

FALCO 202 Evo

Intensive care and transport ventilator

Turbine driven - Adults, Paediatric, Newborns

Code: 980209

rev.3 - 03/03/2016



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 (optional) 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, loops of breathing parameters, trends and other ventilation parameters.

The Falco 202 Evo is equipped with 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).

NORMS



The lung ventilator conforms 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)

Conforms 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.

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 (optional) patients.
Operation principle	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 bpm
Inspiratory Time / Expiratory Time (maximum, minimum)	<ul style="list-style-type: none"> • $T_i \text{ min} = 0.036\text{sec}$ (minimum inspiratory time) • $T_i \text{ max} = 9.6\text{sec}$ (maximum inspiratory time) • $T_e \text{ min} = 0.08\text{sec}$ (minimum expiratory time) • $T_e \text{ max} = 10.9\text{sec}$ (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	<p>from 20 to 3000 ml (from 20 to 350 ml in VC/VAC BABY mode)</p> <p>from 5 to 350 ml in VC/VAC BABY mode (optional)</p>
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 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, 1 to 50 cmH ₂ O

<i>PEEP adjustment Microprocessor controlled valve</i>	
O ₂ concentration	Adjustable from 21 to 100% with electronic integrated mixer.
Trigger detective method	Through sensor (pressure or flow)
<i>Pressure trigger (I)</i>	By adjustable pressure from OFF; -1 to -20 cmH ₂ O under PEEP level <ul style="list-style-type: none"> from -1 cmH₂O to -20 cmH₂O : step of 1 cmH₂O
<i>Flow trigger (I)</i>	Flow adjustable from OFF; 0.3 to 15 L/min <ul style="list-style-type: none"> 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
<i>Trigger E</i>	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 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	<ul style="list-style-type: none"> MENU function, SET function Function to select Loops, Curves, Parameters' Map displaying INSP Block and EXP Block (max. 20 seconds) NEB control O₂ 100% (O₂ 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	<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 with Expiratory valve and proximal flow sensor
Expandability	Software upgradeable for future modalities

USER INTERFACE

Monitor	Module with TFT LED display
<i>Dimensions</i> 9"	
<i>Displaying area</i> 168x126 mm	
Display keyboard	Keyboard for rapid access of functions. Encoder knob for: <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"> • 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	<ul style="list-style-type: none"> • SETUP adjustments • Alarms • Trends • Events • Patient data • Default parameters
SETUP function (settings)	<ul style="list-style-type: none"> • Language • Graphic • Volume • Energy saving • Brightness • Apnoea time • Gas sensor N₂O : unit of measurement • Password • TCP setting • Technical contact • Test on demand • Gas sensor • Colour selection

<i>Trends</i>	Storage capacity (72 h) of all measured parameters.
<i>Events</i>	Memory storage up to 100 machine events including the alarms.
<i>Patient data</i>	The patient data can be set and cancelled
<i>Default parameters</i>	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
<i>Range of measured parameters</i>	<ul style="list-style-type: none"> • PAW: peak, mean, plateau, PEEP (range -20 ÷ 80 cmH₂O) • 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/cmH₂O) • Resistance (range: 0 ÷ 400 cmH₂O/l/s) • % of FiO₂ (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) • EtCO₂: with optional CO₂ module (range: 0 ÷ 10%)
<i>Displayed parameters</i>	FR (bpm), I:E, FiO ₂ (%), Vt (ml), VM (L/min), PAW (cmH ₂ O), PEEP (cmH ₂ O)
<i>Additional displayed parameters</i>	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	<ul style="list-style-type: none"> • CURVES: Pressure - Flow - Volume • LOOPS : Pressure / Volume - Flow / Volume - Pressure/Flow • Auto range
Flow sensor	Magnetic disturbance (patented), multi-usage type
<i>Calibration</i>	Automatic (started by the operator)
<i>Maintenance</i>	By steam or chemical disinfection
Oxymeter	Electronic (value displayed in breathing parameters)
<i>Calibration</i>	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
FiO₂ concentration High – Low
EtCO₂ High – Low (with optional CO₂ 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: O₂ 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
O₂ 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 O₂ 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	<ul style="list-style-type: none">• User's Manual• Dual limb circuit• Antibacterial filter for patient circuit• Nebulizer set• Power cable• Vehicular cable for 12 Vdc• O₂ supply hose
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SIARE applies the UNI EN ISO 13485:2004 Quality System and the 93/42 EEC.

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