

ARIA 150

Intensive care ventilator

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

- Touch Screen -

Code: 960502/A

Rev.7 - 22/02/2022



GENERAL DATA

Aria 150 electronic lung ventilator is equipped with turbine and with a TFT 15" colour monitor touch screen displaying the curves of pressure, flow, volume, the loops of breathing parameters, the trends and the ventilation parameters.

Aria 150 lung ventilator is suitable for ventilation of adult, paediatric and neonatal patients. Aria 150 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 150 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 150 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 62304:2006/ AC:2008; ISO 10993-1:2009/ AC:2010; IEC 62353:2014; EN 60601-2-12:2006; ISO 80601-2-12:2011; ISO 15223-1:2016; DIR. 2011/65/CE; D.Lgs 49/2014; EN ISO 14971:2012; EN ISO 4135:2001

File number reference	2164076						
Unique Device Identification (UDI) number Basic-UDI-DI	0	80	3373726	1	2	9	3

ENVIRONMENTAL CONDITIONS

Operating	<ul style="list-style-type: none"> ▪ Relative humidity: 30 - 95% non-condensing ▪ Temperature: from +10 to +40°C
Storage	<ul style="list-style-type: none"> ▪ Relative humidity: < 95% ▪ Temperature: from -25 to +70°C

TECHNICAL DATA

Dimensions (W x H x D)	Ventilator unit and trolley 530 x 1400 x 460 mm
Weight	26 Kg
Electric power supply	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> 2 batteries (Pb 12 Vdc - 1,3 Ah)
	<i>Internal battery operation</i> 90 minutes max.
	<i>Battery re-charging time</i> About 8 hours
External electric connections	<ul style="list-style-type: none"> ▪ O2 sensor connection ▪ Flow sensor connection ▪ CO2 module connection (RS232) ▪ CPU programming connector (USB 1) ▪ Data transfer connection: patient data, events, trends (USB 2) ▪ External alarm/nurse call
Patient connections	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"> ▪ Inspiratory branch: 0.13 cm H₂O / 60 l / min ▪ Expiratory branch: 0.13 cm H₂O / 60 l / min
<i>Overall Circuit Specifications -Compliance</i>	Adult patient circuit (I.D. 22 mm): 3.85 ml / cm H ₂ O

Supply pressure (O₂)	▪ Low pressure (max 15 l/min)
	▪ High pressure 280 kPa - 600 kPa / 2.8 - 6 bar / 40 - 86 psi

Min flow requested (O₂) 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	53,1/69,1 Front - dBA
/		/	55,4/67,9 Rear - dBA
/		/	55,5/ 69,5 Right - dBA
/		/	53,0/70,4 Left - dBA
Media results; Lower level / Higher level		/	54,2 dBA/69,2dBA
Operator position		/	71,5 dBA/82,1 dBA

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 st /2 nd							117,3 ms		50-125 ms			
	Between 3 rd /4 th							386,7 ms		306,7 ms			
	Between 5 th / 6 th							1,280 s		0,35-1,3s			
	Between 10 th /1 st							5,3 s		2,5-15s			

LUNG VENTILATOR FUNCTIONAL FEATURES

Intended use Ventilator for Intensive Care Therapy; 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)

Leak % visualization	Present
Visualization of the oxygen consumption calculation	Present
Altitude compensation for oxygen sensor	Present
Respiratory parameters default setting	Present (Neonatal, Paediatric, Adult)
Ventilation modalities	<ul style="list-style-type: none"> ▪ 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 ▪ Optional function: HFNC (High Flow Nasal Cannula) ▪ SIGH, NEB (Nebulizer), Apnea BACK-UP (PSV, PSV-TV, CPAP), MANUAL
Additional PRP (optional)	<ul style="list-style-type: none"> ▪ RR SPONT, TV SPONT, MV SPONT, RSBI, TE, WOB, AUTOPEEP (Optional Functions)
Breathing rate VC/VAC	From 4 to 150 bpm
Inspiratory Time / Expiratory Time (maximum, minimum)	<ul style="list-style-type: none"> ▪ Ti min = 0.036 sec (minimum inspiratory time) ▪ Ti max = 12 sec (maximum inspiratory time) ▪ Te min = 0.08 sec (minimum expiratory time) ▪ Te max = 13.6 sec (maximum expiratory time)
Breathing rate V-SIMV e P-SIMV	From 1 to 60 bpm
SIMV Inspiratory time	From 0.2 to 5.0 sec.
Tidal volume	<ul style="list-style-type: none"> ▪ From 100 to 3000 ml (Adult) ▪ From 50 to 400 ml (Paediatric) ▪ From 2 to 100 ml (Neonatal)
I:E ratio	From 1:10 to 4:1
Inspiratory pause	From 0 to 60 % of the inspiratory time
Inspiratory pressure limit	Pinsp: from 2 to 80 cmH ₂ O (in function of low and high pressure alarm set)
Inspiratory ramp Slope	1, 2, 3, 4 (acceleration slope) - (4 max. acceleration) (in operative modes by pressure only)
PEEP	From OFF, 2 to 50 cmH ₂ O Microprocessor controlled
O₂ concentration	Adjustable from 21 to 100% with electronic integrated mixer.
Trigger detective method	Through sensor (Pressure or Flow)
	<i>Pressure trigger (I)</i> Pressure adjustable from OFF; -1 to -20 cmH ₂ O under PEEP level (step of 1 cmH ₂ O)

- Flow trigger (I)* Flow adjustable from OFF; 0.3 to 15 L/min
- from 0.3 to 1 L/min (step of 0.1 L/min)
 - from 1 L/min to 2 L/min (step of 0.5 L/min)
 - from 2 L/min to 15 L/min (step of 1 L/min)

Trigger E From 5 to 90 % of the inspiratory peak flow

Inspiratory flow (FLOW)	190 l/min
Flow-by	Automatic
PS (pressure support)	From 2 to 80 cmH ₂ O (PSV, V-SIMV+PS, P-SIMV+PS)
SIGH in VC/VAC modality	<ul style="list-style-type: none"> ▪ Interval: 40 ÷ 500 bpm (step 1 bpm) ▪ Amplitude: OFF, 10 ÷ 100% of set Tidal Volume (step 10%)
CPAP	Pressure: from 3 to 50 cmH ₂ O
APRV	<ul style="list-style-type: none"> ▪ Time High and Time Low: from 1 to 200 sec. ▪ Pressure High and Pressure Low: from 3 to 50 cmH₂O.
Functions	<ul style="list-style-type: none"> ▪ MENU function (SETUP – PATIENT DATA) ▪ Alarms Limits ▪ Graphics visualization (Auto-Range) ▪ INSP Hold - EXP Hold (max 20 sec.) ▪ O₂ 100% control (O₂ to 100% max. 5 min.) ▪ NEB (6 l/min) ▪ MAN (manual ventilation)
Miscellaneous	Connector for “Remote Alarm”
NEB	Drug nebulizer: selectable to 6 l/min with automatic compensation on forced ventilation modes and dedicated output
Patient circuit	<ul style="list-style-type: none"> ▪ Double hose 150 cm. Adult/Paediatric patient circuit (expiratory valve on the ventilator) ▪ Double hose 150 cm. Neonatal patient circuit (expiratory valve on the ventilator)
Software upgrade	USB 1 port

USER INTERFACE

Touch screen monitor	Module with TFT LED display with touch screen
<i>Dimensions</i>	15”
<i>Displaying area</i>	304 x 228 mm
Display keyboard	<p>Keyboard for rapid access of functions. Encoder knob for:</p> <ul style="list-style-type: none"> ▪ selection, set up and confirmation of physiological breathing parameters ▪ selection and direct activation of function

Displaying and settings	<ul style="list-style-type: none"> ▪ Operative Mode setting ▪ Visualization of alarm messages and signals ▪ Setting and monitoring of physiological breathing parameters ▪ Visualization of additional graphs and breathing parameters ▪ MENU function for setting operation parameters ▪ Activation of special functions ▪ Visualization of operative mode, clock, date and time functions ▪ Visualization of software version
Calibration Programs	<ul style="list-style-type: none"> ▪ Self Test ▪ Turbine Characterization ▪ Expiratory Flow Sensor Calibration ▪ Usage at High Altitude ▪ VTEc ▪ Nebulizer Enable ▪ ScreenShoot Enable ▪ Tourn Off
MENU function - SETUP	<ul style="list-style-type: none"> ▪ Display (Brightness, Energy Saving, Sound Volume, Touch Audio) ▪ Date & Time ▪ Language ▪ Units (Weight, Height, CO2, Pressure) ▪ Default (Erase Trend data, Erase Patient data, Setting & Ventilation Default) ▪ Other (NIV Enable, Power Failure, Apnea Time, Change Password, Save to USB) ▪ Gas Sensor (IRMA/ISA) ▪ Supplementary Tests (Expiratory Flow Sensor Calibration, O2 Sensor Calibration) ▪ Turn Off? ▪ Cancel
MENU function - PATIENT DATA	The PATIENT DATA can be set or deleted
Alarm Limits	PAW (cmH ₂ O), PEEP (cmH ₂ O), Vte (ml), VM (L/min), O ₂ (%), RR (bpm), EtCO ₂ (%)
Displayed graphics	<ul style="list-style-type: none"> ▪ CURVES: Pressure (PAW) - Flow - Volume (Vte) - O₂ (CO₂ optional) ▪ LOOPS: Pressure / Volume - Flow / Volume - Pressure/Flow ▪ Graphics: INSP-EXP cycle ▪ Events ▪ Trends
<i>Events</i>	Memory storage up to 2000 machine events including the alarms.
<i>Trends</i>	Storage capacity (72 h) of all measured parameters.

Physiological breathing parameters setting

Vti (ml), RR (bpm), I:E, Pause (%), PEEP (cmH₂O), O₂ (%), Tr. I (L/min - cmH₂O), SIGH (Sigh. Amp. (%), Sigh. Int. (b)), Vte (ml), P_{Max}, P_{min}, P_{insp} (cmH₂O), Slope, BACK-UP parameters, PS (cmH₂O), RR_{simv} (bpm), T_i (s), T_i Max (s), Tr. E (%), CPAP (cmH₂O), Pressure High - Low (cmH₂O), Time High - Low (s).

Range of measured parameters

- Respiratory rate (range: 0 ÷ 200 bpm)
- Rate accuracy ± 1 Bpm
- I:E ratio (range 1:99 ÷ 99:1)
- % of O₂ (range: 0% ÷ 100%)
- O₂ accuracy ± (2.5% + 2.5% of the reading)
- O₂ from 21% to 90% in less than 80 seconds
- Tidal Volume: Vte, Vti (range: 0 ÷ 3000 ml)
- Expired Minute Volume (range: 0 ÷ 40 l/min)
- Expired Volume Accuracy ± (15% + 4ml) for volumes > 50ml
- Expired Volume Accuracy ± (15% or ± 15ml) whichever is greater for volumes ≤ 50ml
- PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH₂O)
- Pressure accuracy ± (2 cmH₂O + 4% of the reading).
- Inspiratory Peak Flow: F_i (range: 1 ÷ 190 l/min)
- Expiratory Peak Flow: F_e (range: 1 ÷ 150 l/min)
- T_{insp.}, T_{exp}, T_{pause} (range 0.036 ÷ 13.6 sec)
- Time accuracy ± 0.2 seconds
- Static and Dynamic compliance (range: 1 ÷ 100 ml/cmH₂O)
- Resistance (range: 0 ÷ 200 cmH₂O/l/s)
- EtCO₂: with optional CO₂ module (range: 0 ÷ 10%)
- Leak
 - % with PEEP 0 or with PEEP 1
 - l / min with PEEP ≥ 2
- O₂ consumption (range: 0 ÷ 100l/min)

Displayed parameters

PAW, PEEP, CPAP (cmH₂O), RR (bpm), I:E, O₂ (% - l/min), Vte (ml), VM (L/min), EtCO₂ (%), MAP (cmH₂O), P_{plateau} (cmH₂O), F_i , F_e (L/min), T_i, T_{pause}, T_e (sec.), R_i (cmH₂O/l/s), C_s, C_d (ml/cmH₂O), Leak (%)

Flow sensor

Magnetic perturbation (patented), reusable

Calibration Automatic (started by the operator)

Maintenance By steam disinfection

Oxymeter

Electronic (value displayed in breathing parameters)

Calibration Automatic or requested by the operator

CO₂ analyzer

Optional function (Sidestream or Mainstream module available)

ALARMS

Alarm types	By MENU: with limits set by the operator By DEFAULT: the operator cannot set them up
Alarm default setting	Present (Neonatal, Paediatric, Adult)
Alarm priority	High - Mean - Standby
Alarms visualization	Max 3 alarms simultaneously; additional alarms, scroll every 3-5 sec.

Alarms with limits set up by the operator

Pressure of Airways	High – Low
Respiratory Rate	High – Low
Expiratory Volume	High – Low
Volume Minute	High – Low
PEEP	High – Low
O2 Concentration	High – Low
EtCO2	High – Low (with optional CO2 gas analyser)
On Battery	Alarm occurs in case of failure of external power supply
Apnoea	Low Rate (function of Apnoea BACK-UP)

System alarms

Low Battery: 50% Remaining	Battery at 50%
Low Battery: 25% Remaining	Battery at 25%
Low Battery	10 Minutes
Battery Disconnected	Yes / No
Battery Overtemperature	Indication of exceeding the temperature limits inside the battery
Circuit Disconnected	Indication of patient circuit disconnected
O2 Supply	Low (< 2,7 bar)
Turbine Failure	Signals in case of a blower fault condition
Turbine Overtemperature	Indication of exceeding the temperature limits inside the turbine
Turbine Overcurrent	Indication of exceeding the current limits inside the turbine
Maintenance	When the warning signal occurs
CO2 Analyzer	Sampling Line Clogged, No Sampling Line, Replace Adapter, No Adapter, Unspecified Accuracy, Error, No Breaths, Low/High EtCO2.

SELF-TEST alarms

Turbine	The correct functioning of the turbine is tested
Oxygen emptying	It is performed a washing of the remaining oxygen present within the lung ventilator, order to measure the offset of the oxygen sensor
INSP.- EXP. Flow sensor	Verification of EXP flow sensor operation
Pressure sensor	Verification of pressure sensor operation through control of PAW reading
Electrovalve	The correct functioning of electrovalve is tested
Patient circuit	Verification of patient circuit
Battery	Checking on battery power
Oxygen sensor	Cell condition
Acoustic alarm	Verification by the user of acoustic signal emission, the confirmation of the test is made by silencing of that alarm

ACCESSORIES

<i>Supplied Accessories</i>	<ul style="list-style-type: none"> ▪ User's Manual ▪ Double hose patient circuit ▪ Antibacterial filter for patient circuit ▪ Nebulizer set ▪ Power cable ▪ O2 supply hose ▪ O2 cell
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<i>Optional Accessories</i>	Refer to price list.
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SIARE applies the UNI EN ISO 13485:2016 Quality System and the 93/42/EEC.

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