



A world of potential

# The Application of i15 Blood gas and chemistry analyzer in COVID-19

—John. Huang

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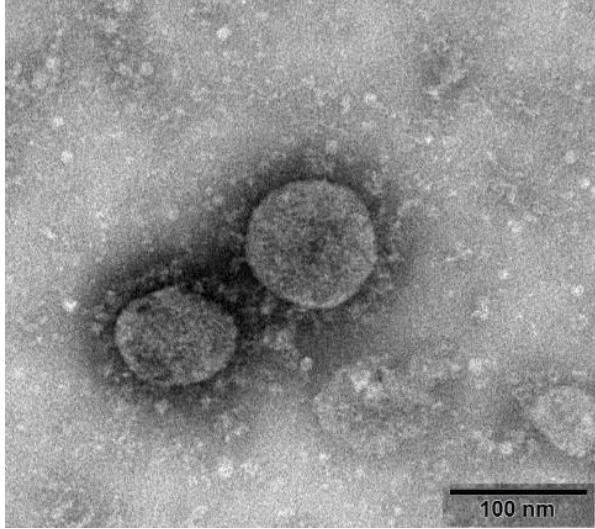




What is COVID-19



# Introduction of COVID-19



The first new coronavirus virus isolated by China CDC

**Name:** The 2019 corona virus was renamed "COVID-19" by the WHO on 2.11.2020, the virus was discovered due to viral pneumonia cases in wuhan in 2019.

**Category :** Coronaviruses are a large family of viruses, of which seven are known that cause symptoms are MERS (Middle East respiratory syndrome), severe acute respiratory syndrome (SARS), and "covid-19".

**Pathophysiology: stimulating the body to produce a strong immune response**  
**Virus infect cells**

**Causing WBC, immune cells to have immune response and gathers to infection site**

**Causing pulmonary infection, edema causes dyspnea, hypoxemia, acid substitution, shock, etc**

**Treatment : General treatment, oxygen therapy, mechanical ventilation, correction of acidosis, even the use of hormone therapy.**



# Clinical Manifestation

## Clinical management of severe acute respiratory infection when novel coronavirus (2019-nCoV) infection is suspected

Interim guidance  
28 January 2020



## Clinical Manifestation

Based on the current epidemiological investigation, the incubation period is 1-14 days, mostly 3-7 days. The main symptoms are usually fever, fatigue and hoarse. fewer patients would have nasal congestion, runny nose, diarrhea and other symptoms. In the most severe cases, dyspnea and/or hypoxemia occurred within one week, with severe cases rapidly progressing to acute respiratory distress syndrome, septic shock, hard-to-correct metabolic acidosis, and bleeding and coagulation dysfunction.

# Clinical Classification

## 1. Light symptoms

The clinical symptoms were mild, and there was no sign of pneumonia on imaging.

## 2. Midium symptoms

Patient is having fever, respiratory symptoms and radiographic manifestations of pneumonia.

## 3. Severe symptoms , in accordance to any of the following:

- a. Respiratory distress,  $RR \geq 30/\text{min}$ ;
- b. Oxygen saturation  $\leq 93\%$ ;
- c. Oxygenation index:  $(PaO_2) / (FiO_2) \leq 300\text{mmHg}$  ;

## 4. Very severe symptoms , in accordance to any of the following :

- 1. Respiratory failure presented, mechanical ventilation required ;
- 2. Coma ;
- 3. Combined with other organ failure requires intensive care unit ;





# The necessity of Blood gas analysis in COVID-19

# The overview of blood gas analyzer

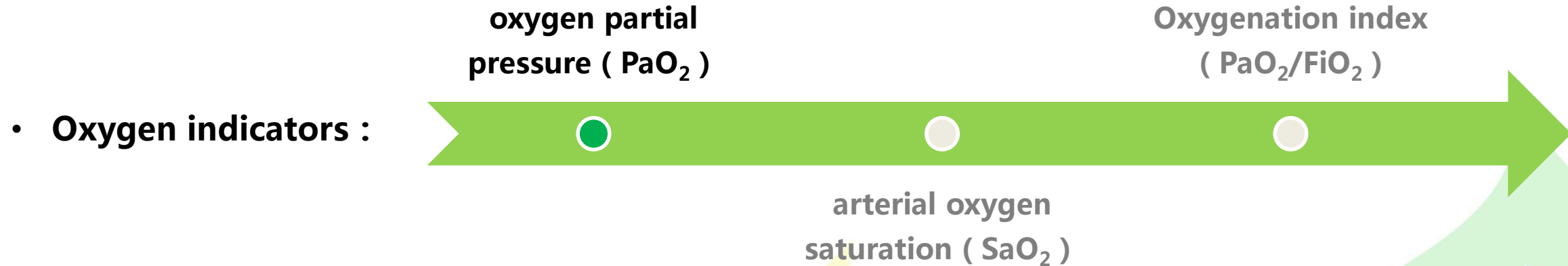
- **Arterial blood gas analysis** : by using the arterial blood gas analyzer to determine the gas in the blood and pH parameters so as to understand the body function;



- Assessing lung respiratory function (ventilation)
- Assessing pH
- Diagnostic of hypoxemia and respiratory failure
- One of the important monitoring parameters in intensive care medicine
- Essential in ECMO
- Important basis for guiding mechanical ventilation mode and parameter regulation



# Introduction of Clinical parameters



1. **oxygen partial pressure (  $\text{PaO}_2$  )** : The pressure caused by the physical dissolution of oxygen molecules in the blood.

Range : 80 ~ 105 mmHg

Blood gas analysis is essential in the treatment of COVID-19!

**\*\*Application in COVID-19** : indicator of hypoxia in a patient ;

# Introduction of Clinical parameters

oxygen partial  
pressure (  $\text{PaO}_2$  )

Oxygenation index  
(  $\text{PaO}_2/\text{FiO}_2$  )

- **Oxygen indicators :**

## 2. Arterial oxygen saturation ( $\text{SaO}_2$ ) :

The degree of oxygen binding to hemoglobin.

**Range:** 95% ~ 98% , The presence of hypoxemia can be determined if less than 90%.

**Affecting factors:** affected by the hemoglobin content

arterial oxygen  
saturation (  $\text{SaO}_2$  )

Fingertip oxygen saturation

Arterial oxygen saturation

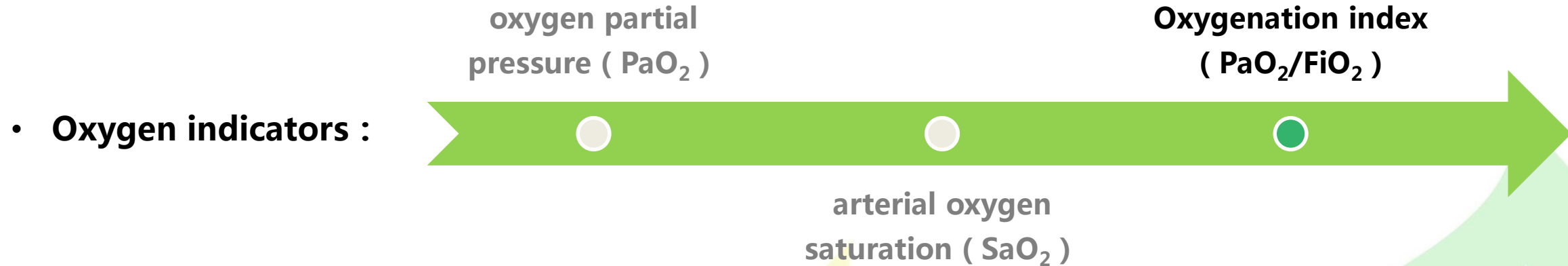
**Severe symptoms , in accordance to any of the following:**

- a. Respiratory distress ,  $\text{RR} \geq 30/\text{min}$  ;
- b. **Oxygen saturation**  $\leq 93\%$  ;
- c. **Oxygenation index** : (  $\text{PaO}_2$  ) / (  $\text{FiO}_2$  )  $\leq 300\text{mmHg}$  ;

**\*\*Application in COVID-19** : determination of **hypoxia status** of patients and the **diagnostic criteria of critical patients;**



# Introduction of Clinical parameters



**3. Oxygenation index (  $\text{PaO}_2/\text{FiO}_2$  ) :** oxygen partial pressure/Oxygen inhalation concentration ,  
Reflect the respiratory function under the oxygen condition. normal value  $\geq 300\text{mmHg}$

In the fifth edition of diagnostic and treatment of COVID-19 , if oxygen partial pressure (  $\text{PaO}_2$  ) /oxygen inhalation concentration (  $\text{FiO}_2$  )  $\leq 300\text{mmHg}$   
together with other casing the patient can be diagnostic with severe COVID-19

**\*\*Application in COVID-19 :** Monitoring hypoxia in patients with oxygen, any existence of ARDS, if mechanical ventilation is required.

# Introduction of Clinical parameters

- **oxygen inhalation concentration (  $\text{FiO}_2$  )**

**4. oxygen inhalation concentration** : the concentration of oxygen inhaled under normal circumstance.

**Methdology : unit ( % )**

During inhalation , oxygen concentration =  $21 + 4 \times \text{flowrate}$   
( L/min ) / 100



**\*\*Application in COVID-19** : Determine whether the patient under oxygen inhalation is having respiratory failure.



# Introduction of Clinical parameters

- **Metabolic index : Lactatic acid、AG**

**1、Lactate acid** : Lactic acid is the final product of anaerobic fermentation, it accumulates when the body is severely deprived of oxygen. Septic shock, respiratory failure, circulatory failure can cause hypoxia, which raise the concentration of lactic acid.

**Range** : 1 ~ 2mmol/L , Lactic acidosis occurs when the concentration exceed 4mmol/L

**\*\*Application in COVID-19** : Determine whether the patient is having hypoxia and prognosis by the concentration level of lactatic acid

# Introduction of Clinical parameters

- Metabolic index : Lactatic acid, **AG**

## BG variation

### 1 . High AG metabolic acidosis ;

- **AG raises ( $AG > 20 \text{ mmol / L}$ ) ;**
- Causes : Ketoacidosis, lactic acidosis, uremia and other causes ;

## BG Variation :

### 2 . Normal AG high Cl- type metabolic acidosis;

- **AG in normal range ;**
- Common in  $\text{HCO}_3^-$  loss or H reduction of renal tubules and renal diseases

**\*\*Application in COVID-19** : AG was used to determine the type of metabolic acidosis so as to treat the protopathy disease.



# Application of BGA in COVID-19 treatment

The COVID-19 has been proven to be the cause of multiple complication, among which the hypoxemia is the direct result of the progression of COVID-19.

**Blood gas test is essential in the monitoring of hypoxemia.** In the progression of hypoxemia, the respiratory support system would be applied to the treatment and based on the level of oxygenation index, the respiratory support system escalates correspondingly.

Respiratory support system would be escalated as following:

- Nasal catheter
- HFNC (High-flow nasal cannula oxygen therapy)
- NIV (Noninvasive Ventilation)
- IMV (Invasive mechanical ventilation)
- RM (Recruitment Maneuver)
- PV (Prone Ventilation)
- ECMO (Extracorporeal Membrane Oxygenation)



# Application of BGA in COVID-19 treatment

1. hypoxemia with  $\text{PaO}_2/\text{FiO}_2$  between 200-300mmHg

a. Nasal catheter or oxygen mask is applied and patient should be assessed if respiratory distress or Hypoxemia is relieved. It is recommended that the oxygen flow in catheter does not exceed 5L/ min; for oxygen mask treatment the oxygen flow rate is between 5-10 L/min.

b. High-flow nasal cannula oxygen therapy (HFNC) :

HFNC should applied to the patient if there is no relieved of respiratory distress and hypoxemia after receiving nasal catheter/oxygen mask treatment for 2 hours.

If HFNC failed to relieve the symptoms in 2 hours, NIV and MIV should be applied

**\*\*Application in COVID-19** : Blood gas is tested during treatment of nasal catheter and HFNC



# Application of BGA in COVID-19 treatment

2. hypoxemia with  $\text{PaO}_2/\text{FiO}_2$  between 150-200mmHg

a. NIV (Noninvasive Ventilation)

NIV treatment is preferred in this case. Although the failure rate of NIV in these patients is very high. If there is no improvement on hypoxemia or even deterioration in a short time (1-2h), NIV should be performed promptly.

**\*\*Application in COVID-19** : Blood gas is tested during treatment of NIV

# Application of BGA in COVID-19 treatment

3. Hypoxemia with  $\text{PaO}_2/\text{FiO}_2$  below 150mmHg

a. IMV (Invasive mechanical ventilation)

IMV is the implementation of lung protective mechanical ventilation strategy

b. (RM) Recruitment Maneuver

When  $\text{FiO}_2$  in IMV is higher than 0.5, recruitment maneuver is applied

c. (PV) Prone Ventilation

Prone ventilation should be applied to the patient for more than 12 hours

If the  $\text{PaO}_2/\text{FiO}_2$  is steadily below 150mmHg



**\*\*Application in COVID-19** : Blood gas is tested during treatment of IMV, RM and PV

# Application of BGA in COVID-19 treatment

3. Hypoxemia with  $\text{PaO}_2/\text{FiO}_2$  below 150mmHg

b. ECMO (Extracorporeal Membrane Oxygenation)

When IMV failed and the following condition is met, the implementation of ECMO should be applied to the patient and it is usually considered as the last resort to save the patient from COVID-19.

A.  $\text{PaO}_2/\text{FiO}_2 < 50$  mmHg over 3h;

B.  $\text{PaO}_2/\text{FiO}_2 < 80$  mmHg over 6h;

C.  $\text{FiO}_2$  1.0,  $\text{PaO}_2/\text{FiO}_2 < 100$  mmHg;

D. Arterial blood pH  $< 7.25$ ,  $\text{PaCO}_2 > 60$ mmHg over 6h, and respiratory rate  $> 35$ /min;

E. Respiratory rate  $> 35$ /min, arterial blood pH  $< 7.2$  and platform pressure  $> 30$ cmH<sub>2</sub>O;

**\*\*Application in COVID-19** : Blood gas is tested during treatment of ECMO





What is Edan I15 blood gas and chemistry analyzer

# Introduction of I15

Dr.Lin



- **Vice President and Chief Scientist at Edan Instruments, INC.**

- Received Doctor degree of Chemistry at Princeton University (USA)
- Post-doctor of Biochemistry and Biophysics at Yale University (USA)
- Guest Professor at Chinese Academy of Science (CAS)
- Distinguished Expert from "Thousand Talents Program" of CAS
- Strong on Clinical Chemistry analysis diagnostic, the micro medical electrochemical sensor, especially in fluorescent chemo-sensor and POCT clinical real-time diagnostic of blood
- **Worked as Senior Scientist, Vice President (R&D) at Abbott (i-STAT), IDEXX OPTI Medical Systems, respectively.**

**The very first US FDA approved POCT blood gas and chemistry analyzer in Asia**



# Introduction of I15



- weights only 3.65 KG
- 12 hours battery, 50 tests available
- portable



# Consumables description



Analyzer



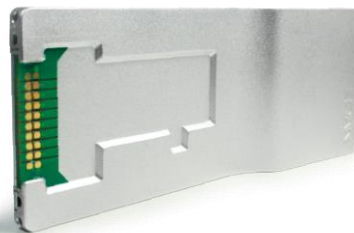
Quality Control



Test cartridge



Calibrator



E-Simulator



## Single-use Catridge

no cross infection

12 month storage,use at anytime

Can be recycled



## Electrochemistry methology

flexible combination of parameters

Good stability

zero maintenance



## Microfluidics

3 levels of control

Good accuracy

# Consumables discription

## Real POCT:

- ✓ Small Size
- ✓ Lightweight
- ✓ Battery
- ✓ Fast
- ✓ Easy
- ✓ Economic
- ✓ Zero Maintenance



Test cartridge

## One Cartridge for Everything!

<b>BG3</b>	PH,PO2,PCO2
<b>BG4</b>	PH,PO2,PCO2,Lac
<b>BC4</b>	Na,K,Ca,Cl,Hct
<b>BG8</b>	PH,PO2,PCO2, Na,K,Ca,Cl,Hct
<b>BG9</b>	PH,PO2,PCO2, Na,K,Ca,Cl,Hct,Glu
<b>BG10</b>	PH,PO2,PCO2, Na,K,Ca,Cl,Hct,Glu,Lac

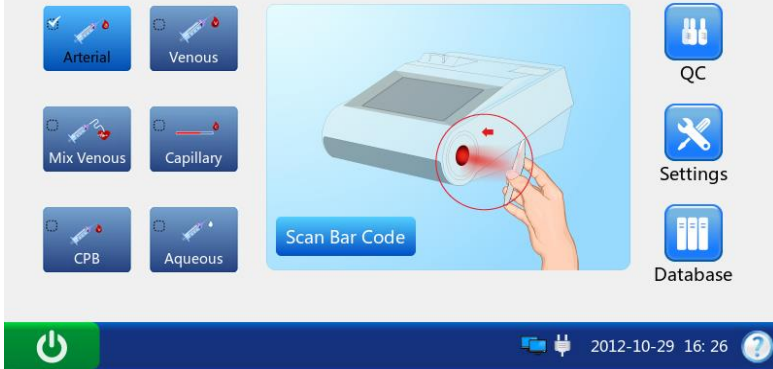
**10 Measured Parameters and 20+ Cal. Parameters**

	Storage	Shelf-life	On board stability/ Stability in RT	Re-warm time
Calibrator	2-8 °C	12 months	1 month	24 hours
Refrigerated Cartridge	2-8 °C	12 months	14 days	5 mins
Quality Control	2-8 °C	2 years	9 months	4 hours

# Operation

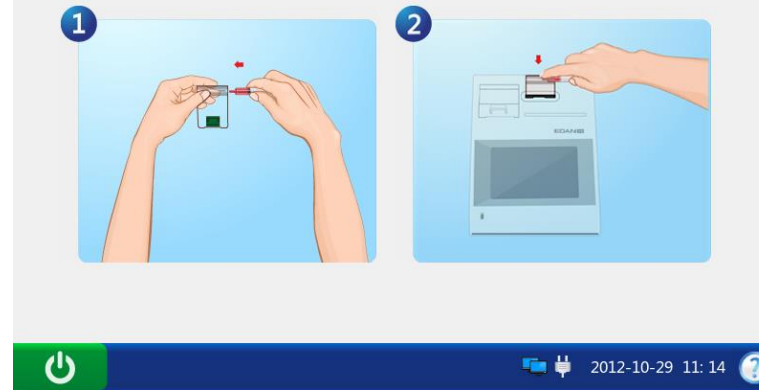
## step 1

### Scan Cartridge Bar Code



## step 2


### Mix Sample and Insert Cartridge into Analyzer



## step 3

### Input Patient Information

Patient Info1

Patient ID  

Temperature  °C

FIO2  x.xx

Operator ID

Calibrating...

## Results

### Sample Results

Measured Parameters		Calculated Parameters	Calibration Parameters	
Parameters	Results		Units	Reference Range
pH	7.361		x.xxx	[7.350-7.450]
pO2	90		mmHg	[80-105]
pCO2	38.3		mmHg	[35.0-45.0]
Na+	141		mmol/L	[138-146]
K+	3.8		mmol/L	[3.5-4.9]



Measurement Finished 2012-10-29 18:00

- very easy operation, only 3 steps
- Support LIS/HIS bi-directional
- Automatic aspiration of sample, no cross infection
- Printer integrated
- Results ready in 3 minutes





# Application of i15 in COVID-19



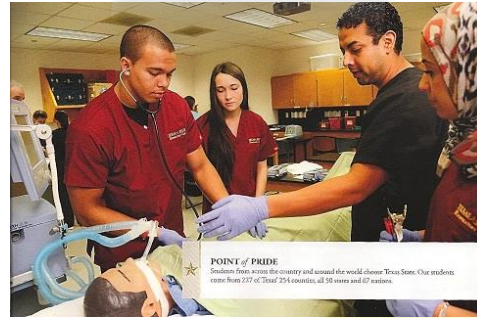


# Clinical Application

ICU/CCU



Respiratory



OB/Neonate



Emergency



Cardiac



Anesthetic



In the fight of COVID-19, the I15 can be placed in any time at any places where necessary

## Excellent adpation



When compared to traditional bench top analyzers

- zero maintenance
- easy to operate
- small and portable
- saving time and space



ICU



Ambulance



Departments



Quarantine



# Excellent Efficiency

## 1. very fast results



**Warning: COVID-19 has been proven to be an deadly infectious disease. Every second counts!**

**V S**



**lab**

- sample collection
- Calling in Nurse
- sample delivery
- operation
- results waiting
- **risk of denatured and exposure of sample**

**20-30min**



**5min**



**departments**

- sample collection
- operation
- results

# Excellent Efficiency

save one minute, save one life——i15 blood gas and chemistry analyzer



## fast results

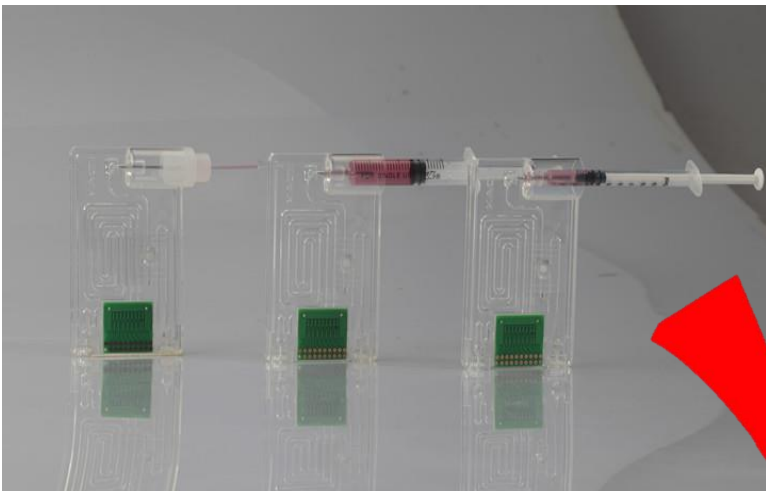
takes only 48s from aspiration to measurement  
print the results at any time  
24 hours standby, no warm up.

# Biohazard prevention

## Safety first



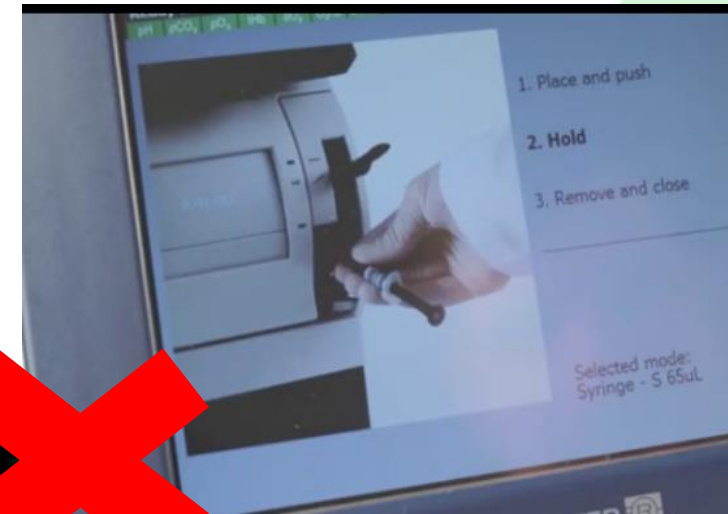
- Automatic aspiration ,  
Avoid Mannual injection  
and cross infection ;
- Single use catridge ,  
avoid maintenance ,  
avoid blood residue.



## Other manufacturer

- mannual injection, risk of cross  
infection

**Warning: COVID-19 has been proven to be highly infectious in the form of gasoloid, exposure of patient's body fluid is extremely dangerous.**



# Full panel

All parameters presented in one test

34 parameters in total, including measured parameters and calculated parameters

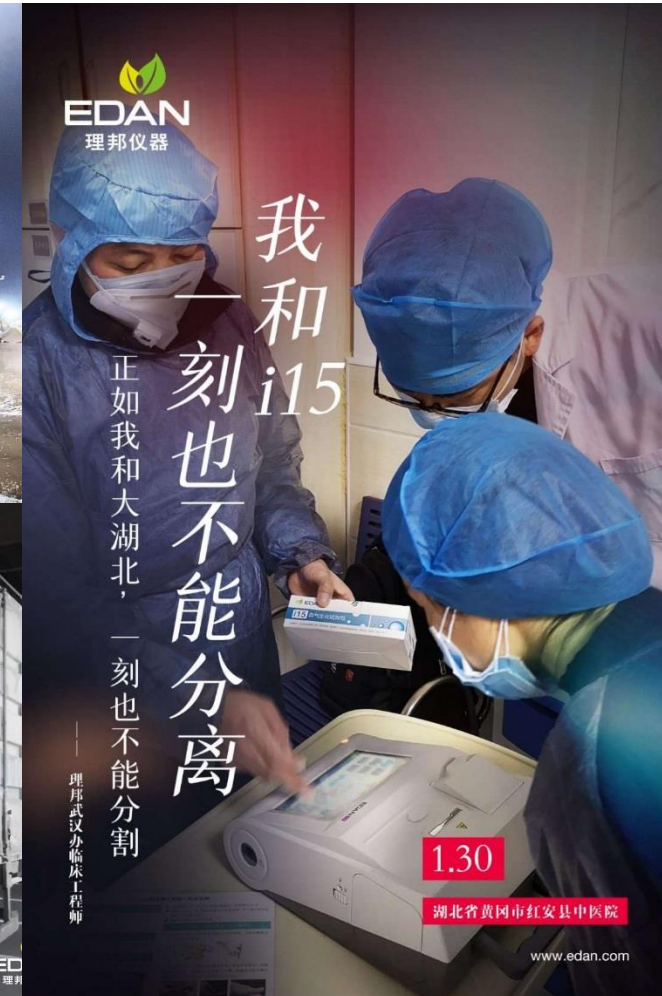
pH , pCO<sub>2</sub> , pO<sub>2</sub> , Na , K ,  
Cl , iCa , Glu , Lac , Hct

cH<sup>+</sup> , HCO<sub>3</sub><sup>--</sup>act , HCO<sub>3</sub><sup>--</sup>std , BE(ecf) , BE(B) , BB(B) , ctCO<sub>2</sub> , sO<sub>2</sub>(est) , Ca<sup>2+</sup>(7.4) ,  
AnGap , tHb(est) , pO<sub>2</sub>(A-a) , pO<sub>2</sub>(a/A) , RI , pO<sub>2</sub>/FiO<sub>2</sub> , cH<sup>+</sup>(T) , pH(T) , pCO<sub>2</sub>(T) ,  
pO<sub>2</sub>(T) , pO<sub>2</sub>(A-a)(T) , pO<sub>2</sub>(a/A)(T) , RI(T) , pO<sub>2</sub>(T)/FiO<sub>2</sub> , mOsm



# i15 in Wuhan

- Until now EDAN has installed 500 units of I15 and supplied 250,000 test cartridges to the hospitals
- Edan has seized over 90% of the market share in POCT ABG.
- During this period of time the shipments of blood gas has increased exponentially.
- We hope our distributors of Edan could learn from our experience in China by making good prediction of the market demand and be prepared, seize the chances and prevail in this long fight of COVID-19 Worldwide!





# Let's Stand Together, Fight Together, And Win Together!

Edan Instruments, Inc.

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Feb 25, 2020