

# FABIAN

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## Service manual

Version 1.1

CE 0124

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PREFACE .....	4
FOR YOUR OWN AND YOUR PATIENTS SAFETY .....	5
READ INSTRUCTIONS FOR USE .....	5
WARNINGS.....	5
ABBREVIATIONS AND SYMBOLS.....	6
CMOS HANDLING PRECAUTIONS.....	8
WARRANTY .....	8
FOR YOUR SAFETY AND THAT OF YOUR PATIENTS .....	9
READ INSTRUCTIONS FOR USE .....	9
MAINTENANCE .....	9
LIABILITY FOR PROPER FUNCTION AND DAMAGE.....	10
INTENDED USE .....	11
CONTRAINDICATIONS .....	11
ADVISE FOR USE .....	11
SCOPE OF SUPPLY .....	12
INTERVALS FOR MAINTENANCE .....	13
OPERATORS INTERFACE .....	14
OPERATORS INTERFACE AND MENU STRUCTURE .....	14
DISPLAY .....	16
CONTROLS AND CONNECTIONS .....	17
ALARM & ERROR CODES .....	20
ALARM PRIORITY .....	20
PATIENT ALARMS.....	21
SENSOR ALARMS.....	23
SYSTEM ALARMS .....	25
PREPARATION, CLEANING STERILISATION .....	27
TROUBLESHOOTING .....	29
TECHNICAL DATA.....	30
SETTINGS .....	30
MEASURED PARAMETERS .....	30
DIMENSIONS .....	33
CONNECTIONS .....	33
ENVIRONMENTAL CONDITIONS .....	33
DISPOSAL OF BATTERIES AND OXYGEN SENSORS .....	34
EXCHANGE OF FUSES.....	35
PREVENTIVE MAINTENANCE.....	36
RECOMMENDED SERVICE PROCEDURE .....	36
REPLACING AIR AND O <sub>2</sub> INLET FILTERS .....	37
REPLACING OXYGEN SENSOR.....	38
REPLACING AIR / OXYGEN BLENDER .....	38
REPLACING INLET PRESSURE REGULATORS.....	39
CALIBRATION .....	40
EQUIPMENT .....	40
CALIBRATION PRESSURE SENSOR .....	41
CALIBRATION EXHALTION VALVE .....	42
CALIBRATION INPUT PRESSURE REGULATORS.....	43
TESTING INSTRUCTIONS .....	43
EQUIPMENT .....	44
TEST .....	44

## PREFACE

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This service manual is intended for use by ACUTRONIC Medical Systems AG trained and authorized service personnel.

ACUTRONIC Medical Systems AG does not condone or approve of service activity on its products by other than ACUTRONIC Medical Systems AG trained or authorized personnel and ACUTRONIC Medical Systems AG is not responsible for any unauthorized repairs or modifications, or any repairs or modifications made by unauthorized procedures.

Use of the incorrect part, or failure to exercise due care in the installation, removal, servicing, checkout or calibration of parts and equipment or the use of unauthorized accessories, may result in damage to the equipment which may in turn result in damage in property and injury (including death) to persons. The purchaser and installer of these parts shall bear full responsibility and liability for the above.

All maintenance performed within the applicable warranty period must be authorized in advance by a ACUTRONIC Medical Systems AG service representative in order to retain the warranty status of the subject unit.

Statements in the operating instructions preceded by words "Warning," "Caution," and "Note" carry special significance. The definitions of these words are as follows:

**WARNING !**

Means there is a possibility of injury to oneself or others

**CAUTION !**

Means there is a possibility of damage to the instrument or other property

**NOTE !**

Indicates points of particular interest for more efficient and convenient operation.

## FOR YOUR OWN AND YOUR PATIENTS SAFETY

### Read instructions for use

Before the use of FABIAN neonatal and infant ventilator on a patient read the instructions for use and make sure to proper understand all functions of the equipment.

FABIAN is intended to be used by physicians only or under their direct control or direction.

Before attempting to use FABIAN in an actual life-supporting situation, the operating personnel must become practiced in FABIANs functions and all effects of the various controls.

Please review this manual thoroughly and operate FABIAN in simulated situations before the dedicated use.

### Warnings

**FABIAN shall only be used by or on the order of a physician.**

**FABIAN shall only be used under supervision of qualified personnel to make sure, that in case of a malfunction of the equipment, corrective action is taken immediately.**

**At the same time of the use of FABIAN, an independent ventilation method such as for example a manual resuscitator, must be available at all times.**

**In case of a visible malfunction of FABIAN when its life supporting function is no longer guaranteed, FABIAN must be replaced immediately by an independent ventilation method such as for example a manual resuscitator.**

**Never use FABIAN in combination with flammable anaesthetics. FABIAN shall be used with air and oxygen only.**

**Acoustic and visible alarms indicate either a patient or a system alarm and require immediate action of qualified medical personnel.**

**If during the self-check or system test a failure or malfunction is recognised, under no circumstances FABIAN shall be used on a patient.**

**The use of FABIAN connected with electrical or electronically equipment others than those mentioned in this instruction for use are not permitted. Contact ACUTRONIC Medical Systems AG in case of special requests.**

**It is not allowed to cover or to set up FABIAN so that its operation is influenced negatively.**

**Only a qualified and trained technician is entitled to do open the housing of FABIAN. In any case, before opening the housing, the power cord must be disconnected.**





**To avoid any malfunctions of FABIAN based on radio frequency, do not use any cellular phone closer than 10 m to it.**

**Mobile phones may cause malfunctions to electro medical equipment.**

**It is not allowed to use antistatic or electrically conductive hoses.**

## ABBREVIATIONS AND SYMBOLS

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Symbol	Description
	Read instructions for use! Important Reference or alarm flag
	Class BF equipment
	High voltage. Disconnect power cord before opening of the enclosure. FABIAN shall be opened by a qualified technician only.
	Potential compensation
<b>O I</b>	Power ON / OFF whereby O = OFF I = ON
<b>SHARE</b>	Minute volume given by the ventilator
<b>ASSIST</b>	Assist-mode; each inspiratory effort from the patient which exceeds the set limit releases a mandatory breath from the ventilator, parameters according TI, PIP
<b>BASE FLOW</b>	Minimum flow, which circulates during exhalation phase in the system
<b>C20/C</b>	Dynamic compliance of the last 20% of the inspiratory phase of a mechanical breath, compared to the compliance of the complete breath. Indicator for over distension of the lung.
<b>CPAP</b>	Continuous Positive Airway Pressure
<b>DYN COMPL</b>	Dynamic compliance of the lung. Indicator for elasticity of lung tissue
<b>E TIME</b>	Expiratory time
<b>BRTH RATE</b>	Breath rate per minute
<b>I TIME</b>	Inspiratory time
<b>INSP FLOW</b>	Inspiratory flow; flow during inspiratory phase of mechanical breath
<b>IPPV</b>	Intermittent Positive Pressure Ventilation

<b>IMV</b>	Intermittent Mandatory Ventilation
<b>CONTROL</b>	Controlled ventilation
<b>LEAK</b>	Endotracheal tube leakage
<b>MIN FLOW</b>	Minimal flow, in case of a loss of the PEEP, it is automatically increased to compensate for the leak
<b>MV TOTAL</b>	Minute Volume of mechanical breath and spontaneous activity
<b>OXYGEN</b>	Inspiratory oxygen concentration
<b>O2 FLUSH</b>	Oxygen flush
<b>P INSP</b>	Inspiratory pressure
<b>PEAK PRESS</b>	Peak inspiratory pressure
<b>MEAN PRESS</b>	Mean airway pressure
<b>PEEP</b>	Positive End Expiratory Pressure
<b>RESISTANCE</b>	Airway resistance
<b>SIMV</b>	Synchronized Intermittent Mandatory Ventilation
<b>TRIG LEVEL VOL</b>	Trigger sensitivity; 0 = most sensitive, 10 = least sensitive
<b>TRIGGER VOL</b>	Required volume to release mechanical breath
<b>TRIGGER</b>	Function to allow synchronisation of ventilator with patients breathing pattern
<b>VT<sub>e</sub></b>	Expiratory tidal volume
<b>VT<sub>e</sub> avrg</b>	Averaged exhaled tidal volume

## CMOS HANDLING PRECAUTIONS

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The following precautions must be observed whenever a circuit board or an integrated circuit is handled. Failure to do so may result in serious damage to the FABIAN.

Place FABIAN and parts on a grounded, conductive work surface

Ground yourself (with a strap having about 1 MOhm resistance?)

Ground the frame of any test instrument or soldering iron to be used

If any circuit boards are to be stored or transported, enclose them in conductive (anti-static) envelopes

## WARRANTY

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We warrant that this product is free from defects in material and workmanship and, when properly used, will perform in accordance with applicable specifications. If within one year after the original shipment it is found not to meet this standard, it will be repaired, at Acutronic Medical Systems AG option, or replaced at no charge when returned to an Acutronic Medical Systems AG service facility. Any modification to the equipment or rework or repair by other than Acutronic Medical Systems AG approved personnel will render this warranty null and void. Acutronic Medical Systems AG shall not be liable for any indirect, special or consequential damages, even if notice has been given of the possibility of such damages.

**THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

The policy of Acutronic Medical Systems AG is to maintain product repair capability for a period of ten years after the original shipment and to make this capability available at the then prevailing schedule of charge.

All maintenance performed within the applicable warranty period must be authorized in advance by a ACUTRONIC Medical Systems AG service representative in order to retain the warranty status of the subject unit



FOR YOUR SAFETY AND THAT OF YOUR PATIENTS

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## Read instructions for use

For correct and effective use of the apparatus and to avoid hazards it is essential to read the following recommendation and to act accordingly. Any use of the apparatus requires full understanding and strict observation of these instructions. The apparatus is only to be used for purposes specified here.

## Maintenance

FABIAN is a Neonatal and Infant Ventilator and classified as II b according all applicable requirements for Medical Products according 93/42 EWG council of European Union dated June 14<sup>th</sup>, 1993 for Medical Products.

- 1.) The apparatus must be inspected and serviced by experts at regular 6 months interval (and a record kept).
- 2.) We recommend obtaining a service contract with ACUTRONIC Medical Systems AG exclusive distributor in your country.
- 3.) Repairs and general overhaul on the apparatus may only be carried out by ACUTRONIC Medical Systems AG Service.
- 4.) Only original ACUTRONIC Medical Systems AG spare parts may be used for maintenance.
- 5.) Power connection: The apparatus is to be used only in rooms with mains power supply installations complying with national standards. The standards laid down in IEC-601/1 Safety for Medical Electrical Equipment, are applicable for electrically powered equipment.

## Liability for proper function and damage

The liability for proper function of the apparatus is irrevocably transferred to the owner or operator to the extent the apparatus has been serviced or repaired by personnel not employed or authorised by ACUTRONIC Medical Systems AG Service or when the apparatus was used in a manner not conforming to its intended use.

ACUTRONIC Medical Systems AG cannot be held responsible for damage caused by non-compliance with the above mentioned recommendations. The warranty and liability provisions of the terms of sale and delivery of ACUTRONIC Medical Systems AG are likewise not modified by the recommendations mentioned above.

ACUTRONIC Medical Systems AG

Service: measures to maintain desired condition

Repair: measures to restore desired condition

Maintenance: inspection, service and if applicable, repair

## Intended use

FABIAN neonatal and infant ventilator is an intensive care ventilator for premature babies, neonates and infants up to 30 kg bodyweight.

FABIAN incorporates the following ventilation modes:

- **I**ntermittent **P**ositive **P**ressure **V**entilation (IPPV)
- **S**ynchronised **I**ntermittent **M**andatory **V**entilation (SIMV)
- **A**ssist Controlled Ventilation (ASSIST)
- **C**ontinuous **P**ositive **A**irway **P**ressure Ventilation (CPAP)

## Contraindications

There are no contraindications known.

For further product information, please contact:

ACUTRONIC Medical Systems AG  
Haldenstrasse 3  
P.O Box 2082  
6342 Baar  
Switzerland

## Advise for use

In case of a visible malfunction of FABIAN, where its proper life support is no longer guaranteed, FABIAN must be replaced immediately with an independent manual ventilation equipment, such as for example a resuscitator.

**During the ventilation, regular blood gas control shall be performed. Continuous supervision of SaPO<sub>2</sub> and CO<sub>2</sub> with pulseoximetry or transcutaneous blood gas monitor is recommended.**

## Scope of supply

The following items are supplied with the standard configuration:

- FABIAN neonatal and infant ventilator
- NIST adapter "Air"
- NIST adapter "Oxygen"
- Power cord
- Test lung

The following items are additionally available:

- Heated patient circuit
- Unheated patient circuit
- Humidifier and accessories
- Trolley for FABIAN
- Flow sensor
- Flow sensor cable
- Water chamber

## Intervals for Maintenance

FABIAN and accessories must be cleaned and sterilised prior any maintenance or repair work, also in case of returning FABIAN to ACUTRONIC Medical Systems AG.

### Every 6 month

- Maintenance and electrical safety check with protocol (IEC 601-1)
- Check alarm limits for proper function
- Check connections for air and oxygen (Leak test)
- Check mechanical and electrical connections

### Every 12 month

- Maintenance and electrical safety check with protocol (IEC 601-1)
- Check alarm limits for proper function
- Check connections for air and oxygen (Leakage test)
- Check mechanical and electrical connections
- Calibration

Replace following components:

- O2-Sensor
- Air and O2 inlet filter

If O2-Sensor alarm is displayed, the sensor must be replaced at earliest convenience to assure a proper function of apparatus. Disposal of old sensor like battery according local rules.

### Every 10000 hours

- Replace following components:
- Air / Oxygen blender
  - Input pressure regulators

### Every 3 years

Internal tube set

**Repairs and general overhaul of FABIAN shall be carried out by ACUTRONIC Medical Systems AG trained and authorised service personnel only.**

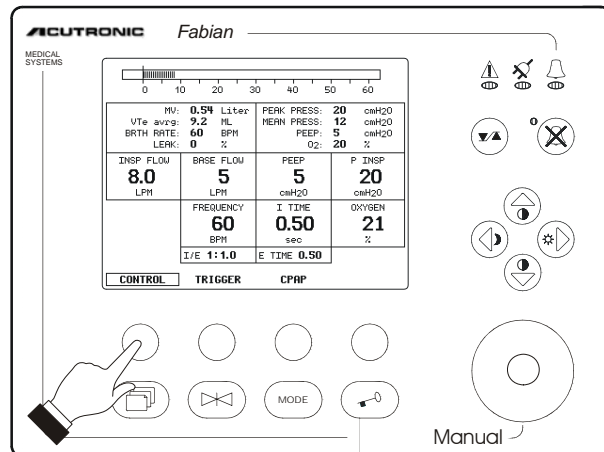
## OPERATORS INTERFACE

### Operators interface and menu structure

#### Self test:

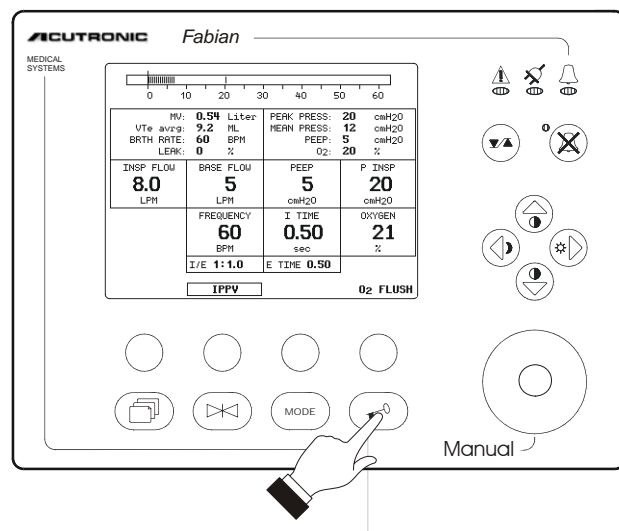
When FABIAN is switched on, the main menu is displayed. In the main menu the ventilation mode as well as the ventilation parameters can be changed.

The ventilation mode is changed by pressing the key "MODE" and thereafter the function key below the required mode of operation.

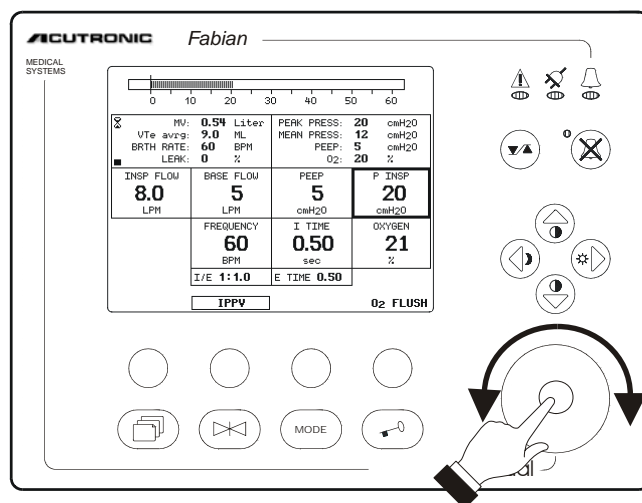


#### Parameter setting:

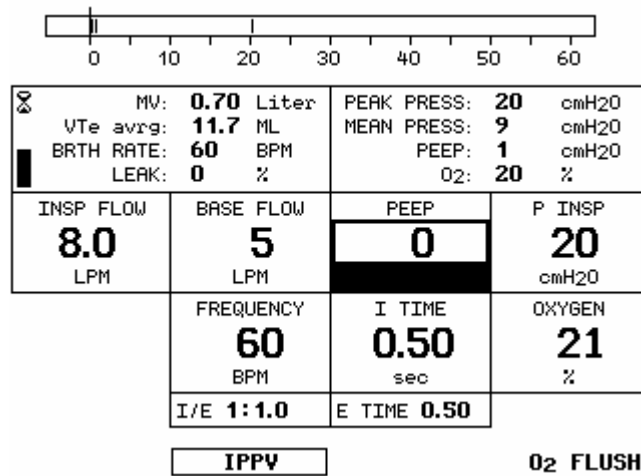
To change the ventilation parameters, the key symbol must be pressed to activate the cursors function. Move the cursor with the alpha dial knob (rotating knob) to the desired parameter.



Press the alpha dial knob to select the parameter and rotate knob clockwise to increase or counter-clockwise to decrease the value. The change is accepted by pressing the knob again or automatically after 10 seconds.

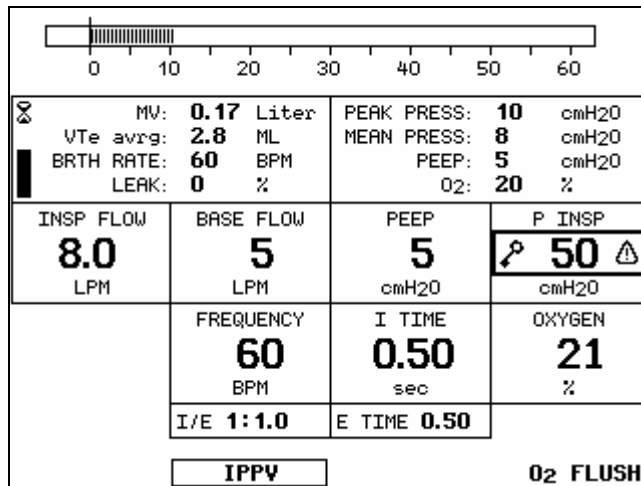


To avoid incorrect settings, safety functions are built in. For example, inspiratory pressure must be set at least 5 cmH<sub>2</sub>O higher than the set PEEP level. If you try to select a value with less than 5 cmH<sub>2</sub>O differences, the message "END OF RANGE" is displayed. At the same time it is indicated, which parameter must be changed.

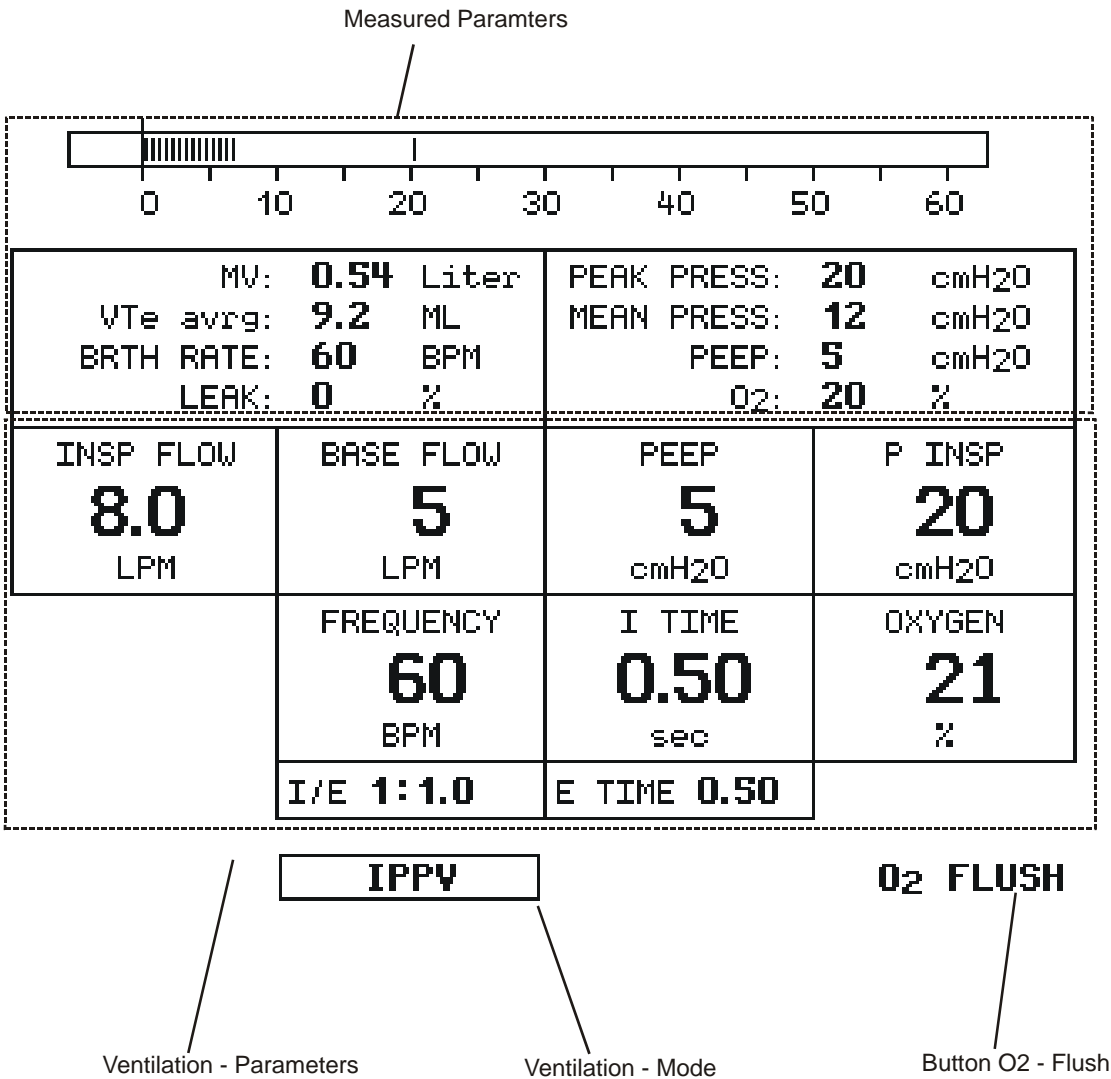


If a parameter has been changed, for example the inspiration pressure, for a limited time period, the key symbol will appear next to the value and you hear the acoustic alarm.

To accept this value the key symbol must be pressed. As long as the parameter is above the limit, next to the value the alarm flag is shown.

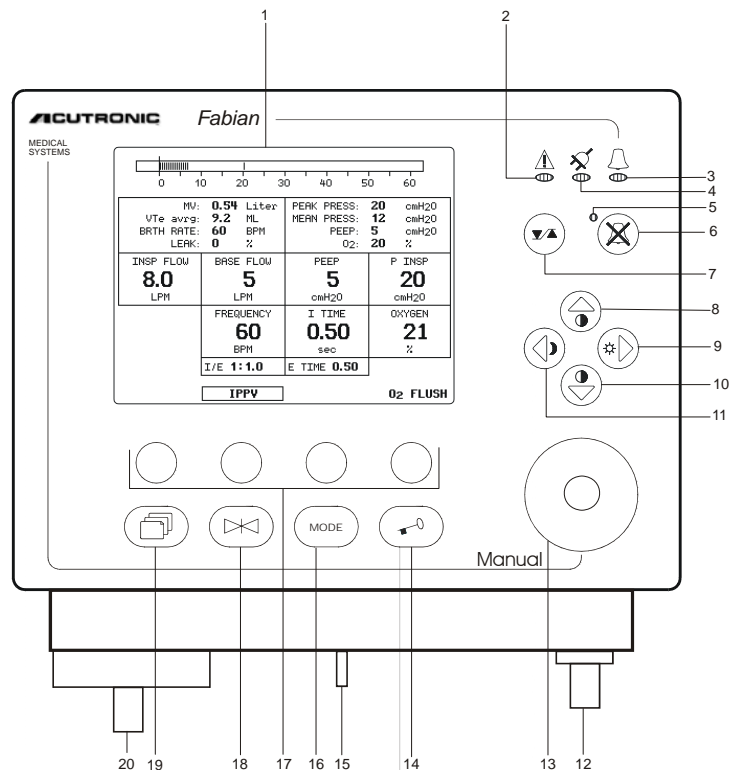


Display





## Controls and connections

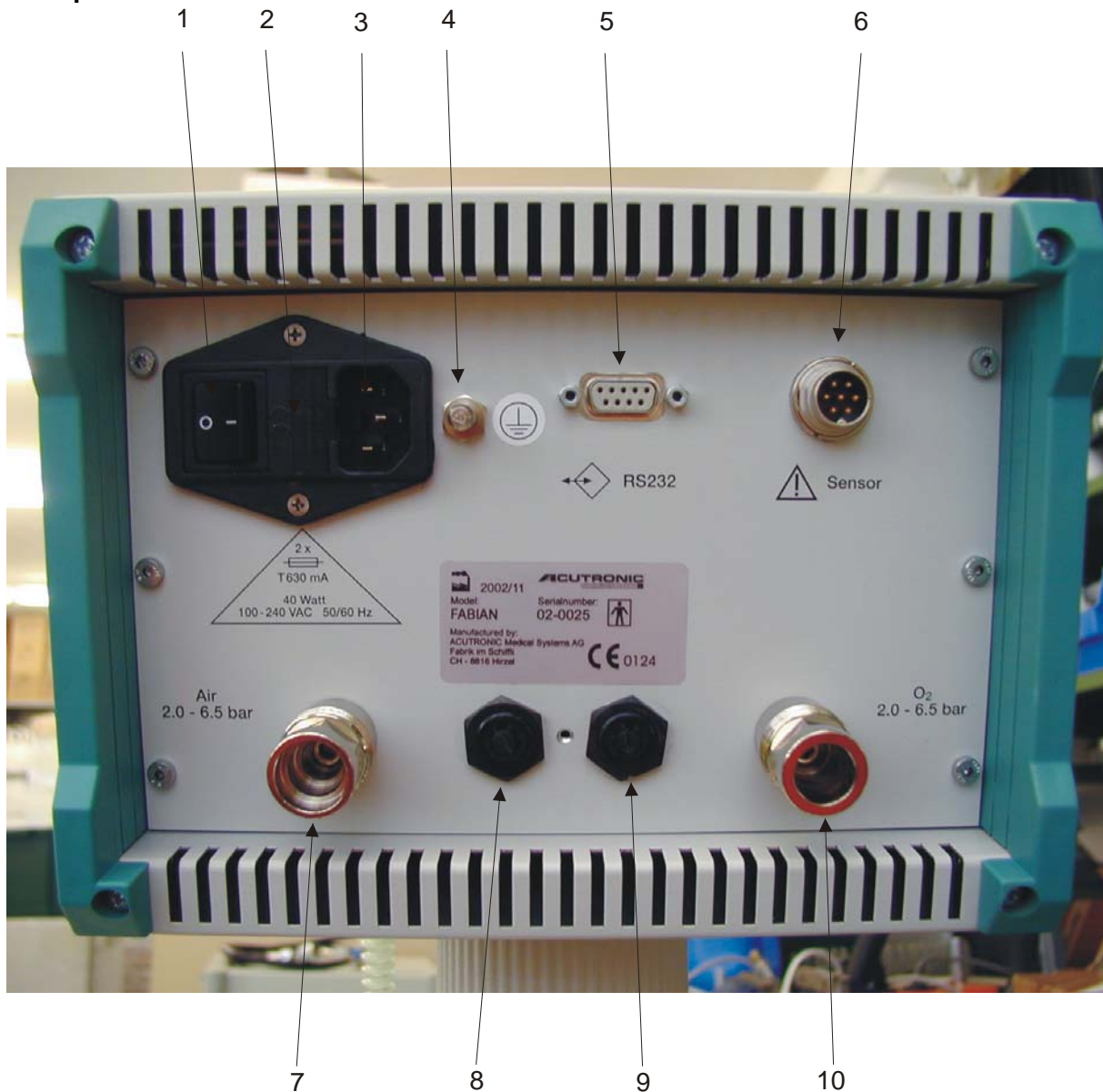


### Legend to front panel

- 1 Display for parameters and measured values
- 2 LED, blinking in case of a system failure
- 3 LED, blinking in case of a patient alarm condition
- 4 LED, blinking in case of power failure
- 5 LED, is light on in case of the acoustic alarm suppression
- 6 Button for acoustic alarm suppression
- 7 Button to enter the alarm menu
- 8 Button with double function, display contrast or cursor movement upwards
- 9 Button with double function, display bright or change of scaling factor in manual scale mode.
- 10 Button with double function, display contrast or cursor movements downwards.
- 11 Button with double function, display dimmed or change of scaling factor in manual scale mode.
- 12 Connection for inspiratory limb
- 13 Alpha dial knob
- 14 Key button
- 15 Proximal airway pressure connection
- 16 Mode button; switches between monitoring or ventilator mode
- 17 Function keys
- 18 Button for calibration menu
- 19 Menu button
- 20 Connection for expiratory limb (exhalation valve)



**Rear panel:**



**Legend to rear panel:**

- 1 Main switch ON / OFF
- 2 Fuse holder
- 3 Mains plug
- 4 Ground
- 5 RS 232 interface
- 6 Connection for flow sensor
- 7 NIST inlet adapter for compressed air
- 8 Inlet control pressure air
- 9 Inlet control pressure air
- 10 NIST inlet adapter for oxygen

## ALARM & ERROR CODES

### Alarm priority

Depending on the alarms, the appliance distinguishes between two priorities and marks it with a specific sound:

**Priority 1:** An immediate action necessitates to the prevention of a live-threatening condition, for example disconnected hoses. The tone of the alarms sounds in fast sequences.


**Priority 2:** An immediate action is necessary to avoid a live-threatening situation. Acted suitably, the action should be completed after 2 minutes at the latest. The tone of the alarm sounds in slow sequences.


ALARM	Priority
INTERNAL ERROR	1
OXYGEN SENSOR DEFECT	1
OXYGEN VALUE DIVERGENCE	1
SENSOR DEVIATION PROXIMAL PRESSURE	1
INPUT PRESSURE BLENDER	1
EXCESS PRESSURE	1
INTERNAL FAILURE	1
VOLTAGE MONITORING	1
INPUT PRESSURE OXYGEN SUPPLY	1
INPUT PRESSURE AIR SUPPLY	1
EXHALATORY TUBE	1
INSPIRATORY TUBE	1
PATIENT DISCONNECT	1
FLOW SENSOR FAILURE	2
FLOW SENSOR DISCONNECTED	2
CLEAN FLOW SENSOR	2
MINUTE VOLUME TOO HIGH	2
MINUTE VOLUME TOO LOW	2
VOLUME TOO HIGH	2
LEAKAGE TOO HIGH	2
FREQUENCY TOO HIGH	2
APNOE – ALARM	1
PRESSURE TOO HIGH	2
PRESSURE TOO LOW	2

## Patient alarms

In case of a patient alarm, an acoustic alarm sounds and the red LED with the bell symbol is flashing. FABIAN enters automatically into the alarm setting screen.

Next to the value that the set threshold was exceeded, a black bell symbol appears.












Press the  to mute the acoustic alarm for the next 60 seconds. Appropriate actions can be taken now to clear the alarm situation. Eventually the alarm threshold must be adjusted. If the alarm condition is cleared, the acoustic alarm is reset and the black bell turns into grey.

After clearing the alarm cause, press the  key to reset the alarm. This has to be done also, if FABIAN has not been used the following 2 minutes after the alarm reset.













Sensor alarms are high priority alarms and may, interrupt a patient alarm.

The screen during a patient alarm is the same as during the alarm setting.

Alarm screen while alarm condition is still not cleared.

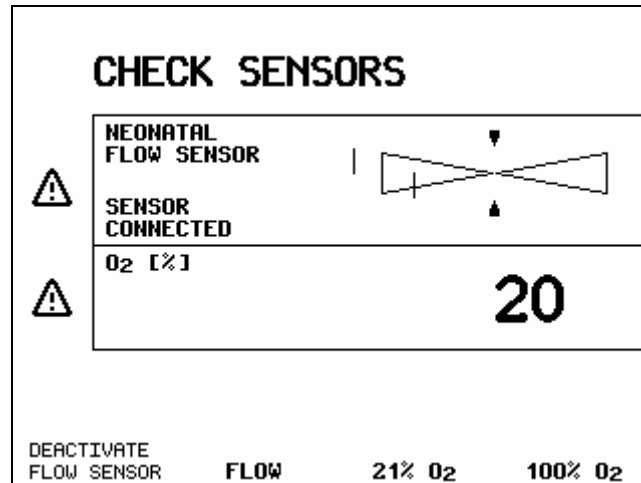
VOLUME LIMITED		⊙ ALL LIMITS AUTO	
MV [L]	 1.30  0.36	<b>0.70</b>	
VOLUME LIMIT VTi [mL]	 9.0	<b>9.1</b>	
LEAK [%]	 10	<b>0</b>	
RATE [BPM]	 90	<b>60</b>	
APNEA [sec]	 8		
P [cmH <sub>2</sub> O]	 23  -3	<b>20</b> <b>1</b>	
  <b>AUTOSET</b> 			

Alarm screen after clearance of the alarm condition

HIGH MINUTE VOLUME		⊙ ALL LIMITS AUTO	
MV [L]		 1.00	0.60
	 0.36		
VOLUME LIMIT VTi [ML]		 13.0	10.9
LEAK [%]		 10	0
RATE [BPM]		 90	60
APNEA [sec]		 8	
P [cmH2O]		 23	20
		 -3	1
 		AUTOSET	

## Sensor alarms

The screen for the sensor alarms is the same as the one for sensor calibration. Error messages are displayed as text messages.



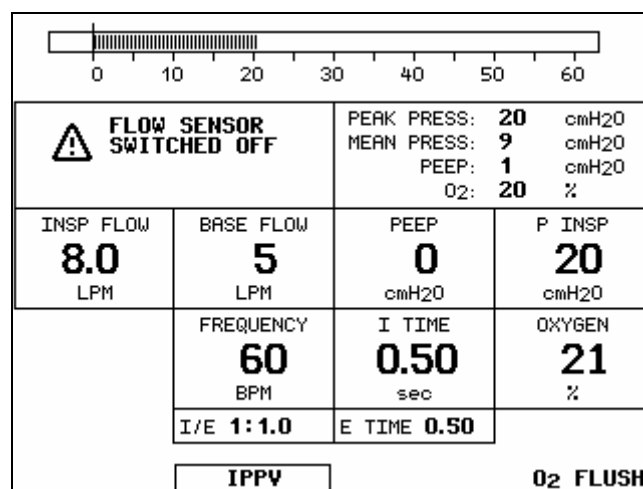
The following error messages may be displayed:

Sensor	Message	Cause
Flow sensor	SENSOR DISCONNECTED	The flow sensor or its cable is not connected to the device
Flow sensor	SENSOR DEFECT	One of the sensor hot wires is broken or there is a cable problem.
Flow sensor	CLEAN FLOW SENSOR	Dirty sensor
Oxygen sensor	REPLACE O2-SENSOR	The oxygen sensor lifetime is finished and it must be exchanged

The alarm "CLEAN SENSOR" can be reset after cleaning of the sensor. This is done by pressing the function key "FLOW" or "MENU"

Always make sure that in case of the "CLEAN SENSOR" alarm, you recalibrate the sensor and make sure there is no excessive amount of water in the patient circuit. Make sure there is no secretion from the patient occluding the sensor or Y-piece. Both ends of the sensor have a filter to protect from damage.





If during operation, the flow sensor is exchanged, the flow sensor can be deactivated by pressing the key "FLOW SENSOR SWITCHED OFF" for this procedure without interruption of the ventilation. However, the flow monitoring function is disabled during this period. After exchange of the flow sensor, make sure to reactivate the flow sensor again by pressing "ACTIVATE FLOW SENSOR".









## System alarms

There are two different types of system failures and alarms. One group is the "OPERATOR FAULTS" and the other group is "DEVICE DEFECTS". The following graphic indicates an occlusion of the inspiratory limb. As long as the alarm condition is present, the bell symbol is black.

* SYSTEM ALARM *	
OPERATOR FAULTS	DEVICE DEFECTS
PATIENT DISCONNECT  MbdSt 0010 0010 ParSt 0000 0000 SerSt 0000 4000 IntSt 0000 0000   INPUT PRESSURE OXYGEN SUPPLY  INPUT PRESSURE AIR SUPPLY EXHALATORY TUBE  INSPIRATORY TUBE	OXYGEN SENSOR DEFECT OXYGEN VALUE DIVERGENCE  SENSOR DEVIATION PROXIMAL PRESSURE  INPUT PRESSURE BLENDER EXCESS PRESSURE  INTERNAL ERROR  VOLTAGE MONITORING
	

As soon as the alarm condition is cleared, the bell symbol becomes empty and the acoustic signal is ceased. See following graphic.

* SYSTEM ALARM *	
OPERATOR FAULTS	DEVICE DEFECTS
PATIENT DISCONNECT  MbdSt 0010 0010 ParSt 0000 0000 SerSt 0000 0000 IntSt 0000 0000   INPUT PRESSURE OXYGEN SUPPLY  INPUT PRESSURE AIR SUPPLY EXHALATORY TUBE  INSPIRATORY TUBE	OXYGEN SENSOR DEFECT OXYGEN VALUE DIVERGENCE  SENSOR DEVIATION PROXIMAL PRESSURE  INPUT PRESSURE BLENDER EXCESS PRESSURE  INTERNAL ERROR  VOLTAGE MONITORING
	

Error	Message	Cause
OPERATOR FAULTS	INPUT PRESSURE OXYGEN SUPPLY	None or not sufficient gas supply pressure in oxygen supply
OPERATOR FAULTS	GAS SUPPLY PRESSURE AIR	No or not sufficient air supply
OPERATOR FAULTS	EXHALATORY TUBE	Occlusion in expiratory limb
OPERATOR FAULTS	INSPIRATORY TUBE	Occlusion in inspiratory limb
DEVICE DEFECTS	INPUT PRESSURE BLENDER	Inlet pressure on blender too low
DEVICE DEFECTS	OXYGEN VALUE DIVERGENCE	Measured and set oxygen do not match
DEVICE DEFECTS	OXYGEN SENSOR DEFECT	Oxygen sensor not connected or broken
DEVICE DEFECTS	EXCESS PRESSURE	
DEVICE DEFECTS	VOLTAGE MONITORING	Inlet voltage too low

**If the gas supply fails, FABIAN does not automatically switch to the remaining gas.**

## PREPARATION, CLEANING STERILISATION

Following each patients use, or if necessary more frequently, it is important to clean the exterior of FABIAN as well as to disassemble and clean the various components of the patient breathing circuit system, exhalation valve, and air inlet water trap. Before cleaning FABIAN, the exterior of the ventilator and humidifier must be unplugged. FABIAN and the pedestal stand can be disinfected by wiping the exterior with an appropriate bactericidal or germicidal agent. Care should be taken not to allow any liquid to penetrate the inside of the ventilator.

**In no case, FABIAN itself shall be sterilised. Only use wiping disinfections with for instance Buraton 10 F or Terralin (Schülke & Mayr, Norderstedt, Germany).**

Carefully follow the instructions for use of the manufacturer.

### Recommendation:

The patient circuit must be changed after each patient or every 48 hours. This is to avoid contamination of the next patient. For this the following procedures can be used:

### Sterilisation of accessories:

Flow sensor  
(without cable!!)

- Rinse the sensor head immediately after use and immerse it in a liquid disinfectant, otherwise it will encrust and become unfit for use. Do not use high–pressure air to dry sensor. It is recommended that gas, steam or liquid sterilisation process such as Alhydex, Glutarex, and CIDEX or similar is used. .
- **Do not clean the sensor with pressure air or a hard water jet, as the sensor wires can be harmed. Do not use cleaning or disinfections automats to clean the sensor**
- Steam sterilisation at 134°C
- **Exchange the sensor daily. This increases lifetime of the sensor.**
- Never use a non–calibrated sensor on a patient. Always calibrate the sensor before its use.

Exhalation valve	<ul style="list-style-type: none"><li>• Wet cleaning with warm water or in washing machine at 93°C / 10 min.</li></ul>
Proximal airway pressure tube	<p><b>After that:</b></p> <ul style="list-style-type: none"><li>• Steam sterilisation at 134°C for 10 minutes</li><li>• Sterilise the exhalation valve to dry out water</li></ul>
Breathing circuits	<ul style="list-style-type: none"><li>• Wet cleaning with warm water or in washing machine at 93°C / 10 min.</li></ul> <p><b>After that:</b></p> <ul style="list-style-type: none"><li>• Steam sterilisation at 134°C for 10 minutes</li><li>• After sterilisation process test for leakage</li></ul>
Y – piece	<ul style="list-style-type: none"><li>• Wet cleaning with warm water or in washing machine at 93°C / 10 min.</li></ul> <p><b>After that:</b></p> <ul style="list-style-type: none"><li>• Steam sterilisation at 134°C for 10 minutes</li><li>• After sterilisation process test for leakage</li></ul>
Heating wire	<ul style="list-style-type: none"><li>• Steam sterilisation at 134°C</li></ul>
Dual airway temperature probe	<ul style="list-style-type: none"><li>• Wipe with alcohol, don't sterilise</li></ul>

## TROUBLESHOOTING

Alarm – Message	Cause	Corrective action
MV HIGH	Change in lung compliance	Reduce PIP or change limit
MV LOW	Change in lung compliance	Increase PIP or change limit
VOLUME LIMIT		Clinical
LEAK	ET tube too small	Clinical
HIGH RATE	Hyperventilation	Clinical
APNEA		
P (PRESSURE)		
FLOW SENSOR NOT CONNECTED	Flow sensor or sensor cable not connected	Change sensor
SENSOR DEFECT	Sensor wire is broken or a wire within the sensor cable	Change sensor
CLEAN FLOW SENSOR	Flow sensor is dirty	Clean sensor
REPLACE O <sub>2</sub> - SENSOR	Oxygen sensor is used up or must be exchanged	Change sensor
INPUT PRESSURE OXYGEN SUPPLY	Pressure in oxygen supply is missing or too low	Check O <sub>2</sub> supply
INPUT PRESSURE AIR SUPPLY	Pressure in air feed is too high or low	Check air supply
EXHALATORY TUBE		Check expiratory limb
INSPIRATORY TUBE		Check inspiratory limb
INLET PRESSURE BLENDER		Call service
OXYGEN VALUE DIVERGENCE		Call service
OXYGEN SENSOR DEFECT		Change O <sub>2</sub> sensor
EXCESS PRESSURE		Check POP off valve
VOLTAGE MONITORING		Call service
INTERNAL ERROR		Call service
SENSOR DEVIATION PROXIMAL PRESSURE		Call service

## TECHNICAL DATA

### Settings

- Inspiratory time (I time) 0.1 – 2.0 sec
- Expiratory time (E time) 0.2 – 30 sec
- Insp. flow neonatal 1 – 20 lpm  
Paediatric 2 – 40 lpm
- Base flow neonatal 2 – 10 lpm  
Paediatric 4 – 10 lpm
- PEEP 0 – 20 cmH<sub>2</sub>O
- PIP 6 – 60 cmH<sub>2</sub>O
- O<sub>2</sub> – concentration 21 – 100 Vol % O<sub>2</sub>
- Rate 2 – 200 bpm
- Trigger level 1 – 10
- CPAP 0 – 20 cmH<sub>2</sub>O
- Min. flow (CPAP) 4 – 10 lpm
- System resistance with 30 lpm < 20 mbar/L/s
- Inspiratory resistance < 12 mbar/L/s
- Expiratory resistance < 8 mbar/L/s

### Measured parameters

- **PIP (PEAK PRESS)**
  - Range: 0 – 100 cmH<sub>2</sub>O
  - Dissolution: 1 cmH<sub>2</sub>O
  - Accuracy: ± 5%
- **MAP (MEAN PRESS)**
  - Range: 0 – 100 cmH<sub>2</sub>O
  - Dissolution: 1 cmH<sub>2</sub>O
  - Accuracy: ± 5%
- **PEEP**
  - Range: -10 – 100 cmH<sub>2</sub>O
  - Dissolution: 1 cmH<sub>2</sub>O
  - Accuracy: ± 5%
- **Minute volume**
  - Neonatal: 0 – 9.99 l ± 8% ± 10 ml
  - Infant: 0 – 99.9 l ± 8% ± 100 ml
- **Tidal volume**
  - Neonatal: 0 – 999 ml ± 8% ± 0.1 ml @ V<sub>te</sub> < 100 ml  
± 8% ± 1.0 ml @ V<sub>te</sub> ≥ 100 ml
  - Infant: 0 – 9.99 l ± 8% ± 1.0 ml @ V<sub>te</sub> < 1l

$\pm 8\%$   $\pm 10.0 \text{ ml}$  @  $V_{te} \geq 1 \text{ l}$

- **ET tube leakage**
  - Range: 10 – 50%
  - Dissolution: 5%
  - Accuracy:  $\pm 10\%$
  
- **Dynamic compliance**
  - Range: 0 – 500 ml/cmH<sub>2</sub>O
  - Dissolution:
    - Neonatal 0.1 ml/cmH<sub>2</sub>O
    - Infant 1 ml/cmH<sub>2</sub>O
  - Accuracy: -23% – 28%
  
- **Airway resistance**
  - Range: 0 – 5000 cmH<sub>2</sub>O/lps
  - Dissolution:
    - Neonatal 0.1 cmH<sub>2</sub>O/lps
    - Infant 0.1 cmH<sub>2</sub>O/lps
  - Accuracy: -24% – 26%
  
- **FiO<sub>2</sub> concentration**
  - Range: 18 – 100%
  - Dissolution: 1%
  - Accuracy:  $\pm 3$  vol. %



## Dimensions

W x H x D	35 cm x 19 cm x 34 cm
Weight	6.5 kg

## Connections

Medical grade compressed air	2.0 – 6.5 bar
Oxygen	2.0 – 6.5 bar
Power supply	100 – 240 VAC 50/60 Hz

## Environmental conditions

### Usage

Temperature	15°C – 40°C
Air pressure	700 – 1060 hPa
Rel. air humidity	30% – 90%, non condensing

### Transport and storage

Temperature	-20°C – 60°C
Air pressure	500 – 1060 hPa
Rel. air humidity	10% – 100%, non condensing

## Disposal of batteries and oxygen sensors

### Disposal of oxygen sensors

- **Do not put oxygen sensors, explosion hazard!**
- **Do not oxygen sensors. Risk for chemical poisoning!**

Please dispose the oxygen sensors in the same way as the batteries.

Local authorities will provide the local hazardous waste disposal guidelines.

## Exchange of fuses

### General note:

Fuses shall be replaced by fuses of the same type and value indicated on FABIAN only. ACUTRONIC Medical Systems AG recommends the exchange of fuses by authorised service personnel only.

The main fuses are located in the fuses compartment of the power entry module at the rear panel of FABIAN.

### Procedure:

1. Disconnect power cord from machine to avoid electrical shock!
2. With a screwdriver, open the fuses compartment. Pull out the drawer, which contains the fuses.
3. Exchange the fuses with fuses of the same type and value.
4. Install the compartment back.
5. Make sure, that the arrow directs to the right side.
6. The correct values for the fuses are indicated on the label above the power entry module.



## PREVENTIVE MAINTENANCE

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### WARNING

**Hazardous voltages exist within the ventilator. Always observe appropriate safety precautions when working on the ventilator while the machine is connected to an electrical power source to prevent possible accidental injurious electrical shock.**

### WARNING

**After calibration and/or replacement of any assembly(ies), always repeat the complete test procedure according the FABIAN checklist.**

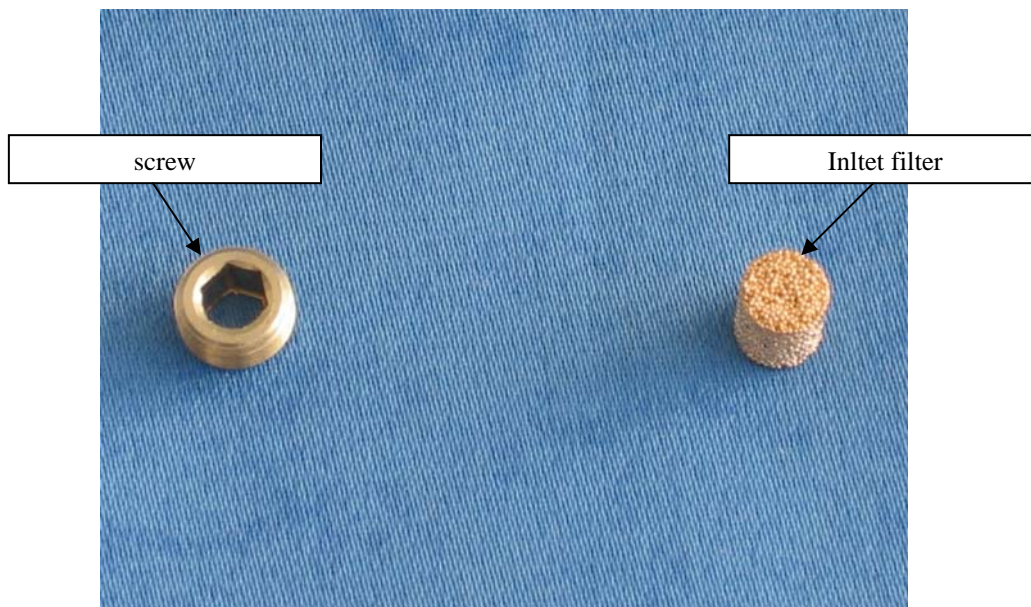
## Recommended Service Procedure

Preventive maintenance on the FABIAN Neonatal and Infant Ventilator should be completed minimum once each year. Maintenance is intended to be done in the hospital by an ACUTRONIC Medical Systems AG authorized service technician or a ACUTRONIC Medical Systems AG trained hospital service technician.

FABIAN preventive maintenance includes:

- Visually inspecting and cleaning of external surfaces, controls, attachments and accessories (every 6 months)
- Opening and cleaning the interior of the unit (every 6 months)
- Visually inspecting all tubing, electrical wiring, connectors, crimps, screws and hardware (every 6 months)
- Checking the general condition of all other internal components or assemblies (every 6 months)
- Replacing Air and O<sub>2</sub> inlet filters (every 12 months)
- Replacing Oxygen sensor (every 12 months)
- Replacing Air / Oxygen blender (every 10000 hours)
- Replacing inlet pressure regulator (every 10000 hours)
- Replacing internal tubes (every 3 years)
- Performing a calibration (every 12 months)
- Performing a complete test according FABIAN checklist

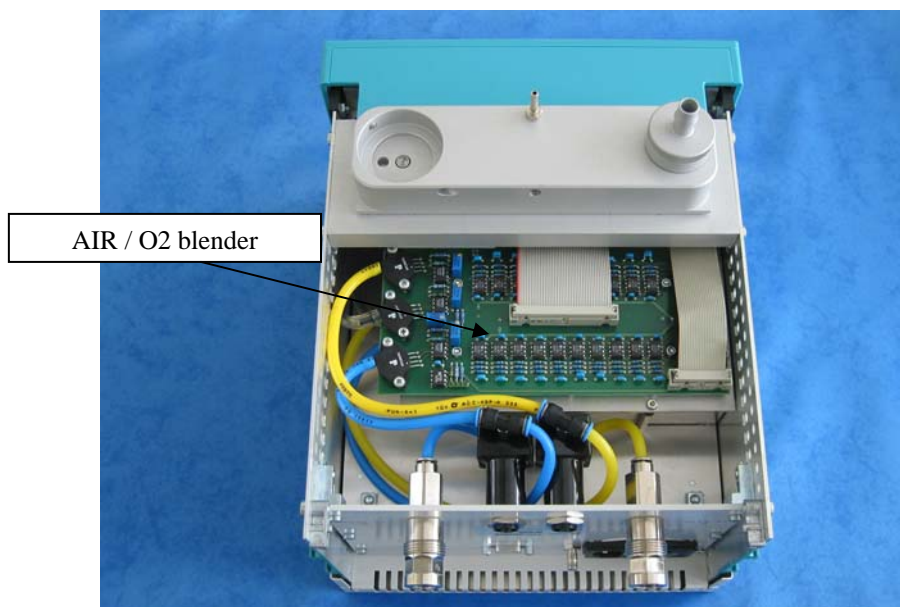
## Replacing Air and O2 inlet filters



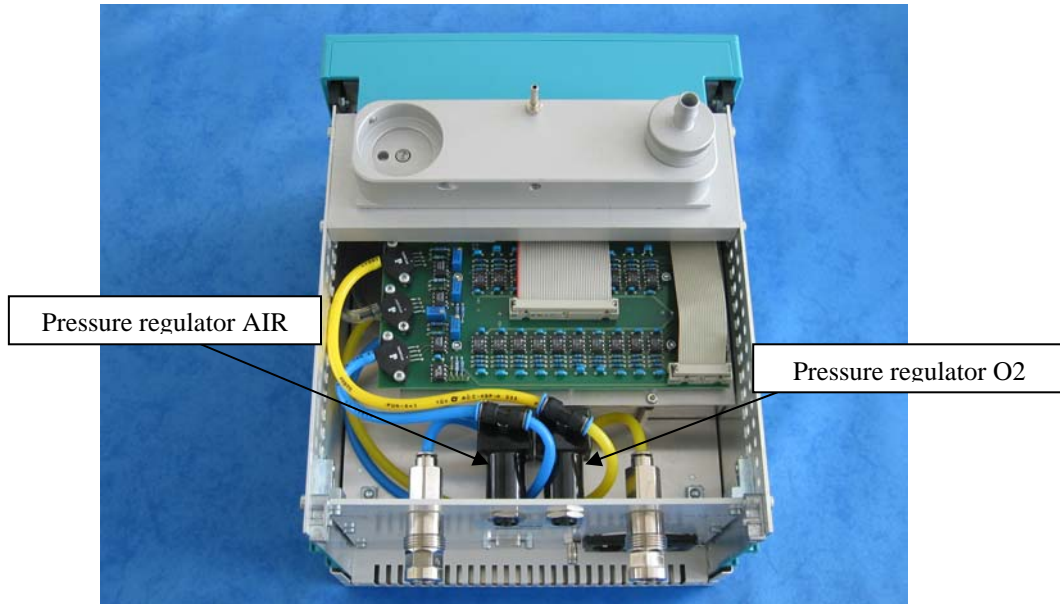
## Replacing Oxygen sensor



## Replacing Air / Oxygen blender



## Replacing inlet pressure regulators





## CALIBRATION

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### **IMPORTANT**

**Before you start with the calibration the unit should be switch on for 15 min.**

### **WARNING**

**Hazardous voltages exist within the ventilator. Always observe appropriate safety precautions when working on the ventilator while the machine is connected to an electrical power source to prevent possible accidental injurious electrical shock.**

### **WARNING**




**After calibration and/or replacement of any assembly(ies), always repeat the complete test procedure according the FABIAN checklist.**

## Equipment

- Pressure meter
- Oxygen analyser
- Neonatal / Pediatric test lung (part no. 1116)
- T –Adapter for oxygen sensor (part no. 1069)
- Adjustable pressure regulator (0 – 100 cmH<sub>2</sub>O)
- Safety Tester
- Service Manual FABIAN
- Test protocol FABIAN



## Calibration pressure sensor

- Press button  until the menu screen of FABIAN appears. Press the two buttons  and  simultaneously to get into the System maintenance menu. Press CAL SYSTEM button.
- Press button 0 cmH<sub>2</sub>O  
**IMPORTANT:** During this step, the airway pressure input nipple must be free. No tube connected !





Connect the airway pressure input nipple with an adjustable pressure regulator and measure the pressure simultaneously with an external pressure meter. Increase the pressure until the external pressure meter shows 60 cmH<sub>2</sub>O and press button 60 cmH<sub>2</sub>O on the FABIAN.

- Press button RETURN on the FABIAN as often until the main menu appears on the screen.

## Calibration exhalation valve

- Set following values in the IPPV mode:

Insp. Flow:	10 lpm
Basis Flow:	5 lpm
PEEP:	10 cmH <sub>2</sub> O
Insp. Pressure:	50 cmH <sub>2</sub> O
Frequency	30
I-Time:	1 Sek.

- Press button  until no frame is activ
- Press the two buttons  and  simultaneously to get into the exhalation valve calibration
- The message "Calibrate Exhalation Valve" appears on the screen.
- The calibration is done as soon the values P<sub>insp</sub> 50 cmH<sub>2</sub>O / P<sub>mean</sub> 29 cmH<sub>2</sub>O / PEEP 11 cmH<sub>2</sub>O are reached.
- Press button  to close the calibration procedure.

## Calibration input pressure regulators

- Set following values in the IPPV mode:

Insp. Flow:	20 lpm
Basis Flow:	10 lpm
PEEP:	10 cmH <sub>2</sub> O
Insp. Pressure:	50 cmH <sub>2</sub> O
Frequency	15
I-Time:	2 Sek.
Oxygen:	21 %

- Connect to flow meter at the inspiration limb
- Turn at the air input pressure regulator at the back panel until flow meter 20 lpm



- Set oxygen value to 100 %
- Connect to flow meter at the inspiration limb
- Turn at the oxygen input pressure regulator at the back panel until flow meter 20 lpm

## TESTING INSTRUCTIONS

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### IMPORTANT

**Before you start with the test procedure the unit should be switch on for 15 min.**

### Equipment

- Pressure meter
- Oxygen analyser
- Neonatal / Pediatric test lung (part no. 1116)
- T –Adapter for oxygen sensor (part no. 1069)
- Glass bottle 1 l
- Safety Tester
- Service Manual FABIAN
- Test protocol FABIAN

### Test

#### **FABIAN Settings:**

- Mode: IPPV
- P Insp. 20 cmH<sub>2</sub>O
- PEEP 5 cmH<sub>2</sub>O
- Base flow: 5 lpm
- Insp. Flow: 10 lpm
- Frequency: 30
- I –Time: 0.4 sec
- Oxygen: 21 %

#### **1. Test of LED displays and acoustic alarms**

- 1.1 Connect FABIAN to 230 VAC and switch the unit. Control display backlight.
- 1.2 Check alarm sound
- 1.3 Remove power cord from the wall socket. Acoustic Power failure alarm and red LED (Power fails) flashes
- 1.4 Press button alarm sound off.

## 2. Patient alarms

- 2.1 Set limit "Leak" 10 % and open red stopcock on the testlung, close red stopcock after the message "leakage too high" appeared on the display.
- 2.2 Set lower minute volume limit to 2.0 lpm. Set limit back after the message "Minute volume too low" appeared on the display.
- 2.3 Set upper minute volume limit to 0.1.0 lpm. Set limit back after the message "Minute volume too high" appeared on the display.
- 2.4 Set frequency to 40. Set limit back after the message "Frequency too high" appeared on the display.
- 2.5 Change to CPAP mode. After 20 sec. alarm "APNEA" appears. Reset FABIAN to IPPV mode.

## 3. Flow sensors alarms

- 3.1 Disconnect flow sensor.
- 3.2 Connect a defective flow sensor

## 4. Pressure measurements

### FABIAN Settings:

- Mode: IPPV
- P Insp. 10 cmH<sub>2</sub>O
- PEEP 5 cmH<sub>2</sub>O
- Base flow: 5 lpm
- Insp. Flow: 10 lpm
- Frequency: 30
- I –Time: 1.0 sec
- Oxygen: 21 %



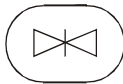
Press button and switch off the flow sensor

- 4.1 Read the values P<sub>max</sub>, P<sub>mean</sub> and PEEP from the FABIAN and fill it into the table. The values should be within the tolerance.
- 4.2 Set P Insp. and PEEP according the table and fill the values into the table. The values from the FABIAN should be within the tolerance.

## 5. Volume calculations

### FABIAN Settings:

- Mode: IPPV
- P Insp. 10 cmH<sub>2</sub>O
- PEEP 5 cmH<sub>2</sub>O
- Base flow: 5 lpm
- Insp. Flow: 10 lpm
- Frequency: 30
- I –Time: 1.0 sec
- Oxygen: 21 %



Press button and switch on the flow sensor

5.1 Read the values MV, Vte and Compliance from the FABIAN and fill it into the table.  
The values should be within the tolerance.

5.2 Set P Insp. and PEEP according the table and fill the values into the table. The values from the FABIAN should be within the tolerance.

## 6. Oxygen measurement

6.1 Connect a external Oxygen analyser with the inspiratory tube of the FABIAN an compare oxygen measurements from the FABIAN with the oxygen analyser.

## 7. System alarms

7.1 Disconnect oxygen gas supply

7.2 Disconnect air gas supply

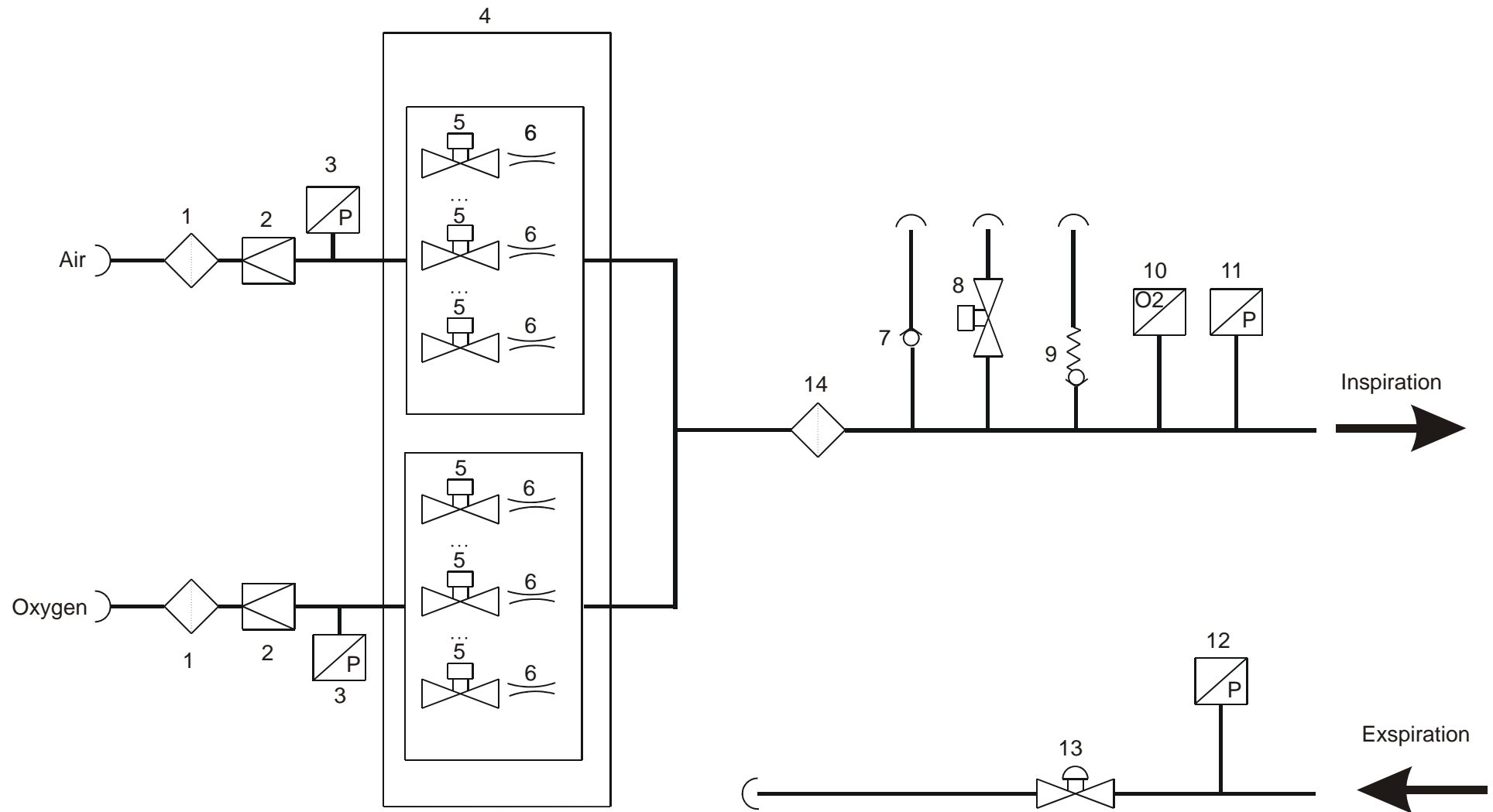
7.3 Kink expiratory tube

7.4 Kink inspiratory tube

7.5 Disconnect oxygen gas supply, mute the alarm and set oxygen to 100%. After 20 sec. alarm "Oxygen value divergence" should appear.

7.6 Kink airway pressure tube

# Pneumatic Schema FABIAN



Legend:

- 1 Inlet filter
- 2 Pressure reduction unit
- 3 Pressure transducer
- 4 Air / Oxygen blender
- 5 Blender Solenoid valve (10 pcs. Air, 10 pcs. Oxygen)
- 6 Sapphire nozzle (10 pcs. Air, 10 pcs. Oxygen)
- 7 Demand recoil nozzle
- 8 Bleed valve
- 9 Pneumatic pressure relief valve
- 10 Dual Oxygen transducer
- 11 Pressure transducer in inspiration circuit
- 12 Proximal pressure transducer at Y-piece
- 13 Exhalation solenoid
- 14 Micro filter