

COMEN



B8 Infant Incubator

<b>Product type</b>			
Name	Type		
Click protection	This incubator belongs to class I devices containing CF applied parts and BF applied parts with internal power supply.		
EMC classification	Class A		
Liquid entering prevention	Common device (IPX0 device whose cover does not prevent liquid from entering)		
Safety with combustible gas	Inapplicable in an environment with combustible anesthesia gas		
Disinfection and disinfection method	For details, see Chapter 6.		
Work mode	Continuous		
Standard compliance	MDD 93/42/EEC as amended by MDD 2007/47/EC、EN 1041 EN980、EN ISO13485、EN 60601-1、EN 60601-1-2 EN ISO14971、EN60601-1-6、EN60601-1-8 IEC 60601-2-19、IEC 60601-2-27、IEC 80601-2-30 IEC 60601-2-49、EN ISO 80601-2-55 EN ISO 80601-2-61、EN ISO10993-1 EN ISO 10993-5、EN ISO 10993-10、EN 1060-3 EN 62366、EN62304 ENISO 80601-2-56、EN 60601-1-10		
<b>Dimension</b>			
<b>Dimension of the whole machine</b>			
Size	1130mm×680mm×1600mm		
Weight	93Kg		
Fuse	T10AL/250V		
<b>Weight</b>			
Weighing range	300 g to 8 kg		
Measurement error	±10 g (position with the highest accuracy: center of the bed)		
Resolution	1 g		
<b>Display</b>			
Screen	12.1-inch high-brightness color touchscreen		
Resolution	800×600		
Displayed information	Incubator parameters and monitoring parameters		
<b>Battery</b>			
Battery specifications	4400 mAh 14.8 V rechargeable lithium-ion battery		
relative error	+5%、-10%		
Battery charging time	At least 2 hours in normal conditions		
Battery operating time	The battery could provide continuous power supply for 2 hours after being fully recharged (such functions as heating, humidifying and lifting shall be excluded).		
<b>Operation environment</b>			
Temperature	20°C - 30°C		
Humidity	Relative humidity: 10% to 95% (noncondensing)		
Air flow speed	Maximum: 0.3 m/s		
<b>Storage condition</b>			
Temperature	-20°C to 55°C		
Relative humidity	0~95% Relative humidity (noncondensing)		
Pressure	70kPa~106kPa		
<b>Power supply</b>			
Input voltage	110-120V~或 220 - 240V~		
Input frequency	50/60 Hz		
Input current	10A		
Power cable	5m		
<b>Auxiliary power supply</b>			
Output voltage	220 - 240 V	220 - 240 V	220 - 240 V
Output frequency	50/60 Hz	50/60 Hz	50/60 Hz
Output current	0.9 A	0.9 A	0.9 A

<b>Performance</b>		
<b>O2 concentration</b>		
Temperature control in infant mode	35°C to 37.5°C in the step size of 0.1°C.	
Temperature control in air mode	25°C to 39°C in the step size of 0.1°C.	
Measurement error	±0.3 °C	
Relative humidity (%)	30% – 95% in the step size of 1%.	
servo-controlled oxygen supply	21~60% in the step size of 1%.	
Control accuracy	±0.7°C ±1.0°C	For “Control Temperature” and “Average Incubator Temperature” (horizontal bed in the manual mode) For “Control Temperature” and “Average Incubator Temperature”
Change	±0.5°C	For “Incubator Temperature” and “Average Incubator Temperature”
Infant measurement accuracy	±0.3°C at 30 - 42°C	Accuracy of the body temperature measurement system within the temperature measuring range
Pre-heating time	< 35 min	Time taken to change from 25°C (indoor temperature) under 50% relative humidity to 36°C
Air flow speed	≤0.1m/s	Air flow speed detected at 10 centimeters above the center of the mattress when the bed is enclosed in alarm muting mode
CO2 level	0.3%	Maximum CO2 level detected according to specification 105.1 in the ENISO 80601-2-55 standard
Sound intensity	≤53dB	Sound intensity detected at 10 centimeters above the center of the mattress when the bed is enclosed in alarm muting mode
Temperature Alarm Range	±1°C or ±2°C of the set value; alarm range shall be 23°C to 41°C. ±0.5°C or ±1°C of the set value; alarm range shall be 34°C to 38.5°C.	Air mode Infant mode
<b>Humidity</b>		
Servo control accuracy	±5% when the set value is less than 85%; ±10% when the set value is more than 85%	For “Humidity Control Setup” and “Average Humidity”, which can be detected at 10 centimeters above the center of the bed
Humidification time	<20 min	Time taken to change from 25°C (indoor temperature) under 50% relative humidity to 33°C under 85 relative humidity
Working time with full water	> 12 h	Time duration for a full water tank when the indoor temperature is 25°C, the relative humidity is 50%, and humidity control setup is 65%
<b>O2 concentration</b>		
Detecting range	10~100%	
Detection accuracy	±2%	
Controlling range	21~60%	
Control accuracy	±5%	
pressure range at O2 supply outlet	280-600kPa	

**CFDA**



Specifications subject to change without notice

Shenzhen Comen Medical Instrument Co.,Ltd  
 Add: No.2 of FIYTA Timepiece Building, Nanhuan Avenue,  
 Gongming Sub-district, Guangming New District, Shenzhen,  
 P.R.China

Tel:+86-755-2640 8879 2641 0713

Fax:+86-755-2643 1232

Website: en.comen.com

E-mail: info@szcomen.com

**COMEN**