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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

SCC Accredited CB-MS OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 091264 0017 Rev. 00

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

Certification Mark:

Scope of Certificate: **See Page 2 for Overall Scope Statement.**

Standard(s): **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **BJ17891026_BJ1889103**

Effective Date: **2018-09-13**

Expiry Date: **2021-09-12**

Date of Issue: 2019-02-05

(Arie Henkin)
Manager, Certification Body MHS

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SCC Accredited CB-MS
OCSM Accrédité CCN

TÜV SÜD America

CERTIFICATE

No. QS5 091264 0017 Rev. 00

Overall Scope Statement: 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, PC ECG, STRESS ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Data Management Software, Trolley (for Medical Use), Veterinary Electrocardiograph, 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); 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 Wide-Range C-Reactive Protein Assay Kit, Assay Buffer, Sample Dilution Buffer, Washing Buffer, Protein Analyzer); Veterinary PC ECG, Veterinary Pulse Oximeter, Veterinary Digital Ultrasonic Diagnostic Imaging System, Veterinary Monitor, Veterinary Diagnostic Ultrasound System, Veterinary Blood Gas and Chemistry Analysis System (including Veterinary Blood Gas and Chemistry Analyzer, Veterinary Calibrant Fluid Pack, Veterinary Test Cartridge)

Date of Issue: 2019-02-05

(Arie Henkin)
Manager, Certification Body MHS

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

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

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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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

.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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TÜV®


EDAN
A world of potential

iM8 Series

Entry-level Patient Monitors

EDAN

A world of potential

Edan Instruments, Inc.

www.edan.com.cn
info@edan.com.cn
Jan 20, 2015

Our Position

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

EDAN
A world of potential

Our R&D Investments

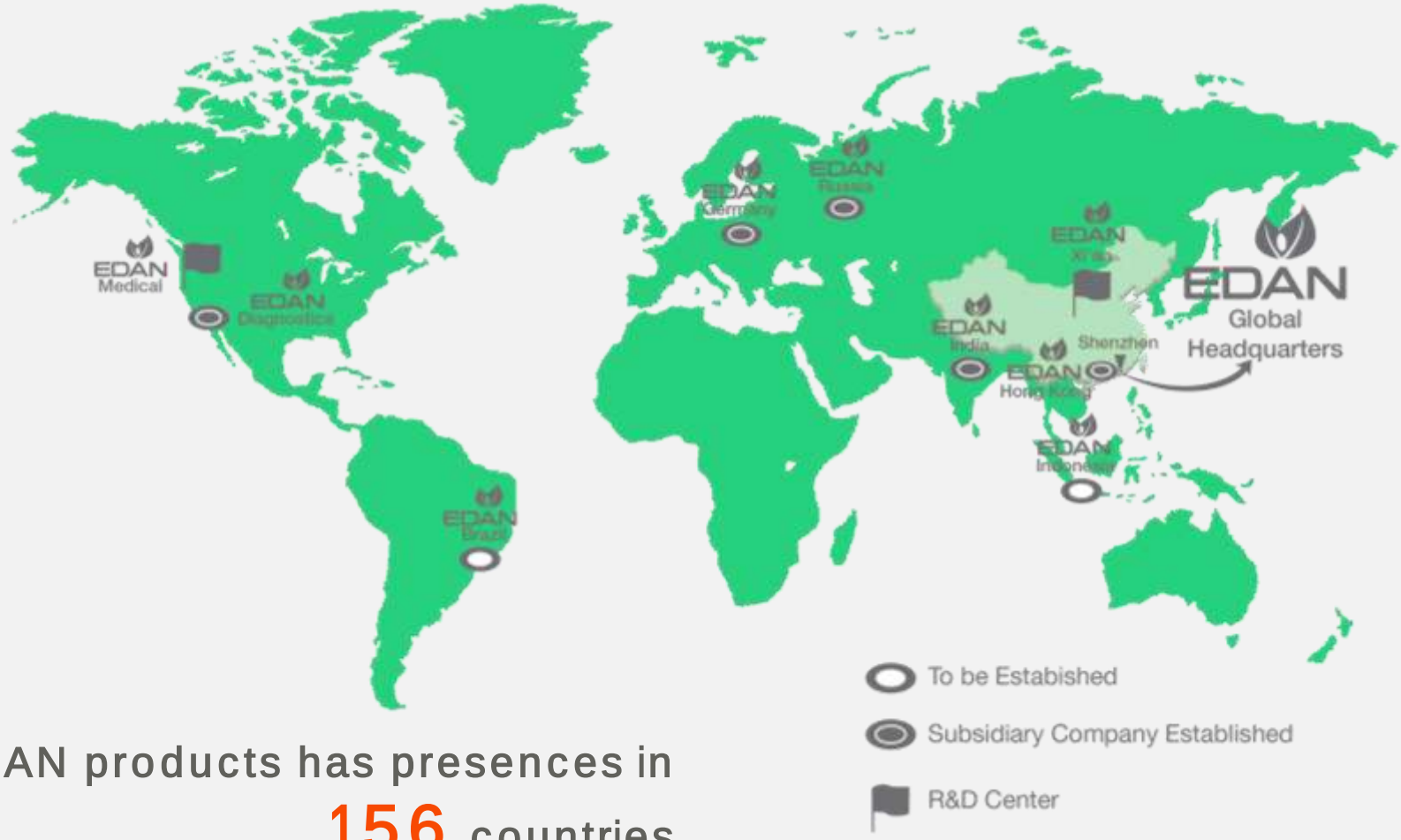
- More than 300 R&D engineers
- 3 R&D centers distributed in China & US
- Industrial design associates in Germany

EDAN
A world of potential

Our Value Proposition

Bring innovation and value together to improve the human condition.

EDAN
A world of potential



EDAN products has presences in

156 countries

EDAN
A world of potential

iM8 Series

iM8

12.1”

iM8A

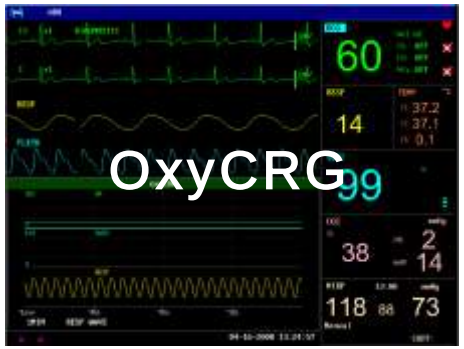
10.4”

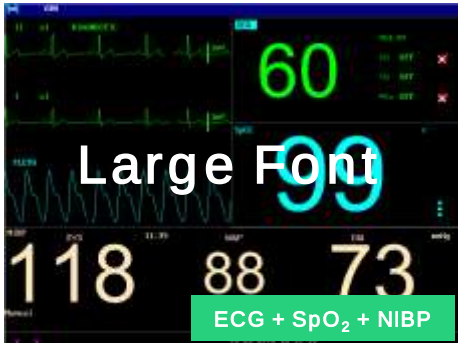
iM8B

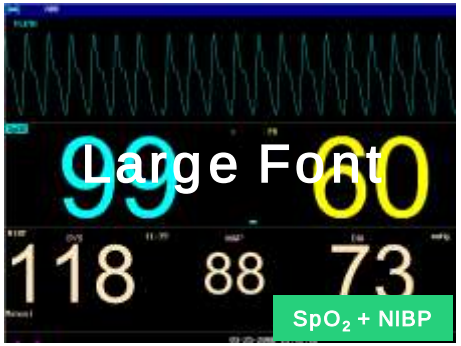
10.1”

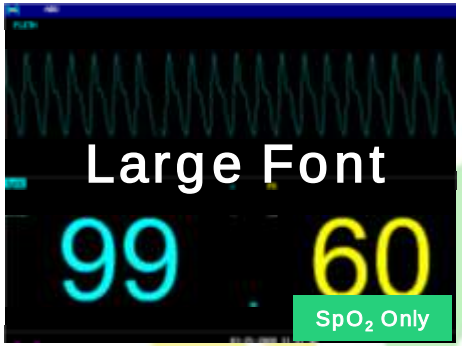
Multiple Display Modes

- Maximum 10 channels
- Maximum 11 waveforms







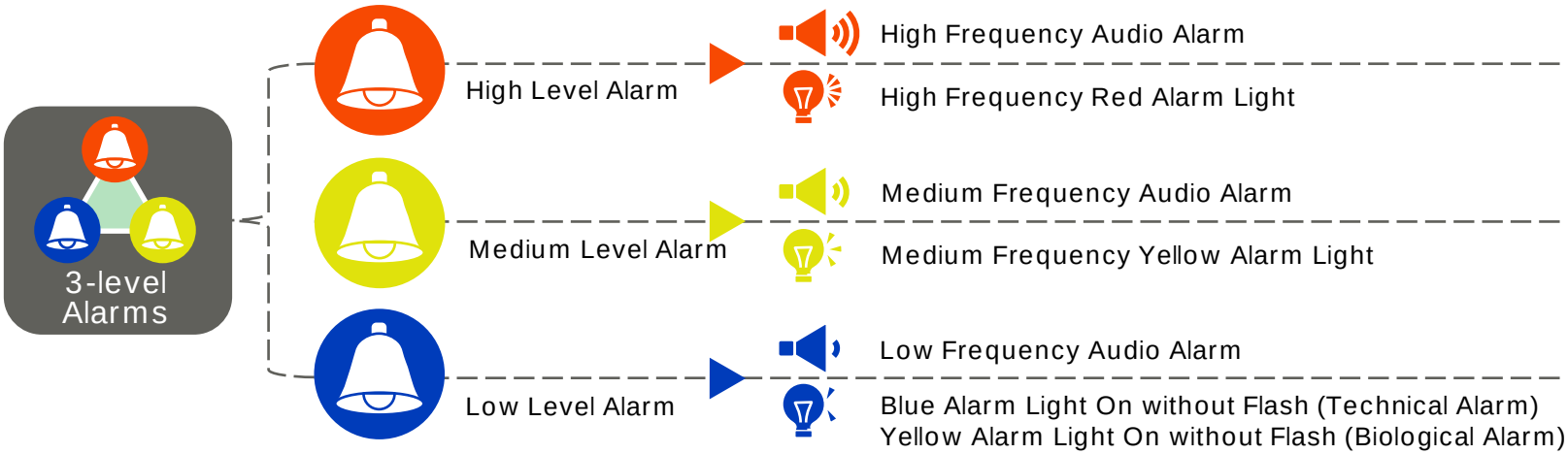


Standby Mode

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.

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.

Alarm Mute/Reset

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

- Ongoing alarm mute
- New alarm will break the mute status

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

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.

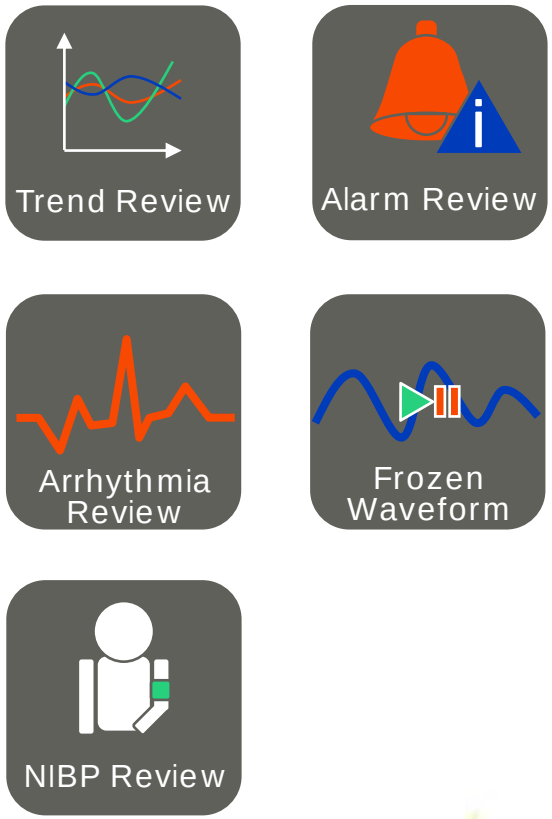
- **Adult Alarm Program**
  Activated when patient type is “Adult”.
- **Pediatric Alarm Program**
  Activated when patient type is “Pediatric”.
- **Neonatal Alarm Program**
  Activated when patient type is “Neonate”.
- **User Configured Alarm Program**
  Activated when selected.

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

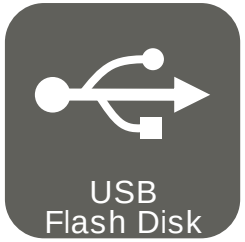


External Memory

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



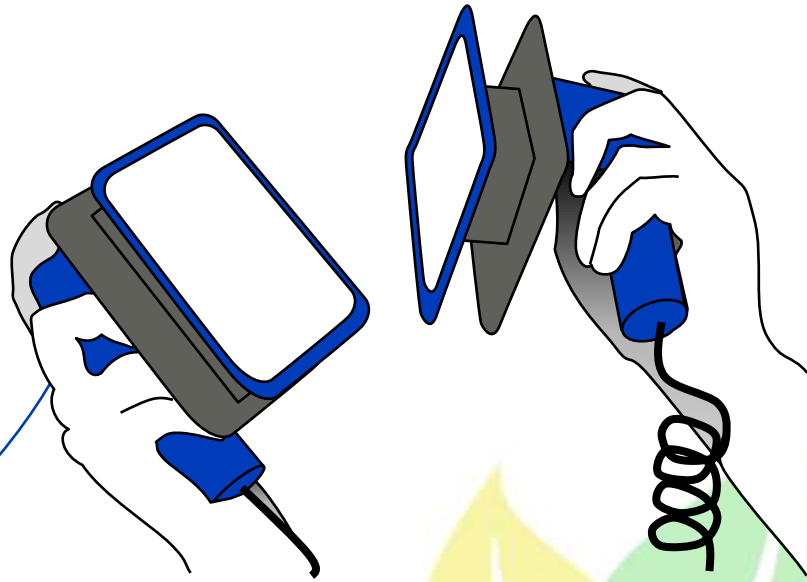
Other Peripherals

Nurse Call

VGA Output

Optional

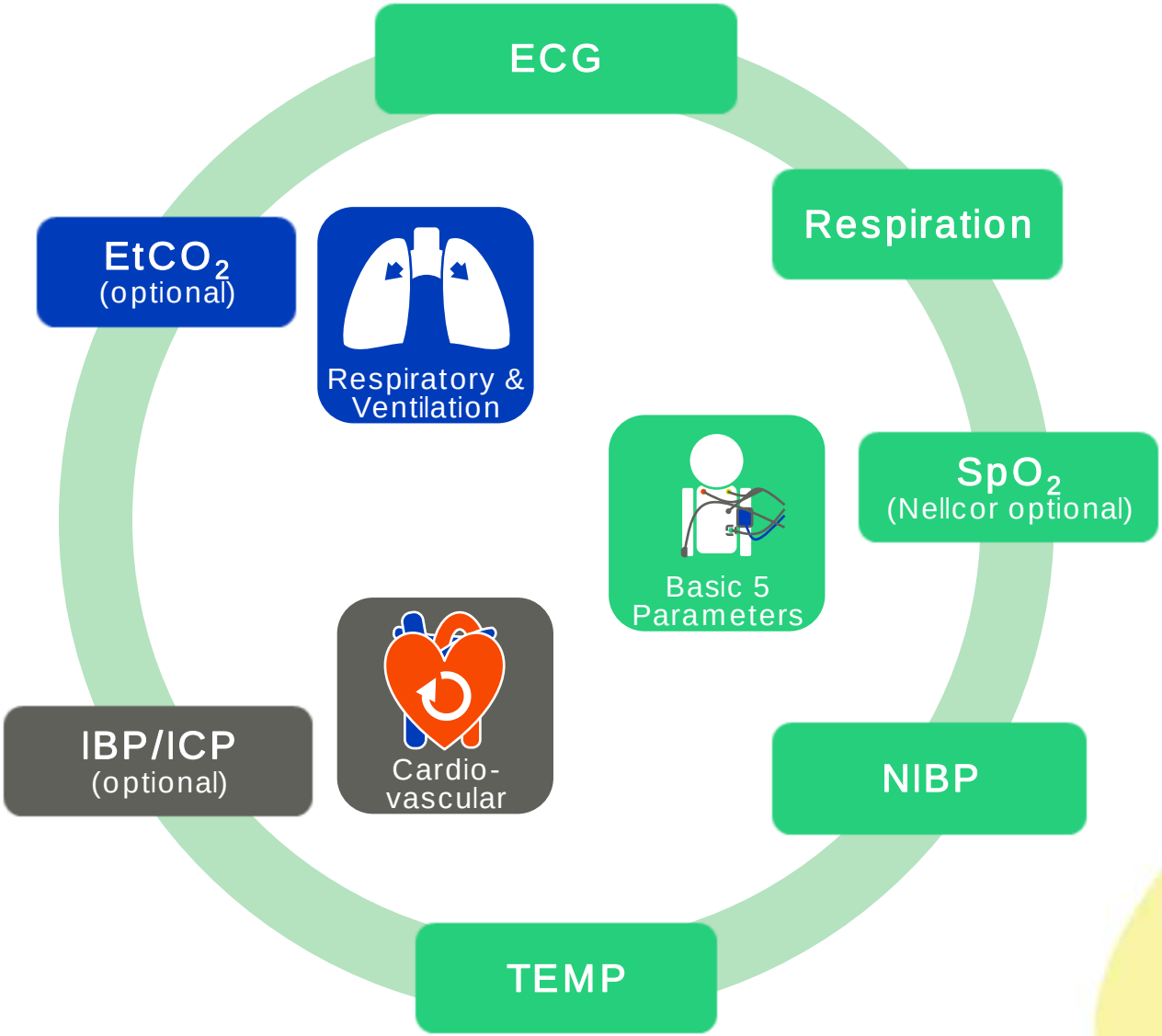
Defib-Sync



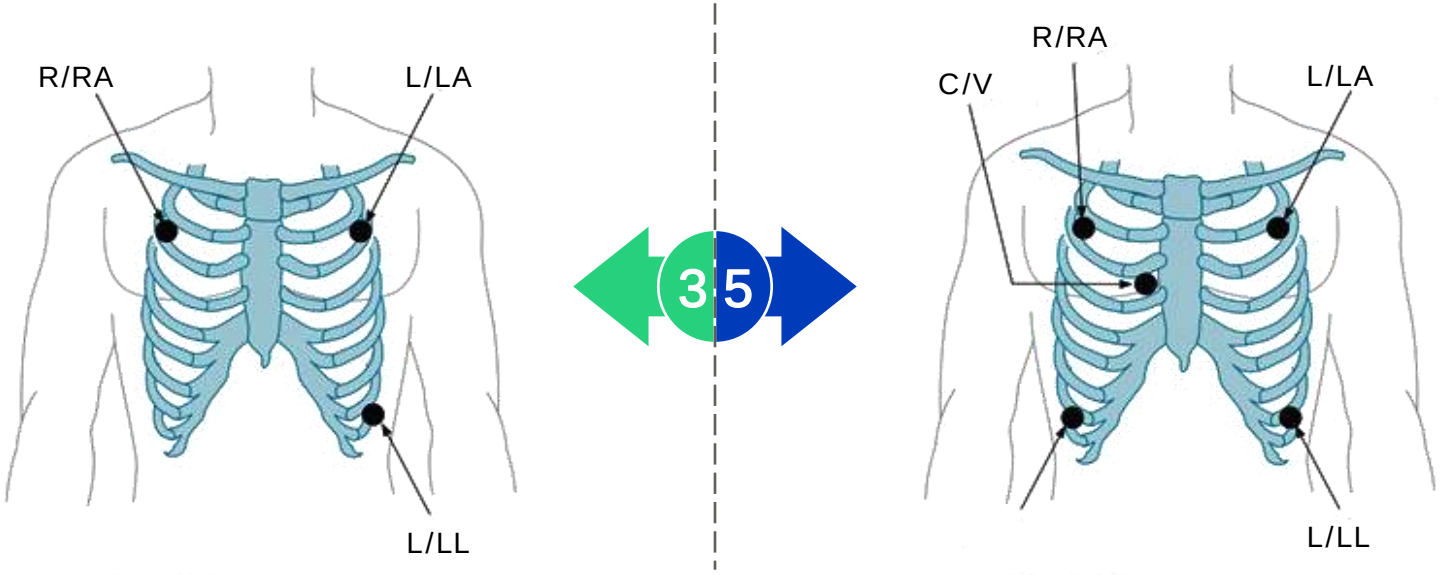
Mounting Solutions

- Rolling Stand
- Wall Mount
- Bedrail Hook

Parameters


ECG
Respiration
SpO_2
(Nellcor optional)
NIBP
TEMP
IBP/ICP
(optional)
$EtCO_2$
(optional)
Respiratory &
Ventilation
Basic 5
Parameters
Cardio-
vascular

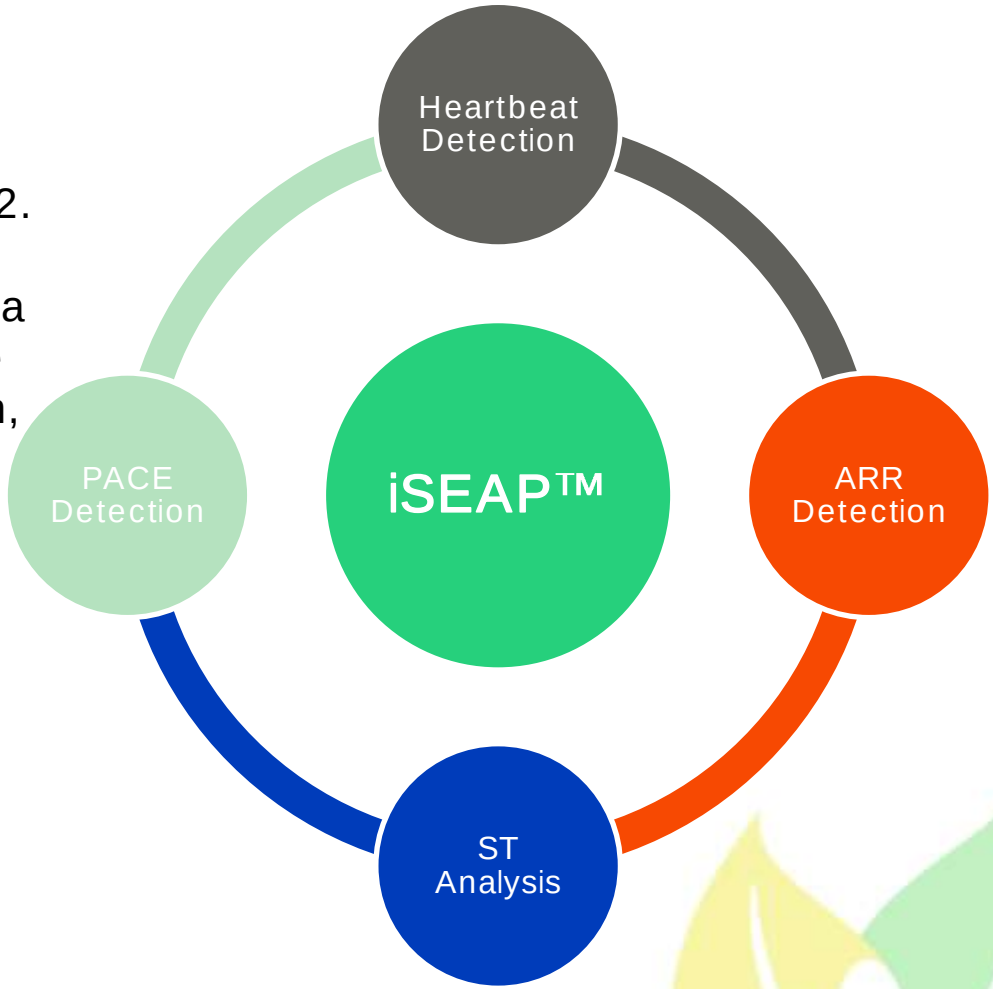
3/5-lead ECG Monitoring



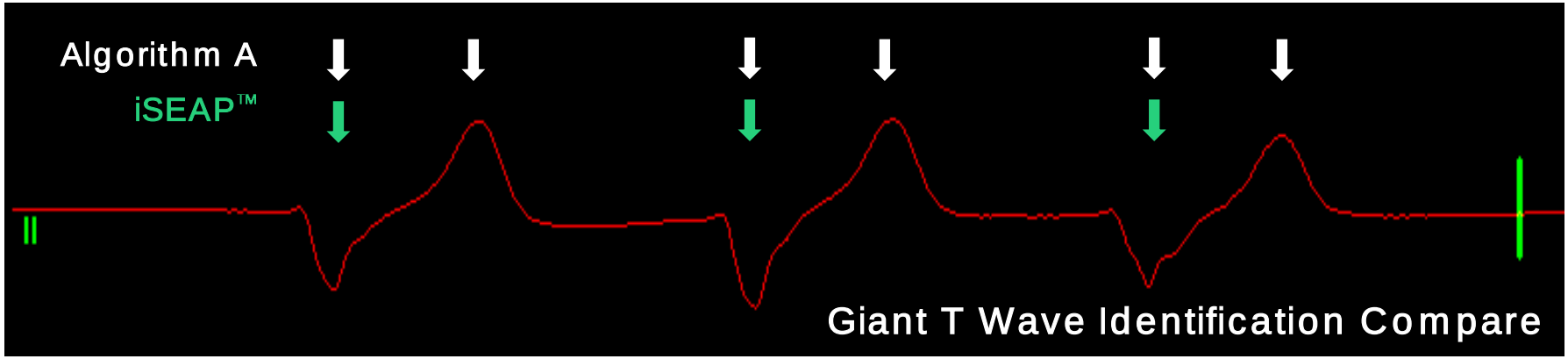
- EDAN iSEAP™ algorithm optimized for arrhythmia detection, pacemaker detection, ST analysis, and HR measurement.
- 16 types of arrhythmia events recording and alarms
- Pacemaker detection
- Defibrillator protection
- ESU protection

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.



EDAN iSEAP™ Heartbeat Detection

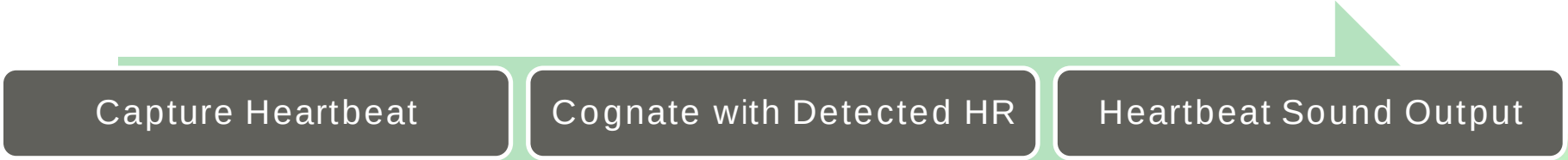


Algorithm A is another algorithm from market as a compare reference.

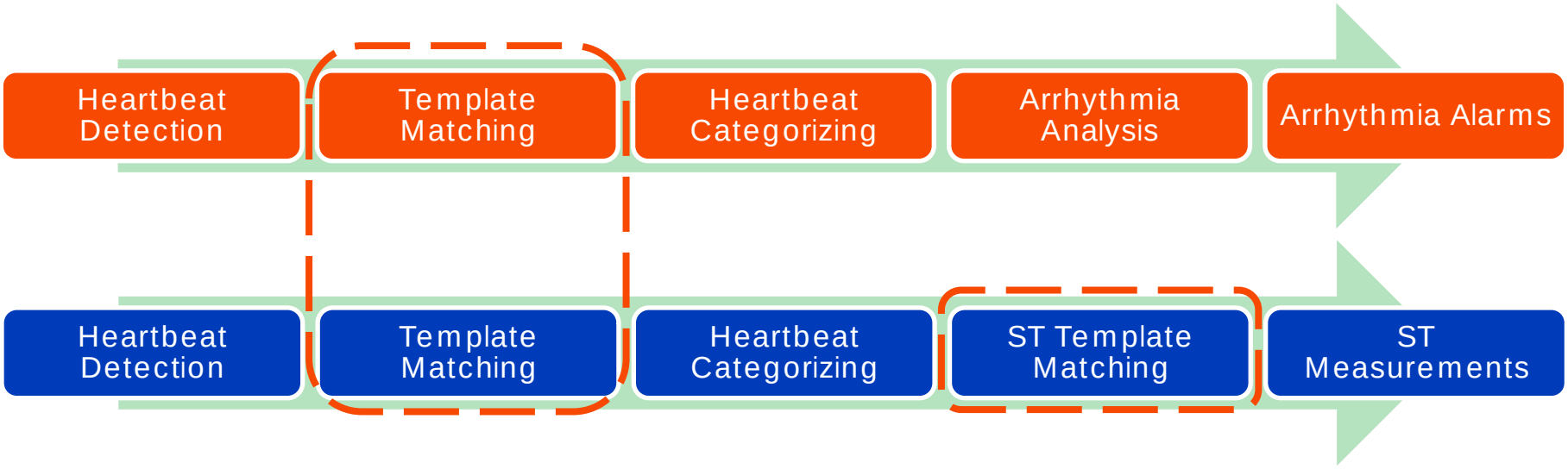
- iSEAP™ identifies giant T waves and avoids false heartbeat, providing accurate HR measurements for patients with ischemic T waves, myocarditis, hyperkaliemia, early repolarization syndrome, and so on.
- For patients with tachycardia, bradycardia, atrial flutter, etc., iSEAP™ makes sure the heart beat 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.



EDAN iSEAP™ Arrhythmia & ST Analysis



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.

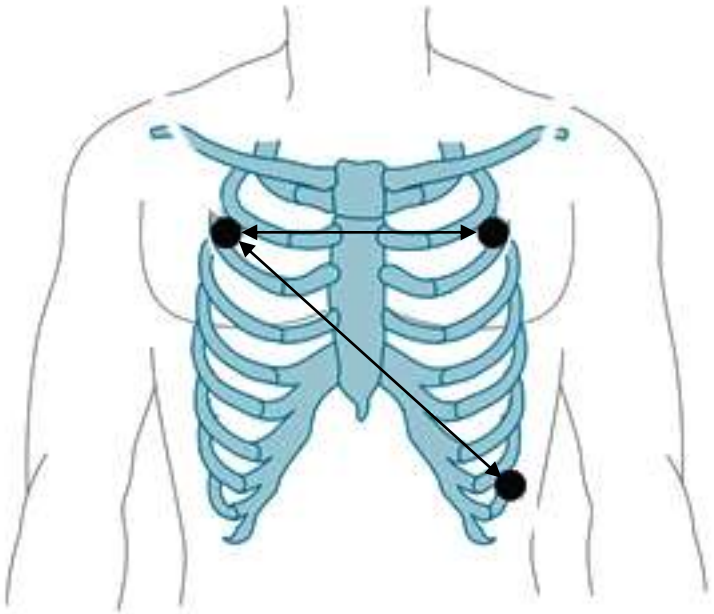
EDAN iSEAP™ Pacemaker Detection

- It rules out the external inferences and avoid false pacemaker detections.
- It picks accurate pacemaker signal immediately with a high sampling rate

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.

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

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.

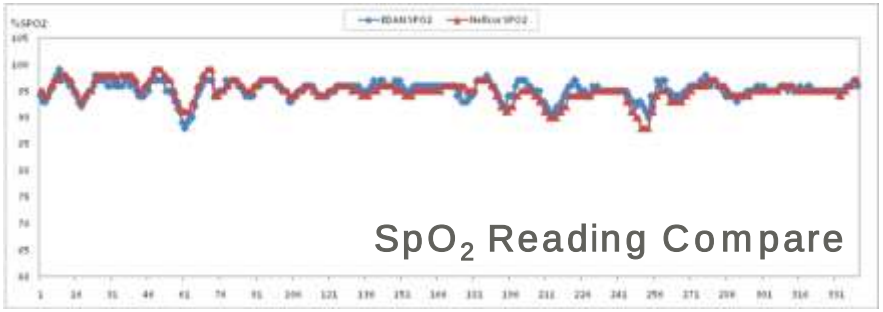
In consideration of this, EDAN developed its anti-interference oximetry, the use of which can largely eliminate the interference even under harsh conditions of high motion and low perfusion. This technique addresses this issue on a combo of hardware and software designs:

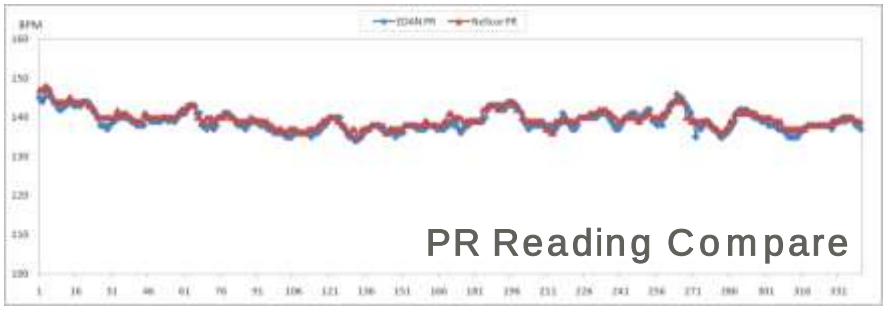
- **Hardware Design**
  A high signal-to-noise ratio circuit with low-noise components is designed for the acquisition of a weak signal under low perfusion.

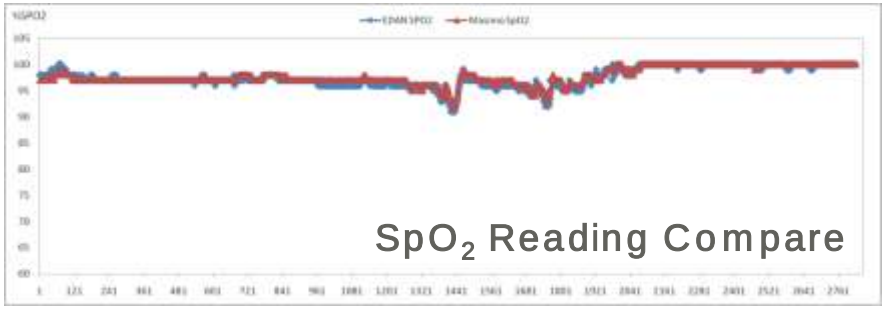
- **iMAT™ Algorithm**
  A unique signal processing algorithm iMAT™ takes advantage of signal characteristics under high motion and low perfusion to improve the accuracy and stability of the measurement. This algorithm employs a special filtering process to reduce the noise caused by motion, as well as from other sources, and amplify the pulse oximetry signal.

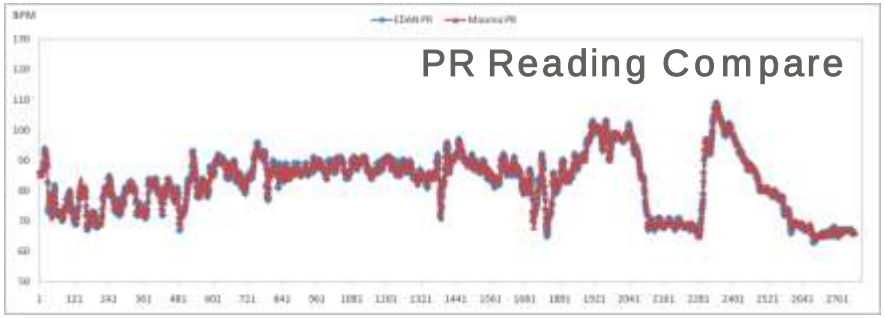
EDAN SpO_2 Compare

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









- **EDAN v.s. MASIMO**
  Tested in OT

Optional

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

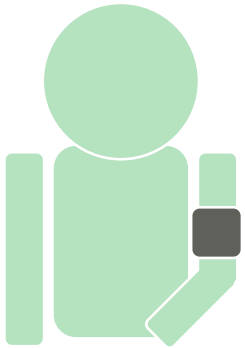
EDAN NIBP

- **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.

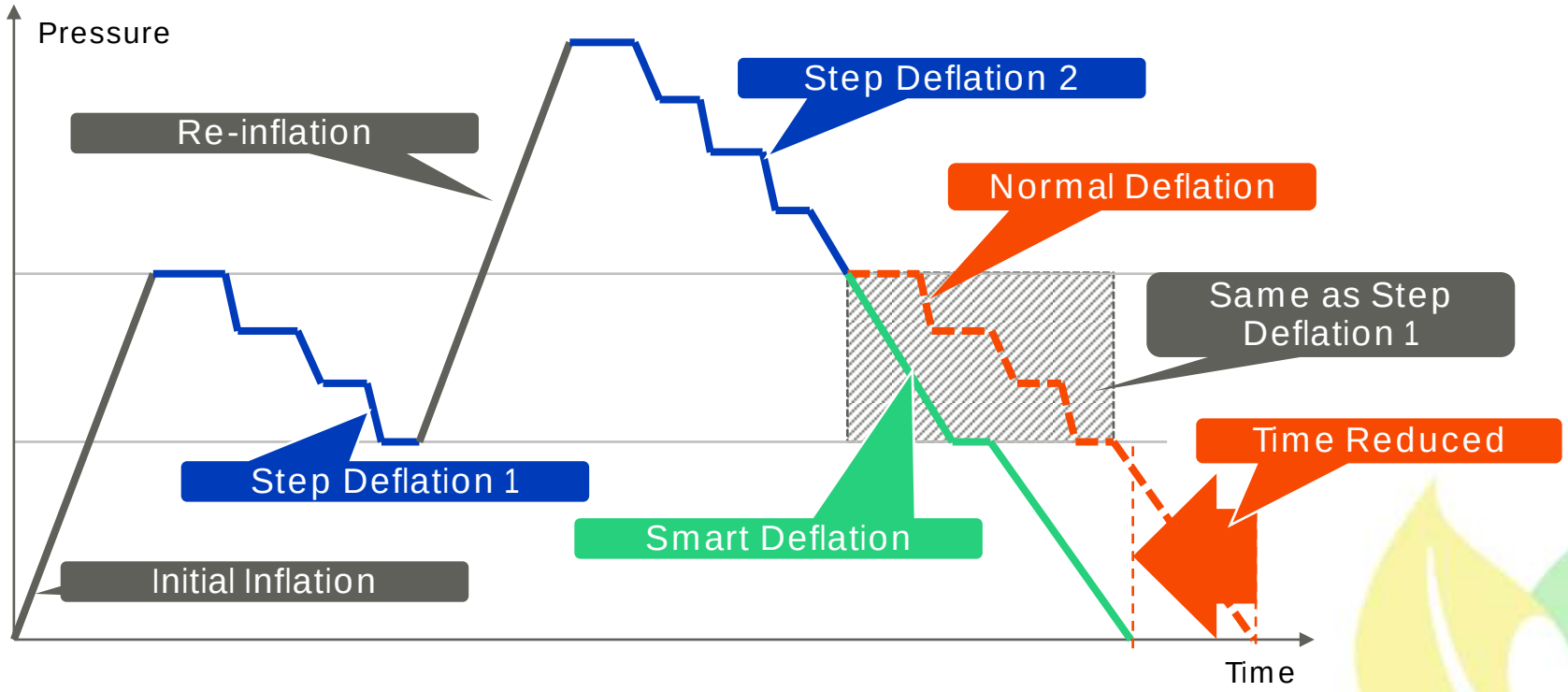
- **Full Range of Optimized Cuff Sizes**
  9 different sizes of cuffs covering from neonates to large adults, from arm to thigh.
  Cuff sizes are optimized according to clinical researches.



EDAN iCUFS™ Smart Deflation

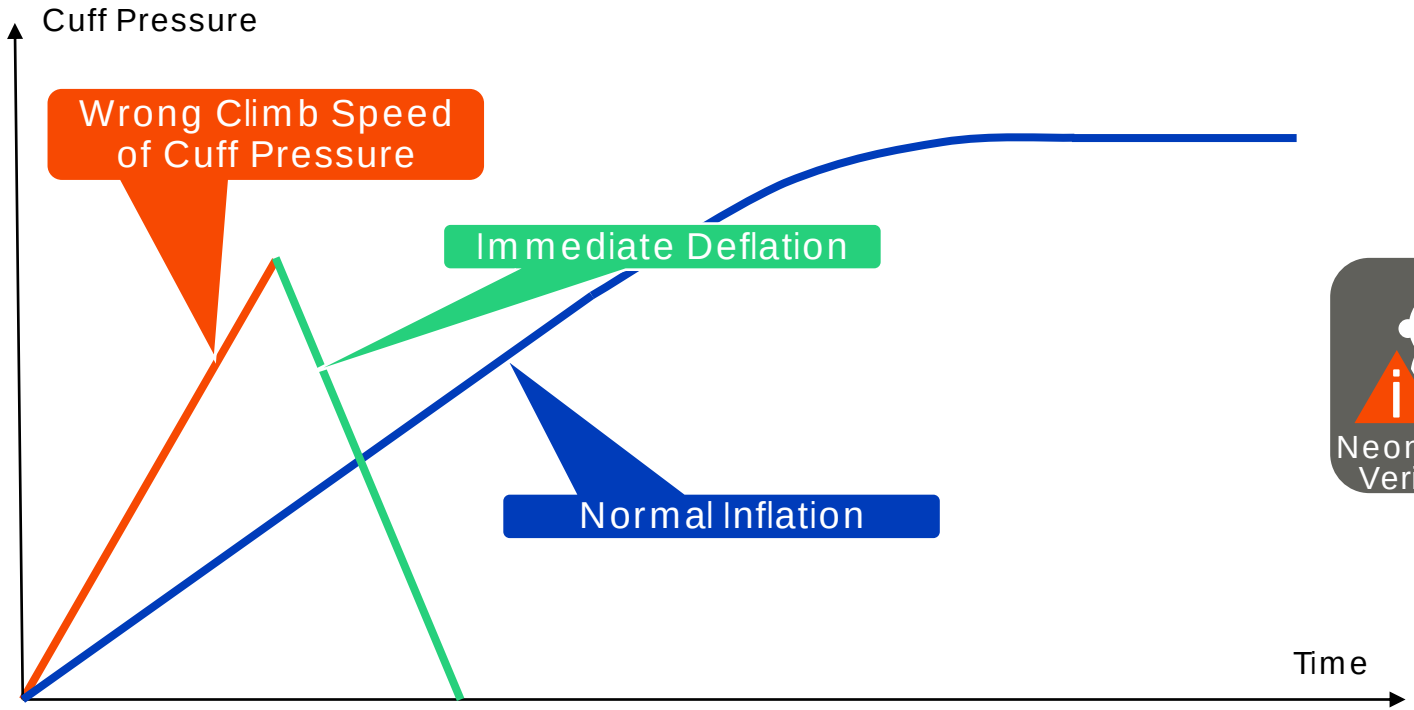
With the smart deflation technology used in EDAN iCUFS™, normal BP measuring time will be decreased by avoiding unnecessary deflation steps, ensuring BP measuring efficiency especially in emergency cares.

- **Time Reduced:**
  Around 5 seconds when there's re-inflation
  Around 2~3 seconds when there's no re-inflation

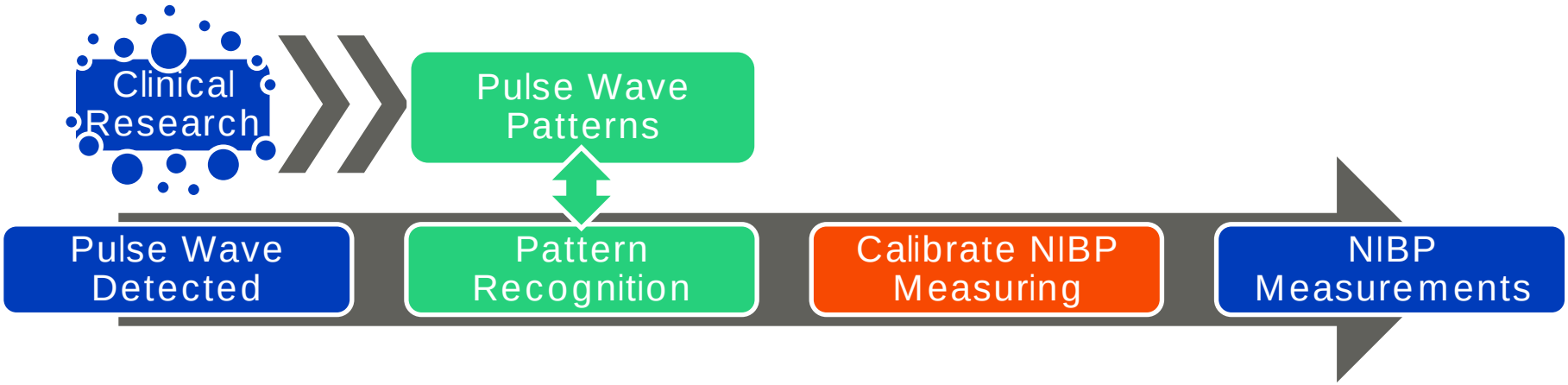


EDAN iCUFS™ Neonatal Cuff Verification

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.



EDAN iCUFS™ Pulse Wave Calibration



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

Temperature

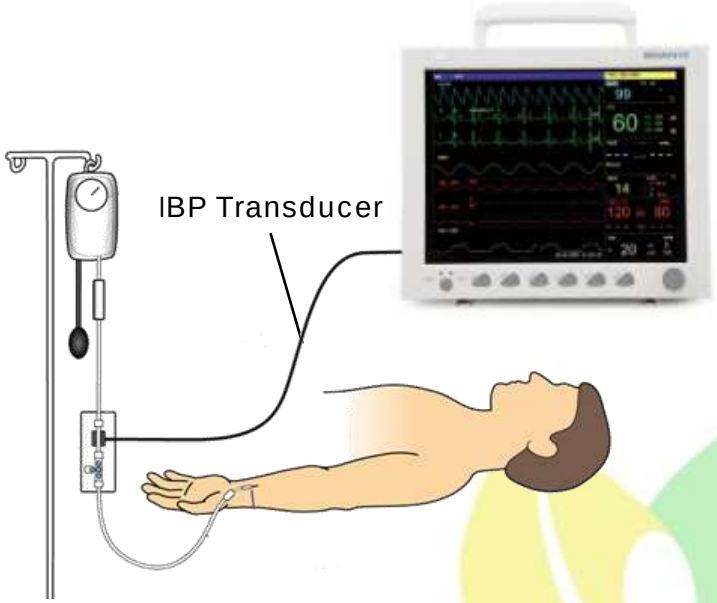
- **2-channel Temperature monitoring**
- **Probes**
  Compatible with CY and YSI probes
  Compatible with 2.252 K/25°C & 10K/25°C probes
- **Measuring Positions**
  Skin, Oral & Rectal temperature measurements

Optional

IBP

Compatible Transducers

- 2-channel IBP monitoring
- **Pressure Labels**
  ART, PA, CVP, RAP, LAP, ICP, PI(User-defined), P2(User-defined)
- **Pressure Units**
  mmHg/kPa/cmH_20
  (cmH_20 is designed specially for venous pressure monitoring)



Optional

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.

Optional

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

Optional

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.

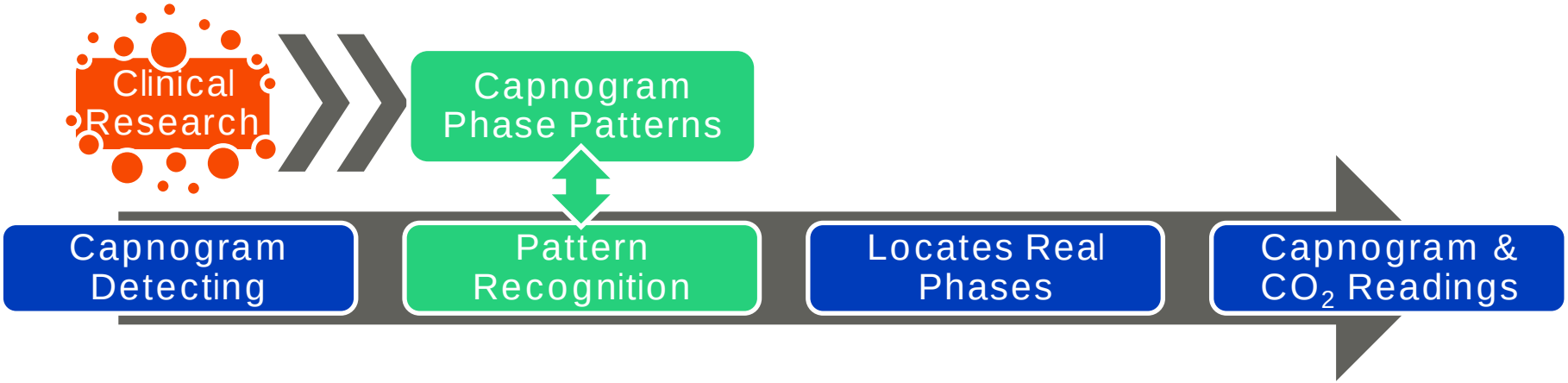
- **Arc Dehumidification Channel**
  A thin arc style dehumidification channel is introduced to G2 water trap. Such design effectively reduced the dead spaces and improves the drainage capability.

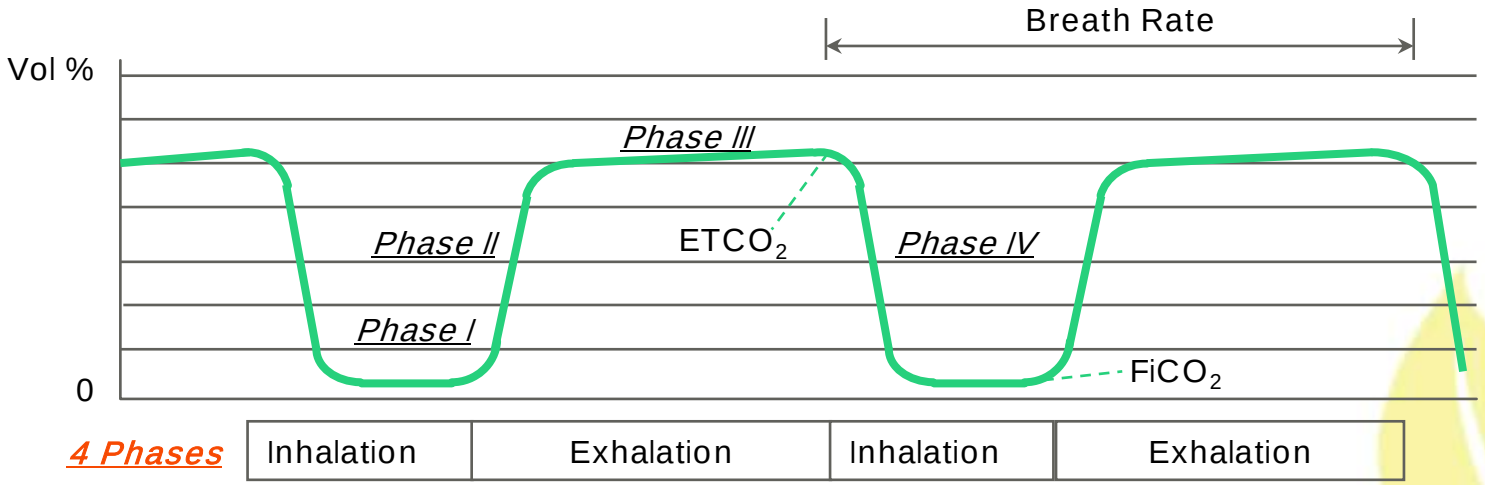
- **One-way Channel Design**
  In order to achieve a lower sampling flow rate, some dehumidification cups introduce tee valve to control the flow rate of the second channel. However, the switch itself causes the air fluctuation and affects the measurement. On G2 water trap, instead of tee valve, a one-way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

Optional

EDAN iCARB™ Pattern Recognition

Based on massive clinical data and analysis, pattern recognition is developed and applied in iCARB™ 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.



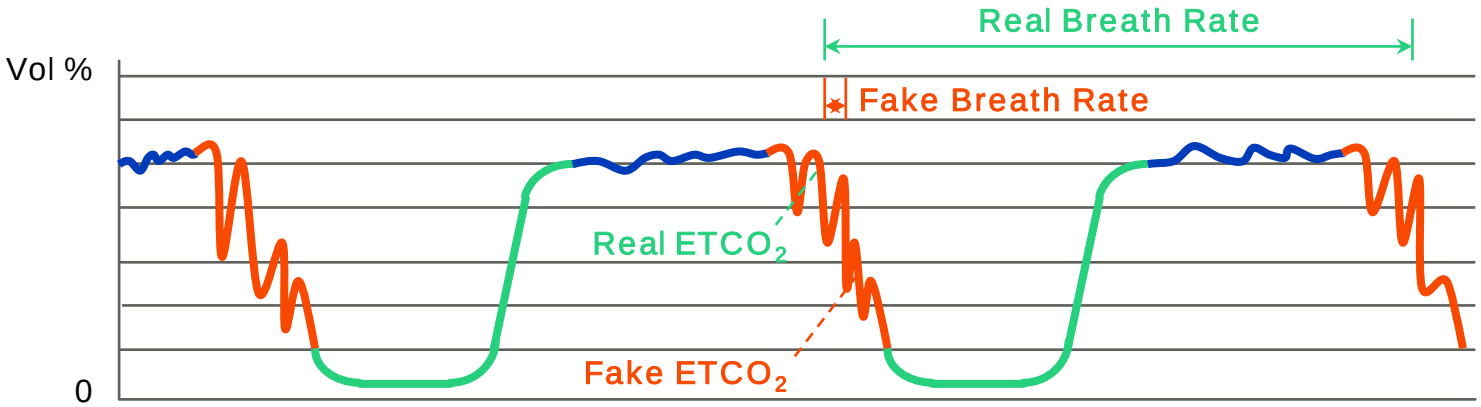


Optional

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.



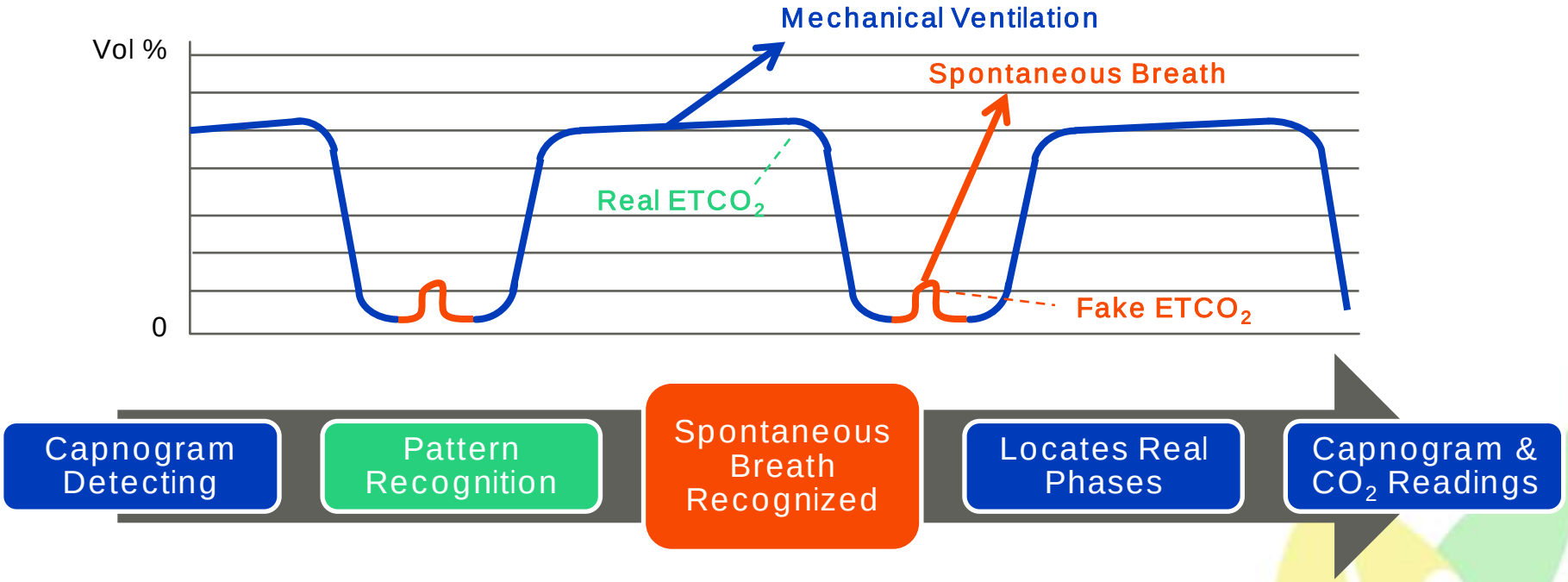
Capnogram Detecting → Pattern Recognition → Cardiogenic Oscillation Recognized → Locates Real Phases → Capnogram & CO_2 Readings

Optional

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 $EtCO_2$.

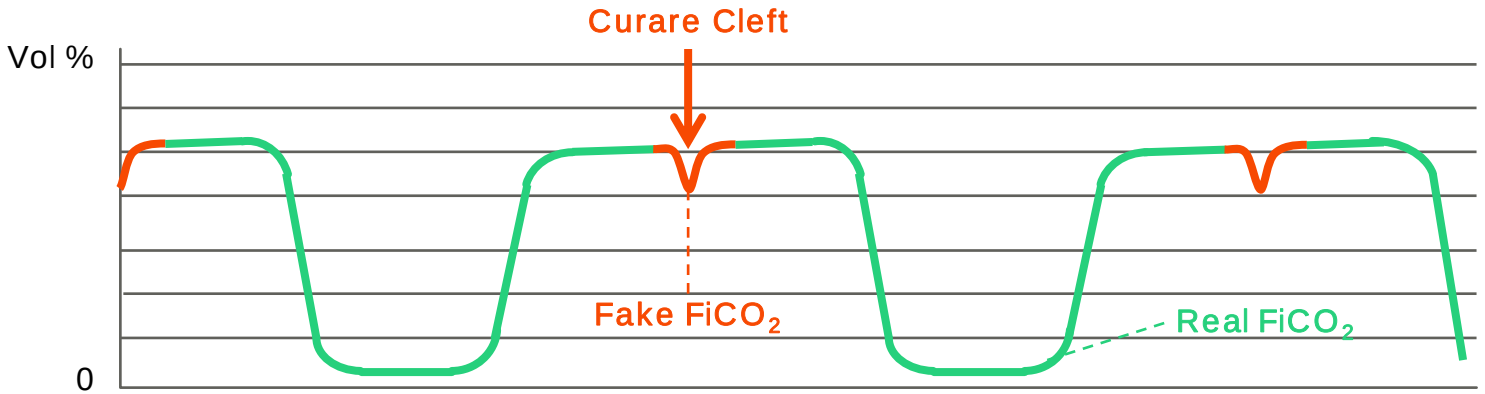
With pattern recognition technology, iCARB™ recognizes spontaneous breaths, and generates accurate readings.



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.



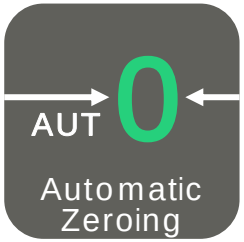
Capnogram Detecting → Pattern Recognition → Curare Clefts Recognized → Locates Real Phases → Capnogram & CO_2 Readings

Optional

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.



Optional

Respironics LoFlo™ Sidestream CO_2

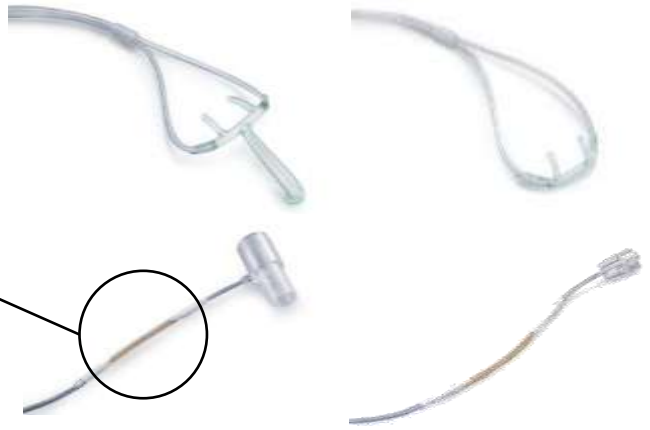
- **Plug & Play LoFlo™ CO_2 Module**
  Modular-like Design
  Needs to work with Respironics CO_2 sampling tubes

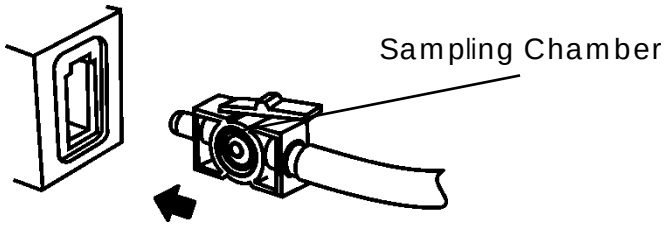
- **Short Warm-up Time**
  10~20 seconds

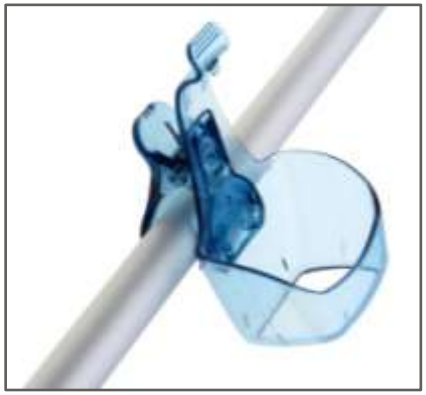
- **Water Trap**
  Dehumidification Tubing Design

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

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







PHILIPS
RESPIRONICS

EDAN

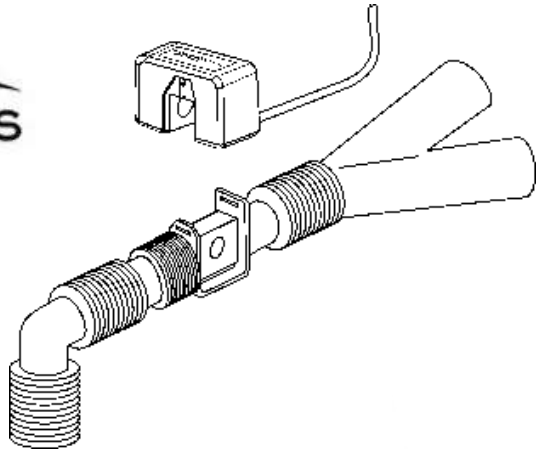
Optional

Respironics CAPNOSTAT® Mainstream CO_2

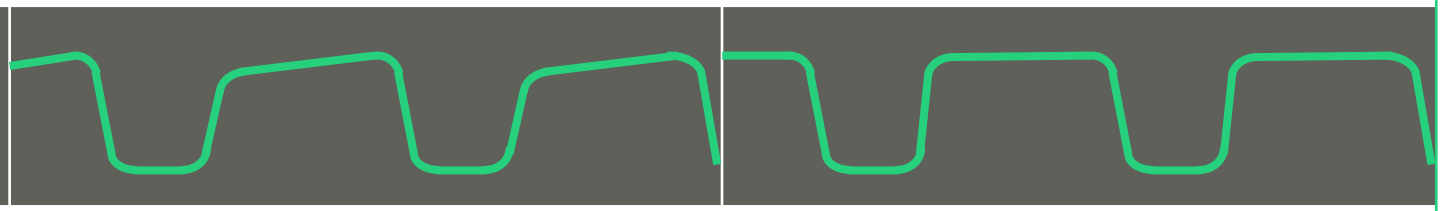
- **Plug & Play Mainstream CO_2 Module**
  Needs to work with a Respironics CAPNOSTAT® CO_2 sensor
- **No Water Trap**
  Installed directly on the airway.
- **Maintenance Free**
  No routine calibration needed
- **Fast Response**

PHILIPS
RESPIRONICS

Plug & Play

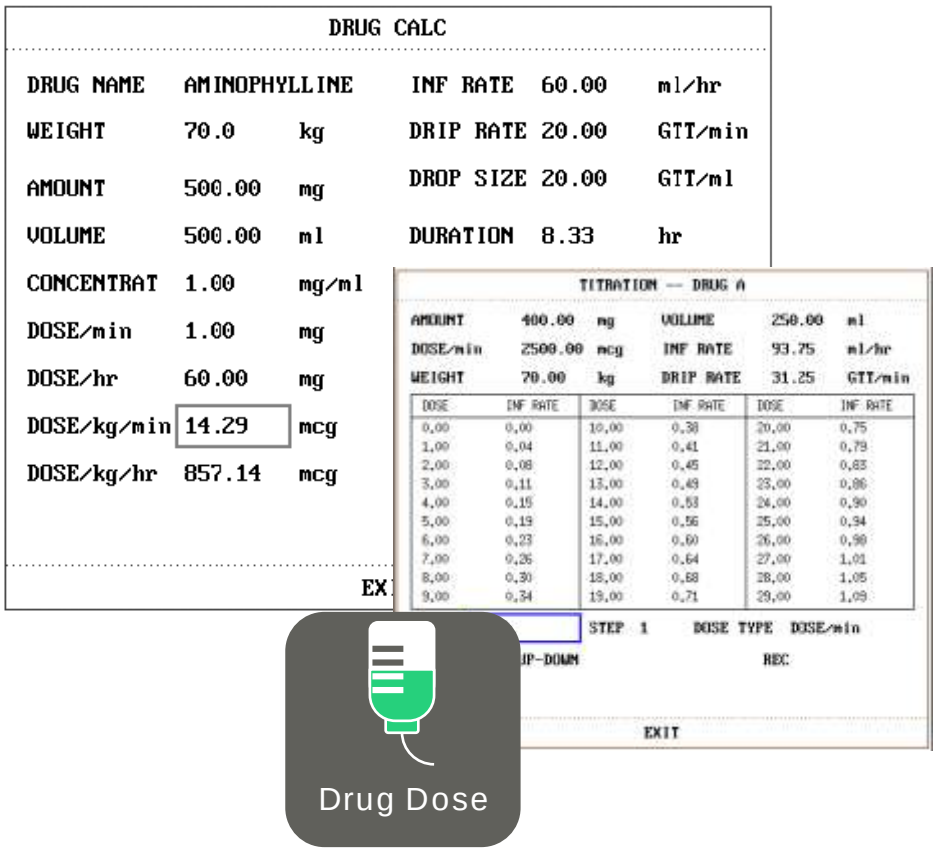


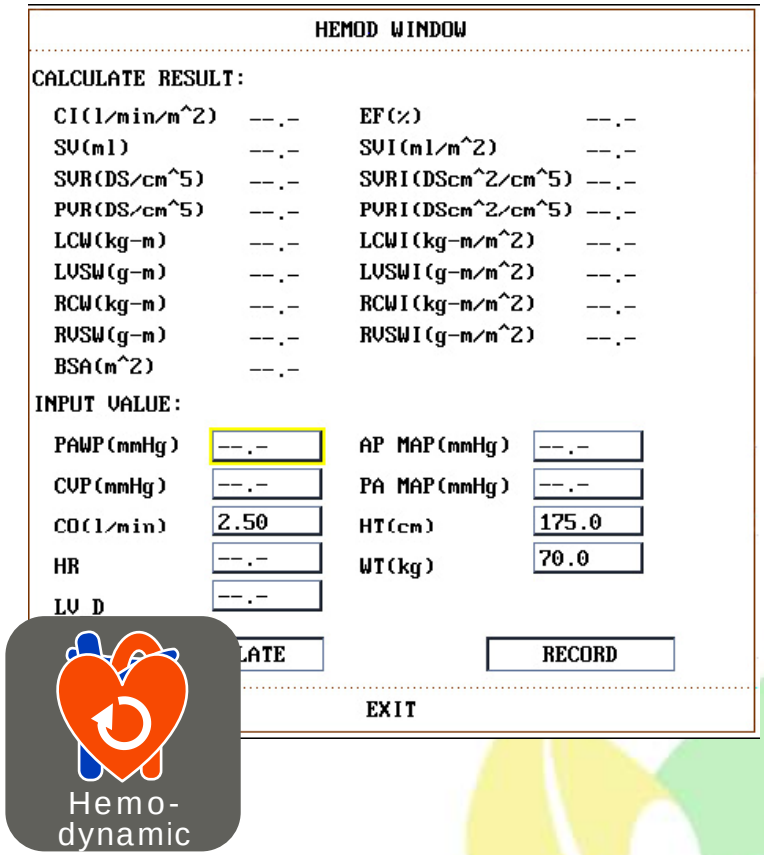
Sidestream v.s. Mainstream CO_2

	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

Clinical Calculations

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





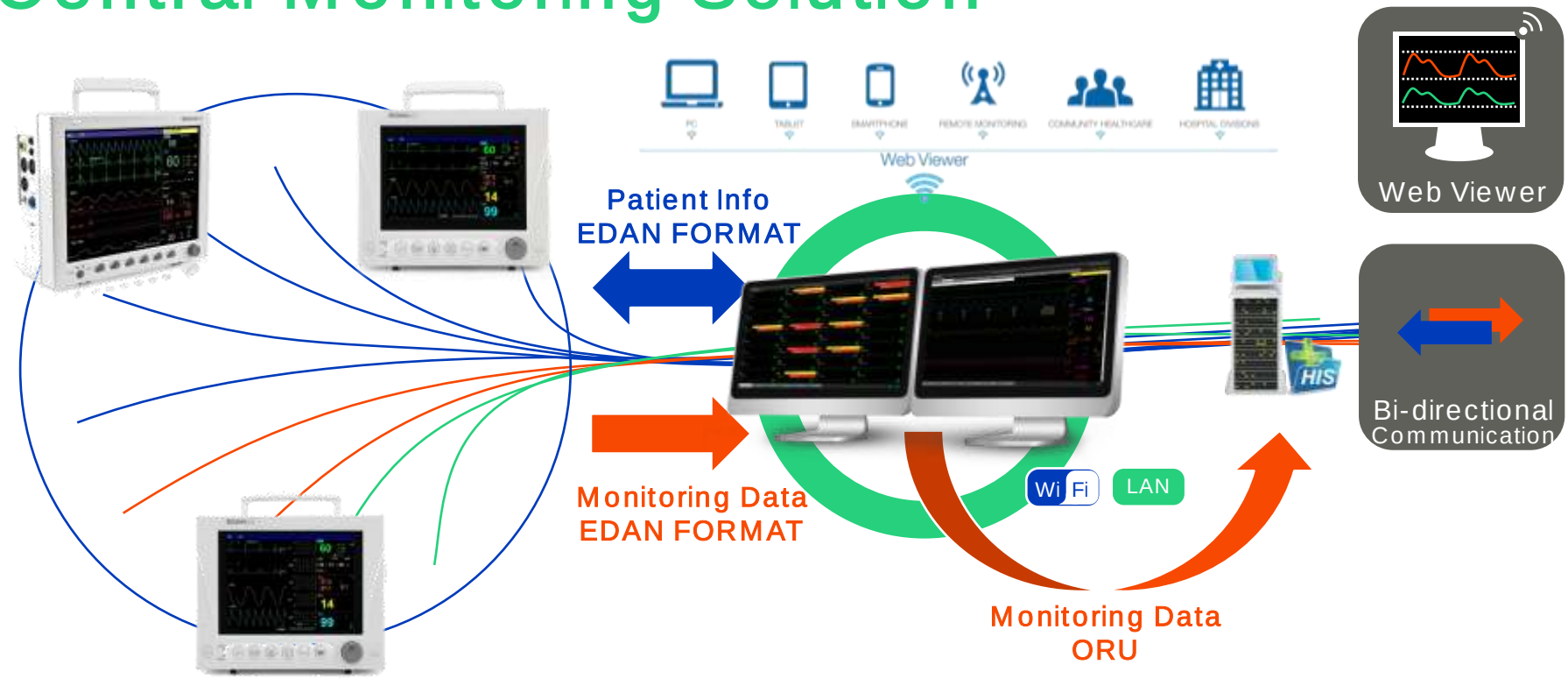
External AP

ASUS WL-330n

External AP

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

Central Monitoring Solution

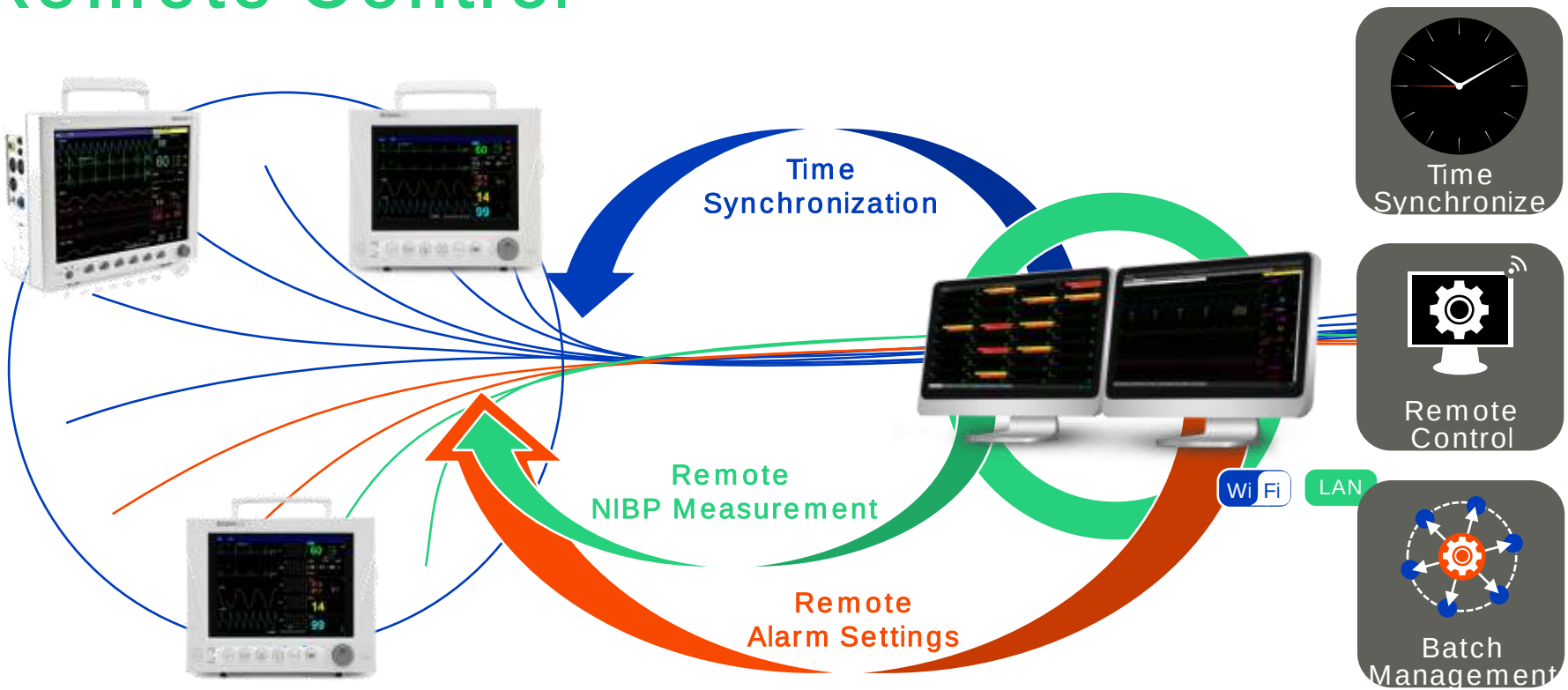


- **Central Monitoring Station**
  EDAN MFM-CMS central monitoring station may communicate with EDAN monitors on a bi-directional basis.

- **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**
  Time setup of each monitor synchronizes with MFM-CMS either automatically or manually.

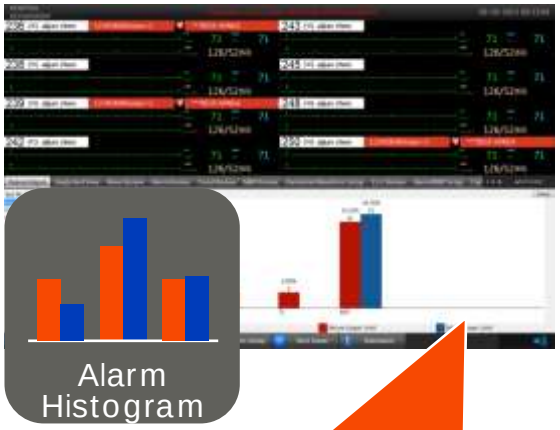
- **Remote NIBP Measurement**
  NIBP measurement can be activated remotely from MFM-CMS.

- **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.

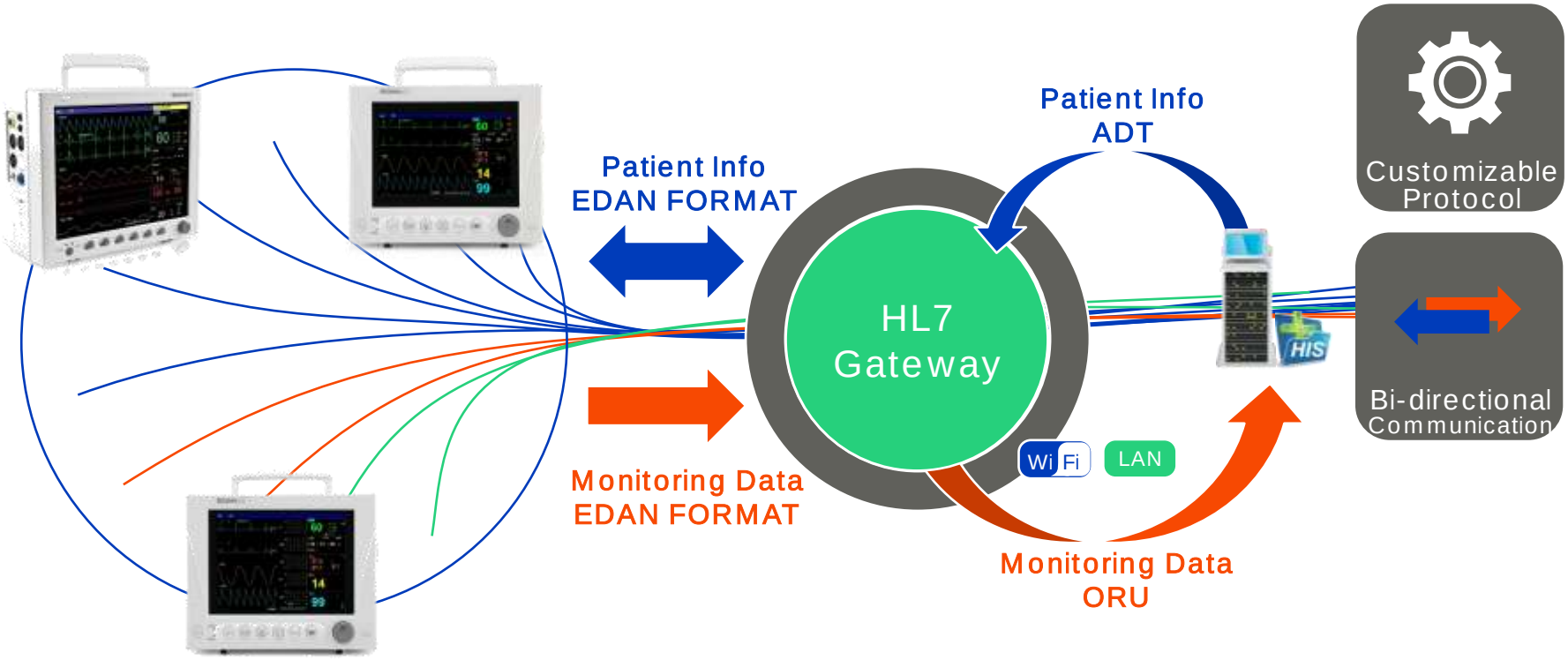
Central Statistics & Analysis

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.



HL7 Gateway Solution

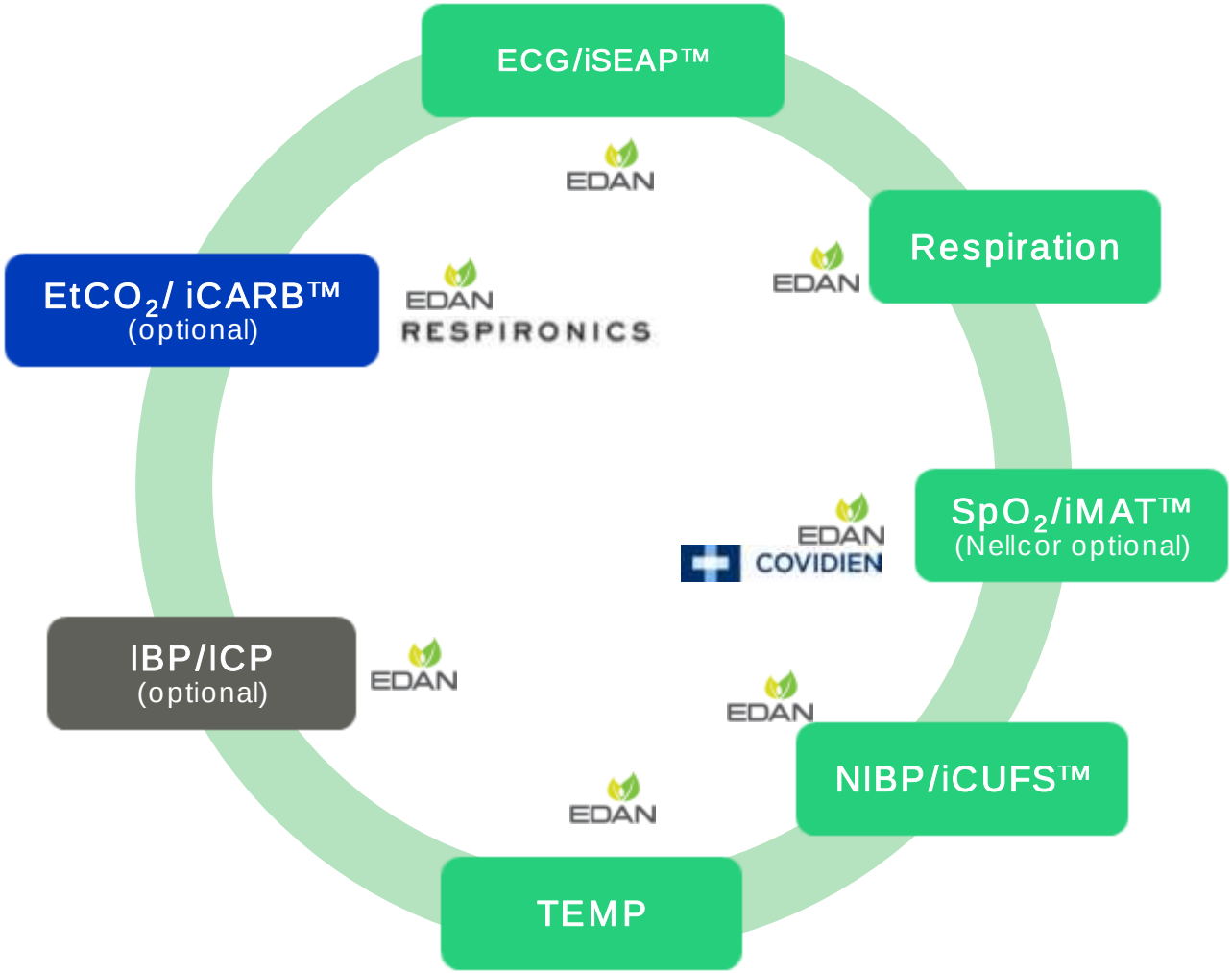


Installed on any device in the network, EDAN HL7 gateway brings machines and HIS together:

- **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.

Design Highlights



Parameter Highlights

Network Highlights

EDAN

A world of potential

THANK YOU

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Jan 20, 2015