SIARETRON 4000 ICU

Intensive care ventilator

Oxygen driven ventilator with built-in turbine

for adults, children and newborns

code: 960402

rev. 3 - 03/03/2016

For Representative purposes only

GENERAL DATA	
Main characteristics	The Siaretron 4000 electronic lung ventilator is equipped with turbine and with a TFT 12" colour monitor displaying the curves of pressure, flow, volume, loops of breathing parameters, the trends and other ventilation parameters.
	Siaretron 4000 lung ventilators is suitable for ventilation of adult, paediatric and neonatal (optional) patients. It 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 SIGH, Non Invasive Ventilation (NIV), Drug Nebulizer and Manual Ventilation (MAN).
	Siaretron 4000 is supplied with back up long lasting batteries and its software can be updated for new modes and last generation ventilation strategies.

NORMS	
$C\epsilon_{0476}$	The lung ventilator conforms to the essential requirements and it is realized according to the references of the Annex II of 93/42/CEE Medical Devices Directive.
Class and type according to IEC 601-1	Class 1 Type B
Class according to 93/42 EEC Directive	Class IIb
Electromagnetic compatibility (EMC)	Conform to the requirements of the IEC 601-1-2 norm.
Norms	IEC 601-1 , IEC 601-1-1 , IEC 601-1-2 , IEC 601-1-4 , IEC 601-1-8 , IEC 601-2-12 , EN 1281-1 , UNI EN 4135.

ENVIRONMENTAL CONDITIONS

Operating	Relative humidity : 30 - 95% non-condensing
	Temperature : from +10 to +40°C
Storage	Relative humidity : < 95%
	Temperature : from -10 to +60°C

TECHNICAL DATA

Dimensions - **Weight**	Ventilator unit and trolley 530 x 1350 x 460 (W x H x D) mm - 26 Kg
Electric power supply	100 ÷ 240 Vac / 47 ÷ 63 Hz
Power	105 Watt
External power supply (low tension)	12 Vdc / 4.2 Ah
Internal battery	2 batteries (Pb 12 Vdc – 1.3 Ah)
Internal battery operation	45 minutes max.
Optional external battery operation	3 hours max.
Battery re-charging time	About 8 hours
External electric connections	15 poles programming connector
Electric external connections (optional)	RS232 for CO_2 module or PC (transfer patient data, events, graphs and trends)
Patient connections	Male conic connectors 22 mm / Female of 15 mm (according to EN 1281-1 norm)
Supply pressure (O_2)	Pressure included between 280 kPa - 600 kPa / 2.8 - 6 bar / 40 – 86 psi
Max flow requested	240 l/min

LUNG VENTILATOR FUNCTIONAL FEATURES

Use destination	Ventilator for Intensive Therapy for adults, children and newborns (optional).
Operation principle	• Time cycled at constant volume • Pressure cycled • Microprocessor controlled flow • Spontaneous breath with integrated valve
Automatic compensation of atmospheric pressure	Automatic compensation of atmospheric pressure on measured pressure: Present

Dead space compensation	Automatic compensation of mechanical and patient circuit dead space
Automatic leaks compensation	Present (with FLOW parameter set in AUTO) in NIV modalities
Ventilation modalities	• APCV (BILEVEL ST), APCV-TV, PSV (BILEVEL S), PSV-TV (AutoWeaning), VC/VAC, VC/VAC BABY, V SIMV+PS, P SIMV+PS SPONT, CPAP, APRV • SIGH, NEB, Apnoea BACK-UP, NIV, MANUAL.
Breathing rate VC/VAC	From 4 to 150 rpm
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 20 to 3000 ml (from 20 to 350 ml in VC/VAC BABY mode) from 2 to 350 ml in VC/VAC BABY mode (optional)
I:E ratio	From 1:10 to 4:1
Inspiratory pause	From 0 to 60 % of the inspiratory time
Inspiratory pressure limit (PLIM)	From 2 to 80 cmH_2O (in function of low and high pressure alarm set)
PEEP	From OFF, 1 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	By adjustable pressure from OFF; -1 to -20 cmH_2O under PEEP level • from -1 cmH_2O to -20 cmH_2O : step of 1 cmH_2O
Flow trigger	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)	240 l/min

Flow-by	2 l/min + Flow Trigger
PS (pressure support)	From 2 to 80 cmH$_2$O (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	From 3 to 50 cmH$_2$O
APRV	Time 1 and Time 2 : from 1 to 200 sec.
	Level 1 and Level 2 : from 3 to 50 cmH$_2$O.
Other controls	• MENU function, SET function
	• Function to select Loops, Curves, Parameters' Map displaying
	• INSP Block and EXP Block (max. 20 seconds)
	• NEB control
	• O$_2$ 100% (O$_2$ al 100% max. 5 min) control
	• MAN control (manual ventilation)
Other features	External alarm / Nurse call
NEB	Drug nebulizer: selectable to 6 l/min with automatic compensation on forced ventilation modes and dedicated output
Patient circuit	Double-hose, non re-breathing
Expandability	Software upgradeable for future modalities

USER INTERFACE	
Monitor	Module with TFT display
Dimensions	12"
Displaying area	245x185 mm
Display keyboard	Lateral 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	• Setting of Operative Mode
	• Visualization of alarm messages and signals
	• Setting and monitoring of physiological breathing parameters
	• Visualization of additional graphs and breathing parameters
	• The function MENU for setting operation parameters
	• Activation of special functions
	• Visualization of operative mode, clock, date and time functions
	• Visualization of software version
MENU function	• SETUP adjustments
	• Alarms
	• Trends
	• Events
	• Patient data
	• Default parameters
SETUP function (settings)	• Language
	• Graphic
	• Volume
	• Energy saving
	• Brightness
	• Apnoea time
	• Gas sensor CO_2 : unit of measurement
	• Password
	• TCP setting
	• Technical contact
	• Test on demand
	• Gas sensor
	• Colour selection
Trends	Storage capacity (72 h) of all measured parameters.
Events	Memory storage up to 100 machine events including the alarms.
Patient data	The patient data can be set and cancelled
Default parameters	The default parameters can be restored

SETTING function (set of physiological breathing parameters)	CPAP (cmH$_2$O), FLOW (L/min), I:E, Level 1 – Level 2 (cmH$_2$O), O$_2$ (%), Pause (%), PEEP (cmH$_2$O), PLIM (cmH$_2$O), PMax - Pmin - PS (cmH$_2$O), RR(bpm), RRsimv (bpm), SIGH (% - bpm), Ti max (s), Ti (s), Trig. E (%), Trig. I (L/min - cmH$_2$O), Time 1 - Time 2 (s), Vte - Vti (ml), BACK-UP parameters
Range of measured parameters	• PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH$_2$O) • Tinsp., Texp, Tpause (range 0.036 ÷ 10,9sec) • I:E ratio (range 1:99 ÷ 99:1) • Static and dynamic compliance (range: 10 ÷ 150 ml/cmH$_2$O) • Resistance (range: 0 ÷ 400 cmH$_2$O/l/s) • % of FiO$_2$ (range: 0% ÷ 100%) • Rate (range: 0 ÷ 150 bpm) • Tidal Volume: Vte, Vti (range: 0 ÷ 3000 ml) • Minute Volume (range: 0 ÷ 40 l/min) • Inspiratory Peak Flow (range: 1 ÷ 240 l/min) • Expiratory Peak Flow (range: 1 ÷ 150 l/min) • EtCO$_2$: with optional CO$_2$ module (range: 0 ÷ 10%)
Displayed parameters	FR (bpm), I:E, FiO$_2$ (%), Vt (ml), VM (L/min), PAW (cmH$_2$O), PEEP (cmH$_2$O)
Additional *displayed parameters*	MAP (cmH$_2$O), Pplateau (cmH$_2$O), Fi (L/min), Fe (L/min), Ti (sec.), Te (sec.) Tpause (sec.), Ri (cmH$_2$O/L/sec.), Cs (ml/cmH$_2$O)
Displayed graphics	• CURVES: Pressure - Flow - Volume - (CO$_2$ optional) • LOOPS : Pressure / Volume - Flow / Volume - Pressure/Flow • Auto range
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)

CAPNOMETRY (optional)

Capnometry connection	Available: CO$_2$
Measuring mode	Mainstream or Sidestream
General specifications	See on relative technical data sheet

ALARMS	
Alarm types	By MENU: with limits set by the operator
	By default: the operator cannot set them up
Alarm priority	High - Mean - Standby

Alarms with limits set up by the operator	
Airways pressure	High – Low
Breathing rate	High – Low
Expired minute volume	High – Low
Expired tidal volume	High – Low
PEEP	High – Low
FiO_2 concentration	High – Low
$EtCO_2$	High – Low (with optional CO_2 module)
Electric power supply	Alarm occurs in case of failure of external power supply
Apnoea	Low rate (function of Apnoea BACK-UP)

System alarms	
Level (charge)	Battery at 50%
Level (charge)	Battery at 25%
Battery level (low)	10 Minutes
Disconnected battery	Yes / No
Gas feeding: O_2	Low (< 2.7 bar)
CAN BUS error	Electronic boards CAN connection wrong
Maintenance	200 hours
Battery over temperature	Indication of exceeding the temperature limits inside the battery
Turbine fault	Signals in case of a blower fault condition
Turbine over temperature	Indication of exceeding the temperature limits inside the turbine

SELF-TEST alarms	
Turbine	The correct functioning of the turbine is tested
O_2 emptying	It is performed a washing of the remaining oxygen present within the lung ventilator, order to measure the offset of the oxygen sensor
Electro-valve	The correct functioning of electro-valve is tested
Gas supply	Verification of the presence of O_2 supply pressure
EXP.- INSP. Flow sensor	Verification of EXP flow sensor operation

Airways pressure sensor	Verification of pressure sensor operation through control of PAW reading
Patient circuit	Verification of patient circuit
Battery	Checking on battery power
Oxygen cell	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
	• O_2 supply hose
	• Nebulizer set
	• Silicone patient circuit
	• Antibacterial filter
	• Power cable

SIARE applies the UNI EN ISO 13485:2004 Quality System and the 93/42 EEC.

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