

SIRIO S2/T

**Emergency ventilator
with breathing monitor**

Code: 09636

Rev. 10 – 08/07/2025



REGULATORY ASPECTS

CE 0476	Certificate No. MDR 00056-A rev2 from Siare Engineering International Group
Class according to Regulation (EU) 2017/745	Class IIb, Rule 12, Type: Active
Class and type according to EN 60601-1	Regulation (EU) 2017 / 745 Annex IX Chapter I and III Class I Type B
Electromagnetic compatibility (EMC)	Conform to the requirements of the EN 60601-1-2 and following updating's
Conformity to technical standards	EN 60601-1:2006/A1:2013; EN 60601-1-2:2015; IEC 60601-1- 6: 2013; EN 60601-1-8:2007 / A11:2017; EN 62304:2006/AC:2008; EN 794-3:1998+A2:2009; DIR. 2011/65/CE; D.Lgs 49/2014 ;EN ISO 14971:2012, EN ISO 13485:2016/A11:2021; 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	The organization Siare Engineering International Group S.p.A. has a Quality Management System certified by Kiwa Cermet Italia S.p.A. according to the UNI CEI EN ISO 13485:2021 standard
National classification of medical devices	Z12030104
Repertory Number	2731048
SRN (single registration number)	IT-MF-000025581
Unique Device Identification number: UDI-DI	08033737260487
Basic-UDI-DI	80337372604PV

ENVIRONMENTAL CONDITIONS

Operating	- Relative humidity: 15 - 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

TECHNICAL FEATURES

Dimensions (W x H x D)	30x16,5x13,5 cm (including handle)		
Weight	3,7 Kg		
Electric power supply	12Vdc or feeder: 100 - 240 Vac / 12Vdc		
<i>Power</i>	9 W		
<i>Power consumption</i>	0,04 A - 220 Vac / 0,8 A - 12Vdc		
Internal battery			
<i>Standard battery</i>	Internal Pb battery		
<i>Internal battery autonomy (standard)</i>	6 hours and 30min (Tolleranza $\pm 15\%$) ¹		
<i>Battery charging time (standard)</i>	8 hours		
Patient connections	Male conic connector 22 mm / Female of 15 mm (according to EN ISO 5356-1:2015 norm)		
<i>Overall Patient Circuit Specifications</i>	Resistance to flow at 30l/min (cmH ₂ O)	Inspiratory	0.3
		Expiratory	1.2
	Compliance at 60mH2O (ml/cmH2O)		0.3
Pneumatic supply (O₂)	Oxygen: the gas pressure should be included between 280 kPa and 600 kPa (2,8 - 6 bar / 40 - 86 psi)		
<i>flow requested (O₂)</i>	Maximum flow required by the lung ventilator: 40 l/min		
Flow generation	Venturi system		
Estimated time to deplete a cylinder:	2 litres of O ₂ : 100 minutes ²		
	3 litres of O ₂ : 150 minutes ²		
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.

¹ The duration is to be considered indicative as it is defined in AUT-AST mode with the following parameters set: pressure 10cmH₂O, PEEP OFF, Rate 15 bpm and minute volume 9l/min.

² The life of the cylinder was calculated theoretically on the basis of a cylinder loaded at 200 bar. The duration is to be considered indicative as it is defined in AUT-AST mode with the following parameters set: pressure 20cmH₂O, PEEP OFF, Frequency 15 bpm and minute volume 7l/min and FiO₂ 50%.

INFORMATION ON RAW MATERIALS

Abs	Present	Latex	Latex Free
Polyurethane	Present	Aluminum	Present
Polycarbonate	Absent	Steel	Absent
Polyester	Present	Stainless steel	Present
Teflon	Absent	Brass	Present
Polyoxymethylene	Absent	Pb	Present
Silicone	Absent	Nimh	Absent
Nbr	Present	Phthalates	Phthalates Free
Human organic materials	Absent	Animal organic materials	Absent
Medicinal substances	Absent	Ionizing substances	Absent
Chemical substances	Absent	Filter material: Mixed synthetic fiber + polypropylene canvas (HEPA)	Absent
PVC present in standard equipment (e.g., gas supply hose, patient circuits)³	Present	Antimicrobial agents	Absent

³ Standard equipment can be replaced by the customer with products having the same characteristics

LUNG VENTILATOR FUNCTIONAL FEATURES

Intended use	The Sirio S2/T lung ventilator is a medical device intended for the ventilation of adult, paediatric and neonatal patients (minimum 3 kg); it is designed for use in healthcare facilities, emergency medical care, during transport in and out of hospital
Type of ventilation	IPPV volumetric - IPPV time cycled with PRESSURE SUPPORT
Control modality	Electronic
Pressure automatic compensation (altitude)	Automatic compensation of atmospheric pressure on measured pressure: present (max. 5000 mt)
Respiratory parameters default setting	The trigger is reset every time the device is turned off. Default -1cmH ₂ O
Ventilation modalities	AUT + AST / PSV + APNOEA BACK UP / PEEP / CPAP
Breathing rate	From 5 to 70 bpm
Inspiratory Time / Expiratory Time (maximum, minimum)	Insp Time: from 0,343 to 4,8 Exp Time: from 0,514 to 7,2
Minute volume	From 1 to 16 l/min
Tidal volume	From 15 to 3000 ml
Inspiratory time	40% of breathing cycle
I:E Ratio	1:1,5
Inspiratory pause	Automatic setting during PSV mode
Pressure support ventilation	Adjustable from 0 (SPONT.) to 50 cmH ₂ O
Pressure limit	Adjustable from 0 to 50 cmH ₂ O
PEEP	Adjustable from 0 to 20 cmH ₂ O
Mixer device	50% O ₂ or 100% O ₂
Trigger detective method	Through pressure transducer
Pressure trigger (I)	Adjustable from -1 to -5 cmH ₂ O
Flow trend	Constant and decreasing (PSV)
Flow-by	Max 40 l/min
Patient circuit	Single hose with exhalation valve and Flow sensor
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
	Controls Knobs for setting parameters and oxygen concentration
Views and settings	▪ Setting the Ventilation Mode and the adjustable parameters ▪ Display of alarm signals and messages
Function	MAN key (manual)
Parametri respiratori fisiologici impostabili	Limite di pressione, Rate, PEEP, Volume minuto, FiO ₂
Measured parameters	▪ Respiratory rate (range: 0 ÷ 200 bpm) Rate accuracy ± 1 Bpm ▪ PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH₂O) Pressure accuracy ± (2 cmH₂O + 4% of the reading). ▪ Tidal Volume: V_te (range: 15 ÷ 3000 ml) Minute Volume (range: 1 ÷ 16 l/min) Volume Accuracy ± 20% for volumes > 50ml Expired Volume Accuracy ± (20% or ± 15ml) whichever is greater for volumes ≤ 50ml
Displayed parameters	Breathing cycle corrected by lungs icon, 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)

ALARMS

Alarm types	SYSTEM: not configurable by the operator
Alarms visualization	Display of the alarm through the lighting of the relevant LEDs.
Alarm types	SYSTEM: not configurable by the operator

System alarms

Remaining battery level from 100% to 51%	Green LED
Remaining battery level from 50% to 26%	Yellow LED
Remaining battery level from 25% to 0%	Red LED
O ₂ Supply	Low gas supply pressure
High PAW	High airway pressure. Higher than 55 cmH ₂ O
Low PAW/Apnea	Low airway pressure. Lower than 8 cmH ₂ O
Power failure	Indicates that the device is disconnected from the mains supply

PACKAGING AND ENVIRONMENT

Instructions for Use	User manual and technical data sheet (this one) Present in every single package
Primary packaging	The device is packed individually: the bag is made of polyethylene
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.
Barcode	Yes
Environmental compatibility / Disposal	Dispose of in accordance with current national legislation



SIARE Engineering International Group S.p.A.

Headquarter

Via Giulio Pastore, 18, Crespellano - 40053 Valsamoggia (BO) - Italy

Registered Office

Via Giulio Pastore, 18, Crespellano - 40053 Valsamoggia (BO) - Italy

Operational headquarter

Via Fini 8/10, Crespellano – 40053 Valsamoggia (Bo) – Italy

Contacts

Tel. +39 051 969802 – E-mail: mail@siare.it - web: www.siare.it   