FALCO 202 EVO

Intensive care and transport ventilator

Turbine driven - Adults, Paediatric, Newborns -

Code: 980210

rev.1 - 13/04/2015

GENERAL DATA

Falco 202 Evo is a lung ventilator conceived 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.

Falco 202 Evo is equipped with a flow generation system by turbine with separate cooling system granting higher quality and safety standards in patient ventilation.

The Falco 202 Evo's colour display shows the curves of pressure, flow, volume, the loops of breathing parameters, the trends and the ventilation parameters.

The Falco 202 Evo 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, APCV-TV), SIMV by Volume and by Pressure, Pressure supported modalities (PSV, PSV-TV), CPAP, BILEVEL S-ST, SIGH, Non Invasive Ventilation (NIV), Drug Nebulizer and Manual Ventilation (MAN).

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 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 601-1-2 , IEC 601-1-4 , IEC 601-1-8 , IEC 601-2-12 , EN 1281-1 , EN 794-3 , 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 (W x H x D)	266 x 244 x 174 mm
Weight	4,9 Kg
Electric power supply	100 ÷ 240Vac / 47 ÷ 63Hz
Power	Max 150 Watt
External power supply (low tension)	12 Vdc / 4,5 Ah
Internal battery	Battery NiMh 12Vcc - 4,5 Ah
Internal battery operation	Max 4 hours
Battery re-charging time	About 24 hours
External electric connections	RJ for O_2 cell connection
Electric external connections (optional)	RS232 for CO_2 module; USB for PC connection (transfer patient data, events, trends)
Patient connections	Male conic connectors 22 mm / Female of 15 mm (according to EN 1281-1 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 (minimum)

LUNG VENTILATOR FUNCTIONAL FEATURES	
Use destination	Falco 202 Evo 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	Automatic compensation of atmospheric pressure on measured pressure: present
Dead space compensation	Automatic compensation of mechanical and patient circuit dead space
Automatic leaks compensation	Max 60 l/min
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 5 to 3000 ml (from 5 to 100 ml in VC/VAC BABY mode)
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)
Inspiratory ramp slope	1, 2, 3, 4 (acceleration slope) - (4 max. acceleration) (in operative modes by pressure only)
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 (I)	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 (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	From 3 to 50 cmH_2O
APRV	Time 1 and Time 2 : from 10 to 200 sec. Level 1 and Level 2 : from 3 to 50 cmH_2O.
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)
NEB	Drug nebulizer: selectable to 6 l/min with automatic compensation on forced ventilation modes and dedicated output
Patient circuit	• Single hose 150 cm. Adult/Paediatric patient circuit with Expiratory valve and proximal flow sensor • Double hose 150 cm. Adult/Paediatric patient circuit (Expiratory valve on the ventilator) • Double hose 150 cm. Neonatal patient circuit with Expiratory valve and proximal flow sensor
Expandability	Software upgradeable for future modalities
USER INTERFACE	
Monitor	Module with TFT LED display
Dimensions	9"
Displaying area	168x126 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	• 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 N_2O : 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_2O), FLOW (L/min), I:E, Level 1 – Level 2 (cmH_2O), O_2 (%), Pause (%), PEEP (cmH_2O), PLIM (cmH_2O), PMax - Pmin - PS (cmH_2O), RR(bpm), RRsimv (bpm), SIGH (% - bpm), Ti max (s), Ti (s), Trig. E (%), Trig. I (L/min - cmH_2O), Time 1 - Time 2 (s), Vte - Vti (ml), BACK-UP parameters
Range of measured parameters	• PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH_2O) • Tinsp., Texp, Tpause (range 0.036 ÷ 10,9 sec) • I:E ratio (range 1:99 ÷ 99:1) • Static and dynamic compliance (range: 10 ÷ 150 ml/cmH_2O) • Resistance (range: 0 ÷ 400 cmH_2O/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 ÷ 190 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_2O), PEEP (cmH_2O)
Additional *displayed parameters*	MAP (cmH_2O), Pplateau (cmH_2O), Fi (L/min), Fe (L/min), Ti (sec.), Te (sec.) Tpause (sec.), Ri (cmH_2O/L/sec.), Cs (ml/cmH_2O)
Displayed graphics	• CURVES: Pressure - Flow - Volume • LOOPS : Pressure / Volume - Flow / Volume - Pressure/Flow • Auto range
Flow sensor	Single patient use type at differential pressure
Calibration	Automatic (started by the operator)
Maintenance	First use: sterilize with gamma rays or with ethylene oxide (ETO), at first use
Oxymeter	Electronic (value displayed in breathing parameters)
Calibration	Automatic (started by the operator)

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	2000 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 • Single hose 150 cm. Adult/Paediatric patient circuit with Expiratory valve and proximal flow sensor • Antibacterial filter for patient circuit • Nebulizer set • Power cable • Vehicular cable for 12 Vdc • O_2 supply hose • O_2 cell • Flow sensor (disposable)
Optional Accessories	See on Export Price List

SIARE applies the UNI EN ISO 13485:2004 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 969366

Email : mail@siare.it - http://www.siare.it