



www.empecs.com



Tianjin Empecs Medical Device Co., Ltd.(Head office in China)
Rm.801, No. 9 Building Caimanjie, #67 GaojingChaoyang
District, Beijing, 100123 China
Phone: +86-10-8578-5529 Fax: +86-10-8578-5526

Tianjin Empecs Medical Device Co., Ltd.(Plant, Lab in China)
No. 35, 37 Yingcheng Street, Hangu, Binhai NewArea
300480 Tianjin China
Phone: +86-22-2569-4463 Fax: +86-22-2569-1103

EMPECS Medical Device Co., Ltd.(Lab. Sales office in Korea)
Rm.701-707, SKn TechnoPark Mega-dong, 124, Sagimakgol-ro,
Jungwon-gu, Seongnam-Si, Gyeonggi-Do, 13207 Korea
Phone: +82-31-776-4489 Fax: +82-31-776-4496

Sales office in U.S.A
11 Roosevelt Avenue, Suite E Mineola, New York 11501
Toll Free: 1-888-885-6677
Phone: +1-516-747-5730 Fax: +1-516-739-8679

XP909-0019A Rev.28.12.22



Medisign

PRODUCT CATALOG





» Location



» Korea

Milestone

- 1992-1993 Founded Tianjin Empecs Medical Device Co., Ltd. in China
- 2004-2009 Established R&D Lab in Korea
 - Completed the Plant for Blood Glucose Monitoring System(BGMS) in Tianjin,China
 - Acquired CFDA approval,CE certificate in China
- 2010-2011 Launched BGMS - MM800 series
- 2012-2013 Launched BGMS - MM1000 series and Cleared by FDA 510(k)
- 2014 Launched BGMS - MM3000 series and Cleared by FDA 510(k)
 - Acquired KGMP - MM1000 series in Korea
- 2015-2017 Launched BGMS - "GH81 /GH81 BT/MM1000 BT"series and Cleared by FDA 510(k)
 - Completed the Plant expansion for BGMS in Tianjin,China
 - Acquired KGMP-GH81 series in Korea
- 2018 Acquired ISO 13485:2016, CE certificate in China
- 2019 Acquired ISO 13485:2016, CE certificate in Korea
 - Acquired ANVISA approval for BGMS - "MM1000/GH81"series
 - Launched BGMS for animal use - Medisign-pet 83
- 2020-2022 Acquired MFDS approval for HbA1c Analyzer and Cartridge in Korea
 - Obtained CE certificate, Launched HbA1c Analyzer and Cartridge-ASUREQUAN
 - Obtained CE certificate, for Ketone, Dual meter(Ketone Glucose),GX/GH series
- 2022-2023 Acquired MFDS approval for ASUREQUAN COVID-19 Ag in Korea
 - CE Declaration of Conformity for the COVID-19 Ag Rapid Test



» Plant 2(China)

Medisign GX / GH Series

High accuracy and precision in readings
Strong competitive edge in terms of price
and performance Easy-to read display

» Specification

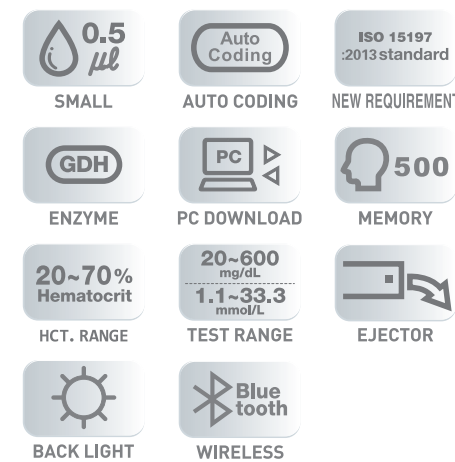
- + 0.5µl blood sample
 - + Auto coding
 - + 500 test results memory
 - + Test strip ejector
 - + Pre/Post meal flags
 - + 7,14,30 days average
 - + USB data transfer
 - + Back light (option)
 - + Bluetooth (option)
- For GX series**
- + 5 seconds test time
 - + GOx enzyme test strip
 - + Hematocrit range 20~60%
- For GH series**
- + 6 seconds test time
 - + FAD-GDH enzyme test strip
 - + Hematocrit range 20~70%

GX21 / GH21



» Specification

- + 0.5µl blood sample
- + 6 seconds test time
- + Auto coding
- + FAD-GDH enzyme test strip
- + Hematocrit range 20~70%
- + 500 test results memory
- + Test strip ejector
- + Pre/Post meal flags
- + 7,14,30 days average
- + USB data transfer
- + Back light (option)
- + Bluetooth (option)



GH81



GX22 / GH22



GH82



GH83



Medisign MM3000 Series

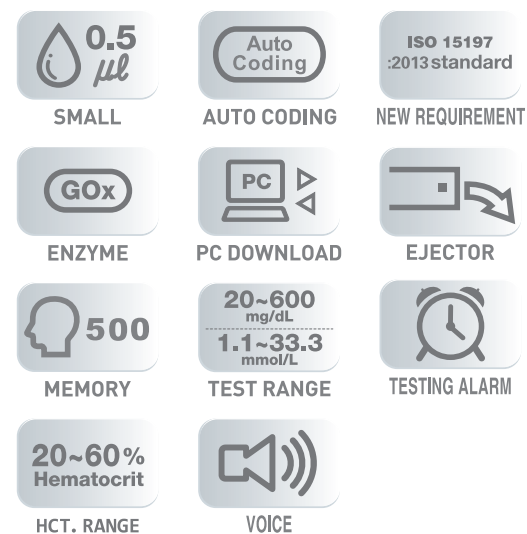
High accuracy and precision in readings
Strong competitive edge in terms of price
and performance Easy-to read display

MM3000



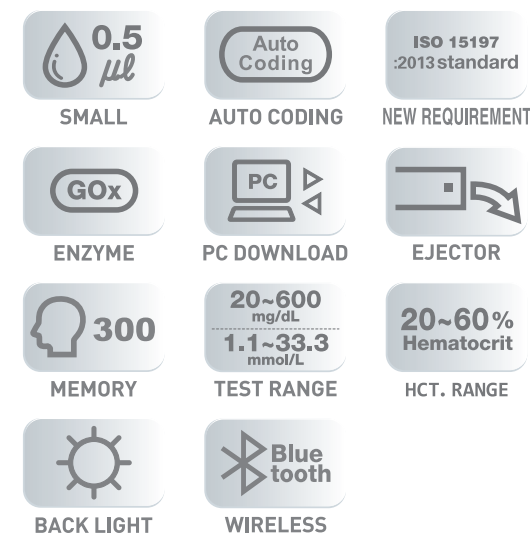
» Specification

- + 0.5µl blood sample
- + 5 seconds test time
- + Auto coding
- + GOx enzyme test strip
- + Hematocrit range 20~60%
- + 500 test results memory
- + Bilingual talking function
- + Large screen
- + Test strip ejector
- + Hypoglycemia indicator
- + Pre/Post meal flags
- + 7,14,30 days average
- + USB data transfer
- + Testing Alarm function



» Specification

- + 0.5µl blood sample
- + 5 seconds test time
- + Auto coding
- + GOx enzyme test strip
- + Hematocrit range 20~60%
- + 300 test results memory
- + Test strip ejector
- + Pre/Post meal flags
- + 14 days average
- + USB data transfer
- + Back light (option)
- + Bluetooth (option)



Medisign MM1000 Series

High accuracy and precision in readings
Strong competitive edge in terms of price
and performance Easy-to read display

MM1000



MM3200



MM3400



MM1100



MM1200



Medisign

MM800 Auto Series

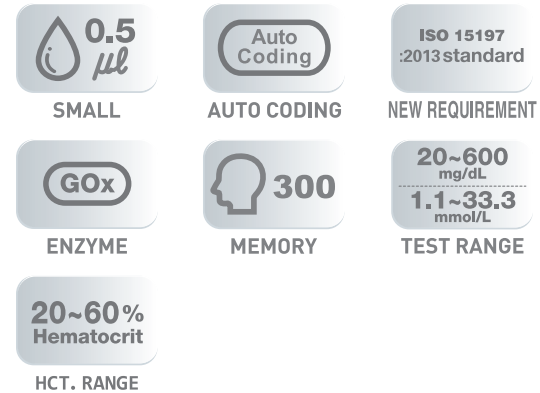
High accuracy and precision in readings
Strong competitive edge in terms of price
and performance Easy-to read display

MM800 Auto



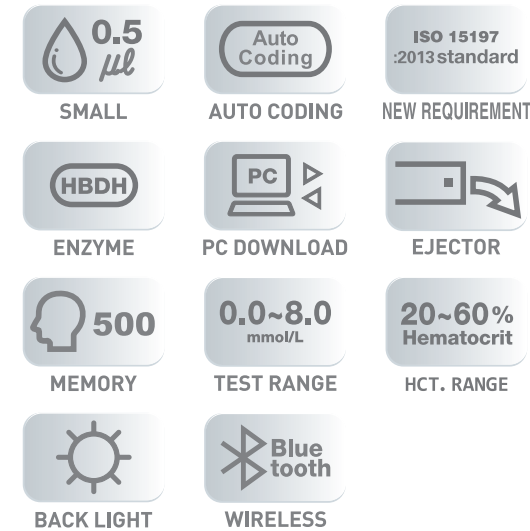
» Specification

- + 0.5µl blood sample
- + 5 seconds test time
- + Auto coding
- + GOx enzyme test strip
- + Hematocrit range 20~60%
- + 300 test results memory
- + Special/Post meal flags
- + 14 days average



» Specification

- + 0.5µl blood sample
- + 8 seconds test time
- + Auto coding
- + HBDH enzyme test strip
- + Hematocrit range 20~60%
- + 500 test results memory
- + Test strip ejector
- + USB data transfer
- + Back light (option)
- + Bluetooth (option) (except KT22)



Medisign

Ketone Series

High accuracy and precision in readings
Strong competitive edge in terms of price
and performance Easy-to read display

MediKeto 82



MediKeto 83



MM600 Auto



MM200 Auto



KT21



KT22



KT26



Medisign Multi Series

High accuracy and precision in readings
Strong competitive edge in terms of price
and performance Easy-to read display

» Specification

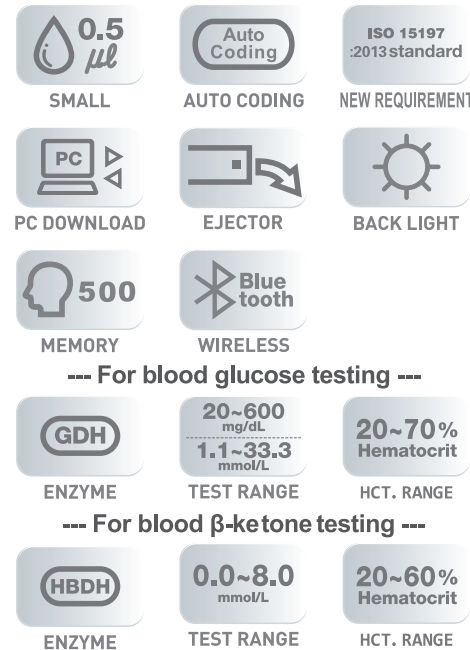
- + 0.5µl blood sample
- + Auto coding
- + 500 test results memory
- + Test strip ejector
- + USB data transfer
- + Back light (option)
- + Bluetooth (option)
- (except Multi K2)

- For blood glucose testing**
- + 6 seconds test time
 - + FAD-GDH enzyme test strip
 - + Hematocrit range 20~70%
 - + Pre/Post meal flags
 - + 7,14,30 days average
- For blood β-ketone testing**
- + 8 seconds test time
 - + HBDH enzyme test strip
 - + Hematocrit range 20~60%

MediKeto Plus 82



MediKeto Plus 83



Medisign ASUREQUAN COVID-19 Ag

ASUREQUAN COVID-19 Ag Rapid Test is a rapid immuno-chromatographic assay for qualitative detection of specific antigens to SARS-CoV-2 present in human nasopharynx. This test contains colloid gold conjugate pad and a membrane strip pre-coated with antibodies specific to SARS-CoV-2 antigen on the test lines

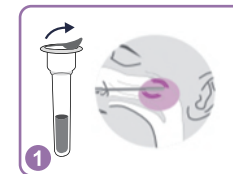
Intended Use

ASUREQUAN COVID-19 Ag Rapid Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swabs from individuals suspected of COVID-19

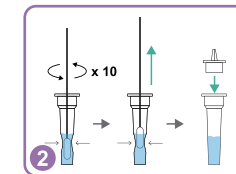
Specification

- Target : Nucleocapsid protein antigen from SARS-CoV-2
- Storage : 2~30°C / 36~86°F
- Specimen Type : Nasopharyngeal specimen
- Measuring Time : 20 mins
- Shelf Life : 12 Months

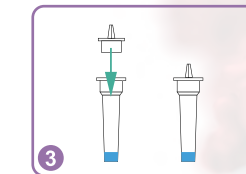
Test Procedure



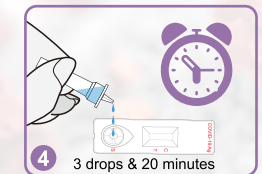
Remove the sealing film from the extraction tube with buffer. Insert a sterile swab into the nostril of the patient, swab over the surface of the posterior nasopharynx. Withdraw the sterile swab from the nasal cavity.



Insert the swab into an extraction tube. While squeezing the buffer tube, stir the swab strongly more than 10 times. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

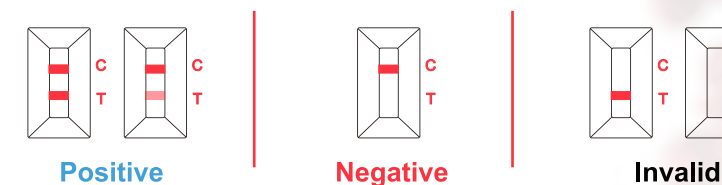


Screw the filter cap tightly onto the tube.



Apply 3 drops of extracted specimen to the specimen well of the test device. Then, Read the test result at 20 minutes.

Interpretation



Clinical Evaluation

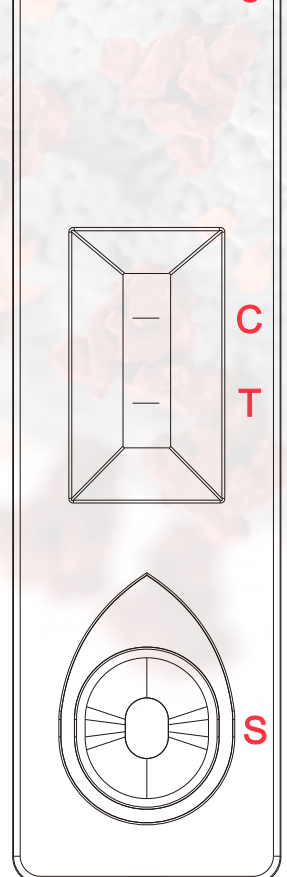
Clinical Evaluation 1		Real-Time PCR		Total
		Positive	Negative	
AsureQuan COVID-19 Ag Rapid Test	Positive	30	0	30
	Negative	0	30	30
Total		30	30	60

- Ct value distribution (ORF1ab) : 14.87~27.86
- Sensitivity = 100.0% (30/30). (95% CI : 88.6%~100.0%)
- Specificity = 100.0% (30/30). (95% CI : 88.6%~100.0%)

Clinical Evaluation 2		Real-Time PCR		Total
		Positive	Negative	
AsureQuan COVID-19 Ag Rapid Test	Positive	133	0	133
	Negative	17	170	187
Total		150	170	320

- Ct value distribution (ORF1ab) : 11.34~33.79
- Sensitivity = 88.7% (133/150). (95% CI : 82.6%~92.8%)
- Specificity = 100.0% (170/170). (95% CI : 97.8%~100.0%)

COVID-19 Ag



Medisign

Product List

MODEL	GX Series		GH Series		GH81 Series			MM3000 Series			MM1000 Series		
	GX21	GX22	GH21	GH22	GH81	GH82	GH83	MM3000	MM3200	MM3400	MM1000	MM1100	MM1200
	Glucose		Glucose		Glucose			Glucose			Glucose		
Enzyme	GOx	GOx	FAD-GDH	FAD-GDH	FAD-GDH	FAD-GDH	FAD-GDH	GOx	GOx	GOx	GOx	GOx	GOx
Blood Sample (0.5 μ l)	○	○	○	○	○	○	○	○	○	○	○	○	○
Result Time	5 sec	5 sec	6 sec	6 sec	6 sec	6 sec	6 sec	5 sec	5 sec	5 sec	5 sec	5 sec	5 sec
Auto coding	○	○	○	○	○	○	○	○	○	○	○	○	○
Test Range (20~600 mg/dL, 1.1~33.1 mmol/L)	○	○	○	○	○	○	○	○	○	○	○	○	○
Test Range (0.0~8.0 mmol/L)													
Hematocrit Range	20~60%	20~60%	20~70%	20~70%	20~70%	20~70%	20~70%	20~60%	20~60%	20~60%	20~60%	20~60%	20~60%
Blood Sample (Capillary whole blood)	○	○	○	○	○	○	○	○	○	○	○	○	○
Blood Sample (Venous whole blood)			○	○	○	○	○						
Strip Ejector	○	○	○	○	○	○	○	○	○	○	○	○	○
PC Download (Comatible Software)	○	○	○	○	○	○	○	○	○	○	○	○	○
Voice Function								○	○	○			
Testing Alarm Function								○	○	○			
Bluetooth (option)	○		○		○	○	○				○	○	○
Back light (option)	○	○	○	○	○	○	○				○	○	○

Medisign

Product List

MODEL	MM800 Auto Series			Ketone Series					Multi Series (Glucose + Ketone)	
	MM200 Auto	MM600 Auto	MM800 Auto	KT21	KT22	KT26	MediKeto 82	MediKeto 83	Multi K1, K2, K6, MediKeto Plus 82, 83	
	Glucose			Ketone					Glucose	Ketone
Enzyme	GOx	GOx	GOx	HBDH	HBDH	HBDH	HBDH	HBDH	FAD-GDH	HBDH
Blood Sample (0.5 μ L)	○	○	○	○	○	○	○	○	○	○
Result Time	5 sec	5 sec	5 sec	8 sec	8 sec	8 sec	8 sec	8 sec	6 sec	8 sec
Auto coding	○	○	○	○	○	○	○	○	○	○
Test Range (20~600 mg/dL, 1.1~33.1 mmol/L)	○	○	○						○	
Test Range (0.0~8.0 mmol/L)				○	○	○	○	○		○
Hematocrit Range	20~60%	20~60%	20~60%	20~60%	20~60%	20~60%	20~60%	20~60%	20~70%	20~60%
Blood Sample (Capillary whole blood)	○	○	○	○	○	○	○	○	○	○
Blood Sample (Venous whole blood)				○	○	○	○	○	○	○
Strip Ejector				○	○	○	○	○	○	○
PC Download (Comatible Software)				○	○	○	○	○	○	○
Voice Function										
Testing Alarm Function										
Bluetooth (option)				○		○	○	○	○ (except Multi K2)	○ (except Multi K2)
Back light (option)				○	○	○	○	○	○	○

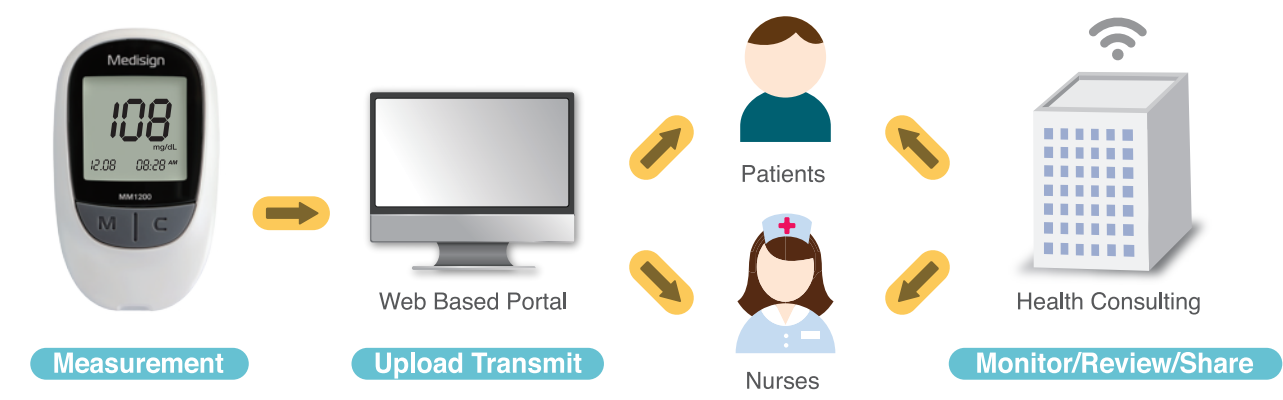
» Smart Care Solution

MedisignBLE with Mobile Devices

Product name	Wireless Glucose Monitoring System
Wireless communication	Bluetooth 4.0 Low Energy
Device compatibility	Android device (requires OS 4.3 or higher) Apple iOS device (requires iOS 8.0 or higher) Mobile devices compatible with Bluetooth 4.0
Wireless access distance	Approximately 10 meters(33ft) - line of sight at open space

**Visit www.empecs.com for information on which wireless devices are compatible with your Medisign BLE meter. Glucose meters track your daily glucose levels and send the information directly to your device, or doctor automatically keeping your records up to date.

U-healthcare Business Model

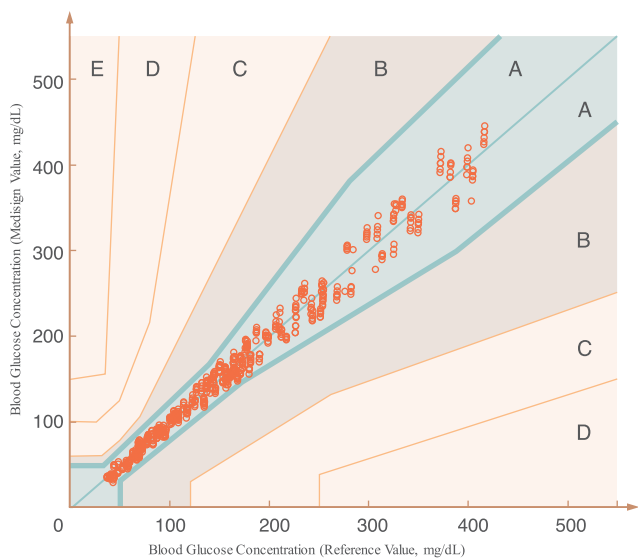


Diabetes Management Using Medisign Bluetooth



» Clinical Performance

System Accuracy Test Result

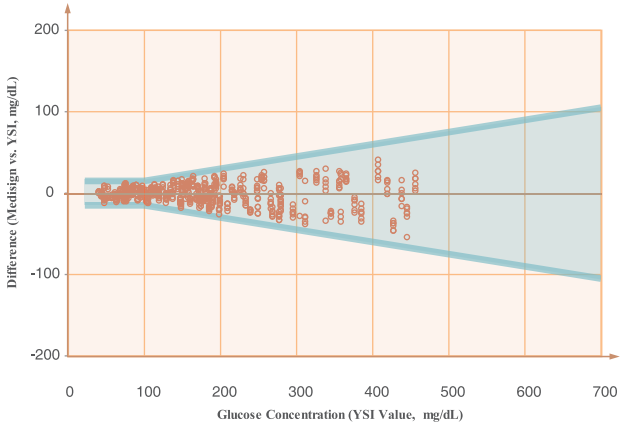


The consensus error grid shows that 100% of individual measurement results of Medisign Blood Glucose Monitoring System(with the MS-2 Test Strip) fell within Zone A(no effect on clinical action). As shown the Table 1. the Medisign Blood Glucose Monitoring System shows a good correlation of $R^2=0.9843$ for the YSI plasma equivalent method.

Table1. Regression Statistics (y: Medisign glucose value, x: YSI reference value)

Tested Range, mg/dL	N	Regression Equation	R ²	95% Slope CI	95% Int.CI (mg/dL)
40~456	660	$y = 0.9852x + 1.3926$	0.9843	0.976 ~ 0.995	-0.594 ~ 3.380

System Accuracy Plot



The System Accuracy Plot shows that more than 95% of individual bias results between the Medisign Blood Glucose Monitoring System and YSI 2300 STAT Plus fell within the required accuracy limits based on the criteria stated in ISO15197:2013.

Table2. Accuracy results for glucose concentration (n=660)

System accuracy results for glucose concentration < 100mg/dL (<5.6 mmol/L)

Within ± 0.28 mmol/L (Within ± 5 mg/dL)	Within ± 0.56 mmol/L (Within ± 10 mg/dL)	Within ± 0.83 mmol/L (Within ± 15 mg/dL)
105 / 168 (62.5%)	163 / 168 (97.0%)	168 / 168 (100%)

System accuracy results for glucose concentration ≥ 100 mg/dL (≥ 5.6 mmol/L)

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$
250 / 492 (50.8%)	446 / 492 (90.7%)	492 / 492 (100.0%)

Medisign

ASUREQUAN HbA1c Analyzer

ASUREQUAN



- ✓ Easy Test Process
- ✓ Lab-quality Results
- ✓ No maintenance required

Medisign

Blood Pressure Monitor EM870

EM870

AVERAGING OF
THREE
READINGS

WHO
BLOOD PRESSURE
INDICATION

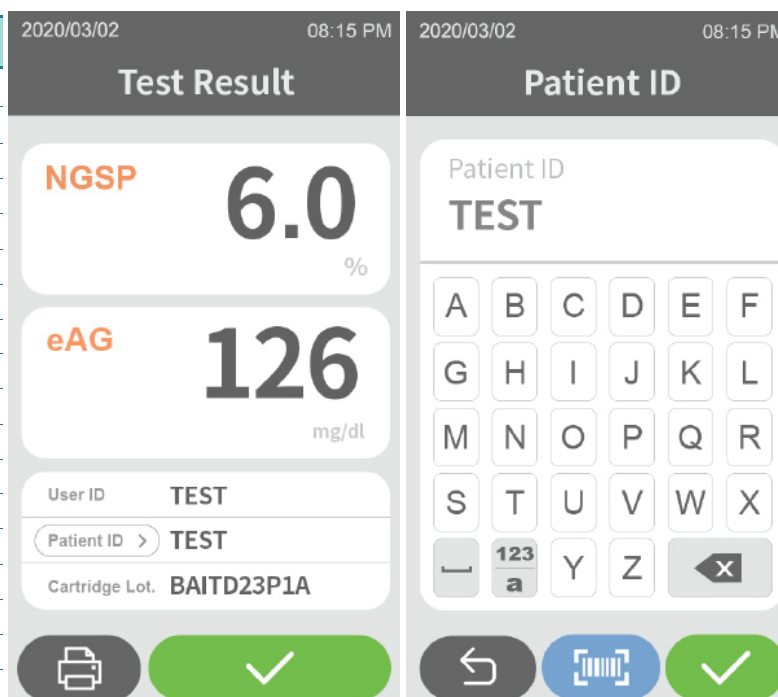
4 USERS
INTERFACE
(4 Users x 30 Memories)



Easy Home Monitoring

Specification

Principle	Enzymatic assay
Sample type	Capillary whole blood or Venous whole blood
Sample volume	4 μ l
Measurement time	Around 7min
Measurement range	4.0 ~ 15.0% (20 ~ 140 mmol/mol)
Precision	CV < 3%
Accuracy	< \pm 5%
Display	4.95 inch color touch LCD
Capacity of result records	2000 results
Capacity of operator list	20 operators
Control solutions	2 Levels
Operating Temperature	18 ~ 32 $^{\circ}$ C (64.4 ~ 89.6 $^{\circ}$ F)
Operating humidity	10 ~ 70%
Printer	On board, 2 inch thermal
Port	USB 2.0
Bar Code Reader	Optional
Dimension (W x L x H)	194x306x164 mm
Weight	3.0Kg



Specification

Name	Blood Pressure Monitor
Model	EM870
Display	LCD Digital Display
Measurement Method	Oscillometric method
Measurement Range	Pressure 0mmHg~299mmHg Pulse 40~180 Beats/minute
Measurement Accuracy	Pressure \pm 3mmHg Pulse \pm 5%
Operating Environment	Temperature 5 $^{\circ}$ C ~ 40 $^{\circ}$ C (41 $^{\circ}$ F ~ 104 $^{\circ}$ F) Humidity 15% ~ 80% RH
Operation, Transportation and Storage Atmospheric Pressure	70kPa~106kPa
Storage Environment	Temperature -20 $^{\circ}$ C ~ 60 $^{\circ}$ C (-4 $^{\circ}$ F ~ 140 $^{\circ}$ F) Humidity 10% ~ 90% RH
Memory	120 memories (4 users \times 30 times)
Function	Low Battery Detection Last 3 Results Average WHO Classification Indicator
Power Source	4 \times 1.5V AA Batteries (No.5) Power adapter : AC100~240V (optional or for sale)
Limit of Use	5 years (6 times per day)
Manufacturing Date	Date of production can be seen on the product or package.
Unit Weight	Approximately 229g (8.08 oz.) Approximately 310g (10.93 oz.)
Unit Dimensions (Without Cuff)	Approximately 102 \times 134 \times 68mm Approximately 110 \times 153 \times 70mm
Cuff Circumference	Approximately 155 (Wide) \times 490 (Long) mm Applicable arm circumference Approximately 230~330mm
Electric Shock Protection	Internal Powered Equipment, Class II Equipment, Type B Application Part
Accessories	Cuff and inflatable tube, 4 \times 1.5V AA batteries (No. 5), instruction manual, soft bag, certificates, power adapters (for sale)

