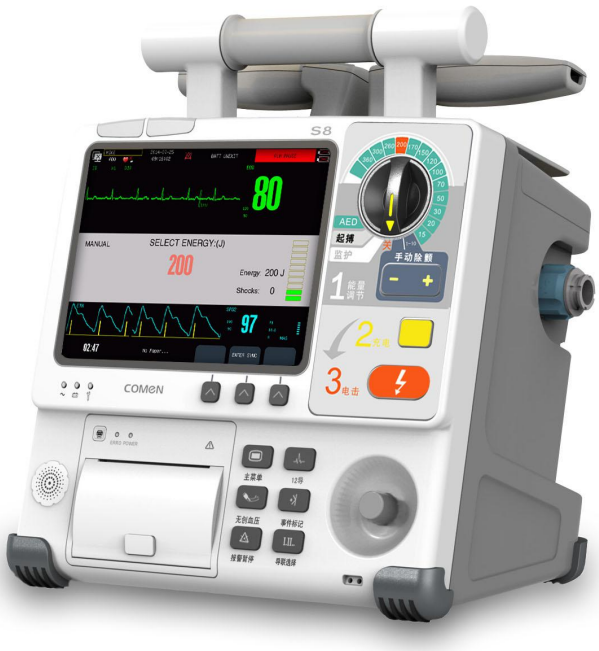
COMEN



S8/S6

Defibrillator Monitor

General Specification

Size and weight

Item	Specifications
Size and weight	Size:324mm(L)×220mm(W)×345mm(H)(Including external paddles) Size:301mm(L)×220mm(W)×345mm(H)(Not including external paddles)
	Weight: 7.5Kg (not including batteries) Weight of one battery: 0.7Kg

Environmental Requirements

Item	Specifications	
Work environment	Environmental temperature	0℃～45℃
	Relative humidity	Humidity 10%～95%, no condensation
	Atmospheric pressure	700hPa～1060hPa
Power requirements	Voltage	100V～240V
	Frequency	50Hz/60Hz±1Hz
	Input current	2.0A-1.0A
Transport	Avoid severe shock ,vibration, rain and snow during transport	
Storage	The packaged defibrillator/monitor should stored in the room with environment temperature of -20℃～+70℃, with humidity 10%~95%(no condensation), with good ventilation and without corrosive gas	

Display

Item	Specifications
Screen size	8.4 inch color TFT display screen
Displayed information	Up to 2 waveforms can be displayed.
Resolution	800×600 pixels

Recorder

Item	Specifications
Paper width	80mm
Paper speed	12.5/25/50 mm/s
Real-time recording time	8s,16s,32s
Number of waveform channels	Up to four waveform channels
Recording triggered by alarms	With this function

Battery

Item	Specifications
Battery	Two rechargeable lithium-ion battery 4500mAh, 14.8V
Charge time	Charge time to 80% charge level in less than 2 hours; charge time to 100% charge level in less than 3 hours
Running time	Running time of one battery in the environmental temperature of 20℃ is as follows: (Running time of two batteries is twice of that of one battery) (1) Monitoring mode: more than 5 hours(interval of NIBP measurement is 15 minute and no printing); (2) Defibrillation mode: more than 100 discharges(maximum energy level, charge interval more than 1 minute and no printing) (3) Pacing mode: more than 2 hours (50Ω load, frequency 80bpm, current 60mA and no printing)
Battery capacity indicator	There is multiple LEDs on the battery to indicate its approximate charge
Low battery alarm	After low battery alarm, 20 minutes vital sign monitoring and at least 6 maximum energy discharges can be conducted at the same time.

Data storage

Item	Specifications	
Trend data	Short trend	1 hour with resolution of 1 second
	Long trend	120 hours with resolution of 1 minute
Trend graph and trend table	120 hours	
Alarm events	200 alarm events with relevant parameter values and waveforms of 32s at alarm moment.	

NIBP measurement data	2000
12-lead diagnosis report	5 12-lead diagnosis reports for each patient
Taping	Store up to 480min taping (up to 60min for each patient)
Parameter waveforms	120 hours

Defibrillation

Item	Specifications
Defibrillation mode	Manual defibrillation, synchronized defibrillation and AED
Defibrillation waveform	BTE waveform. The waveform parameters are compensated automatically according to patient impedance.
Type of defibrillation electrode	External paddles, therapy electrodes and internal paddles; child external paddles are inside adult external paddles
Controls and indicators of external paddles	There are charge button, shock button and energy select button on external paddles and there is instruction when charge completes.

Energy select	
External defibrillation	1/2/3/4/5/6/7/8/9/10/15/20/30/50/70/100/120/150/170/200/220/250/270/300/360J
Internal defibrillation	1/2/3/4/5/6/7/8/9/10/15/20/30/50J

Range of patient impedance	
External defibrillation	20Ω~250Ω
Internal defibrillation	15Ω~250Ω

Charge time	
Powered by new fully charged battery(with 20℃ environmental temperature)	Charge time to 200J in less than 5s; charge time to 360J in less than 8s
Powered by AC power supply	Charge time to 200J in less than 7s; charge time to 360J in less than 11s

Synchronized discharge delay	
Local synchronized discharge delay	Less than 60ms
Remote synchronized discharge delay	Less than 25ms(from synchronized signal rising edge)

AED	
Serial shock	Shock energy: 100～360J Shock times: 1, 2,3
Shockable rhythm	VF, VT (heart rate >150bpm and QRS width >120ms)

AED algorithm performance		
Type of heart rhythm	Performance requirements	Remark
Shockable rhythm-VF	Sensitivity>90%	Comply with AAMI DF80 and AHA

		(sensitivity>90%)
Shockable rhythm- VT	Sensitivity >75%	Comply with AAMI DF80 and AHA (sensitivity>75%)
Nonshockable rhythm-NSR	Specificity >99%	Comply with AAMI DF80 and AHA (specificity >99%)
Nonshockable rhythm-asystole	Specificity >95%	Comply with AAMI DF80 and AHA (specificity >95%)
All other nonshockable rhythms	Specificity >95%	Comply with AAMI DF80 and AHA (specificity >95%)

Noninvasive pacing

Pacing	
Pacing mode	Fixed pacing and demand pacing
Pacing waveform	One-way square-wave pulse with pulse with of 20ms±1.5ms
Pacing rate	40bpm~170bpm with accuracy of ±1.5%
Pacing current	0mA~200mA with accuracy of ±5% or 5mA (larger one)
Pacing with decreased speed	When this function is enabled, pacing rate decreased to 1/4 of original rate.
Output protection	The output end of S8/S6 defibrillator/monitor can stand 360J discharge without any damage.

ECG

Item	**Specifications**	
ECG input	Support ECG detected through 3-lead ECG cable, 5-lead ECG cable, 12-lead ECG cable, paddles and therapy electrodes	
Sweep speed	50mm/s, 25mm/s, 12.5mm/s with error less than ±10%	
Lead mode	12-lead (R、L、F、N、C1、C2、C3、C4、C5、C6 or RA、LA、LL、RL、V1、V2、V3、V4、V5、V6)	
Lead selection	I、II、III、avR、avL、avF、V1、V2、V3、V4、V5、V6	
Waveform display	12 channels	
Lead mode	5-lead (R, L, F, N, C or RA,LA, LL, RL, V)	
Lead selection	I, II, III, avR, avL, avF, V,	
Waveform display	2 channels	
Lead mode	3-lead (R, L, F or RA, LA, LL)	
Lead selection	I, II, III,	
Waveform display	1 channel	
Range of ECG signal	±0.2~±8mV	
Overload protection	Load 1V, power frequency and difference mode alternating voltage have no damage within 10s (p-v)	
Respiration, lead off detection and active noise suppression	Measuring electrode <0.1μA Drive electrode<1μA	
Range of QRS amplitude and interval	Range of amplitude (p-v RTI)	0.5mV～5mV
	Range of QRS	70ms～120ms

	width(adult)	
	Range of QRS width(pediatric/neonate)	40ms～120ms
	No response for the following signals	a) signals with amplitude (p-v RTI) ≤0.15mV(except from pediatric/neonate operating mode) b) signals with 1mV amplitude and 10ms width (except from neonate/ pediatric operating mode)
Power frequency voltage tolerance	＞100μV（p-v）	
Notch filter	Power frequency interference inhibition capacity≥20 dB Monitor and cure mode: supporting 50/60 Hz notch function Diagnosis mode: supporting setting 50/60 Hz notch manually	
Drifting tolerance	Amplitude of pyramidal wave (p-v RTI)	4mV
	Amplitude of QRS wave (p-v RTI)	0.5 mV
	Width of QRS wave	100ms
	Repetition rate of QRS wave	80bpm
HR measurement range and error	Adult	15～300bpm
	Pediatric/neonate	15～350bpm
	Error	±1% or ±1 bpm, the large one
	Adult maximum measurement value	300 bpm
	Pediatric/neonate maximum measurement value	350 bpm
Range of alarm limits	Adult	Upper limit: (lower limit＋2)～300bpm Lower limit: 15bpm～（upper limit－2）bpm
	Pediatric/neonate	Upper limit: (lower limit＋2)～350bpm Lower limit: 15bpm～（upper limit－2）bpm
Alarm resolution	±1 bpm	
Error	±1 bpm	
Starting time for cardiac arrest, the high heart rate alarm and the lower heart rate alarm	＜10s	
Frequency characteristic	Cure mode : 1 Hz～20 Hz (-3.0dB～+0.４dB); Monitor mode: 0.5 Hz～40 Hz (-3.0dB～+0.４dB); Diagnosis mode: 0.05Hz～150 Hz (-3.0dB～+0.４dB); ST mode: 0.05 Hz～40 Hz (-3.0dB～+0.４dB);	
Dynamic range of inputting	Amplitude of input signal	±5mV
	Rate(RTI)	320mV/s
	offset voltage of direct current	-650～+650mV
	Changes in output signal	±10％
	Display of the	No declining below 50%

	non-operation condition (displaying the degree of attenuation)		
Input impedance	No more than 20% signal attenuation (0.67Hz～40Hz)		
System noise (p-v RTI)	＜25μV		
Multichannel crosstalk	＜5％		
Gain control and stability	Gain selection	All display	×2.5mm/mV ×5.0mm/mV,×10mm/mV, ×20mm/mV
		Permanent display	10mm/mV
	Gain control	Supporting changing gains manually	
	gain variation in every minute	No more than 0.66％/min	
	General gain variation in an hour	No more than ±10％	
Time reference selection and accuracy	Time reference selection	Permanent display	25mm/s
		Impermanent display	12.5 mm/s, 25 mm/s, 50 mm/s
	Accuracy	±10％。	
Output display	Width of channels	30mm	
	Aspect rate	0.4s/mV	
Input signals reconstruction accuracy	General error of system	±20％ or ±100μV, the larger one	
	Frequency response	Sinusoidal input	0.67～40Hz(attenuation -3dB)
		Response to the input pyramidal wave with width of 20ms	Amplitude of the wave peak attenuates from 0 to 25 Hz
	Response to the 0.3 mVs shock in its range	Deviation(RTI)	No more than 0.1mV
		Slop (RTI)	No more than 0.30mV/s
	Electrode weighting factor	No less than ±5％	
	hysteresis effect of 15 mm deviation	No more than 0.5mm	
Error of calibration voltage 1mV	±5%		
CMRR	Diagnostic mode＞90dB Monitor mode ＞105dB Therapy mode ＞105dB ST mode ＞105dB		
Baseline control and stability	recovery time after resetting	3s	

	Drift rate within 10s	10μV/s	
	Baseline drift within 1h	≤500μV	
	Baseline drift under work temperature	≤50μV/℃	
Pacing pulse inhibition without overshoot	Amplitude: ± 2mV ～ ± 700mV, width: 0.1ms ～ 2.0ms, overshoot less than 0.05φ, settling time less than 5μs; the start rise and fall time of pulse, all no more than100μs; the start time of pulse goes ahead of the QRS wave's start time in or less than 40ms, that is to say, having the same pulse earlier than that pacing pulses in 150ms to 250ms.		
Inhibition of the pacing pulse detector for fast ECG signal	Minimum input slew rate: 830mV/s		
Display capabilities of pacing pulses	Amplitude: ± 2mV ～ ± 700mV, width: 0.5ms ～ 2.0ms, maximum rise time: 100μS, display of ECG when 100 pacing pulses appear per minute.		No less than 0.2mV
ST segment measurement	Range	-2.0mV-+2.0mV	
	Accuracy	-0.8 mV～+0.8mV: ±0.02mV or ±10%, the larger one	
Resolution	0.01 mV		
ST alarm limits and error	Upper limit:（lower limit +0.2）～2.0 mV; Lower limit: -2.0～（upper limit -0.2 mV） Error:±0.1 mV		
Type of arrhythmia	Asystole, ventricular fibrillation / tachycardia, ventricular rhythm, a single ventricular ectopic, two ventricular ectopic, multiple ventricular ectopic, ventricular ectopic bigeminy, trigeminy, the R-on –T, tachycardia, bradycardia missed beat, extreme tachycardia, extreme bradycardia, irregular heartbeat, PVCs two high		
Leakage current	< 10 uA		
Electrosurgical interference inhibition	The change of HR is not more than ±10% compared with the HR without interference		
Electrotome protection	Cut mode: 300W; coagulation mode: 100W, recovery time:≤10s		

HR calculation	
Maximum T-wave inhibition capability	1.2mV
HR calculation	As required in Section 4.1.2.1 d of YY 1079, the HR is calculated like this: if all of the last 3 RR intervals are longer than 1200ms, the average of the last 4 RR intervals is the HR; in other cases, the average of the last 12 RR intervals (with the longest interval and shortest interval excluded) is the HR.
HR calculation accuracy and response to arrhythmia	As required in Section 4.1.2.1 e of YY 1079, the HR is displayed as follows after the 20s stable segment: Figure 3 a) (bigeminy): 80±1bpm Figure 3 b) (slowly varying bigeminy): 60±1bpm Figure 3 c) (quickly varying bigeminy): 120±1bpm Figure 3 d) (two-way contraction): 90±2bpm
Response time for HR	As required in Section 4.1.2.1 f of YY 1079: the response time for

change	a HR change from 80bpm to 120bpm or from 80bpm to 40bpm is less than 10s.
Tachycardia alarm start time	Meet the requirements of IEC 60601-2-27: Clause 201.7.9.2.9.101 b) 6), the waveform: Figure B1 1 - range: 11s Figure B1 0.5 - range: 11s Figure B1 2 - range: 11s Figure B2 1 - range: 11s Figure B2 0.5 - range: 11s Figure B2 2 - range: 11s

Pacing pulse	
Pacing marker	There will be pacing marker for the pacing pulse that meets the following conditions: Amplitude: ±2～±700mV Width: 0.1～2ms Uprising time: 10～100μs
Pacing inhibition	In accordance with the requirements in section 4.1.4.1 and section 4.1.4.3 of YY1079-2008 regulation, the pulse meets the following conditions will be inhibited. Amplitude: ±2～±700mV Width: 0.1～2ms Uprising time: 10～100μs Minimum input slew rate: 10V/s RTI

RESP

Item	**Specifications**		
Technique	Thoracic impedance		
RESP lead	Lead I and II available		
Measurement range and accuracy	Range	Adult	0bpm-120bpm
		Pediatric/neonate	0bpm-150bpm
	Accuracy	±1bpm	
Alarm limits and error	Adult	Upper limit	(Lower limit＋2)～120bpm
		Lower limit	6bpm～(Upper limit－2)bpm
	Pediatric/neonate	Upper limit	(Lower limit＋2)～150bpm
		Lower limit	6bpm～(Upper limit－2)bpm
	Error	±1bpm	
Apnea alarm time and error	Apnea alarm time	Adult:10s ~ 60s Pediatric/neonate: 10s~ 20s	
	Error	±5s	
CVA recognition function	S8/S6 defibrillator/monitor will give alarm message in the event of the same HR and RR		

NIBP

Item	**Specifications**
Measurement	Oscillometric method

technique			
Measurement range and accuracy	Adult	Systolic pressure	5.3～36kPa（40～270mmHg）
		Diastolic pressure	1.3～28.7kPa（10～215mmHg）
		Mean arterial pressure	2.7～31.3kPa（20～235mmHg）
	Pediatric	Systolic pressure	5.3～26.7kPa（40～200mmHg）
		Diastolic pressure	1.3～20kPa（10～150mmHg）
		Mean arterial pressure	2.7～22kPa（20～165mmHg）
	Neonate	Systolic pressure	5.3～20kPa（40～135mmHg）
		Diastolic pressure	1.3～13.3kPa（10～100mmHg）
		Mean arterial pressure	2.7～14.7kPa（20～110mmHg）
	Accuracy	±5mmHg; when the measured NIBP exceeds the ranges described above, there is still reading on the screen but the accuracy is not specified.	
Static pressure measurement range and accuracy	0 mmHg（0 kPa）～300 mmHg（40.0 kPa）; ±3 mmHg（±0.4 kPa）		
Overpressure protection range and error	Adult		300mmHg
	Pediatric		240mmHg
	Neonate		150mmHg
	Error		±3mmHg
Alarm limit and error	Adult	Systolic	High limit:5.6kPa～36kPa(42mmHg～270mmHg); Low limit:5.3kPa～35.7kPa（40mmHg～268mmHg）
		Diastolic	High limit:1.6kPa～28kPa（12 mmHg～210mmHg）; Low limit:1.3kPa～27.7kPa（10 mmHg～208mmHg）
		Mean	High limit:2.9kPa～30.6kPa（22 mmHg～230mmHg）Low limit:2.6kPa～30.3（20 mmHg～228mmHg）
	Pediatric	Systolic	High limit: 5.6kPa～26.6kPa（42mmHg～200mmHg） Low limit:5.3kPa～26.3kPa（40mmHg～198mmHg）
		Diastolic	High limit:1.6kPa～22kPa（22mmHg～165mmHg） Low limit:1.3kPa～21.7kPa（20 mmHg～163mmHg）
		Mean	High limit:2.9kPa～22kPa（22mmHg～165mmHg） Low limit:2.6kPa～21.7kPa（20mmHg～163mmHg）
	Neonate	Systolic	High limit:5.6kPa～18kPa（42mmHg～135mmHg）

			Low limit:5.3kPa～17.7kPa（40mmHg～133mmHg）
		Diastolic	High limit:1.6kPa～12.6kPa（12 mmHg～95mmHg）Low limit:1.3kPa～12.3kPa（10 mmHg～93mmHg）
		Mean	High limit:2.9kPa～14.6kPa(22mmHg～110mmHg) Low limit:2.6kPa～14.3kPa(20 mmHg～108mmHg）
	Error	±0.1kPa or ±1mmHg, the larger one	
Measure mode	Manual, auto and continuous		
	Interval of auto mode	1、2、3、4、5、10、15、30、60、90、120、180、240、480min	
	Continuous	5min	

SPO2

Item	Specifications	
Display range	1%～100%	
Display resolution	1%	
Measurement accuracy	(1) Comen SpO2: Measurement range: 0%～100%; Accuracy: ±2％ (measured without motion in adult/pediatric mode) or ±3% (measured without motion in neonate mode) in the range of 70%～100% (2) Masimo SpO2: Measurement range: 1%～100%; Accuracy: ±2% (measured without motion in adult/pediatric mode), ±3% (measured with motion in adult/pediatric mode) or ±3 % (measured without motion and with motion in neonate mode) in the range of 70%～100% (3) Nellcor SpO2: Measurement range: 0%～100% Accuracy: ±2％ (measured without motion in adult/pediatric mode) or ±3% (measured without motion in neonate mode) in the range of 70%～100% (4) Accuracy is not specified in other ranges.	
Alarm limits and accuracy	Upper limit	(lower limit ＋1)%～100%
	Lower limit	0%～(upper limit －1)%
	Accuracy	±1%
Perfusion index (PI)	MasimoSpO2 module has the perfusion index indication function. Measurement range: 0.02 % ~20 %. Accuracy: not specified. Resolution: 0.01% in the range of 0.02%~9.99%; 0.1% in the range of 10.0% ~20.0%.	

PR

Item	Specifications
Measurement range and error	(1) Comen SpO2 module Measurement range: 20bpm～254bpm; resolution: 1bpm; error: ±1bpm (2) Masimo SpO2 module Measurement range: 25bpm～240bpm; resolution: 1bpm; error: ±3bpm (without motion) and ±5bpm (with motion) (3) Nellcor SpO2 module Measurement range: 20bpm～300bpm; resolution: 1bpm; error: ±3bpm in the range of 20bpm～250bpm, no specified in the range of 251bom ～300bpm
Alarm limits and accuracy	Upper limit: (lower limit ＋1)～350bmp Lower limit: 0～(upper limit －1) bpm
	±1 bpm

TEMP

Item	Specifications	
Measurement range and accuracy	Range	0℃～50℃
	Accuracy	±0.1℃
Alarm limits and error	Range of alarm limits	Upper limit: (lower limit ＋0.1)～50.0˚C Lower limit: 0℃～(upper limit －0.1)˚C
	error	±0.1℃
Display resolution	0.1°C	
Number of channels	Two channels	

CO2

Item	Specifications
Measurement range	Respironics CO2 module Range: 0mmHg～150mmHg,0%～19.7%, 0kPa～20kPa;
	Masino CO2 module Range: 0mmHg～190mmHg, 0%～25%, 0kPa～25.3kPa;
	Comen CO2 module Range: 0mmHg～150mmHg, 0%～20%, 0kPa～20kPa
CO2 resolution	1mmHg/ 0.1kPa/0.1%
CO2 accuracy	a) Respironics CO2 module 1)0mmHg～40mmHg:±2mmHg; 2)41mmHg～70mmHg: ±5%; 3)71mmHg～100mmHg: ±8%; 4)101mmHg～150mmHg:±10%.
	b)Masimo CO2 module 1)0mmHg～114mmHg:±1.52mmHg+2%; 2)114mmHg～190mmHg: not specified.

	c)Comen CO2 module 1) 0mmHg～40mmHg:±2mmHg; 2) 41mmHg～70mmHg:±5%; 3) 71mmHg～100mmHg:±8%; 4) 101mmHg～150mmHg:±10%.	
AwRR measurement range and accuracy	a) Respironics CO2 module Adult measurement range: 2rpm～150rpm; Accuracy: ±1rpm	
	b) Masimo CO2 module Adult measurement range: 0rpm～150rpm; Accuracy: ±1rpm	
	c) Comen CO2 module Adult measurement range: 2rpm～150rpm; Accuracy: ±1rpm	
Alarm range	Respironics and Comen CO2 module	0 mmHg～150mmHg or 0 kPa～20kPa
	Masimo CO2 module	0 mmHg～190mmHg or 0 kPa～25.3kPa
Alarm error	±0.1kPa/±1mmHg	

IBP

Item	**Specifications**	
Number of IBP channels	Two channels	
IBP label	ART, PA, CVP, RAP, LAP, ICP, P1, P2	
Measurement range	ART	0～40kPa(0～300mmHg)
	PA	-0.8～16kPa(-6～120 mmHg)
	CVP	-1.3～5.3kPa(-10～40mmHg)
	RAP	-1.3～5.3kPa(-10～40mmHg）
	LAP	-1.3～5.3kPa(-10～40mmHg)
	ICP	-1.3～5.3kPa (-10～40mmHg)
	P1, P2	-6.6～40kPa(-50～300mmHg)
Measurement accuracy	±1mmHg or ±2%, the larger one (not including transducer error)	
Range of static pressure measurement	-1.3kPa～＋40kPa(-50mmHg～＋300mmHg)	
Display resolution of static measurement	0.1kPa or 1mmHg	
Static measurement error	±1mmHg or ±2%, the larger one (not including transducer error)	
Range of IBP alarm limits	ART	Upper limit: (Lower limit＋2)-300 mmHg Lower limit: 0－(Upper limit－2)mmHg
	PA	Upper limit: (Lower limit＋2)～120mmHg Lower limit: -6～(Upper limit－2)mmHg
	CVP	Upper limit: （Lower limit＋2)～40mmHg Lower limit: -10～(Upper limit－2)mmHg
	RAP	Upper limit: （Lower limit＋2)～40mmHg

		Lower limit: -10～(Upper limit－2)mmHg
	LAP	Upper limit: （Lower limit＋2)～40mmHg Lower limit: -10～(Upper limit－2)mmHg
	ICP	Upper limit: （Lower limit＋2)～40mmHg Lower limit: -10～(Upper limit－2)mmHg
	P1	Upper limit: （Lower limit＋2)～300 mmHg Lower limit: -50～(Upper limit－2)mmHg
	P2	Upper limit: (Lower limit＋2)～300 mmHg Lower limit: -50～(Upper limit－2)mmHg
IBP alarm error	±0.1/±1mmHg	
Pressure transducer	Sensitivity : 5μV/V/mmHg	
	Impedance: 300～3000Ω	

COMEN, one of the leading medical device manufacturers in China, and admitted to be the quickest developing company in medical industry.
COMEN design and produce medical devices for OR, NICU, and ICU. The product range covers Anesthesia devices, Monitoring & diagnostic products, Infant incubators, ventilators, medical pendants, operation light, all designed with specific patient data managing system to link-in to multiple medical database.
Based in Shenzhen - the hi-tech "headquarter" of China, COMEN has 30 branch offices operating business in China and 8 international branch offices in: USA, Russia, Turkey, Mexico, Thailand, India, Malaysia and Indonesia.
With all over 50,000 install bases in hospitals and medical centers globally, COMEN products are accepted and favored with its friendly design and excellent performance.

Specifications subject to change without notice

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