

# ARIA 104

## 10" Portable intensive care ventilator

Oxygen driven ventilator with built-in turbine  
for adults, children and newborn

- Touch Screen -



Cod.: 980104/A

Rev. 8 - 22/02/2022

### GENERAL DATA

Aria 104 electronic lung ventilator is equipped with turbine and with a TFT 10,4" colour monitor touch screen displaying the curves of pressure, flow, volume, the loops of breathing parameters, the trends and the ventilation parameters.

Aria 104 lung ventilator is suitable for ventilation of adult, paediatric and neonatal patients. Aria 104 lung ventilator is equipped with a flow generation system by turbine with separate cooling system granting higher quality and safety standards in patient ventilation.

Aria 104 is equipped with a flow and pressure trigger, it provides the most advanced volume-controlled ventilation modalities VC/VAC, VC/VAC-BABY, pressure-controlled ventilation modalities APCV (BILEVEL ST), APCV-TV, SIMV by Volume and by Pressure, Pressure supported modalities PSV (BILEVEL S), PSV-TV, CPAP, APRV, SIGH, Non-Invasive Ventilation (NIV APCV - NIV PSV), Drug Nebulizer and Manual Ventilation (MAN).

Aria 104 is supplied with back up long-lasting batteries and its software can be updated for new modes and last generation ventilation strategies.

### NORMS



The lung ventilator is conform to the essential requirements and it is realized according to the references of the Annex II of 93/42/EEC Medical Devices Directive.

**Class and type according to EN 60601-1** Class I Type B

**National classification of medical devices** Z1203010504

**Class according to 93/42 EEC Directive** Class IIb, Rule 9, Type: Active according to MDD 93/42 EEC Annex IX

**Electromagnetic compatibility (EMC)** EN 60601-1-2: 2015 and following

**Norms** DIR. 93/42/EEC (2007); EN 60601-1:2006/ A1:2013; EN 60601-1-2:2015; IEC 60601-1-6:2013; EN 60601-1-8:2007 / A11:2017; EN 60601-2-12:2006; ISO 80601-2-12:2011; EN60601-1-11:2015; EN 62304:2006/ AC:2008; ISO 10993-1:2009; ISO 15223-1:2016; EN ISO 4135: 2001; EN ISO 14971:2012; DIR. 2011/65/CE; D. Lgs 49/2014.

<b>File number reference</b>	2164134						
<b>Unique Device Identification (UDI) number</b>	0	80	3373726	1	2	3	1
<b>Basic-UDI-DI</b>							

## ENVIRONMENTAL CONDITIONS

<b>Operating</b>	Relative humidity: 30 - 95% non-condensing Temperature: from -10 to +40°C
<b>Storage</b>	Relative humidity: < 95% Temperature: from -25 to +70°C

## TECHNICAL DATA

<b>Dimensions (W x H x D)</b>	290 x 245 x 215 mm
<b>Weight</b>	5,5 Kg
<b>Electric power supply</b>	100 - 240Vac / 50 - 60Hz
<i>Power</i>	Max 60 VA
<i>External power supply (low voltage)</i>	12 Vdc / 7 A
<i>Internal battery</i>	Battery NiMh 12Vdc - 4.2 Ah
<i>Internal battery operation</i>	Max 4 hours
<i>Battery re-charging time</i>	About 10 hours
<b>External electric connections</b>	<ul style="list-style-type: none"> <li>▪ O2 sensor connection</li> <li>▪ Flow sensor connection</li> <li>▪ CO2 module connection (RS232)</li> <li>▪ CPU programming connector (USB 1)</li> <li>▪ Data transfer connection: patient data, events, trends (USB 2)</li> <li>▪ External alarm/nurse call</li> </ul>
<b>Patient connections</b>	Male conic connectors 22 mm / Female of 15 mm (according to EN ISO 5356-1:2015 norm)
<i>Overall circuit specifications - Resistance</i>	Adult patient circuit (22 mm I.D., 60 l / min flow): <ul style="list-style-type: none"> <li>▪ Inspiratory branch: 0.13 cm H<sub>2</sub>O / 60 l / min</li> <li>▪ Expiratory branch: 0.13 cm H<sub>2</sub>O / 60 l / min</li> </ul>
<i>Overall Circuit Specifications -Compliance</i>	Adult patient circuit (I.D. 22 mm): 3.85 ml / cm H <sub>2</sub> O
<b>Supply pressure (O<sub>2</sub>)</b>	<ul style="list-style-type: none"> <li>▪ Low pressure (max 15 l/min)</li> <li>▪ High pressure 280 kPa - 600 kPa / 2.8 - 6 bar / 40 - 86 psi</li> </ul>
<i>Min flow requested (O<sub>2</sub>)</i>	80 l/min

### IP degree of protection

IP21

The **first number** indicates the degree of protection against the penetration of solid foreign bodies.

2	protected against solid bodies greater than 12 mm in diameter
1	protected against vertical drops of water

The **second number** indicates the degree of protection against liquid penetration.

### Sound pressure level measurements

Operating mode	Maximum sound measured from operator's normal position [dBA] / [dBC]	Maximum sound measured 1 m from any position of device [dBA] / [dBC]
Lower level / Higher level -	63,8/93,7dBA	53,5/82,4 Front - dBA
/	/	55,8/85,3 Rear - dBA
/	/	50,9/ 79,6 Right - dBA
/	/	51,9/82,3 Left - dBA
/	/	57,9/87,2 On - dBA
Media results; Lower level / Higher level	/	54,0 dBA/83,36dBA

Supplementary information:

Referenced background sound pressure measurement: \_38,2\_ dBA

### Audio alarm

Operating mode / pulse spacing	Number of pulses			Limit			Pulse spacings			Limit		
	High	Medium	Low	High	Medium	Low	High	Medium	Low	High	Medium	Low
Physiological/technical alarm	10			10								
Between 1 <sup>st</sup> /2 <sup>nd</sup>							60,6 ms		50-125 ms			
Between 3 <sup>rd</sup> /4 <sup>th</sup>							480 ms		306,7 ms			
Between 5 <sup>th</sup> / 6 <sup>th</sup>							1,227 s		0,35-1,3s			
Between 10 <sup>th</sup> /1 <sup>st</sup>							4,987 s		2,5-15s			

Supplementary information:

Referenced background sound pressure measurement: \_38,2\_ dBA

## LUNG VENTILATOR FUNCTIONAL FEATURES

### Intended use

Aria 104 is a lung ventilator for use in emergency rooms, transport, intensive care units and with patients affected by respiratory diseases and it is suitable for ventilation of adult, paediatric and neonatal patients.

### Operation principle

- Time cycled at constant volume
- Pressure cycled
- Microprocessor controlled flow
- Spontaneous breath with integrated valve

### Pressure automatic compensation (altitude)

Automatic compensation of atmospheric pressure on measured pressure: present (max. 5000 mt)

### Automatic leaks compensation

Max 60 l/min (NIV APCV, NIV PSV)

<b>Leak % visualization</b>	Present
<b>Visualization of the oxygen consumption calculation</b>	Present
<b>Altitude compensation for oxygen sensor</b>	Present
<b>Respiratory parameters default setting</b>	Present (Neonatal, Paediatric, Adult)
<b>Ventilation modalities</b>	<ul style="list-style-type: none"> <li>▪ APCV (BILEVEL ST), APCV-TV, PSV (BILEVEL S), PSV-TV (Auto Weaning), VC/VAC, VC/VAC BABY, V-SIMV+PS, P-SIMV+PS, CPAP, APRV</li> <li>▪ Optional Function: HFNC (High Flow Nasal Cannula)</li> <li>▪ SIGH, NEB (Nebulizer), Apnea BACK-UP (PSV, PSV-TV, CPAP), MAN (Manual).</li> </ul>
<b>Additional PRP (optional)</b>	<ul style="list-style-type: none"> <li>▪ RR SPONT, TV SPONT, MV SPONT, RSBI, TE, WOB, AUTOPEEP (Optional Functions)</li> </ul>
<b>Breathing rate VC/VAC</b>	From 4 to 150 bpm
<b>Inspiratory Time / Expiratory Time (maximum, minimum)</b>	<ul style="list-style-type: none"> <li>▪ Ti min = 0.036 sec (minimum inspiratory time)</li> <li>▪ Ti max = 12 sec (maximum inspiratory time)</li> <li>▪ Te min = 0.08 sec (minimum expiratory time)</li> <li>▪ Te max = 13.6 sec (maximum expiratory time)</li> </ul>
<b>Breathing rate V-SIMV e P-SIMV</b>	From 1 to 60 bpm
<b>SIMV Inspiratory time</b>	From 0.2 to 5.0 sec.
<b>Tidal volume</b>	<ul style="list-style-type: none"> <li>▪ From 100 to 3000 ml (Adult)</li> <li>▪ From 50 to 400 ml (Paediatric)</li> <li>▪ From 2 to 100 ml (Neonatal)</li> </ul>
<b>I:E ratio</b>	From 1:10 to 4:1
<b>Inspiratory pause</b>	From 0 to 60 % of the inspiratory time
<b>Inspiratory pressure limit</b>	P <sub>insp</sub> : from 2 to 80 cmH <sub>2</sub> O (in function of low and high-pressure alarm set)
<b>Inspiratory ramp Slope</b>	1, 2, 3, 4 (acceleration slope) - (4 max. acceleration) (in operative modes by pressure only)
<b>PEEP</b>	From OFF, 2 to 50 cmH <sub>2</sub> O Microprocessor controlled
<b>O<sub>2</sub> concentration</b>	Adjustable from 21 to 100% with electronic integrated mixer.
<b>Trigger detective method</b>	Through sensor (Pressure or Flow)
<i>Pressure trigger (I)</i>	Pressure adjustable from OFF; -1 to -20 cmH <sub>2</sub> O under PEEP level (step of 1 cmH <sub>2</sub> O)
<i>Flow trigger (I)</i>	Flow adjustable from OFF; 0.3 to 15 L/min <ul style="list-style-type: none"> <li>▪ from 0.3 to 1 L/min (step of 0.1 L/min)</li> <li>▪ from 1 L/min to 2 L/min (step of 0.5 L/min)</li> <li>▪ from 2 L/min to 15 L/min (step of 1 L/min)</li> </ul>
<i>Trigger E</i>	From 5 to 90 % of the inspiratory peak flow

<b>Inspiratory flow (FLOW)</b>	190 l/min
<b>Flow-by</b>	Automatic
<b>PS (pressure support)</b>	From 2 to 80 cmH <sub>2</sub> O (PSV, V-SIMV+PS, P-SIMV+PS)
<b>SIGH in VC/VAC modality</b>	<ul style="list-style-type: none"> <li>▪ Interval: 40 ÷ 500 bpm (step 1 bpm)</li> <li>▪ Amplitude: OFF, 10 ÷ 100% of set Tidal Volume (step 10%)</li> </ul>
<b>CPAP</b>	Pressure: from 3 to 50 cmH <sub>2</sub> O
<b>APRV</b>	<ul style="list-style-type: none"> <li>▪ Time High and Time Low: from 1 to 200 sec.</li> <li>▪ Pressure High and Pressure Low: from 3 to 50 cmH<sub>2</sub>O.</li> </ul>
<b>Functions</b>	<ul style="list-style-type: none"> <li>▪ MENU function (SETUP – PATIENT DATA)</li> <li>▪ Alarms Limits</li> <li>▪ Graphics visualization (Auto-Range)</li> <li>▪ INSP Hold - EXP Hold (max 20 sec.)</li> <li>▪ O<sub>2</sub> 100% control (O<sub>2</sub> to 100% max. 5 min.)</li> <li>▪ NEB (6 l/min)</li> <li>▪ MAN (manual ventilation)</li> </ul>
<b>NEB</b>	Drug nebulizer: selectable to 6 l/min with automatic compensation on forced ventilation modes and dedicated output
<b>Patient circuit</b>	<ul style="list-style-type: none"> <li>▪ Double hose 150 cm. Adult/Paediatric patient circuit (expiratory valve on the ventilator)</li> <li>▪ Double hose 150 cm. Neonatal patient circuit (expiratory valve on the ventilator)</li> </ul>
<b>Software upgrade</b>	USB 1 port

## USER INTERFACE

<b>Touch screen monitor</b>	Module with TFT LED display with touch screen
<i>Dimensions</i>	10,4"
<i>Displaying area</i>	262x163 mm
<b>Display keyboard</b>	Keyboard for rapid access of functions. Encoder knob for: <ul style="list-style-type: none"> <li>▪ selection, set up and confirmation of physiological breathing parameters</li> <li>▪ selection and direct activation of function</li> </ul>
<b>Displaying and settings</b>	<ul style="list-style-type: none"> <li>▪ Operative Mode setting</li> <li>▪ Visualization of alarm messages and signals</li> <li>▪ Setting and monitoring of physiological breathing parameters</li> <li>▪ Visualization of additional graphs and breathing parameters</li> <li>▪ MENU function for setting operation parameters</li> <li>▪ Activation of special functions</li> <li>▪ Visualization of operative mode, clock, date and time functions</li> <li>▪ Visualization of software version</li> </ul>

<b>Calibration Programs</b>	<ul style="list-style-type: none"> <li>▪ Self-Test</li> <li>▪ Turbine Characterization</li> <li>▪ Expiratory Flow Sensor Calibration</li> <li>▪ Usage at High Altitude</li> <li>▪ VTEc</li> <li>▪ Nebulizer Enable</li> <li>▪ ScreenShoot Enable</li> <li>▪ Tourn Off</li> </ul>
<b>MENU function - SETUP</b>	<ul style="list-style-type: none"> <li>▪ Display (Brightness, Energy Saving, Sound Volume, Touch Audio)</li> <li>▪ Date &amp; Time</li> <li>▪ Language</li> <li>▪ Units (Weight, Height, CO2, Pressure)</li> <li>▪ Default (Erase Trend data, Erase Patient data, Setting &amp; Ventilation Default)</li> <li>▪ Other (NIV Enable, Power Failure, Apnea Time, Change Password, Save to USB)</li> <li>▪ IRMA/ISA (Gas Sensor)</li> <li>▪ Supplementary Tests (Expiratory Flow Sensor Calibration, O2 Sensor Calibration)</li> <li>▪ Turn Off?</li> <li>▪ Cancel</li> </ul>
<b>MENU function - PATIENT DATA</b>	The PATIENT DATA can be set or deleted
<b>Alarm Limits</b>	PAW (cmH2O), PEEP (cmH2O), Vte (ml), VM (L/min), O2 (%), RR (bpm), EtCO2 (%)
<b>Displayed graphics</b>	<ul style="list-style-type: none"> <li>▪ CURVES: Pressure (PAW) - Flow - Volume (Vte) - O2 (CO2 optional)</li> <li>▪ LOOPS: Pressure / Volume - Flow / Volume - Pressure/Flow</li> <li>▪ Graphics: INSP-EXP cycle</li> <li>▪ Events</li> <li>▪ Trends</li> </ul>
<i>Events</i>	Memory storage up to 2000 machine events including the alarms.
<i>Trends</i>	Storage capacity (72 h) of all measured parameters.
<b>Physiological breathing parameters setting</b>	Vti (ml), RR (bpm), I:E, Pause (%), PEEP (cmH2O), O2 (%), Tr. I (L/min - cmH2O), SIGH (Sigh. Amp. (%), Sigh. Int. (b)), Vte (ml), PMax, Pmin, PInsp (cmH2O), Slope, BACK-UP parameters, PS (cmH2O), RRsimv (bpm), Ti (s), Ti Max (s), Tr. E (%), CPAP (cmH2O), Pressure High - Low (cmH2O), Time High - Low (s).

<i>Range of measured parameters</i>	<ul style="list-style-type: none"> <li>▪ Respiratory rate (range: 0 ÷ 200 bpm)</li> <li>▪ Rate accuracy <math>\pm 1</math> Bpm</li> <li>▪ I:E ratio (range 1:99 ÷ 99:1)</li> <li>▪ % of O<sub>2</sub> (range: 0% ÷ 100%)</li> <li>▪ O<sub>2</sub> accuracy <math>\pm (2.5\% + 2.5\%</math> of the reading)</li> <li>▪ O<sub>2</sub> from 21% to 90% in less than 80 seconds</li> <li>▪ Tidal Volume: V<sub>te</sub>, V<sub>ti</sub> (range: 0 ÷ 3000 ml)</li> <li>▪ Expired Minute Volume (range: 0 ÷ 40 l/min)</li> <li>▪ Expired Volume Accuracy <math>\pm (15\% + 4\text{ml})</math> for volumes &gt; 50ml</li> <li>▪ Expired Volume Accuracy <math>\pm (15\%</math> or <math>\pm 15\text{ml})</math> whichever is greater for volumes <math>\leq 50\text{ml}</math></li> <li>▪ PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH<sub>2</sub>O)</li> <li>▪ Pressure accuracy <math>\pm (2 \text{ cmH}_2\text{O} + 4\%</math> of the reading).</li> <li>▪ Inspiratory Peak Flow: F<sub>i</sub> (range: 1 ÷ 190 l/min)</li> <li>▪ Expiratory Peak Flow: F<sub>e</sub> (range: 1 ÷ 150 l/min)</li> <li>▪ T<sub>insp.</sub>, T<sub>exp</sub>, T<sub>pause</sub> (range 0.036 ÷ 13.6 sec)</li> <li>▪ Time accuracy <math>\pm 0.2</math> seconds</li> <li>▪ Static and Dynamic compliance (range: 1 ÷ 100 ml/cmH<sub>2</sub>O)</li> <li>▪ Resistance (range: 0 ÷ 200 cmH<sub>2</sub>O/l/s)</li> <li>▪ EtCO<sub>2</sub>: with optional CO<sub>2</sub> module (range: 0 ÷ 10%)</li> <li>▪ Leak (%) (range: 0 ÷ 100%) <ul style="list-style-type: none"> <li>- % with PEEP 0 or with PEEP 1,</li> <li>- l / min with PEEP <math>\geq 2</math></li> </ul> </li> <li>▪ O<sub>2</sub> consumption (range: 0 ÷ 100l/min)</li> </ul>
<i>Displayed parameters</i>	PAW, PEEP, CPAP (cmH <sub>2</sub> O), RR (bpm), I:E, O <sub>2</sub> (% - l/min), V <sub>te</sub> (ml), VM (L/min), EtCO <sub>2</sub> (%), MAP (cmH <sub>2</sub> O), P <sub>plateau</sub> (cmH <sub>2</sub> O), F <sub>i</sub> , F <sub>e</sub> (L/min), T <sub>i</sub> , T <sub>pause</sub> , T <sub>e</sub> (sec.), R <sub>i</sub> (cmH <sub>2</sub> O/l/s), C <sub>s</sub> , C <sub>d</sub> (ml/cmH <sub>2</sub> O), Leak ( % )
<b>Flow sensor</b>	Magnetic perturbation (patented), reusable
<i>Calibration</i>	Automatic (started by the operator)
<i>Maintenance</i>	By steam disinfection
<b>Oxymeter</b>	Electronic (value displayed in breathing parameters)
<i>Calibration</i>	Automatic or started by the Operator
<b>CO<sub>2</sub> analyzer</b>	Optional function (Sidestream or Mainstream module available)
<b>ALARMS</b>	
<b>Alarm types</b>	<ul style="list-style-type: none"> <li>▪ By MENU: with limits set by the operator</li> <li>▪ By DEFAULT: the operator cannot set them up</li> </ul>
<b>Alarm default setting</b>	Present (Neonatal, Paediatric, Adult)
<b>Alarm priority</b>	High - Mean - Standby

<b>Alarms visualization</b>	Max 3 alarms simultaneously; additional alarms, scroll every 3-5 sec.
<b>Alarms with limits set up by the operator</b>	
<b>Pressure of Airways</b>	High – Low
<b>Respiratory Rate</b>	High – Low
<b>Expiratory Volume</b>	High – Low
<b>Volume Minute</b>	High – Low
<b>PEEP</b>	High – Low
<b>O2 Concentration</b>	High – Low
<b>EtCO2</b>	High – Low (with optional CO2 gas analyser)
<b>On Battery</b>	Alarm occurs in case of failure of external power supply
<b>Apnoea</b>	Low Rate (function of Apnoea BACK-UP)
<b>System alarms</b>	
<b>Low Battery: 50% Remaining</b>	Battery at 50%
<b>Low Battery: 25% Remaining</b>	Battery at 25%
<b>Low Battery</b>	10 Minutes
<b>Battery Disconnected</b>	Yes / No
<b>Battery Overtemperature</b>	Indication of exceeding the temperature limits inside the battery
<b>Circuit Disconnected</b>	Indication of patient circuit disconnected
<b>O2 Supply</b>	Low (< 2,7 bar)
<b>Turbine Failure</b>	Signals in case of a blower fault condition
<b>Turbine Overtemperature</b>	Indication of exceeding the temperature limits inside the turbine
<b>Turbine Overcurrent</b>	Indication of exceeding the current limits inside the turbine
<b>Maintenance</b>	To be carried out when the warning appears
<b>CO2 Analyzer</b>	Sampling Line Clogged, No Sampling Line, Replace Adapter, No Adapter, Unspecified Accuracy, Error, No Breaths, Low/High EtCO2.
<b>SELF-TEST alarms</b>	
<b>Turbine</b>	The correct functioning of the turbine is tested
<b>Oxygen emptying</b>	It is performed a washing of the remaining oxygen present within the lung ventilator, order to measure the offset of the oxygen sensor
<b>INSP.- EXP. Flow sensor</b>	Verification of EXP flow sensor operation
<b>Pressure sensor</b>	Verification of pressure sensor operation through control of PAW reading
<b>Electrovalve</b>	The correct functioning of electrovalve is tested
<b>Patient circuit</b>	Verification of patient circuit
<b>Battery</b>	Checking on battery power
<b>Oxygen sensor</b>	Cell condition
<b>Acoustic alarm</b>	Verification by the user of acoustic signal emission, the confirmation of the test is made by silencing of that alarm



## ACCESSORIES

- |                             |  |
|-----------------------------|--|
| <b>Supplied Accessories</b> | <ul style="list-style-type: none"><li>▪ User's Manual</li><li>▪ Double hose patient circuit</li><li>▪ Antibacterial filter for patient circuit</li><li>▪ Nebulizer set</li><li>▪ Power cable</li><li>▪ Vehicular cable for 12 Vdc</li><li>▪ O2 supply hose</li><li>▪ O2 cell</li></ul> |
|-----------------------------|--|

---

<b>Optional Accessories</b>	Refer to price list
-----------------------------	---------------------

---

SIARE applies the UNI EN ISO 13485:2016 Quality System and the 93/42/EEC.

**SIARE ENGINEERING INTERNATIONAL GROUP s.r.l.**

Via Pastore, 18 - Località Crespellano, 40053 Valsamoggia (BO), ITALY

Tel.: +39 051 969802 - Fax: +39 051 969809

Email: [mail@siare.it](mailto:mail@siare.it) - Web: <http://www.siare.it>