Aria 104

10” Portable intensive care ventilator

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

- Touch Screen -

Code: 980104/A

Rev.1- 27/02/2020

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

CE 0476	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 IEC 601-1	Class I Type B
Class according to 93/42 EEC Directive	Class IIb
Electromagnetic compatibility (EMC)	EN 60601-1-2: 2015 and following
Norms	DIR. 93/42/CEE (2007); EN 60601-1 :2006/A1 :2011/A1 :2013; EN 60601-1-2 :2015; IEC 601-1-6:2013; IEC 601-1-8:2012; EN 62304:2006/AC:2008; ISO 10993-1:2009; IEC 62353:2014; EN 60601-2-12:2007; ISO 80601-2-12:2011; ISO 15223-1:2016; DIR. 2011/65/CE; D.Lgs 49/2014; ISO 14971:2012; EN ISO 4135:2001

ENVIRONMENTAL CONDITIONS

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

TECHNICAL DATA

Dimensions (W x H x D)	290 x 245 x 215 mm
Weight	5,5 Kg
Electric power supply	100 - 240Vac / 50 - 60Hz
Power	Max 60 VA
External power supply (low voltage)	12 Vdc / 7 A
Internal battery	Battery NiMh 12Vdc - 4.2 Ah
Internal battery operation	Max 4 hours
Battery re-charging time	About 10 hours
External electric connections	▪ O_2 sensor connection ▪ Flow sensor connection ▪ CO_2 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)
Supply pressure (O_2)	▪ Low pressure (max 15 l/min) ▪ High pressure 280 kPa - 600 kPa / 2.8 - 6 bar / 40 - 86 psi
Max flow requested (O_2)	80 l/min
IP degree of protection	IP21

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)
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	• 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 • SIGH, NEB (Nebulizer), Apnea BACK-UP (PSV, PSV-TV, CPAP), MAN (Manual).
Breathing rate VC/VAC	From 4 to 150 bpm
Inspiratory Time / Expiratory Time (maximum, minimum)	• Ti min = 0.036sec (minimum inspiratory time) • Ti max = 9.6sec (maximum inspiratory time) • Te min = 0.08sec (minimum expiratory time) • Te max = 10.9sec (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	• 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_2O (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_2O Microprocessor controlled
O_2 concentration	Adjustable from 21 to 100% with electronic integrated mixer.
Trigger detective method	Through sensor (Pressure or Flow)
Pressure trigger (I)	Pressure adjustable from OFF; -1 to -20 cmH_2O under PEEP level (step of 1 cmH_2O)
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_2O (PSV, V-SIMV+PS, P-SIMV+PS)
SIGH in VC/VAC modality	• Interval: 40 ÷ 500 bpm (step 1 bpm) • Amplitude: OFF, 10 ÷ 100% of set Tidal Volume (step 10%)
CPAP	Pressure: from 3 to 50 cmH_2O
APRV	• Time High and Time Low: from 1 to 200 sec. • Pressure High and Pressure Low: from 3 to 50 cmH_2O.

Functions	• MENU function (SETUP – PATIENT DATA) • Alarms Limits • Graphics visualization (Auto-Range) • INSP Hold - EXP Hold (max 20 sec.) • O_2 100% control (O_2 to 100% max. 5 min.) • NEB (6 l/min) • MAN (manual ventilation)
NEB	Drug nebulizer: selectable to 6 l/min with automatic compensation on forced ventilation modes and dedicated output
Patient circuit	• 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
Dimensions	10,4”
Displaying area	262x163 mm
Display keyboard	Keyboard for rapid access of functions. Encoder knob for: • selection, set up and confirmation of physiological breathing parameters • selection and direct activation of function
Displaying and settings	• 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	• Self Test • Turbine Characterization • Expiratory Flow Sensor Calibration • Usage at High Altitude • VTEc • Nebulizer Enable • ScreenShoot Enable • Tourn Off
MENU function - SETUP	• Display *(Brightness, Energy Saving, Sound Volume, Touch Audio)* • Date & Time • Language • Units *(Weight, Height, CO_2, Pressure)* • Default *(Erase Trend data, Erase Patient data, Setting & Ventilation Default)* • Other *(NIV Enable, Power Failure, Apnea Time, Change Password, Save to USB)* • IRMA/ISA *(Gas Sensor)* • Supplementary Tests *(Expiratory Flow Sensor Calibration, O_2 Sensor Calibration)* • Turn Off? • Cancel
MENU function - PATIENT DATA	The PATIENT DATA can be set or deleted
Alarm Limits	PAW (cmH_2O), PEEP (cmH_2O), Vte (ml), VM (L/min), O_2 (%), RR (bpm), $EtCO_2$ (%)
Displayed graphics	• CURVES: Pressure (PAW) - Flow - Volume (Vte) - O_2 (CO_2 optional) • LOOPS: Pressure / Volume - Flow / Volume - Pressure/Flow • Graphics: INSP-EXP cycle • Events • Trends
Events	Memory storage up to 100 machine events including the alarms.
Trends	Storage capacity (72 h) of all measured parameters.

Physiological breathing parameters setting	Vti (ml), RR (bpm), I:E, Pause (%), PEEP (cmH_2O), O_2 (%),Tr. I (L/min - cmH_2O), SIGH (Sigh. Amp. (%), Sigh. Int. (b)), Vte (ml), PMax, Pmin, Pinsp (cmH_2O), Slope, BACK-UP parameters, PS (cmH_2O), RRsimv (bpm), Ti (s), Ti Max (s), Tr. E (%), CPAP (cmH_2O), Pressure High - Low (cmH_2O), Time High - Low (s).
Range of measured parameters	• Respiratory rate (range: 0 ÷ 200 bpm) • I:E ratio (range 1:99 ÷ 99:1) • O_2% (range: 0% ÷ 100%) • Tidal Volume: Vte, Vti (range: 0 ÷ 3000 ml) • Minute Volume (range: 0 ÷ 40 l/min) • PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH_2O) • Inspiratory Peak Flow: Fi (range: 1 ÷ 190 l/min) • Expiratory Peak Flow: Fe (range: 1 ÷ 150 l/min) • Tinsp., Texp, Tpause (range 0.036 ÷ 10.9 sec) • Static and Dynamic compliance (range: 10 ÷ 150 ml/cmH_2O) • Resistance (range: 0 ÷ 400 cmH_2O/l/s) • $EtCO_2$: with optional CO_2 module (range: 0 ÷ 10%) • Leak (%) (range: 0 ÷ 100%) • O_2 consumption (range: 0 ÷ 100l/min)
Displayed parameters	PAW, PEEP, CPAP (cmH_2O), RR (bpm), I:E, O_2 (% - l/min), Vte (ml), VM (L/min), $EtCO_2$ (%), MAP (cmH_2O), Pplateau (cmH_2O), Fi , Fe (L/min), Ti , Tpause, Te (sec.), Ri (cmH_2O/l/s), Cs, Cd (ml/cmH_2O), Leak (%)
Flow sensor	Magnetic perturbation (patented), reusable
Calibration	Automatic (started by the operator)
Maintenance	By steam or chemical disinfection
Oxymeter	Electronic (value displayed in breathing parameters)
Calibration	Automatic or started by the Operator
CO_2 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
O_2 Concentration	High – Low
$EtCO_2$	High – Low (with optional CO_2 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
O_2 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	1000 hours
CO_2 Analyzer	Sampling Line Clogged, No Sampling Line, Replace Adapter, No Adapter, Unspecified Accuracy, Error, No Breaths, Low/High $EtCO_2$.

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

Supplied Accessories	• User's Manual • Double hose patient circuit • Antibacterial filter for patient circuit • Nebulizer set • Power cable • Vehicular cable for 12 Vdc • O_2 supply hose • O_2 cell
Optional Accessories	*Refer to price list*

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

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