SIARETRON 4000 15”

Intensive care ventilator

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

GENERAL DATA

Siaretron 4000 15” 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.

Siaretron 4000 15” lung ventilator is suitable for ventilation of adult, paediatric and neonatal patients. Siaretron 4000 15” lung ventilator is equipped with a flow generation system by turbine with separate cooling system granting higher quality and safety standards in patient ventilation.

Siaretron 4000 15” 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).

Siaretron 4000 15” 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 complies with 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)	Conform to the requirements of the EN 60601-1-2:2015 and following
Norms	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 ▪ Atmospheric pressure: 600hPa -1200hPa
Storage	▪ Relative humidity: < 95% ▪ Temperature: from -25 to +70°C ▪ Atmospheric pressure: 200hPa -1200hPa

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
Power	Max 60 VA
External power supply (low tension)	12 Vdc / 7 A
Internal battery	2 batteries (Pb 12 Vdc - 1,3 Ah)
Internal battery operation	90 minutes max.
Battery re-charging time	About 8 hours
External electric connections	▪ RJ connector for O_2 cell connection ▪ RJ connector for Flow sensor connection
Electric external connections (optional)	▪ RS232 for CO_2 module ▪ USB 1 (connector for CPU programming) ▪ USB 2 (connector for transfer patient data, events, trends)
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	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	Automatic compensation of atmospheric pressure on measured pressure: present (max. 5000 mt)
Dead space compensation	Automatic compensation of mechanical and patient circuit dead space
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), 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
PEEP adjustment	*Microprocessor controlled valve*
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 flow peak
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/PSV	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 Block - EXP Block (max 20 sec.) • O_2 100% control (O_2 to 100% max. 5 min.) • NEB control (6 l/min) • MAN control (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	• 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)
Expandability	Software upgradeable
USER INTERFACE	
Touch screen monitor	Module with TFT LED display with touch screen
Dimensions	15”
Displaying area	304 x 228 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

MENU function - SETUP	• Display *(Brightness, Energy Saving, Sound Volume, Touch Audio)* • Date & Time • Language • Units (Weight, Height, CO2, Pressure) • Default (Default parameters: 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?
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) • % of 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 disturbance (patented), multi-usage type
Calibration	Automatic (started by the operator)
Maintenance	By steam or chemical disinfection
Oxymeter	Electronic (value displayed in breathing parameters)
Calibration	Automatic (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 electro-valve 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 • O_2 supply hose • O_2 cell
Optional Accessories	Refer to price list.