the heart, or subtract 0.75 mmHg (0.10 kPa) from the displayed reading for each inch of elevation below the heart.

4. Check whether the patient mode is appropriately selected. Access **PATIENT SETUP** menu from **SYSTEM MENU** and pick **PAT TYPE** item and turn the knob to select the required patient type.

5. Select a measurement mode in the **NIBP SETUP** menu. Refer to the following paragraphs **Operation Hints** for details.

6. Press the "**Start**" button on the front panel to start a measurement.
7. Wait until the first reading is taken.

NOTE:
1. The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 80-100% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, use another cuff with suitable size to avoid errors.

2. If a NIBP measurement is suspected, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.

3. Please make sure the cuff is well connected. A leak of air may cause measurement error.

4. Please select the cuff with the suitable size. An unsuitable cuff may cause incorrect measurements.

5. Avoid incursion of liquid into the cuff. If this happens, please desiccate the cuff completely.

Operation Hints

1. To start auto measurement:
   Access **NIBP SETUP** menu and pick the **INTERVAL** item, in which the user may choose the options other than **MANUAL** to set up the time interval for auto measurement. After that, press the "**Start**" button on the front panel to start the **AUTO** measurement according to the selected time interval.

WARNING

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurement.

2. To stop auto measurement:
   During auto measurement, press the "Start" button on the front panel at any time to stop the auto measurement in process.

3. To start a manual measurement:

   ◆ Access **NIBP SETUP** menu and pick the **INTERVAL** item. Select the **MANUAL** option. Then press the **Start** button on the front panel to start a manual measurement.

4. To start a continuous measurement:
   Access the **NIBP SETUP** menu and pick the **CONTINUAL** item to start a continuous measurement. The continuous measurement will last 5 minutes.

WARNING

Prolonged non-invasive blood pressure measurements in CONTINUAL mode may be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

5. To stop a measurement:
   During measurement press the **Start** button on the front panel at any time to stop measurement.

NOTE:
If you are in doubt about the accuracy of any reading(s), check the patient's vital signs by an alternative method before checking the functioning of the monitor.

WARNING

If liquid is inadvertently splashed on the equipment or its accessories, or enters the conduit or inside the monitor, contact local Customer Service Center.

15.6 NIBP SETUP

Pick the NIBP hot key on the main screen to open the **NIBP SETUP**.

- **NIBP alarm setting**
  - **ALM**: pick **ON** to enable prompt message during the NIBP alarm; pick **OFF** to disable the alarm function, and there will be a besides **NIBP**.

WARNING

In order to avoid endangering the patient's life, the user should use this function cautiously.

  - **ALM LEV**: selectable from **HIGH, MED**. **HIGH** represents the most serious case.
  - **ALM REC**: pick **ON** to enable report printing upon NIBP alarm.
  - **SYS ALM HI, SYS ALM LO, MAP ALM HI, MAP ALM LO, DIA ALM HI, DIA ALM LO** are for the user to set up the alarm limit for each type of pressure. NIBP alarm is activated when the pressure exceeds the set upper alarm limit or falls below lower alarm limit.

- **UNIT**

  Options include **mmHg** and **kPa**.

- **INTERVAL**

  It is used to set time interval for automatic measuring. Available selections include **1/2/3/4/5/10/15/30/60/90/120/240/480** min. Press **START** button to start the first auto measuring. Pick **MANUAL** selection in **INTERVAL** item to set up the measuring mode to **MANUAL**.

- **CONTINUAL**

  It is used to start continuous measuring. Once this function is activated, the menu will not be shown on the screen and continual measurement will perform immediately.

- **DEFAULT**

  It enables you to access the menu for default configuration of NIBP. Two options are available: factory default config and user default config. A dialog box will pop up for your confirmation after either option is selected.

15.7 Resetting NIBP

When the pressure does not work properly and the system fails to give a message for the problem,

click on **RESET** via **USER MAINTAIN > NIBP MAINTAIN** to activate self-test procedure, and thus restore the system from abnormal performance.

15.8 Calibrating NIBP

NIBP is not user-calibrated. NIBP pressure transducers must be verified at least once every two years by a qualified service professional, and calibrated, if necessary. See the Service Manual for details.

15.9 Leak Test

This item is used for leak test. Turn the knob to pick the **LEAK TEST** item in the **USER MAINTAIN > NIBP MAINTAIN** menu to start the air leakage test. When the item is selected, it will change into **STOP LEAK TEST**. If this item is selected again, the system will stop air leakage test. And the item returns to **LEAK TEST**.

WARNING

This pneumatic test other than being specified in the EN 1060-1 standard is to be used by the user to simply determine whether there are air leaks in the NIBP airway. If at the end of the test the system gives the prompt that the NIBP airway has air leaks, please contact the manufacturer for repair.

Procedure of Leak Test

● Connect the cuff securely with the socket for NIBP air hole.

● Wrap the cuff around the cylinder of an appropriate size.

● Access **USER MAINTAIN > NIBP MAINTAIN**.

● Turn the knob to the **LEAK TEST** item and press the item. Then the prompt of **Leak testing…** will appear indicating that the system has started performing leak test.

The system will automatically inflate the pneumatic system to about 180 mmHg. After 20 seconds to 40 seconds, if system leakage has detected, the system will automatically open the deflating valve to stop the leak test and indicates NIBP Leak. If no system leakage is detected when the pneumatic system is inflated to 180 mmHg, the system will perform a deflation to an approximate value of 40 mmHg and subsequently perform the second phase leak test. After 20 seconds to 40 seconds, the system will automatically open the deflating valve and provide corresponding indication based on the test result.

● If the prompt of **Leak test over** appears, it indicates that the airway is in good situation and no air leaks exist. However if the alarm information of **NIBP AIR LEAK** appears, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the pneumatic test. If the failure prompt still appears, please contact the manufacturer for repair.
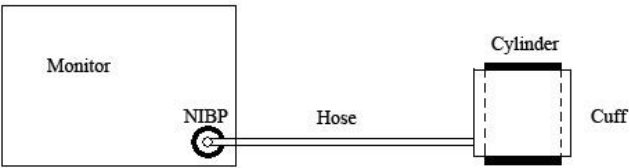
Diagram of NIBP Air Leakage Test

Chapter 16 Monitoring TEMP

16.1 TEMP Monitoring

Body temperature is measured by means of a thermistor probe (a semiconductor whose resistance changes with temperature) that is applied to the skin or to the rectum.

Two TEMP probes can be used simultaneously to measure two TEMP values, and get the temperature difference. The standard configuration is axilla sensor for adult.

The reference body site temperature is the same as the temperature of the measuring site.

TEMP Monitoring Setup

◆ With a reusable TEMP probe you can plug the probe directly into the TEMP connector.

◆ Apply the TEMP probes securely to the patient.

◆ Switch on the monitor.

It takes 5 minutes for the temperature measurement to stabilize.

WARNING

1 Verify probe cables fault detection before the beginning of monitoring phase. Unplug the temperature probe cable of the channe1 from the socket, and then the screen will display the error message **TEMP1 SENSOR OFF** and the audible alarm is activated. It is the same to the other channel.

2 Take the TEMP probe and cable carefully. When they are not in use, you should coil up the probe and cable into a loose circle. If the wire inside the cable is tensely pulled, it may cause mechanical damage to the probe and the cable.

3 Verification of the temperature module is necessary as frequently as dictated by your Hospital Procedures Policy. When you need to calibrate the temperature measurement, please contact the manufacturer.

16.2 TEMP SETUP

Pick the **TEMP** hot key on the screen to call up the **TEMP SETUP** menu shown as below:

```
                    ┌──────────────────────────────────────┐
                    │            TEMP SETUP                 │
                    │ ······································ │
                    │  ALM        ┌────┐    T2 ALM HI   39.0│
                    │             │ ON │                    │
                    │             └────┘                    │
                    │  ALM LEU     MED      T2 ALM LO   36.0│
                    │                                       │
                    │  ALM REC     OFF      TD ALM HI    2.0│
                    │                                       │
                    │  T1 ALM HI   39.0     TEMP UNIT   °C  │
                    │                                       │
                    │  T1 ALM LO   36.0     DEFAULT >>      │
                    │                                       │
                    │                                       │
                    │ ······································ │
                    │               EXIT                    │
                    └──────────────────────────────────────┘
```

Figure 16-1 TEMP SETUP

◆ **ALM**: pick **ON** to enable prompt message during the TEMP alarm; pick **OFF** to disable the alarm function, and prompt the ❌ symbol besides TEMP numeric.

WARNING

In order to avoid endangering the patient's life, the user should use this function cautiously.

◆ **ALM LEV**: used to set up the alarm level, selectable from **HIGH**, **MED** or **LOW**.
◆ **ALM REC**: used to start/stop recording TEMP alarms. Pick **ON** to enable report printing upon TEMP alarm.
◆ Alarm for T1, T2, TD occurs when the measured temperature exceeds the set alarm upper limit or falls below alarm lower limit.

T1 represents the TEMP of Channel 1, T2 represents the TEMP of Channel 2, TD represents the TEMP difference of T1 and T2.

◆ **UNIT**: To set temperature unit (℃ or ℉).
◆ **DEFAULT**: Pick this item to access the **TEMP DEFAULT CONFIG** dialog box, in which the user may select whether the **FACTORY DEFAULT CONFIG** or the **USER DEFAULT CONFIG** is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.

Chapter 17 Monitoring IBP (Optional)

17.1 Introduction

The monitor measures direct blood pressure (SYS, DIA and MAP) of one selected blood vessel through two channels, and displays two waveforms of measured direct blood pressure (SYS, DIA and MAP).

The available pressure labels are:

Label	Definition
ART	Arterial Blood Pressure
PA	Pulmonary Artery Pressure
CVP	Center Venous Pressure
RAP	Right Atrial Pressure
LAP	Left Atrial Pressure
ICP	Intracranial Pressure
P1-P2	Alternative non-specific pressure labels

17.2 IBP Safety Information

WARNING

1   The operator should avoid contact with the conductive parts of the appurtenance when it is connected or applied.

2   When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided from conductive connection to the HF equipment. This is to protect against burns to the patient.

3   Disposable IBP transducer or domes should not be reused.

4   If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or enters the transducer or the monitor, contact the Hospital Service Center immediately.

5   All invasive procedures have risks to the patient. Use aseptic technique and follow catheter manufacturer's instructions.

6   Mechanical shock to the invasive blood pressure transducer may cause severe shifts in zero and calibration, and then cause erroneous readings.

NOTE:

1 Use only the pressure transducer listed in the IBP Accessories.

2 If measuring intracranial pressure (ICP) on a sitting patient, adjust the transducer on the same level with the top of the patient's ear. Incorrect leveling may lead incorrect values.

3 Confirm you set correct alarm limit for labels, the alarm limit you set are stored for its label only. Changing label may change the alarm limit.

4 Don't perform IBP calibration when a patient is being monitored.

5 When using high frequency ventilation, make sure that the ventilator catheter is not connected to or indirectly connected to the arterial catheter at zero pressure. This can lead to less pressure variations, thus interfere the zeroing process.

The specified transducer is designed to have the special ability to protect against the electricity shock (especially for the leak current allowed), and it is protected against the effects of a discharge of a cardiac defibrillator. It can be used in the surgical operation. When the patient is in the defibrillation, the waveform of the pressure maybe distorted temporarily. After the defibrillation, the monitoring will go on normally, and the operation mode and the user configuration are not affected.

WARNING

1 Verify transducer cables fault detection before the beginning of monitoring phase. Unplug the transducer of the channel 1 from the socket, and then the screen will display the error message **IBP1 SENSOR OFF** and the audible alarm is activated. The channel 2 is the same as the above channel 1.

2 If any kind of liquid, other than solution to be infused in pressure line or transducer, is splashed on the equipment or its accessories, or enters the transducer or the monitor, contact the Hospital Service Center immediately.

NOTE:

Calibrate the instrument either whenever a new transducer is used, or as frequently as dictated by your Hospital Procedures Policy.

17.3 Monitoring Procedure

Preparatory steps for IBP measurement:

1. Plug the pressure cable into the corresponding socket and switch on the monitor.

2. Prepare the flush solution.

3. Flush through the system, exhaust all air from the tube, ensure that the transducer and stopcocks are free of air bubbles.

4. Connect the patient catheter to the pressure line, making sure that there is no air present in the catheter or pressure line.

5. Position the transducer so that it is at the same level with the patient's heart, approximately mid-axillary line.

6. Check if you have selected the correct label name. See the next section for details.

7. Zero the transducer. See the next section for details.

WARNING

If there are air bubbles in the tube system, you should flush the system with the solution again. The bubbles may cause erroneous pressure readings.
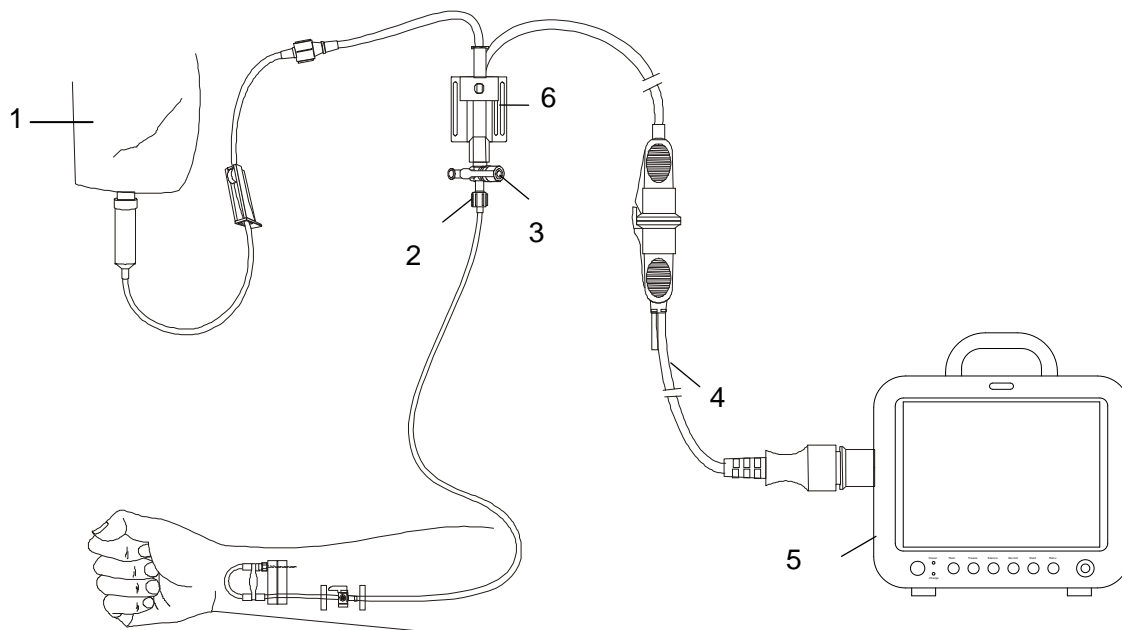
1: Normal Saline with Heparin; 2: Distal end to patient; 3: 3-way stopcok; 4: Pressure transducer interface cable; 5: Monitor; 6: Pressure transducer.

Figure 17-1 IBP Monitoring

17.4 IBP Menu

Pick the IBP hot key on the screen to access the **IBP SELECT** menu shown as follows:
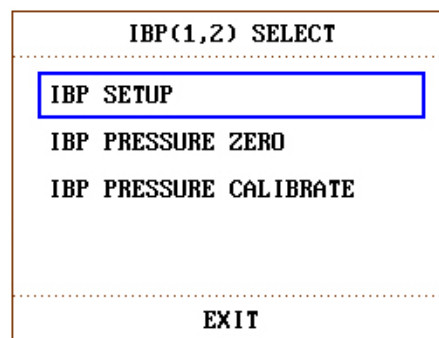
Figure 17-2 IBP SELECT Menu

Pick the **IBP SETUP** item to call up the **IBP SETUP** menu shown as follows:

```
                        IBP(1,2) SETUP
.................................................................
   ALM          ON        FILTER        12.5 HZ

   ALM LEV      MED        CALC MODE     REALTIME

   ALM REC      OFF        ALM LIMIT SETUP >>

   AMP ADJUST   MANUAL     SCALE ADJUST >>

   SWEEP        25.0       DEFAULT >>

   UNIT         mmHg


.................................................................
                         EXIT
```

Figure 17-3 IBP SETUP Menu

The items to be set up in the menu include:

◆ **ALM**: select **ON** to enable alarm prompt during IBP alarm. Select **OFF** to disable audio alarm and prompt the [X] symbol beside **IBP** numeric.

WARNING

In order to avoid endangering the patient's life, the user should use this function cautiously.

◆ **ALM LEV**: set the alarm level. Two levels are available: **HIGH** and **MED.**

◆ **ALM REC**: select **ON** to enable recording during the IBP alarm or to **OFF** to disable the alarm recording function.

◆ **AMP ADJUST**: set to adjust waveform amplitude. Two selections are available: **MANUAL, AUTO**. Set it to **AUTO**, the pressure names of IBP become P1 and P2, and the IBP scale is adjusted by system automatically. Set it to **MANUAL**, the pressure names of IBP can choose one of **ART, PA, CVP, RAP, LAP, ICP, P1, P2** and the IBP scale is adjusted by the user via **SCALE ADJUST** item.

◆ **SWEEP**: set to select the scanning speed of the IBP wave. Four selections are available: **6.25mm/s**, **12.5 mm/s**, **25 mm/s** or **50.0mm/s**.

◆ **UNIT**: set to select the pressure unit (mmHg, kPa, or cmH2O).

◆ **FILTER**: set this item to **12.5Hz** or **40.0 Hz**.

◆ **ALM LIMIT SETUP**: used to access the sub-menu of **IBP ALM LIMIT SETUP**, in which the user may set up the upper and lower alarm limits of systolic pressure, diastolic pressure and mean pressure respectively for channel 1 and channel 2.

◆ **SCALE ADJUST**: used to access the sub-menu of **IBP SCALE ADJUST**, in which the user may adjust the position of the high, reference and low scales for the two waveforms displayed on the screen.

◆ **DEFAULT**: used to access the **IBP DEFAULT CONFIG** dialog box, in which the user may select whether the **FACTORY DEFAULT CONFIG** or the **USER DEFAULT CONFIG** is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.

◆ **EXIT**: used to exit the menu and return to the main interface.

WARNING

Before setting the alarm limits, confirm to choose the correct label.

```
              IBP ALM LIMIT SETUP

                        SYS      MAP      DIA

   CH1:ART ALM HI        160      110      90

   CH1:ART ALM LO         90       70      50

   CH2:CVP ALM HI        ---       10      ---

   CH2:CVP ALM LO        ---        0      ---



   ┌─────────────────────────────────────────┐
   │                  EXIT                   │
   └─────────────────────────────────────────┘
```

Figure 17-4 IBP ALM LIMIT SETUP

The alarm occurs when the value exceeds the set limits.

IBP Transducer Zero

Press the **IBP PRESSURE ZERO** button on the **IBP SELECT** menu to call up **IBP PRESSURE ZERO** menu as shown below:

```
            IBP PRESSURE ZERO

       Being Prepared,Press ZERO key!

   ┌──────────────┐
   │  CH1 ZERO    │    00-00-0000 00:00:00
   └──────────────┘


      CH2 ZERO         00-00-0000 00:00:00



                  EXIT
```

Figure 17-5 IBP PRESSURE ZERO

NOTE:

It is the responsibility of the user to ensure that a zero procedure has recently been done on the transducer: otherwise there will be no recent, valid zero value for the instrument to use, which may result in inaccurate measurement results.

Zero Calibration of Transducer

Select CH1, and then IBP1 returns to zero. Select CH2, and then IBP2 returns to zero.

CAUTION

1   Turn off the patient stopcock before you start the zero procedure.

2   The transducer must be vented to atmospheric pressure before the zero procedure.

3   The transducer should be placed at the same height level with the heart, approximately mid-axillary line.

4   Zero procedure should be performed before the monitoring starts, and at least once a day after each disconnect-and-connect of the cable.

The prompt information related to zero calibration, take CH1 for example.

◆ "**CH1 ZERO SUCCESS!**"

Indicate that zero calibration is over，so you can turn off the stopcock that was open to atmospheric pressure, and turn on the patient stopcock.

◆ "**CH1 ZERO FAIL!**"

Make sure that the transducer is not attached to the patient.

◆ "**CH1 SENSOR OFF, FAIL!**"

Make sure that transducer is not off, and then proceed zeroing.

◆ "**IN DEMO, FAIL!**"

Make sure that the monitor is not in **DEMO** mode. Contact service technician if necessary.

◆ "**PRESSURE OVER RANGE, FAIL!**"

Make sure that the stopcock is vented to atmosphere. If the problem persists, please contact service technician.

IBP Calibration

Press the **IBP PRESSURE CALIBRATE** button on the **IBP (1, 2) SELECT** menu to call up the **IBP PRESSURE CALIBRATE** menu as shown below:

```
IBP PRESSURE CALIBRATE

CH1 CAL VALUE        26.7    CALIBRATE
0   ( 0  )   00-00-0000 00:00:00

CH2 CAL VALUE        26.7    CALIBRATE
0   ( 0  )   00-00-0000 00:00:00



            EXIT
```

Figure 17-6 IBP Calibration Menu

Calibrate the transducer:

Turn the knob to select the item **CH1 CAL VALUE,** press and turn the knob to select the pressure value to be calibrated for channel 1. Then turn the knob to select **CALIBRATE** in the menu to start calibrating channel 1.

Turn the knob to select the item **CH2 CAL VALUE,** press and turn the knob to select the pressure value to be calibrated for channel 2. Then turn the knob to select **CALIBRATE** in the menu to start calibrating channel 2.

◆   The pressure calibration of the portable patient monitor
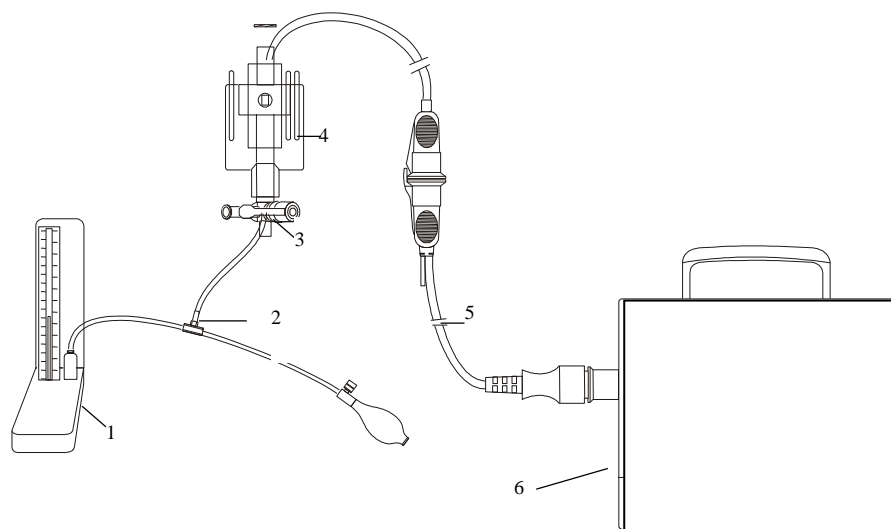
1: Hydrargyrum pressure meter; 2: 3-way connector; 3: 3-way stopcock; 4: Pressure transducer; 5: Pressure transducer interface cable; 6: Monitor

Figure 17-7 IBP Calibration

CAUTION

1 Mercury calibration should be performed by the biomedical engineering department either whenever a new transducer is used, or as frequently as dictated by your Hospital Procedures Policy.

2 The purpose of the calibration is to ensure that the system gives you accurate measurements.

3 Before starting a mercury calibration, a zero procedure must be performed.

4 If you need to perform this procedure yourself you will need the following equipment: Standard sphygmomanometer, 3-way stopcock and Tubing (approximately 25 cm long).

WARNING

It is forbidden to perform this procedure while patient is being monitored.

The Calibration Procedure: (See Figure 17-7)

1. Close the stopcock that was open to atmospheric pressure for the zero calibration.
2. Attach the tubing to the sphygmomanometer.
3. Ensure that connection that would lead to patient is off.
4. Connect the 3-way connector to the 3-way stopcock that is not connected to the patient catheter.
5. Open the port of the 3-way stopcock to the sphygmomanometer.
6. Select the channel to be calibrated in the menu and select the pressure value to which the IBP is to be adjusted.
7. Inflate to make the mercury bar rise to the setup pressure value.
8. Adjust repeatedly until the value in the menu is equal to the pressure value shown by the mercury calibration.
9. Press the Start button, the device will begin calibrating.
10. Wait for the calibrated result. You should take corresponding measures based on the prompt information.
11. After calibration, disassemble the blood pressure tubing and the attached 3-way valve.

The prompt information related to calibration, take CH1 for example.

◆ "**CH1 CAL SUCCESS!**"

   Indicate that CH1 works normally, you can use CH1 to monitor the patient.

◆ "**CH1 CAL FAIL!**"

   Make sure that pressure value shown by hydrargyrum pressure meter is change- less.

◆ "**CH1 SENSOR OFF, FAIL!**"

   Make sure that sensor is not off, then start the calibration.

◆ **"IN DEMO, FAIL!"**

Make sure that the monitor is not in **DEMO** mode. Contact service technician if necessary.

◆ **"PRESSURE OVER RANGE, FAIL!"**

Make sure that you have selected transducer value in **IBP CAL**, then start the calibration.

IBP SCALE ADJUST Submenu

```
        IBP SCALE ADJUST

              HI      LO      VAL

  CH1:ART    20.0    0.0     10.0

  CH2:CVP     5.3    0.0      2.7



              EXIT
```

Figure 17-8 IBP SCALE ADJUST Menu

The waveform and corresponding scale appears in the IBP Waveform Area with 3 dotted lines representing High Limit Scale, Reference Scale, and Low Limit Scale from the top to the bottom. Values of the three scales can be user-set according to the instruction given below.

◆ IBP label: selectable from **ART, PA, CVP, RAP, LAP, ICP, P1, P2;**
◆ **HI**: IBP value of High Limit scale, its range is the measuring range of the current pressure.

NOTE:
The HI value must be higher than the LO value.
◆ **LO**: IBP value of Low Limit scale, its range is the measuring range of the current pressure.

NOTE:
The LO value must be lower than the HI value.
◆ **VAL**: IBP value of Reference scale (between HI and LO).

NOTE:
When change HI scale, Low scale or Reference scale of IBP waveform and the corresponding IBP waveforms are displayed under the menu window, the waveform will come penetratingly through the menu window for observing.

Chapter 18 Monitoring CO_2 (Optional)

18.1 General

This chapter offers some relevant data concerning CO_2 monitoring.

The monitor provides the Sidestream and MainStream method for CO_2 monitoring. EDAN $EtCO_2$ module and Respironics Sidestream CO_2 module are used for sidestream measuring, and Respironics Mainstream CO_2 module is used for mainstream measuring.

SideStream measurement takes a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with a remote CO_2 sensor. You can measure SideStream CO_2 using the monitor's built-in CO_2 measurement.

MainStream measurement uses a CO_2 sensor attached to an airway adapter directly inserted into the patient's breathing system.

The CO_2 module can be applied in an operation room, monitor units etc. It can measure the CO_2 partial pressure or concentration of patient Air Way, obtain End tidal CO_2 ($EtCO_2$), Fraction of inspired CO_2 ($FiCO_2$), and Air Way Respiration Rate (AwRR), and display CO_2 concentration waveforms. The parameter symbols displayed on the screen are defined as follows:

CO_2:	$EtCO_2$
FI:	$FiCO_2$
AWRR:	Air Way Respiration (AwRR) (Resp. times/min)

WARNING

1   CO_2 module shall be avoided from crash and vibration.
2   Do not use the device in the environment with flammable anesthetic gas. For example, do not use it in the environment where flammable anesthetic is mixed with air, oxygen or nitrous oxide.
3   The device should be used by trained and qualified personnel who are familiar with the manual.
4   Nitrous oxide, elevated levels of oxygen, helium, xenon, halogenated hydrocarbons, and barometric pressure can influence the CO_2 measurement.
5   The accuracy of the CO_2 measurement will be affected by the following reasons: the airway was highly obstructed; the leakage of air way connection or quick variation of environment temperature.
6   Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from other equipment.
7   Do not place the sensor cables or tubing in any manner that may cause entanglement or strangulation.
8   Do not store the CO_2 Module at temperatures less than -40 ºF (-40 ºC) or greater than 158 ºF (70 ºC). Do not operate the CO_2 Module at temperatures less than 32 ºF (0 ºC) or greater than 104 ºF (40 ºC).

WARNING

9   The patient monitor will be damaged if the water quantity in the water trap reaches the limit.

10   The monitor will be damaged if any pipeline from the CO$_2$ module has been disconnected, or the air tube/air inlet/air outlet are plugged by water or other materials.

11   When using with mask, the measurement result may be relatively low due to O$_2$ supply.

12   When using mechanical ventilation, gas compensation should be well set. Inappropriate setting may cause incorrect measurement result.

13   Respironics module is not equipped with automatic air pressure compensation, before you start the CO$_2$ measurement for the first time, you must set the correct altitude. Incorrect altitude settings can cause incorrect CO$_2$ readings. EDAN EtCO$_2$ module is equipped with automatic air pressure compensation, and manual setting is not required.

14   Leakage in the respiratory system or sampling system may result in a significant low display of the etCO$_2$ value. Always keep all components connected firmly and check for leaks according to standard clinical procedures.

15   The etCO$_2$ reading is not always closely related to the paCO$_2$ value, especially in neonatal patients, and patients with pulmonary disease, with pulmonary embolism or inappropriate ventilation.

16   Don't measure CO$_2$ while nebulized medications are being delivered.

17   The CO$_2$ module temporally stops measuring during zeroing.

NOTE:

1. After the Low battery alarm is activated, please do not start the CO$_2$ measurement, or the monitor may be turned off for the low capacity of battery.

2. For disposal of hospital waste such as accumulated fluids, calibration gases, sampled gases, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

3. If the measurement or sensor fails, stop measurement before the qualified service personnel solves the problem.

18.2 Monitoring Procedure

The principle of CO$_2$ measurement is primarily based on the fact that CO$_2$ molecule can absorb 4.3μm infrared ray. Absorption intensity is proportional to CO$_2$ concentration of patient sample, the CO$_2$ concentration will compute according to the detecting CO$_2$ absorption intensity of patient sample. The relation between partial pressure and percentage of CO$_2$ concentration is given below:

$$P \text{ (mmHg)} = \text{Percentage (\%)} \times \text{Pamp (Ambient Pressure)}$$

18.2.1 Zeroing the sensor

You must perform zeroing following the steps when using the new airway adapter.

1.   Expose the sensor to room air and keep it away from all sources of CO_2 including the ventilator, the patient's breath and the operator's.

2.   In the **CO₂ SETUP** menu, please set the **WORK MODE** to **MEASURE**.

3.   For EDAN module, select **User Maintain** > **CO₂ Maintain**, and click **Zero**, or select **ZERO CAL**. in the **CO₂ SETUP** menu. For Respironics modules, click **ZERO CAL**. in the **CO₂ SETUP** menu.

4.   The messages indicate: "**zeroing**", "**zero successfully**". After the zero calibration is finished, the user can start CO_2 Monitoring.

NOTE:
For EDAN module, automatic zero is performed when turning on the monitor.

18.2.2 Sidestream CO₂ Module

18.2.2.1 Measurement Steps

EDAN EtCO₂ module

1   Fix the water trap to the water trap holder on the right side of the monitor, confirm it is well fixed.

2   Connect the sampling cannula or the sampling line to the water trap.

3   Set **WORK MODE** to **MEASURE**.

4   For intubated patients, an airway adapter is required. For non-intubated patients, place the nasal cannula or the sampling mask onto the patient.

EDAN EtCO₂ Module Water Trap

CAUTION

1   The water trap collects water drops condensed in the sampling line and therefore prevents them from entering the module. If the water trap is nearly filled, you should replace it to avoid blocking the airway.

2   Based on a sample gas temperature of 37 °C, a room temperature of 23 °C and sample relative humidity of 100%, the water trap will be filled after approximately 90 hours with the flowrate of 100 ml/min and approximately 130 hours with the flowrate of 70 ml/min. In clinical practice, the water trap can be used for a longer time before it is filled. It is recommended to replace the water trap once every month.

3   When replacing the water trap or suspecting the measurement value, please check if the O-rings of the water trap holder are normal and well installed. If the O-rings get damaged or loose, contact the manufacturer's service staff.

4   To prevent the module from abnormal work, please ensure the water trap detection button is not mistakenly touched.

5   Please replace and discard the water trap when blocking. Don't reuse it, otherwise the reading is not accurate and even the device may be damaged.

NOTE:

1. Disconnect the water trap from the holder or set **WORK MODE** to **STANDBY** when the module is not in use.

2. To avoid patient cross infection, do not connect the exhaust tube to the ventilator circuit. If the sampled gas is returned to the breathing system, always use the bacterial filter of the sample gas return kit.

Respironics Sidestream Module

Figure 18-1 Respironics Sidestream Module

1   Plug the sensor cable into the monitor's CO$_2$ input connector. Allow the sensor two minutes for warm-up.

2   Connect the cannula, airway adapter, or sample line as appropriate, to the sensor. It will click into place when seated correctly.

Figure 18-2 Connecting Respironics Sidestream Module

3   To zero the sensor, please refer to zeroing the sensor.

4   For intubated patients requiring an airway adapter;
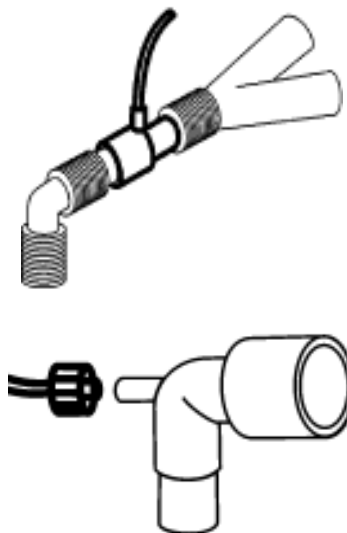
Figure 18-3 Air adapter

For non-intubated patients: Place the nasal cannula onto the patient.

Figure 18-4 Place the nasal cannula

NOTE:

1   You must perform a zero calibration as described in this procedure each time the ambient temperature changes more than 10 °C (for example during transport).

2   Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.

3   Always disconnect the cannula, airway adapter or sample line from the sensor when the sensor is not in use.

4   To extend the lifetime of the module, set **Work Mode** to **Standby** when the module is not in use.

5   The sidestream CO_2 module continuously extracts a quantity of gas from the patient's airway per minute. Please do not use this module in any patient who will be affected by this sampling rate.

6   If the catheter falls off during the measurement, it is necessary to re-zero after the catheter is well connected, and then measurement can be performed.

18.2.2.2 Removing Exhaust Gases from the System

WARNING

Do not connect the exhaust tube to the ventilator circuit, connect the outlet to a scavenging system, cross infection can occur if sampling gas is returned to the breathing system. When using the sidestream CO_2 measurement on patients who are receiving or have recently received anesthetics, please avoid exposing medical staff to anesthetics.

Use an exhaust tube to remove the sample gas to a scavenging system. Attach it to the sidestream sensor at the outlet connector.

18.2.3 Mainstream CO₂ Module

18.2.3.1 Measurement Steps

Respironics Mainstream Module

NOTE:
You must perform a zero calibration as described in this procedure each time you use a new airway adapter.

Figure 18-5 Respironics Mainstream CO$_2$ Module

1   Attach mainstream CO$_2$ module to the monitor.

2   Wait two minutes, allowing the sensor to reach its operating temperature and a stable thermal condition.

3   Choose the appropriate airway adapter and connect it to the sensor head. The airway adapter clicks into place when seated correctly.
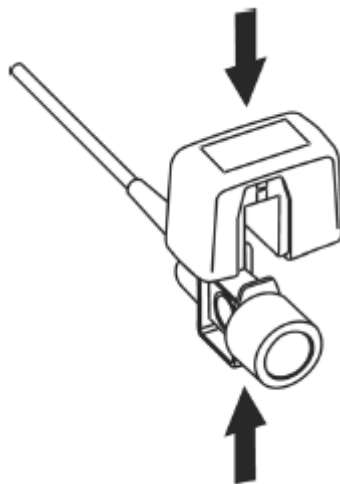
Figure 18-6 Connecting sensor

4   To zero the sensor, please refer to zeroing the sensor.

5   Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y-section.
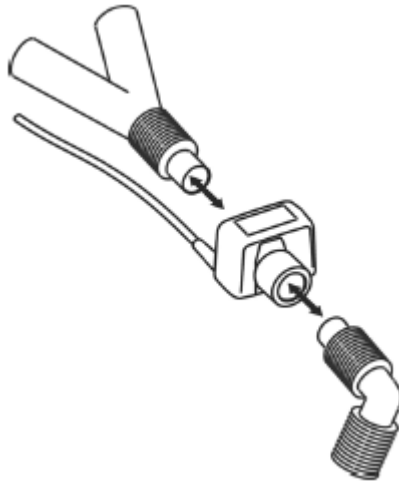
Figure 18-7 Connecting airway adapter

WARNING

1   No routine user calibration is required.

2   Accuracy is affected by temperature and barometric pressure.

NOTE：

1   If the catheter falls off during the measurement, it is necessary to re-zero after the catheter is well connected, and then measurement can be performed.

2   Replace the airway adapter if excessive moisture or secretions are observed in the tubing or if the CO$_2$ waveform changes unexpectedly without a change in patient status.

3   To avoid cross infection, only use disinfected or disposable airway adapters.

4   Inspect the airway adapters prior to use. Do not use if airway adapter appears damaged or broken. Observe airway adapter color coding for patient population.

5   Periodically check the flow sensor and tubing in case of excessive moisture or secretion buildup.

6   Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.

7   To avoid dead space, place the sensor as close to the patient as possible.

18.3 CO$_2$ SETUP

Parameter Setup and Adjustment

Turn the knob to select and press CO$_2$ hot key on the screen to activate **CO$_2$ SETUP**.

The items to be set up in the menu include:

◆ **ALM**: Select **ON** to enable and store alarm prompt when CO_2 parameters have alarms. Select **OFF** to disable alarm and display beside CO_2. The default is **ON**.

<div align="center">

WARNING

</div>

In order to avoid endangering the patient's life, the user should use this function cautiously.

◆ **ALM LEV**: Select from **HIGH, MED**. Level **HIGH** represents the most serious alarm, followed by Level **MED**. Change in **ALM LEV** can only affect the physiological alarm levels of CO_2 parameters including $EtCO_2$ upper limit, $EtCO_2$ lower limit, $FiCO_2$ upper limit, AwRR upper limit and AwRR lower limit. The default alarm level is **MED**.

◆ **ALM REC**: Select **ON** to generate output from the recorder ever since CO_2 parameter alarm occurs. The default value is **OFF**.

◆ **CO_2 ALM HI**: to adjust the upper alarm limit of $EtCO_2$. If the measuring value is larger than CO_2 upper alarm limit, **CO_2 HIGH** appears on the screen. After the measuring value returns to the normal one, the information disappears.

◆ **CO_2 ALM LO**: to adjust the lower alarm limit of $EtCO_2$. If the measuring value is smaller than CO_2 lower alarm limit, **CO_2 LOW** appears on the screen. After the measuring value returns to the normal one, the information disappears.

◆ **$FiCO_2$ ALM HI**: to adjust the upper alarm limit of $FiCO_2$. If the measuring value is larger than $FiCO_2$ upper alarm limit, **$FiCO_2$ HIGH** appears on the screen. After the measuring value returns to the normal one, the information disappears.

◆ **AWRR ALM HI**: to adjust the upper alarm limit of AwRR. If the measuring value is larger than the upper alarm limit of AwRR, **AWRR HIGH** appears on the screen. After the measuring value returns to the normal one, the information disappears.

◆ **AWRR ALM LO**: to adjust the lower alarm limit of AwRR. If the measuring value is smaller than the lower alarm limit of AwRR, **AWRR LOW** appears on the screen. After the measuring value returns to the normal one, the information disappears.

◆ **WORK MODE**: to change the work mode of CO_2 with between **MEASURE** and **STANDBY**. The default is **STANDBY**. When it is required to monitor CO_2, you should select **MEASURE**. In **STANDBY** mode, the air pump in SideStream module is disabled, which decreases the power consumption and extends the lifecycle of IR source and the whole CO_2 module.

NOTE:
When the CO_2 monitoring function is not in use, please set the **WORK MODE** to **STANDBY**.

◆ **UNIT**: to change the display units of CO_2 and $FiCO_2$ parameters. **mmHg** and **kPa** are available for selection.

◆ **APNEA ALM**: After selecting the alarm time for **APNEA** alarm (having 7 levels, which are

10S, 15S, 20S, 25S, 30S, 35S and **40S**), the **CO_2 APNEA** information will appear on the screen after the corresponding selected time. The alarm level is **HIGH**.

◆ **SWEEP**: to adjust the display rate of CO_2 waveforms with **6.25 mm/s, 12.5 mm/s ,25.0 mm/s** or **50.0 mm/s** selectable.

◆ **ZERO CAL**: used to perform CO_2 model zero calibration.
When a dramatic change in CO_2 measurement or the accuracy of reading is suspected by the clinician, please select "**ZERO CAL**" item, then the system will automatically inhale clean CO_2-free room air to the air inlet of CO_2 module beside the monitor, and start zero calibration.

◆ **Exit**: to exit **CO_2 SETUP** menu.

WARNING

Safety and effectiveness of the respiration measurement method in the detection of apnea, particularly the apnea of prematurity and apnea of infancy, has not been established.

NOTE:
1 **APNEA ALM** cannot be canceled.
2 When various alarms occur simultaneously, the alarm information of the highest level will be displayed on the screen.

◆ **DEFAULT >>**: pick this item to access the **CO_2 DEFAULT CONFIG** dialog box, in which the user may select whether the **FACTORY DEFAULT CONFIG** or the **USER DEFAULT CONFIG** is to be used. After selecting any of the items and exiting the dialog box, the system will pop up the dialog box asking for the user's confirmation.

◆ **OTHER SETUP**: pick this item in the menu to call up **CO_2 SETUP** submenu.

NOTE:
When using Respironics CO_2 module, **WATERVAPOR**, **BTPS**, **PUMP RATE**, and **COMPENSATE** are disabled, and cannot be selected.

The selection of functions available on your monitor depends on your monitor configuration. Now we introduce you to the functions of each item in **CO_2 SETUP** submenu.

■ **WAVE SCALE**: to adjust full scale size of CO_2 waveform display area with **LOW** or **HIGH** selectable. The default value is **LOW**.

■ **BARO PRESS**: to set the barometric pressure value. For gaining accurate readings, you should set this barometric pressure correctly.

■ **O_2 COMPENS**: to adjust the O_2 compensation concentration as per the selection of the user. Input the proper O_2 compensate value according to the O_2 concentration of the inhaled gas.

■ **N_2O COMPENS**: to adjust the N_2O compensation concentration as per the selection of the user. Input the proper N_2O compensate value according to the N_2O concentration of the inhaled gas. Only applicable to EDAN EtCO2 module.

■   **ANE AGENT**: to adjust the anaesthetic compensation concentration as per the selection of the user. The concentration ranges from 0% to 2.0%. Input the proper concentration value according to the anaesthetic gas concentration of the inhaled gas.

■   **BALAN GAS**: to balance the gas compensating operations. Select different compensating types for balancing gas. The compensation types are **ROOM AIR, N$_2$O** and **HELIUM**.

■   **WATERVAPOR**: determine whether to make watervapor compensate.

Water vapor compensation accounts for the effect of water vapor on the CO$_2$ IR (Infra-Red) absorption characteristics. The user may disable this compensation in certain situations. During normal operation, CO$_2$ measurements are adjusted mathematically to compensate for this effect.

The host may choose to disable this compensation when performing dry gas measurements in which the gas does not contain water vapor.

For EDAN EtCO$_2$ module, the water vapour compensation is **OFF** by default.

For Respironics CO$_2$ module, the water vapor compensation is **ON** by default and may be enabled or disabled via a host system command.

■   **BTPS**: The user may want to choose whether to correct values for gas that is at body temperature, ambient pressure and is saturated with water vapor (BTPS) or the ambient temperature and pressure and is dry (ATPD). BTPS compensation (Body Temperature and Pressure, Saturated) is a user-selectable compensation that accounts for the differences between the airway sample and "deep lung" CO$_2$. Since the intent is to report "deep lung" CO$_2$, where the sample is at 37℃ and fully saturated, BTPS compensates for the variance of water vapor content due to temperature. The BTPS compensation of CO$_2$ module is on by default.

■   **PUMP RATE**: to adjust the pump rate of the air pump in the CO$_2$ module. 70ml/min and 100ml/min are selectable, which is only applicable to EDAN EtCO$_2$ module.

■   **COMPENSATE**: to perform different compensate operations as per the selection of the user. The selections are **GENERAL, O$_2$, N$_2$O** and **ALL**. The work conditions for calculating compensation are shown in the following table. Here is the operation method. First, select the gas compensation to be used, including general compensation, O$_2$ compensate, N$_2$O compensate and ALL compensate. Then, determine whether to make VA compensate and BTPS compensate.

Work Conditions for CO$_2$ Calculation compensation:

Calculation Compensate Method	O$_2$ Modification	N$_2$O Modification	Work Conditions
General	OFF	OFF	O$_2$ 20%, no N$_2$O
O$_2$	ON	OFF	O$_2$ 80%, no N$_2$O
ALL	OFF	ON	O$_2$ 60%, N$_2$O 40%
N$_2$O	ON	ON	O$_2$ 40%, N$_2$O 60%

NOTE:

1   If Compensate item is not correctly set as per the operation conditions, the result will be far from the actual value, thus leading to severe misdiagnosis.

2   The default value of Water Vapor Compensate is on. Turn it off when measuring dry gas, such as when performing regular maintenance or measurement validation by using dry calibrated gas.

3   The default of BTPS is on. Turn it on when measuring the VA saturated "damp" gas at the body temperature and ambient pressure and turn it off when measuring the "dry" gas at the ambient temperature and pressure.

4   Operate by strictly observing the Compensate operation method.

5   The standard barometric pressure is 760mmHg, O$_2$ concentration is about 16%.

6   If the **ANE AGENT, O$_2$ COMPENS, BALAN GAS** are set incorrectly, the measure readings will deviate from the reality, leads to misdiagnosis.

7   The **ZERO CAL** needs about 20 seconds. During this period, you'd better not do other operations, such as respiration measuring. Or the zero calibration will fail, and you should do calibration operation again.

18.4 Setting CO$_2$ Corrections

Temperature, water vapor in the patient's breath, barometric pressure, and the proportions of O$_2$, N$_2$O and Helium in the mixture all influence CO$_2$ absorption. If values seem inaccurately high or low, check that the monitor is using the appropriate corrections.

For the EDAN sidestream module, the following items are available in the **CO$_2$ SETUP** > **OTHER SETUP** menu: **N$_2$O COMPENS**, **O$_2$ COMPENS**, **ANE AGENT**, **WATERVAPOR**, and **PUMP RATE**. The concentration of compensated gas should be set based on the current gas concentration which is supplied for patient. As for O$_2$ and N$_2$O, Make the supplied gas concentration multiply to its volume to get the concentration. For instance, supply 100% O$_2$, and its volume is 60%, then O$_2$ compensation is: 100%*60%=60%. AG concentration is decided by anaesthesia apparatus.

For the Respironics CO$_2$ modules, there are **BARO PRESS**, **O$_2$ COMPENS**, **ANE AGENT**, and **BALAN GAS** in **CO$_2$ SETUP** > **OTHER SETUP** menu. The concentration of compensated gas (including O$_2$ and AG) should be set based on the current gas concentration which is supplied for patient. The selection of balance gas depends on actual situation. For instance, N$_2$O should be selected as balance gas if the real balance gas is N$_2$O.

NOTE:

Make sure compensation value is correctly set, otherwise the measurement accuracy may be affected.

Chapter 19 Accessories

You can order accessories from the manufacturer's supplies or consult your local representative for details.

WARNING

1   Never reuse disposable transducers, sensors, accessories and their casing that are intended for single use; or only use them on a single patient. Reuse may compromise device functionality and system performance and cause a potential hazard.
2   Use only the manufacturer's approved accessories. Using accessories not approved by the manufacturer may compromise device functionality and system performance and cause a potential hazard. It is not recommended to use accessories supplied by the manufacturer with patient monitors by other manufacturers.
3   The specification of accessories recommended is listed below. Using other accessories may damage the monitor.
4   IBP sterilized accessories are already sterilized, refer to the package labelling for detailed method. Do not use a sterilized accessory if its casing is damaged.

NOTE：

1.   Transducers and sensors have a limited shelf life. Refer to the package labelling.
2.   The following cables may not all be available in all countries. Please check availability with your local supplier of the manufacturer.
3.   The following table lists the optional configuration for the monitor.
4.   The part name may vary depending on context, but the part number is constant.

The following accessories are recommended when using this monitor.

SpO_2	
02.01.210119	SH1 Adult Reusable SpO_2 Sensor (Lemo)
02.01.210120	SH1 Adult Reusable SpO_2 Sensor (DB9)
02.01.210673	SH3 Neonate Warp SpO_2 Sensor
02.01.210122	SH4 Adult Silicone Soft-tip SpO_2 Sensor
02.01.210121	SH5 pediatric Silicone Soft-tip SpO_2 Sensor
01.13.210001	SpO_2 adapter cable, standard (Lemo to DB9)
01.57.471235	Adult Single-Patient SpO_2 sensor SHD-A (forefinger, for patients over 30 kg)
01.57.471236	Pediatrics Single-Patient SpO_2 sensor SHD-P (forefinger, for patients between 10kg to 50 kg)

01.57.471237	Infant Single-Patient SpO$_2$ sensor SHD-I (big toe, for patients between 3kg to 20 kg)
01.57.471238	Neonate Single-Patient SpO$_2$ sensor SHD-N (foot, for patients less than 3 kg)
01.13.036336	SpO$_2$ adapter cable, extended (Lemo to DB9)
NIBP	
01.57.471326	NIBP Cuff, E5, Infant, 10 cm -15 cm, reusable
01.57.471327	NIBP Cuff, E6, Small child, 13 cm -17 cm, reusable
01.57.471328	NIBP Cuff, E7, Child, 16 cm -21.5 cm, reusable
01.57.471329	NIBP Cuff, E8, Small adult,20.5 cm -28 cm, reusable
01.57.471330	NIBP Cuff, E9, Adult, 27 cm -35 cm, reusable
01.57.471331	NIBP Cuff, E10, Large adult, 34 cm -43 cm, reusable
01.57.471005	NIBP Hose, Quick Connect to Quick Connect
01.57.471323	NIBP Cuff, Neonate, 10 cm-15 cm, reusable
01.57.471324	NIBP Cuff, Neonate, 6 cm-11 cm, reusable
01.57.471157	NIBP Cuff, neonatal #1, 3 cm -6 cm, for single patient use
01.57.471158	NIBP Cuff, neonatal #2, 4 cm -8 cm, for single patient use
01.57.471159	NIBP Cuff, neonatal #3, 6 cm -11 cm, for single patient use
01.57.471160	NIBP Cuff, neonatal #4, 7 cm -13 cm, for single patient use
01.57.471161	NIBP Cuff, neonatal #5, 8 cm -15 cm, for single patient use
01.57.471303	NIBP spiral Tube with connector
01.57.471291	NIBP Tube (3 m) with RECTUS quick connector
TEMP	
01.15.040257	Temperature Probe Skin, neonatal/Infant, 3 m, reusable
01.15.040258	Temperature Probe, rectal/oral, neonatal/Infant,3 m, reusable
01.15.040422	Neonatal/pediatric Skin Temperature Probe (10K)
01.15.040423	Neonatal/pediatric Rectal/Oral Temperature Probe (10K)
01.15.040185	Skin Temperature Probe (2.252 KΩ)
01.15.040184	Intracavitary Temperature Probe (2.252 KΩ)

01.15.040420	Skin Temperature Probe (10K)
01.15.040421	Rectal/Oral Temperature Probe (10K)
ECG	
01.57.471391	ECG Cable, IEC, 3 lead, 6 pin, snap, ESU-proof
01.57.471383	ECG Cable, IEC, 3 lead, 6 pin, snap, Defib
01.57.471390	ECG Cable, AHA, 3 lead, 6 pin, clip, ESU-proof
01.57.471382	ECG Cable, AHA,3 lead, 6 pin, clip, Defib
01.57.471384	ECG Cable, AHA,3 lead, 6 pin, snap, Defib
01.57.471389	ECG Cable, IEC, 3 lead, 6 pin, clip, ESU-proof
01.57.471381	ECG Cable, IEC, 3 lead, 6 pin, clip, Defib
01.57.471392	ECG Cable, AHA,3 lead, 6 pin, clip, ESU-proof
01.57.471230	ECG trunk cable, 5-lead, 6pin, ESU, AHA/IEC, 2.7 m, reusable
01.57.471231	ECG trunk cable, 5-lead, 6pin, ESU, AHA/IEC, 5.0 m, reusable
01.57.471232	ECG trunk cable, 5-lead, 6pin, defibrillator-proof, AHA/IEC, 2.7 m, reusable
01.57.471233	ECG trunk cable, 5-lead, 6pin, defibrillator-proof, AHA/IEC, 5.0 m, reusable
01.13.036620	ECG limb wires, 5-lead, clip, AHA, 1.0 m&1.6 m, reusable
01.13.036621	ECG limb wires, 5-lead, clip, AHA, 1.0 m, reusable
01.13.036622	ECG limb wires, 5-lead, snap, AHA, 1.0&1.6 m, reusable
01.13.036623	ECG limb wires, 5-lead, snap, AHA, 1.0 m, reusable
01.13.036624	ECG limb wires, 5-lead, clip, IEC, 1.0 m&1.6 m, reusable
01.13.036625	ECG limb wires, 5-lead, clip, IEC, 1.0 m, reusable
01.13.036626	ECG limb wires, 5-lead, snap, IEC, 1.0&1.6 m, reusable
01.13.036627	ECG limb wires, 5-lead, snap, IEC, 1.0 m, reusable
01.57.471461	3-lead, Clip, IEC, 1.0m, Reusable
01.57.471462	3-lead, Snap, IEC, 1.0m, Reusable
01.57.471463	3-lead, Clip, AHA, 1.0m, Reusable
01.57.471464	3-lead, Snap, AHA, 1.0m, Reusable

01.57.471469	5-Lead, 6-pin, Defib, Clip, IEC, 3.4m, Reusable
01.57.471470	5-lead, 6-pin, Defib, Clip, AHA, 3.4m, Reusable
01.57.471471	5-Lead, 6-pin, Defib, Snap, IEC, 3.4m, Reusable
01.57.471472	5-Lead, 6-pin, Defib, Snap, AHA, 3.4m, Reusable
01.57.471477	5-lead, 6-pin, ESU-proof, Clip, IEC, 3.4m, Reusable
01.57.471478	5-lead, 6-pin, ESU-proof, Clip, AHA, 3.4m, Reusable
01.57.471479	5-lead, 6-pin, ESU-proof, Snap, IEC, 3.4m, Reusable
01.57.471480	5-lead, 6-pin, ESU-proof, Snap, AHA, 3.4m, Reusable
01.57.471485	3-lead, 6-pin, ESU-proof, AHA/IEC, 2.7m, Reusable
01.57.471486	3-lead, 6-pin, ESU-proof, AHA/IEC, 5.0m, Reusable
01.57.471487	3-lead, 6-pin, Defib, AHA/IEC, 2.7m, Reusable
01.57.471488	3-lead, 6-pin, Defib, AHA/IEC, 5.0m, Reusable
01.57.471196	ECG limb cable, 3-lead, snap, AHA, 0.63 m, DIN, reusable
01.57.471198	ECG limb cable, 3-lead, clip, AHA, 0.63 m, DIN, reusable
01.57.471195	ECG limb cable, 3-lead, snap, IEC, 0.63 m, DIN, reusable
01.57.471197	ECG limb cable, 3-lead, clip, IEC, 0.63 m, DIN, reusable
01.57.471193	ECG trunk cable, 3-lead, 6 pin, defibrillator-proof, AHA/IEC, 2.9 m, DIN, reusable
01.57.471276	ECG conductive adhesive electrodes, TYCO KENDALL MEDI TRACE 210, 10PCS/package
01.57.471056	Adult disposable adhesive electrodes, TYCO H99SG, 30 PCS/package
01.57.471060	Adult disposable adhesive electrodes, TYCO Medi-Trace 200, 100 PCS/package
01.57.471057	Children/Neonatal disposable adhesive electrodes, TYCO H124SG, 50 PCS/package
01.57.002091	3-lead, 6-pin, Defib, AHA, Banana

CO$_2$	
For EDAN Module	
02.01.210520	Dewatering Cup(Single Patient Use, Adult/Pediatric 10ml)
01.57.471275	CO$_2$ Sampling Line with Male Luer Lock, 2.0m
01.57.471282	All Purpose Sampling Cannula without filter (Non Sterile). Size: Adult
01.57.471283	All Purpose Sampling Cannula without filter (Non Sterile). Size: Infant
01.57.471284	All Purpose Sampling Cannula without filter (Non Sterile). Size: Neonate
01.57.471285	Duo Flow O$_2$+CO$_2$ Sampling Cannula (Non Sterile). Size: Adult
01.57.471286	Duo Flow O$_2$+CO$_2$ Sampling Cannula (Non Sterile). Size: Child
01.57.471287	Capnomask O$_2$+CO$_2$ Sampling Cannula (Non Sterile). Size: Adult
01.57.471288	Capnomask O$_2$+CO$_2$ Sampling Cannula (Non Sterile). Size: Child
For Respironics Module	
02.08.078137	Respironics EtCO$_2$ Module/ (Side-stream) 1022054
02.08.078166	LoFloTM Module Mounting Bracket (Respironics 1027730)
01.57.078139	Disposable CO$_2$ Nasal Cannula – Adult (Respironics 3468ADU-00)
01.57.078140	Disposable CO$_2$ Nasal Cannula - Pediatric (Respironics 3468PED-00)
01.57.078141	Infant Nasal Sampling Cannula, sidestream, 3468INF-00
01.57.078154	Disposable Sampling Line Kit with Dehumidification Tubing (Respironics 3475-00)
01.15.040143	Respironics CAPNOSTAT 5 EtCO$_2$ (Main-stream) Module 1015928
01.59.078155	Disposable Adult Airway Adapter (6063-00)
01.59.078156	Disposable Neonatal (Infant/Pediatric) Airway Adapter (6312-00)
01.57.471019	Reusable Adult/Pediatric Airway Adapter (7007-01)
01.57.471020	Reusable Neonate/Infant Airway Adapter (7053-01)
01.57.078142	Adult Nasal CO$_2$ with O$_2$ delivery sampling cannula (Respironics 3469ADU-00)
01.57.078143	Pediatric Nasal CO$_2$ with O$_2$ delivery sampling cannula (Respironics 3469PED-00)
01.57.078144	Infant Nasal CO$_2$ with O$_2$ delivery sampling cannula (Respironics 3469INF-00)
01.57.101019	Adult Nasal/Oral CO$_2$ sampling cannula (Respironics 3470ADU-00)
01.57.101020	Pediatric Nasal/Oral CO$_2$ sampling cannula (Respironics 3470PED-00)
01.57.101021	Adult Nasal/Oral CO$_2$ with O$_2$ delivery sampling cannula (Respironics 3471ADU-00)

01.12.031598	Adult/Pediatric Airway adapter kit (Respironics 3472ADU-00)
01.57.078151	Adult/Pediatric Airway adapter kit with dehumidification tubing (Respironics 3473ADU-00)
01.57.078152	Pediatric/Infant Airway adapter kit with dehumidification tubing (Respironics 3473INF-00)
01.57.078158	Pediatric Mask /Mainstream 9960PED-00
01.57.078159	Adult standard mask /mainstream 9960STD-00
01.57.078160	Adult large mask /mainstream 9960LGE-00
01.57.078161	Band /Mainstream 8751-00
01.12.078162	Card Slot /Mainstream 6934-00
IBP	
01.57.471014	Pressure transducer interface cable, BD
01.57.40121	IBP Pressure transducer kit, BD, disposable(BD DT-4812)
01.57.471013	Pressure transducer interface cable, EDWARD
01.57.471027	Pressure transducer interface cable, Hospira
01.57.471028	Pressure transducer interface cable, Utah
02.57.471280	ICP transfer cable
01.57.471664	Disposable Pressure transducer PT161103, compatible with BD
01.57.471665	Disposable Pressure transducer PT151103, compatible with Edward
01.57.471666	Disposable Pressure transducer PT141103, compatible with Abbott
01.57.471880	Reusable pressure transducer
01.57.471881	Disposable dome
OTHERS	
01.21.064143	Rechargeable Lithium-Ion Battery/TWSLB-003
01.21.064142	Rechargeable Lithium-Ion Battery/TWSLB-002
01.57.78035	Printing Paper
02.04.241047	Unicode recorder assembly kit, Serial/parallel port
02.01.101206	Wireless AP upgrade assembly bag
02.04.240445	Patient Monitor wireless AP assembly bag
02.04.241689	Patient monitor mounting arm assembly kit (iM8/iM9/iM80)
83.60.101952	Trolley assembly kit
02.04.101976	MT206 Trolley Basket (in the bottom)
01.13.037122	Power cord (USA), 1.8 m

01.13.036638	Power Cable (IEC Standard), 1.8 m
01.13.114214	Ground Cable
01.18.052245	Netac USB flash disk (U208, 4 G, USB2.0)
02.01.214392	Dust-free filter assembly

Chapter 20 Warranty and Service

20.1 Warranty

The manufacturer warrants that the manufacturer's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

a)damage caused by mishandling during shipping.

b) subsequent damage caused by improper use or maintenance.

c)damage caused by alteration or repair by anyone not authorized by the manufacturer.

d) damage caused by accidents.

e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, the manufacturer will, at its discretion, repair or replace the defective part(s) free of charge. The manufacturer will not provide a substitute product for use when the defective product is being repaired.

20.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Appendix I Specifications

A1.1 Classification

Anti-electroshock Type	Class I equipment and internal powered equipment
Anti-electroshock Degree	ECG (RESP), TEMP, IBP CF SpO_2, NIBP, CO_2 BF
Ingress Protection	IPX1
Degree of Safety in Presence of Flammable Gases	Not suitable for use in presence of flammable gases
Disinfection/Sterilizing method	Refer to *Chapter 12* for details.
Working System	Continuous operation equipment
Compliant with Safety Standards	IEC 60601-1: 2005+A1: 2012; EN 60601-1: 2006+A1: 2013; IEC 60601-1-2: 2007; EN 60601-1-2: 2007; IEC60601-2-49: 2011

A1.2 Specifications

NOTE:
The performance of the equipment with ☆ mark is determined to be essential performance.

A1.2.1 Physical Specifications

Product	Size (W×H×D)	Shell figure / Screen size	Weight	Remark
iM8	319 mm×267.8 mm×154 mm	Square /12.1-inch	<5kg	not including the battery and recorder
iM8A	319 mm×267.8 mm×154 mm	Square /10.4-inch	<5kg	
iM8B	319 mm×267.8 mm×154 mm	Square /10.1-inch Wide-screen	<5kg	
M8	320 mm×265 mm×150 mm	Square /12.1-inch	<5kg	

Product	Size (W×H×D)	Shell figure / Screen size	Weight	Remark
M8A	320 mm×265 mm×150 mm	Square /10.4-inch	<5kg	
M8B	320 mm×265 mm×150 mm	Square /10.1-inch Wide screen	<5kg	

A1.2.2 Environment

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

Temperature	
Working	0 °C to +40 °C(32 ℉~104 ℉)
Transport and Storage	-20 °C to +55 °C(-4 ℉~131 ℉)
Humidity	
Working	15%RHto 95%RH (non-condensing)
Transport and Storage	15%RH to 95%RH (non-condensing)
Altitude	
Working	86 kPa to 106 kPa
Transport and Storage	70 kPa to 106 kPa
Power Supply	100 V to 240 V~, 50 Hz/60 Hz Current: 1.0 A -0.5 A; FUSE T3.15 AH250 VP

A1.2.3 Function Configuration

Product	Standard Configuration	Optional Configuration
iM8	ECG, RESP, SpO_2, NIBP, TEMP	IBP, CO_2, recorder
iM8A	ECG, RESP, SpO_2, NIBP), TEMP	IBP, CO_2, recorder
iM8B	ECG, RESP, SpO_2, NIBP, TEMP	IBP, CO_2, recorder
M8	ECG, RESP, SpO_2, NIBP, TEMP	IBP, CO_2, recorder
M8A	ECG, RESP, SpO_2, NIBP, TEMP	IBP, CO_2, recorder
M8B	ECG, RESP, SpO_2, NIBP, TEMP	IBP, CO_2, recorder

A1.2.4 Display

Display Screen	10.1- inch /10.4- inch /12.1-inch, multicolour TFT LCD, 10.1-inch: Resolution 800×480; 10.4-inch /12.1-inch: Resolution 800×600.
Messages	A maximum of 11 waveforms
	iM8/M8 One charge LED (Orange) One power LED (Green) One alarm LED (Yellow/Red)
	iM8A/iM8B/M8A/M8B One charge LED (Orange/ Green) One alarm LED (Yellow/Red)
	Three indicator modes corresponding to alarm mode.

A1.2.5 Battery

Capacitance	2500 mAh/5000 mAh
Typical Working Period	2500 mAh : 2.5 h 5000 mAh : 6 h

	At 25 °C, with a new fully charged battery, in continual SpO_2 measuring mode and NIBP automatic measuring mode with the operating interval of 15 minutes; ECG/TEMP module connected; the recording interval of 10 minutes.
Maximum Rechargeable Period	2500 mAh: 3.5 h (100% charge) 3.15h (90% charge) 5000 mAh : 6 h (100% charge) 5.4 h (90% charge)
	Monitor is on or in standby mode.

A1.2.6 Recorder (Optional)

Record Width	48 mm
Paper Speed	25 mm/s, 50 mm/s
Channels	3
Recording Types	Continual real-time recording 8 second real-time recording Automatic interval recording Physiological alarm recording Frozen waveform recording Trend graph/table review recording NIBP review recording Alarm event review recording Arrhythmia review recording Titration table recording

A1.2.7 Recall

Trend Recall	1 hrs, 1-second resolution
	96 hrs, 1-min. resolution
Recall	500 sets NIBP measurement data

A1.2.8 ECG

Complies with IEC 60601-2-27: 2011.

Lead Mode	3-Lead: I, II, III 5-Lead: I, II, III, aVR, aVL, aVF, V
Lead naming style	AHA, IEC
☆ Display Sensitivity (Gain Selection)	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), AUTO gain
☆Sweep speed	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s
Bandwidth (-3dB)	Diagnosis: 0.05 Hz to 150 Hz Monitor: 0.5 Hz to 40 Hz Surgery: 1 Hz to 20 Hz
☆ CMRR (Common Mode Rejection Ratio)	Diagnosis: >95 dB Monitor: >105 dB Surgery: >105 dB
Notch	50 Hz/60 Hz (Notch filter can be turned on or off manually)
☆Differential Input Impedance	>5 MΩ
☆Input Signal Range	±10 mV PP
☆ Accuracy of Input Signal Reproduction	The total error and frequency response comply with IEC 60601-2-27:2011 Sec. 201.12.1.101.1.
☆ Electrode Offset Potential Tolerance	±500 mV
Auxiliary Current (Leads off detection)	Active electrode: <100 nA Reference electrode: <900 nA
☆ Recovery time after Defibrillation	<5 s (measured without electrodes as IEC60601-2-27:2011, Sect. 201.8.5.5.1 requires.)
Sampling Frequency	1000 Hz
Sampling Channel Switch Time	< 80 μS
A/D Precision	24 Bits
Leakage current of patient	<10 μA
Scale signal	1 mVPP, accuracy is ±5％

☆System noise	<30 μVPP
☆ESU Protection	Cut mode: 300 W Coagulation mode: 100 W Restore time: ≤10 s
Electrosurgical Interference Suppression	Test according to ANSI/AAMI EC13:2002, Sect. 5.2.9.14. Complied with ANSI/AAMI EC13:2002, Sect. 4.2.9.14.
Pace Pulse	
☆Pulse indicator	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to2.0 ms Ascending time: 10 μs to 100 μs
☆Pulse Rejection	Pulse is rejected if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.13 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2 ms Ascending time: 10 μs to 100 μs
Minimum input slew rate (Lead II)	>2.5 V/S
☆Baseline reset	<3 s
Pace Pulse Detecting Lead	one among I, II, III, AVR, AVL, AVF, V1, V2, V3,V4, V5, V6
Heart rate	
☆Range	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm
☆Accuracy	±1% or 1 bpm, whichever is greater
Resolution	1 bpm
Sensibility	≥300 μVPP
PVC	
Range	ADU: 0 PVCs/ min to 300 PVCs/ min PED/NEO: 0 PVCs/ min to 350 PVCs/ min
Resolution	1 PVCs/min
ST value	
Range	-2.0 mV to +2.0 mV

Accuracy	±0.02 mV or 10% (-0.8 mV to +0.8 mV), whichever is greater. Beyond this range: not specified.
Resolution	0.01 mV
HR averaging method	
Method 1	Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals.
Method 2	If each of three consecutive RR intervals is greater than 1200ms, then the four most recent RR intervals are averaged to compute the HR.
Range of Sinus and SV Rhythm	
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s.
	Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
Normal	Adult: 0.5s < RR interval for 5 consecutive QRS complex < 1.5 s.
	Pediatric/neonatal: 0.375s < RR interval for 5 consecutive QRS complex < 1 s.
Brady	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s.
	Pediatric/neonatal: RR interval for 5 consecutive QRS complex ≥ 1 s.
Range of Ventricular Rhythm	
Ventricular Tachycardia	The interval of 5 consecutive ventricular wave is less than 600 ms
Ventricular Rhythm	The interval of 5 consecutive ventricular wave ranges from 600 ms to 1000 ms
Ventricular Bradycardia	The interval of 5 consecutive ventricular wave is more than 1000 ms
Maximum Start-up Alarm Time for Tachycardia	
Ventricular Tachycardia 1 mV 206bpm	Gain 0.5: 10 s
	Gain 1.0: 10 s
	Gain 2.0: 10 s
Ventricular Tachycardia 2 mV 195bpm	Gain 0.5: 10 s
	Gain 1.0: 10 s
	Gain 2.0: 10 s

Response time of Heart Rate Meter to Change in HR	HR range: 80 bpm to 120 bpm
	Range : Within 11 s
	HR range: 80 bpm to 40 bpm
	Range : Within 11 s
Tall T-wave Rejection	Complies with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude
Accuracy of Heart Rate Meter and Response to Irregular Rhythm	Complies with IEC 60601-2-27: 2011, Sect. 201.7.9.2.9.101 b) 4) the HR value after 20 seconds of stabilization is displayed as follows:
	Ventricular bigeminy: 80 bpm±1 bpm
	Slow alternating ventricular bigeminy: 60 bpm±1 bpm
	Rapid alternating ventricular bigeminy: 120 bpm±1 bpm
	Bidirectional systoles: 91 bpm±1 bpm

Arhythmia analysis	ASYSTOLE	VFIB/VTAC	COUPLET
	VT>2	BIGEMINY	TRIGEMINY
	VENT	R on T	PVC
	TACHY	BRADY	MISSED BEATS
	IRR	VBRADY	PNC
	PNP		

A1.2.9 RESP

Method	Trans-thoracic impedance: R-F(RA-LL), R-L (RA-LA)
☆RR measuring range	
Adult:	0 rpm to 120 rpm
Neo/Ped	0 rpm to 150 rpm
Resolution	1 rpm
☆Accuracy	
Adult	6 rpm to 120 rpm: ±2 rpm
	0 rpm to 5 rpm: Undefined

Neo/Ped	6 rpm to 150 rpm: ±2 rpm
	0 rpm to 5 rpm: Undefined
Respiration excitation waveform	<500 µA, sinusoid, 62.8 kHz (±10%)
Measuring Sensitivity	Within baseline impedance range: 0.3 Ω
☆Gain selection	×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
☆Sweep	6.25 mm/s, 12.5 mm/s, 25.0 mm/s, 50.0 mm/s
Measurement lead	Options are lead I and II. The default is lead II.
Calculation Type	Manual /Automatic
Measuring sensitivity	0.3 Ω (baseline impedance 200 Ωto 4500 Ω)
Maximum dynamic range	Baseline impedance: 500 Ω
	Variable impedance: 3 Ω
	No clipping
Baseline Impedance Range	200 Ω to 2500 Ω(with ECG cables of 1 KΩ resistance)
Waveform bandwidth	0.2 Hz to 2.5 Hz (-3 dB)
☆Apnea Alarm Time	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.

A1.2.10 NIBP

Complies with IEC 80601-2-30: 2009

Method	Oscillometric
Mode	Manual, Auto, Continuous
Measuring Interval in AUTO Mode (unit: min)	1/2/3/4/5/10/15/30/60/90/120/240/480
Continuous	5 min, interval is 5 s
Measuring Type	SYS, DIA, MAP, PR
☆Alarm Type	SYS, DIA, MAP
☆Measuring Range	

Adult Mode	SYS: 40 mmHg to 270 mmHg
	DIA: 10 mmHg to 215 mmHg
	MAP: 20 mmHg to 235 mmHg
Pediatric Mode	SYS: 40 mmHg to 230 mmHg
	DIA: 10 mmHg to 180 mmHg
	MAP: 20 mmHg to 195 mmHg
Neonatal Mode	SYS: 40 mmHg to 135 mmHg
	DIA: 10 mmHg to 100 mmHg
	MAP: 20 mmHg to 110 mmHg
☆ Cuff Pressure Measuring Range	0 mmHg to 300 mmHg
☆Pressure Resolution	1 mmHg
☆Maximum Mean Error	±5 mmHg
☆Maximum Standard Deviation	8 mmHg
Maximum Measuring Period	
Adult/ Pediatric	120 s
Neonatal	90 s
Typical Measuring Period	20 s to 35 s (depend on HR/motion disturbance)
Overpressure Protection	
Adult	297 mmHg±3 mmHg
Pediatric	245 mmHg±3 mmHg
Neonatal	147 mmHg±3 mmHg
PR	
☆Measuring range	40 bpm to 240 bpm
☆Accuracy	±3 bpm or 3.5%, whichever is greater

A1.2.11 SpO$_2$

Complies with ISO 80601-2-61: 2011.

Measuring Range	0% to 100%

☆Adjustable Range of Alarm Limits	20% to 100%
Resolution	1%
☆Data Update Period	1 s
☆Accuracy	
Adult (including Pediatric)	±2% (70% to 100% SpO$_2$)
	Undefined (0% to 69% SpO$_2$)
Neonatal	±3% (70% to 100% SpO$_2$)
	Undefined (0% to 69% SpO$_2$)
PI	
Measuring Range	0-10. It displays 0 for invalid PI value.
Resolution	1
Pulse Rate	
Measuring Range	25 bpm to 300 bpm
☆Adjustable Range of Alarm Limits	30 bpm to 300 bpm
Resolution	1 bpm
☆Accuracy	±2 bpm
Sensors	
Wave Length	Red Light: 660 nm±3 nm
	Infrared Light: 905 nm±10 nm
	Emitted Light Energy: <15 mW
	Information about the wave length range can be especially useful to clinicians (for instance, when photodynamic therapy is performed)

NOTE:

The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

A1.2.12 TEMP

Complies with EN 12470-4: 2000+ A1: 2009 and ISO 80601-2-56: 2009.

Channel	2

Sensor type	YSI-10K and YSI-2.252K
Technique	Thermal resistance
Measuring Mode	Direct Mode
Position	Skin, oral cavity, rectum
Measuring Range	0 °C to 50 °C (32 °F to 122 °F)
Resolution	0.1 °C (0.1 °F)
☆Accuracy[1]	±0.3 °C
Refresh Time	Every 1 s to 2 s
Transient Response Time	≤30 s
Temperature Calibration	At an interval of 5 to 10 minutes

Note 1: The accuracy consists of two parts, as following:

(1) Accuracy (not including sensor): ±0.1 °C

(2) Sensor accuracy: ≤±0.2 °C

A1.2.13 IBP (Optional)

Complies with IEC 60601-2-34: 2011.

Technique	Direct invasive measurement
☆Measuring range	
Art	0 mmHg to +300 mmHg
PA	-6 mmHg to +120mmHg
CVP/RAP/LAP/ICP	-10 mmHg to +40 mmHg
P1/P2	-50 mmHg to +300 mmHg
Resolution	1 mmHg
☆Accuracy (not including sensor)	±2% or ±1 mmHg, whichever is greater
Unit	kPa, mmHg, cmH_2O
Zero calibration range	±200 mmHg
Filter	DC～12.5 Hz; DC～40 Hz
Pressure sensor	
Sensitivity	5 (μV/V/mmHg)
Impedance	300 Ω to 3000 Ω

A1.2.14 CO_2 (Optional)

Complies with ISO 80601-2-55: 2011.

EDAN EtCO₂ Module

Intended patient	Adult, pediatric, neonatal			
Measurement method	Non-dispersive infrared gas analysis (NDIR)			
Unit	mmHg, %, kPa			
☆ Measuring Range	CO₂	0 mmHg to 150 mmHg (0% to 20%)		
	AwRR	2 rpm to 150 rpm		
Resolution	EtCO₂	1 mmHg		
	FiCO₂	1 mmHg		
	AwRR	1 rpm		
☆Accuracy	EtCO₂	± 2 mmHg, 0 mmHg to 40 mmHg	Respiratory rate: ≤60 rpm	Typical conditions: Ambient temperature: 25 °C ± 3 °C Barometric pressure: 760 mmHg ± 10 mmHg Balance gas: N₂ Sample gas flowrate: 100 ml/min
		± 5% of reading, 41 mmHg to 70 mmHg		
		± 8% of reading, 71 mmHg to 100 mmHg		
		± 10% of reading, 101 mmHg to 150 mmHg		
		±12% of reading or ± 4 mmHg, whichever is greater	Respiratory rate: > 60 rpm	
	AwRR	±1 rpm		
Drift of measurement accuracy	Meets the measurement accuracy above.			
Pump rate	70 ml/min or 100 ml/min, (Accuracy: ±15 ml/min). Default: 100 ml/min			
Warm-up time	Display waveform within 20 s; Reach the design accuracy within 2 minutes.			
Rise time	<400 ms (using water trap, 2 m sampling cannula, pump rate:100 ml/min)			
Response time	<4 s (using water trap, 2 m sampling cannula, pump rate:100 ml/min)			
Work mode	Standby, measure. Default: Standby			
O₂ compensation	Range: 0% to 100% Resolution: 1% Default: 16%			

N$_2$O compensation	Range: 0% to 100% Resolution: 1% Default: 0%	
AG compensation	Range: 0% to 20% Resolution: 0.1% Default: 0%	
Humidity compensation method	ATPD (default), BTPS	
Barometric pressure compensation	Automatic (Barometric pressure change will not bring additional deviation to measuring accuracy).	
Calibration	Support	
☆Alarm	EtCO$_2$, FiCO$_2$, AwRR	
☆ Apnea alarm delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s.	
Data Sample Rate	100 Hz	
EtCO$_2$ Change [1]	AwRR>80 rpm, ETCO$_2$ degrades 8%; AwRR>120 rpm ETCO$_2$ degrades 10%.	

Note 1:Use a test device equivalent to EN ISO 80601-2-55 fig 201.101 to measure at 1:2 I/E ratio. Respiration rate accuracy is determined by frequency of device, and ET READING change refers to the nominal value.

Respironics Module

Applicable Patient Type	Adult, pediatric and neonatal patients	
Method	Infra-red Absorption Technique	
Unit	mmHg/ %/ kPa	
☆Measuring Range	EtCO$_2$	0 mmHg to 150 mmHg
	FiCO$_2$	3 mmHg to 50 mmHg
	AwRR	2 rpm to 150 rpm (Sidestream) 0 rpm to 150 rpm (Mainstream)
Resolution	EtCO$_2$	1 mmHg
	FiCO$_2$	1 mmHg
	AwRR	1 rpm

☆Measuring Accuracy	
☆EtCO$_2$	±2 mmHg, 0 mmHg to 40 mmHg
	±5% of reading, 41 mmHg to 70 mmHg
	±8% of reading, 71 mmHg to 100 mmHg
	±10% of reading, 101 mmHg to 150 mmHg
	±12% of reading, RR is over 80 rpm (Sidestream) There will be no degradation in performance due to Respiration Rate. （mainstream）
☆AwRR	±1 rpm
Sample Gas Flow Rate (Sidestream)	50 ml /min ±10 ml /min
O$_2$ Compensation	
Range	0% to 100%
Resolution	1%
Default	16%
Anesthetic Gas Compensation	
Range	0% to 20%
Resolution	0.1%
Default	0.0%
Balance Gas Compensation	Options: N$_2$O, helium, room air
Barometric pressure compensation	User setup
Work Mode	Standby, measure. Default: Standby
Stability	
Short Term Drift	< 0.8 mmHg over 4 hours
Long Term Drift	Accuracy specification will be maintained over 120 hours period

Initialization time	It displays the value within 15 s and meets the requirement for measurement accuracy within 2 min. (Mainstream)
	It displays the value within 20 s and meets the requirement for measurement accuracy within 2 min. (Sidestream)
Response time	60 ms (Mainstream)
Calibration	Not required.
☆Alarm	$EtCO_2$, $FiCO_2$ and AwRR alarm
☆Apnea Alarm Delay (Unit: s)	10, 15, 20, 25, 30, 35, 40; 20 s by default
Data Sample Rate	100 Hz
CO_2 Rise Time/Response Time(Mainstream)	< 60 ms
Sensor Response time (Sidestream)	<3 seconds - includes transport time and rise time

Interfering Gas and Vapor Effect on $EtCO_2$ Measurement Values:

Gas or vapour	Gas level (%)	Quantitative effect/Comments
Nitrous oxide	60	Dry and Saturated Gas
Halothane	4	0 mmHg– 40 mmHg: ±1 mmHg additional error
Enflurane	5	41 mmHg – 70 mmHg: ±2.5% additional error
Isoflurane	5	71 mmHg – 100 mmHg: ±4% additional error
Sevoflurane	5	101 mmHg – 150 mmHg: ±5% additional error
Xenon	80	*Additional worst case error when compensation for P_B, O_2, N_2O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.
Helium	50	
Desflurane	15	Desflurane:
		The presence of desflurane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3 mmHg at 38 mmHg.
		Xenon:
		The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5 mmHg at 38 mmHg.

Barometric Pressure on EtCO$_2$ Measurement Values:

Quantitative effect
Ambient Barometric, Operational
0 mmHg – 40 mmHg: ±1 mmHg additional error
41 mmHg– 70 mmHg: ±2.5% additional error
71 mmHg– 100 mmHg: ±4% additional error
101 mmHg – 150 mmHg: ±5% additional error
*Additional worst case error when compensation for P$_B$, O$_2$, N$_2$O, anesthetic agents, or helium is correctly selected for the actual fractional gas constituents present.

NOTE:
Respiration Rate accuracy was verified by using a solenoid test setup to deliver a square wave of known CO$_2$ concentration to the device. 5% and 10% CO$_2$ concentrations were used. Respiration rate was varied over the range of the device. Pass/Fail criteria was comparison of the respiratory rate output from the sensor to the frequency of the square wave.

A1.2.15 Interfaces

USB Interface

Number of USB Interfaces	Standard: 1
Drive Mode	HOST interface, USB1.0/2.0 protocol
Power Supply	5 VDC±5%, 500 mA Max.
Interface Type	USB A-type port

VGA Interface

Number of VGA Interface	1
Horizontal Refreshing Rate	30 KHZ - 94 KHZ
Video Signal	0.7 Vpp @ 75 Ohm, HSYNC/VSYNC signal TTL
Interface Type	DB-15 female receptacle

Network Interface

Bandwidth	10 M/100 M
Interface Type	Standard RJ-45 network interface; PIN7 and PIN8 are used for nurse call.

Appendix II EMC Information

- Guidance and Manufacture's Declaration

A2.1 Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emission		
The patient monitors of iM8 & M8 series patient monitor are intended for use in the electromagnetic environment specified below. The customer or the user of the iM8 & M8 series patient monitor should assure that they are used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The patient monitors of iM8 & M8 series use RF energy only for internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The patient monitors of iM8 & M8 series are suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

A2.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The patient monitors of iM8 & M8 series are intended for use in the electromagnetic environment specified below. The customer or the user of the iM8 & M8 series patient monitors should assure that they are used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should

			be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50 Hz/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Patient Monitor requires continued operation during power mains interruptions, it is recommended that the Patient Monitor be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

A2.3 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The patient monitors of iM8 & M8 series are intended for use in the electromagnetic environment specified below. The customer or the user of iM8 & M8 series patient monitors should assure that they are used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 V$_{rms}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V$_{rms}$ 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the iM8 & M8 series patient monitors, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each 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 range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a	Field strengths from fixed 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 patient monitors of iM8 & M8 series are used exceeds the applicable RF compliance level above, the patient monitors of iM8 & M8 series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the patient monitors of iM8 & M8 series.
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

A2.4 Recommended Separation Distances

<table>
<tr><td colspan="4">Recommended separation distances between
portable and mobile RF communications equipment and the monitor</td></tr>
<tr><td colspan="4">The patient monitors of iM8 & M8 series are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the iM8 & M8 series patient monitors can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.</td></tr>
<tr><td rowspan="2">Rated maximum output power of transmitter (W)</td><td colspan="3">Separation distance according to frequency of transmitter(m)</td></tr>
<tr><td>150 kHz to 80 MHz
$d = 1.2\sqrt{P}$</td><td>80 MHz to 800 MHz
$d = 1.2\sqrt{P}$</td><td>800 MHz to 2.5 GHz
$d = 2.3\sqrt{P}$</td></tr>
<tr><td>0.01</td><td>0.12</td><td>0.12</td><td>0.23</td></tr>
<tr><td>0.1</td><td>0.38</td><td>0.38</td><td>0.73</td></tr>
<tr><td>1</td><td>1.2</td><td>1.2</td><td>2.3</td></tr>
<tr><td>10</td><td>3.8</td><td>3.8</td><td>7.3</td></tr>
<tr><td>100</td><td>12</td><td>12</td><td>23</td></tr>
<tr><td colspan="4">For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

Appendix III Default Settings

This appendix documents the most important default settings of your monitor as it is delivered from the factory.

NOTE:

If your monitor has been ordered preconfigured to your requirements, the settings at delivery will be different from those listed here.

A3.1 Patient Information Default Settings

Patient Information Settings	
Patient Type	Adult
Pace	Off

A3.2 Alarm Default Settings

Alarm Settings	
Pause Time	120 s
Audio Alarm Off	Off
Sensor off Alarm	On
Alarm Latch	Off
Disconnect Alarm	Off

A3.3 ECG Default Settings

ECG Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100
Pace	Off		
Lead Type	5 Leads		
Display	Normal		
Filter	Diagnostic		
Smart Lead Off	Off		
Heart Volume	2		

ST Analysis	ADU	PED	NEO
ST Analysis	Off		
Alarm Switch	Off		
Alarm Level	Medium		
Alarm Record	Off		
Alarm High Limit (ST-X)	0.2		
Alarm Low Limit (ST-X)	-0.2		
X stands for Ⅰ, Ⅱ, Ⅲ, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6.			
ARR Analysis			
ARR Analysis	On		
PVCs Alarm Level	Medium		
PVCs Alarm Switch	Off		
PVCs Alarm Record	Off		
ARR Alarm Settings	**Alarm Switch**	**Alarm Level**	**Alarm Record**
ASYSTOLE	On	High	Off
VFIB/VTAC	On	High	Off
R ON T	On	Medium	Off
VT > 2	On	Medium	Off
COUPLET	On	Medium	Off
PVC	On	Medium	Off
BIGEMINY	On	Medium	Off
TRIGEMINY	On	Medium	Off
TACHY	On	Medium	Off
BRADY	On	Medium	Off
MISSEDBEATS	On	Medium	Off
IRR	On	Medium	Off
PNC	On	Medium	Off
PNP	On	Medium	Off
VBRADY	On	Medium	Off
VENT	On	Medium	Off

A3.4 RESP

RESP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	30	30	100
Alarm Low Limit	8	8	30
Apnea Time	20 s		
Calculation Type	Auto		
Resp Type	Ⅱ		
Sweep	12.5 mm/s		
Amplitude	2		

A3.5 SpO$_2$

SpO$_2$ Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	100	100	95
Alarm Low Limit	90	90	88
Pitch Tone	Off		
Sweep	12.5 mm/s		

A3.6 PR

PR Settings	ADU	PED	NEO
PR Source	SpO$_2$		
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit	120	160	200
Alarm Low Limit	50	75	100
Pulse Volume	3		
Alarm Source	HR		

A3.7 NIBP

NIBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (SYS)	160	120	90
Alarm Low Limit (SYS)	90	70	40
Alarm High Limit (Map)	110	90	70
Alarm Low Limit (Map)	60	50	25
Alarm High Limit (Dia)	90	70	60
Alarm Low Limit (Dia)	50	40	20
Inflation value	160	140	100
Unit	mmHg		
Interval	Manual		

A3.8 TEMP

TEMP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Alarm High Limit (T1)	39.0	39.0	39.0
Alarm Low Limit (T1)	36.0	36.0	36.0
Alarm High Limit (T2)	39.0	39.0	39.0
Alarm Low Limit (T2)	36.0	36.0	36.0
Alarm High Limit (TD)	2.0	2.0	2.0
Unit	℃		

A3.9 IBP

IBP Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		

Unit	mmHg		
Filter	12.5 Hz		
	SYS, DIA, MAP	SYS, DIA, MAP	SYS, DIA, MAP
Alarm High Limit (ART, P1, P2)	160, 90, 110	120, 70, 90	90, 60, 70
Alarm Low Limit (ART, P1, P2)	90, 50, 70	70, 40, 50	55, 20, 35
Alarm High Limit (PA)	35, 16, 20	60, 4, 26	60, 4, 26
Alarm Low Limit (PA)	10, 0, 0	24, -4, 12	24, -4, 12
	MAP	MAP	MAP
Alarm High Limit (CVP, RAP, LAP, ICP)	10	4	4
Alarm Low Limit (CVP, RAP, LAP, ICP)	0	0	0

A3.10 CO_2

CO_2 Settings	ADU	PED	NEO
Alarm Switch	On		
Alarm Record	Off		
Alarm Level	Medium		
Work Mode	Standby		
Unit	mmHg		
Apnea Time	20 s		
O_2 Compensate	16%		
Anes Agent	0%		
Alarm High Limit (EtCO$_2$)	50	50	45
Alarm Low Limit (EtCO$_2$)	15	20	30
Alarm High Limit (FiCO$_2$)	4	4	4
Alarm High Limit (AWRR)	30	30	100
Alarm Low Limit (AWRR)	8	8	30
Sweep	12.5 mm/s		
Amplitude	Low		

Appendix IV Abbreviations

Abbr	English Full Name/Description
AC	Alternating current
Adu	Adult
Art	Arterial
aVF	Left foot augmented lead
aVL	Left arm augmented lead
aVR	Right arm augmented lead
awRR	Airway respiration rate
BP	Blood pressure
BTPS	Body temperature and pressure, saturated
CISPR	International Special Committee on Radio Interference
CMS	Central monitoring system
CO_2	Carbon dioxide
COHb	Carboxyhemoglobin
CVP	Central venous pressure
DC	Direct current
Des	Desflurane
Dia	Diastolic
ECG	Electrocardiogram
EEC	European Economic Community
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
Enf	Enflurane
ESU	Electrosurgical unit
Et	End-tidal
$EtCO_2$	End-tidal carbon dioxide
EtN_2O	End-tidal nitrous oxide
Eto	Ethylene oxide
EtO_2	End-tidal oxygen
FCC	Federal Communication Commission
FDA	Food and Drug Administration
Fi	Fraction of inspired

$FiCO_2$	Fraction of inspired carbon dioxide
FiN_2O	Fraction of inspired nitrous oxide
FiO_2	Fraction of inspired oxygen
Hal	Halothane
Hb	Hemoglobin
Hb-CO	Carbon mono-xide hemoglobin
HR	Heart rate
ICP	Intracranial pressure
ICU	Intensive care unit
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
Iso	Isoflurane
LA	Left arm
LAP	Left atrial pressure
LCD	Liquid crystal display
LED	Light emitting diode
LL	Left leg
MAP	Mean arterial pressure
MDD	Medical Device Directive
MetHb	Methemoglobin
MRI	Magnetic resonance imaging
N/A	Not applied
N_2	Nitrogen
N_2O	Nitrous oxide
Neo	Neonate
NIBP	Non-invasive blood pressure
O_2	Oxygen
oxyCRG	Oxygen cardio-respirogram
PA	Pulmonary artery
PAWP	Pulmonary artery wedge pressure
Ped	Pediatric
Pleth	Plethysmogram
PR	Pulse rate
PVC	Premature ventricular complex

R	Right
RA	Right arm
RAP	Right arterial pressure
Resp	Respiration
RHb	Reduced hemoglobin
RL	Right leg
RR	Respiration Rate
Sev	Sevoflurane
SpO$_2$	Pulse Oxygen Saturation
SYS	Systolic pressure
TD	Temperature difference
TEMP	Temperature
USB	Universal serial bus

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