

SIRIO BABY 200

**Lung ventilator with
breathing monitor**

Cod.: 09637

Rev. 11 – 08/07/2025



REGULATORY ASPECTS



Certificate N MDR 00056-A rev2 of Siare Engineering International Group.

Class according to Regulation (EU) 2017 / 745	Class IIb, Rule 12, Type: Active Regulation (EU) 2017 / 745 Annex IX Chapter I and III
Class and type according to EN 60601-1	Class I Type B
Electromagnetic compatibility (EMC)	Conform to the requirements of the EN 60601-1-2:2015 and following updating's
Conformity to technical standards	IEC 60601-1:2005+AMD1:2012+AMD2:2020; EN 60601-1-2:2015/A1:2021; IEC 60601-1-6:2010+AMD1:2013+AMD2:2020; IEC 60601-1-8:2006+AMD1:2012+AMD2:2020; IEC 62304:2006+AMD1:2015; EN 794-3:1998+A2:2009; ISO 18562-2:2017; ISO 18562-3:2017; EN ISO 14971:2019; ISO 4135:2022; DIR. 2011/65/UE RoHS 2 and subsequent modifications and integrations; DIR. Delegated UE 2015/863 RoHS 3 and subsequent modifications and integrations; D.Lgs 49/2014 RAEE and subsequent modifications and integrations; EN 1789:2007+A2:2014
Company quality system certifications	UNI CEI EN ISO 13485:2021
National classification of medical devices	Z1203010503
Repertory Number	2731058
SRN (single registration number)	IT-MF-000025581
Unique Device Identification number: UDI-DI	08033737260432
Basic-UDI-DI	80337372604PV

ENVIRONMENTAL CONDITIONS

Operating	- Relative humidity: 15 al 95% non-condensing - Temperature: from -10 to +40°C - Atmospheric pressure: 600hPa -1200hPa
Storage	- Relative humidity: < 95% non-condensing - Temperature: from -25 to +70°C - Atmospheric pressure: 200hPa -1200hPa

LUNG VENTILATOR TECHNICAL FEATURES

Dimensions (W x H x D)	30x16,5x13,5 cm cm (with handle)	
Weight	4,3 Kg	
Electric power supply	12Vdc or feeder: 100 - 240 Vac / 12Vdc	
Power	15 W	
External power supply (low voltage)	0,07 A - 220 Vac / 1,25 A - 12Vdc	
Internal battery	1 battery (Pb 12V – 2.3Ah)	
Internal battery operation	3 hours (Tolerance ± 20%) ¹	
Battery re-charging time	Charging time: 8 hours with the supplied feeder	
Pneumatic supply Air and O ₂	High pressure 280 kPa - 600 kPa / 2.8 - 6 bar / 40 - 86 psi	
IP degree of protection	IP44	
The first number indicates the degree of protection against the penetration of solid foreign bodies.	4	protection from solid bodies > 1 mm in diameter
	4	Protected against water splashed from all directions.
The second number indicates the degree of protection against liquid penetration.		
Audio alarm	The sound pressure level is 69dBa	
	High priority alarm	A sequence of 3 + 2 beeps, short pause, 3 + 2 beeps, long pause

INFORMATION ON RAW MATERIALS

Abs	Present	Latex	Latex Free
Polyurethane	Present	Aluminum	Present
Polycarbonate	Present	Steel	Present
Polyester	Present	Stainless steel	Present
Teflon	Absent	Brass	Present
Polyoxymethylene	Absent	Pb	Present
Silicone	Present	Nimh	Absent
Nbr	Present	Phthalates	Phthalates Free
Human organic materials	Absent	Animal organic materials	Absent
Medicinal substances	Absent	Ionizing substances	Absent

LUNG VENTILATOR FUNCTIONAL FEATURES

Intended use	The Sirio Baby 200 lung ventilator is a medical device intended for the pediatric, newborn and premature patients in emergency, first aid and transport situations, (minimum 0.8 kg), it is designed for use in healthcare facilities, emergency medical care, during transport in and out of hospital.
Pressure automatic compensation (altitude)	Automatic compensation of atmospheric pressure on measured pressure: present (max. 5000 mt)
Type of ventilation	IPPV Volumetric - IPPV Pressometric
Control modality	Electronic

¹ The duration is to be considered indicative as it is defined in IPPV mode with the following parameters set: Pressure: 10 cmH₂O, PEEP: OFF, Tinsp: 1.5 sec and Texp: 3 sec.

Medical gas	Medical oxygen and air
Modes of ventilation	IPPV / CPAP / IMV / Manual Breath
Breathing rate	From 1 to 100 bpm (shown on display)
Inspiratory Time / Expiratory Time	▪ From 0.2 to 3 sec. ▪ From 0.4 to 30 sec
Flow trend	Constant
Adjustable mixer	▪ Adjustable from 21% to 75% or from 45% to 100% in according to Mixer selector positioning, O2 or Air ▪ The ventilator can also work with oxygen only; in such case the mixture is adjustable from 45% to 100%
Inspiratory flow (FLOW)	8.5 l/min constant
Flow-by	▪ In IMV and CPAP = 8.5 l/min constant ▪ In IPPV = 0.5 l/min max.
Mean pressure	Shown on display
Software upgrade	Updatable by the parent company

USER INTERFACE

User's interface	▪ Electronic digital bronchomanometer ▪ Breathing parameters display ▪ Battery level LED ▪ External power supply indicator ▪ Leds and acoustics alarms ▪ Control knobs
Measured parameters	Breathing Rate (RATE), Expired Tidal Volume (VT), Minute Volume (VM), Instant Airways Pressure and Peak Airways Pressure (PAW), Mean Pressure (MAP), End Expiration Pressure (PEEP)
Monitoring	Breathing cycle corrected by lungs icon
Bronchomanometer	Electronic, digital (from -10 to 60 cmH ₂ O)
Safety	Mechanical limit of airways pressure adjustable from 0 to 60 cmH ₂ O
Low pressure alarm	Adjustable from 0 to 25 cmH ₂ O
High pressure alarm	Adjustable from 0 to 60 cmH ₂ O
PEEP/CPAP	Adjustable from 0 to 20 cmH ₂ O
Pressure limit	Adjustable from 0 to 60 cmH ₂ O

ALARMS

Alarm types	Battery Level / Low and High Airways Pressure / Apnoea / Gas Supply / Power Failure
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PACKAGING AND ENVIRONMENT

Instructions for Use	User manual and technical data sheet (this one) Present in every single package
Single bag (primary packaging)	The device is packed individually: the bag is made of polyethylene
Packaging (secondary packaging)	Corrugated cardboard box equipped with graphic symbols for the correct management of the goods, identification of the manufacturer and of the contents.
Label	Compliant with the requirements of Annex I of Regulation (EU) 2017 / 745 and subsequent updates.
Environmental compatibility / Disposal	Dispose of in accordance with current national legislation



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