

# **MONSOON** UNIVERSAL JET VENTILATOR



# Instructions for Use Version 5.6e

This manual only applies to: monsoon with software Version: 1.15 or higher



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Instructions for use MONSOON 5.6e 20/09/2010



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#### FOR YOUR SAFETY AND THAT OF YOUR PATIENTS

## **Read Instructions for Use**

Any use of this apparatus requires full understanding and strict observation of these instructions for use.

This apparatus is only to be used for purposes specified here.

## Safety Notices

#### Always observe



Any use of the ventilator requires full understanding and strict observation of these instructions. The apparatus is only to be used for purposes specified here.



The ventilator is only to be operated by qualified technical staff or under their supervision to immediately provide assistance in the event of malfunction.



If the new value is not confirmed by the operator by pressing the rotary pulse encoder or the touch monitor the value will automatically be reset after a few seconds.



Always have an alternate ventilation system (e.g. resuscitation bag) when using the ventilator.



If the life support function can no longer be ensured due to an obvious ventilator defect, immediately provide artificial ventilation to the patient via a self-contained ventilator (e.g. resuscitation bag).



Never use the ventilator together with flammable gas or Anaesthetics – acute fire and explosion hazard!



Do not use the ventilator in explosion-risk areas!



An audible sound indicates a system or patient alert and always requires action by medical staff.





An audible alarm will sound in the event of power failure. Resetting the alarm requires the on/off switch to be pressed.



Never use the ventilator on patients when a fault is detected during equipment check!



Do not connect to electrical devices not specified in this manual without consulting the manufacturers or an expert professional.



Never cover the ventilator or position in a way which will negatively impact operation or function.



Always unplug before opening the housing!



Never use mobile phones within 10 metres of the ventilator. Mobile phones may interfere with the performance of electromedical equipment.



Never use antistatic or electroconductive tubes.



Note: the absence of e.g. allergy stimulating or genetically harmful substances, e.g. Phthalates, in our products ensures user safety and health.



## Maintenance<sup>1</sup>

MONSOON is a Universal Jet ventilator classified as device group IIb according to European directive.

- 1.) The apparatus must be safety inspected and serviced at regular 6 months intervals in compliance with the manufacturer instructions as well as §6 MPBetreibV Medical Devices Operator Ordinance dated 6/29/1998.
- 2.) Service must be performed by professionals trained by ACUTRONIC Medical Systems AG with the suitable measuring and testing devices.
- 3.) ACUTRONIC Medical Systems AG recommends obtaining a service contract with an exclusive representative of ACUTRONIC Medical Systems AG.
- 4.) Only use genuine ACUTRONIC Medical Systems AG replacement parts.

<sup>1</sup> Definition:

- Inspection Service Repair Maintenance
- = Determine actual condition
- = Measures to maintain desired condition
- = Measures to restore desired condition
- = Inspection, maintenance, repair



### Accessories

Use only accessories specified in the accessory list.

## Safe Use

#### Do not use in explosion-risk areas.

This equipment is not approved for use in explosion-risk areas.

#### Safe connection with electrical devices

Do not connect to electrical devices not specified in this manual without consulting the manufacturers or an expert professional.

## Liability for Proper Function and Damage

Any and all liability for the proper function of the apparatus is irrevocably transferred to the owner or operator if the apparatus has been serviced or repaired by personnel not associated with ACUTRONIC Medical Systems AG Service or if the apparatus was used in a manner not conforming to its intended use.

ACUTRONIC Medical Systems AG assumes no liability for damages caused by non-compliance with preceding notices. 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



## **Medical Purpose**

Universal Jet ventilator is designed for use in ICU (long term applications) and in the operating theatre for laryngoscopy, rigid bronchoscopy, microsurgeries with or without laser. The apparatus is also suitable for use combined with imaging procedures to minimise organ motion due to artificial ventilation.

For ICU long-term applications we recommend performing routine blood gas analyses as the applied minute volume cannot be accurately measured with Jet ventilation and could fluctuate greatly due to modified pulmonary compliance.

## Contraindications

With respect to contraindications please note Jet ventilation shall only be used by clinical specialists with extensive knowledge of Jet ventilation.

There are no known contraindications in the area of laryngoscopy, bronchoscopy or laser surgery. In a few cases  $CO_2$  exhalation in heavy weight patients was associated with problems during Single Jet ventilation. In these cases Jet ventilation was temporarily suspended and conventional ventilation used until the  $CO_2$  values returned to normal. With Double Jet  $CO_2$  exhalation is supported through the low-frequency Jet, suspending Jet ventilation is therefore no longer required. Always monitor the  $CO_2$  values when using artificial ventilation. This may be done using a  $CO_2$  module for the MONSOON sold separately, a capnograph or transcutaneous  $CO_2$  measurement.

For detailed studies and experienced data please contact:

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## **Indications for Use**

Always have a manual resuscitator ready when using a Jet ventilator in the event of insufficient  $CO_2$  elimination or insufficient oxygenation in the patient.

## Oxygen saturation and CO<sub>2</sub> should be routinely monitored via capnograph and pulse oximeter or blood gas analysis.

With long-term use of the Jet apparatus routinely check the function of the mucous membranes of the trachea for sufficient humidification to prevent desiccation. Since the MONSOON features an efficient heating and humidification system no problems have occurred in the field.

A large number of surgical procedures of the ventilation system are performed through the use of laser. This poses a risk of flammable materials (e.g. catheter, swab, residual tissue) in the operating field igniting, which could be further promoted by an increased concentration of oxygen.

#### Laser procedures may therefore only be performed together with the Jet catheter "Laserjet".

The MONSOON features a function specifically for laser procedures allowing the user to set the oxygen concentration to be administered during a laser procedure. This feature is activated with the *Laser on/off* switch, the blender as quickly as possible regulates at the set default oxygen concentration of < 40 %Vol, the concentration cannot be increased with active laser function. Once the blender reaches an oxygen concentration of < 40 %Vol the notification "*Laser Ok*" is displayed.

Once the laser procedure is completed or the function is deactivated the blender automatically returns to the last 0, value setting.

The notification "*Laser Ok*" merely refers to having reached the default oxygen concentration in the blender. An increased oxygen concentration may still be present in the respiratory tracts of the patient as the ventilation parameters or constricted respiratory tracts results in a decreased depletion of the oxygen.



## **Ventilation Modes**

The Single Jet version features one port, the Double Jet features two ports for Jet ventilation. The frequency, inspiration time and emission pressure are adjustable.

The apparatus further features an outlet for a so-called AUX-Flow, which may be used for patient preoxygenation or emergency ventilation.

Only use this apparatus under the supervision of trained medical staff to provide immediate assistance in the event of a malfunction.

Never use the apparatus with flammable gasses or anaesthetics, fire hazard!

Never use mobile phones within 10 metres of the apparatus!

Mobile phones may interfere with the function of electromedical apparatuses.

Also Note:

Availability of manual ventilation

If the life support function can no longer be ensured due to an obvious ventilator defect, immediately provide artificial ventilation to the patient via a self-contained ventilator (e.g. resuscitation bag).



## Maintenance Intervals, Batteries

Apparatus and/or parts must be cleaned and disinfected prior to any maintenance\* - including returning the apparatus for repair.

Every 6 months

Maintenance and safety inspection according to

IEC 60601-1:1988+A1:1991+A2:1995+Cor.1995

#### Perform:

- Check alarm and limit functions
- Check pressure connections
- Check electrical connections
- Check safety shut-offs

#### Every 12 months

- Maintenance and safety inspection according to
  - IEC 60601-1:1988+A1:1991+A2:1995+Cor.1995
    - Check alarm and limit functions
    - Check pressure connections
    - Check electrical connections
    - Check safety shut-offs
    - Calibration

- Replace the following components:

- 0, sensor (P/N 7003)
- Qty. 2 gas supply input filter (P/N 1171)
- Water intake needle(s) (P/N 1265), qty. 2 on Double jet
- Water tube set:
  - Double Jet (P/N 7918)
  - Single Jet (P/N 7919)

#### Every 1000 operating hours

- Replace the following components:
  - MATRIX Jet valve (P/N 7867), qty. 2 on Double jet
    - Heating cartridge (P/N 7942)
- **Every 3 years** replace all internal tubing
- **Every 10 years** replace lithium battery for data backup (dispose of used battery) Standard lithium battery CR 2032

Maintenance and safety inspection must be performed by professionals trained by ACUTRONIC Medical Systems AG with the suitable measuring and testing devices.



### Contents

The MONSOON is available in the following configurations:

#### MONSOON Basic

\_

- o 1-channel Jet
- Pause pressure monitor
- o Respiratory tract pressure monitor
- o AUX-Flow 15 lpm
- Air/oxygen blender
- 9" touch screen colour display
- Optional:
  - Video camera
  - etCO<sub>2</sub> module

#### - MONSOON +

- o 1-channel Jet
- Pause pressure monitor
- o Respiratory tract pressure monitor
- $\circ$  Flow monitor
- o Built-in heater and humidification
- $\circ~$  AUX-Flow 0 -70 lpm
- $\circ$  Air/oxygen blender
- o 9" touch screen colour display
- Optional:
  - Video camera
  - 2nd Jet channel
  - etCO, module



## Front View / Connectors



Figure 1: MONSOON – front view

#### Legend:

- Element 1: Control panel (MMI = ManMachineInterface) with rotary pulse encoder
- Element 2: Main unit
- Element 3: Control panel connection
- Element 4: Controls for main unit
- Element 5: Ports for patient tubes, water supply, etCO<sup>2</sup> measuring tube
- Element 6: Connection cable control panel to main unit



## **Control Panel Overview**



Figure 2: Control panel overview

#### Legend:

- Element 1: Patient alarm LED
- Element 2: System alarm LED
- Element 3: Display
- Element 4: Jet on/off switch (with LED); hold key in manual mode
- Element 5: Manual/automatic mode switch (with LEDs)
- Element 6: Video channel activation for camera
- Element 7: Laser function on/off switch (with LED)
- Element 8: Reset alarms and notifications
- Element 9: Mute alarm (with LED) (2 minutes)
- Element 10: Rotary pulse encoder



## Main Unit Overview

In the event of an control panel defect ventilation will continue with the previously set parameters, the defective piece can meanwhile be replaced with a new control panel during operation.

For safety reasons the Jet may only be switched off from the main unit.

#### Legend:

- Element 1: Patient alarm LED
- Element 2: System alarm LED
- Element 3: Connected power LED
- Element 4: Mute alarm (with LED) (2 minutes)
- Element 5: Jet on/off switch (with LED)



Figure 3: Main unit overview



## **Display - Single Jet**



Figure 4: Single Jet display

#### Legend:

- Element 1: Parameter Jet channel 1
- Element 2: Graphics respiratory tract pressure and etCO<sub>2</sub>
- Element 3: Alarm and notification field
- Element 4: Measurements
- Element 5: Help, menu and patient data keys
- Element 6: Oxygen, Aux and humidification parameters
- Element 7: Respiratory tract- and pause pressure limits



## Display - Double Jet



Figure 5: Double Jet display

#### Legend:

Element 1: Parameter Jet channel 1

- Element 2: Graphics respiratory tract pressure and etCO,
- Element 3: Alarm and notification field
- Element 4: Measurements
- Element 5: Help, menu and patient data keys
- Element 6: Parameter Jet channel 2
- Element 7: Oxygen parameter
- Element 8: Respiratory tract- and pause pressure limits



#### Monsoon

Depending on the model the MONSOON features a built-in  $O_2$ -air supply blender, a separate mixed gas outlet as well as a built-in heater coupled with ventilatory gas humidification.

Brief summary of built-in features:

- Adjustable frequency
- Adjustable inspiration time
- Adjustable operating pressure
- Adjustable oxygen concentration
- Respiratory tract pressure measurement and monitoring including graphics
- Pause pressure measurement
- Continuous gas mixture volume via separate connection
- Jet air flow heating and humidification (optional)
- Pause pressure limit monitoring with automatic shut-off
- Ventilatory volume measurement
- etCO, measurement (optional)
- Built-in clock with date



**PRESSURE LIMITS** 

## PIP Limit (Respiratory Tract Pressure)

This limit can only be used with a separate measuring lead (proximal lead). The control panel displays the current patient respiratory tract pressure in graphics and numbers. This allows ventilation patterns to easily be recognised.

The display is automatically gauged based on the PIP alarm settings. If the pressure exceeds the defined limit the main valve shuts off and an alarm notification appears on the display. The valve will only be reactivated once the pressure has fallen to 40% of the limit. The audible alarm is automatically reset once the main valve is cleared.

#### In graphics this PIP limit is displayed as a broken line!

## PP Limit (Pause Pressure)

The PP alarm is activated as soon as the MONSOON is in automatic mode and the *"Start / stop"* key has been pressed.

The pause pressure corresponds to the pressure inside the Jet lead and is measured a few milliseconds prior to engaging the main valve. The current patient respiratory tract pressure is indicated numerically on the control panel. This method allows the residual pressure inside the lead to be measured. If the value exceeds the limit the valve can only be activated once the pressure inside the lead falls to 20% of the limit. The audible alarm is automatically reset once the main valve is cleared.

## Superimposed Pressure Limit (Superimposed Ventilation)

The SIPL limit works similar to the PIP limit, but will only disable the Jet valve 1 while the value exceeds the limit, without triggering an alarm. This method allows the use of superimposed Jet ventilation.

Setting the SIPL limit below 10mbar will disable this limit.



The SIPL limit must be set to below the PP limit or ventilation will be interrupted due to responding to the PP limit.

The SIPL is further automatically limited by the PIP. The following formula applies: SIPLmax = PIP lst - 5mbar

In graphics the PIP limit is displayed as a broken line!



## **Apparatus Preparation**

The following must be performed prior to initial use of the apparatus.

#### CAUTION: Do not connect patients to this apparatus until these eight steps have been completed.

- 1. Connect apparatus to mains and switch on for 1 minute, then shut off. Unplug apparatus from mains and switch on again. An audible alarm must sound.
- 2. Connect air and oxygen supply tubes to the respective ports at the back of the apparatus and wall ports. The inputs are marked and coded to prevent reversing the two gas connections.

The maximum available operating pressure is 3.5 Bar.

The following applies to supply pressures below 4 Bar:

Maximum operating pressure = lower supply pressure – 0.5 Bar.

- 3. Connect the apparatus to a suitable outlet using the power cable. The apparatus may be operated at 100 VAC to 240 VAC and automatically adjusts to the respective voltage without manual intervention. However, be sure the fuse used conforms to the value indicated on the label for the respective voltage. Fuses may only be exchanged by a trained technician. When exchanging fuses always use the same value fuse.
- 4. Connect patient tube to the port at the front of the apparatus labelled JET.
- 5. Connect pressure sensing line to the port labelled accordingly. Acutronic recommends using the separate pressure sensing line, if possible. This eliminates the risk of pneumothorax.
- 6. Finally, connect the AUX-Flow tube to the port labelled accordingly. The AUX-Flow is primarily intended to pre-oxygenate the patient via mask, as well as for emergency patient ventilation via resuscitation bag. (e.g. AMBU or Laerdal)
- 7. Switch on apparatus. The power switch is located at the back of the apparatus to prevent accidental apparatus switch-off.
- After being switched on the internal oxygen sensor will automatically be calibrated. The apparatus is automatically calibrated every 24 hours. If calibration fails due to disconnected gas supply, calibration can be started manually from the "<u>Settings</u>" menu.



## **Check P-Pressure and PIP Safety Limits**

## CAUTION: the limits of the pressure switch-off must be tested using the included test lung prior to using the Jet ventilator.

- 1. Connect Jet patient tube to one of the two LUER-LOCK connections on the test lung.
- 2. Connect pressure sensing line to the second LUER-LOCK connection on the test lung.
- 3. Set PIP pressure limit to 15 mbar
- 4. Set PP pressure limit to 20 mbar
- 5. Use the operating pressure control to set the operating pressure to 1.5 bar.
- 6. Switch apparatus to automatic mode. To do so press the key labelled *auto/manual*. The LED must light on *auto*. LED = green
- 7. Set frequency to 150 CPM. Select inspiration time of 40%.
- 8. Start Jet ventilation by pressing the *start/stop* key.
- 9. Use your thumb to close the opening at the side of the test lung. Pressure will build and the apparatus will suspend ventilation once the set pressure limit is reached. The alarm notification "*PIP too high*" will appear and an audible signal will sound; release test lunch. The apparatus will continue ventilation and the audible alarm will mute.
- 10. Disconnect the pressure sensing line from the test lung and repeat test. The apparatus will suspend ventilation. The alarm notification "*PP too high*" will appear and an audible signal will sound. Once the test lung is released ventilation will continue and the audible alarm will mute.

If using a Double Jet the second Jet must be tested by repeating steps 1 through 10.



#### Using the MONSOON with Single Lumen Catheter

Caution: Limited space may not always allow the use of a Jet catheter with second lumen for continuous pressure monitoring or capnography. For this reason the MON-SOON features a built-in pause pressure monitor.

It monitors the pressure still present in the respiratory tracts after applying the Jet pulse. This determines whether the respiratory tract pressure has decreased during expiration.

This safety feature provides reliable protection from patient barotrauma. To ensure this safety feature is effective the Jet frequency must be higher than 80 CPM. At a Jet frequency below 80 CPM the volume of a single Jet pulse may be big enough to cause barotrauma.

The following graphic illustrates the PP (Pause Pressure) measurement:





### **O**PERATION

## **Parameter Settings**

Select the ventilation parameter you would like to adjust. The parameter window will open. Turn the rotary pulse encoder to set the desired value and confirm by pressing the rotary pulse encoder.

The following parameters may be set:

- Supply pressure Jet 1 (Jet 2)
- Frequency Jet 1 (Jet 2)
- Inspiration time Jet 1 (Jet 2)
- Pause pressure limit
- Proximal pressure limit
- Oxygen concentration
- Bypass flow (Aux.)
- Humidification

If no entry is made within 10 seconds of the parameter window opening it will automatically close.





#### Menu The menu key allows access to additional settings: SIPL Double Jet \_ Aux-Flow \_ Humidification \_ Settings \_ Language \_ Service \_ Disconnect Humidi Double let These may be opened and activated/set by touch-8 ing the tabs. If no entry is made within 10 seconds of the parameter window opening it will automatically close and return to the main screen.

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## **Superimposed Pressure Limit (SIPL)**

The SIPL limit is works similar to the PIP limit but will only block Jet valve 1 as long as the limit is exceeded, without triggering an alarm. This method allows superimposed Jet ventilation to be implemented.

## The SIPL is only available on the MONSOON+ in IPS mode (see: *Settings*).

The SIPL limit must be set to below the PP limit or ventilation will be interrupted in response to the PP limit.

In addition the SIPL is automatically limited by the PIP. The following formula applies:

 $SIPL_{max} = PIP_{ls} - 5mbar$ 

Setting the SIPL limit below 10mbar will disable this limit; the maximum value is 40 mbar.

In graphics this SIPL limit is displayed as a broken line!

	SIPL 0 25 mbar	40	
	SIPL limited by	PIP	
Settings	Language	aintenance D	isconnection
Disconnect supervi	sing active	vti svi b kPa 0 kPa 0 kPa	48 ml 12 lpm 13 mbar 13 mbar 12 mbar 13 mbar 12 mbar 0 Level
0 min 0.9 DP (bar) 50 IT (%)	F [cpm]	21 0, (%) 24 PIP [mbar]	Aux [lpm]
л [%]	PP [mbar]	PIP [mbar]	Humidity

## **Double Jet (Optional)**

When activating the Double-Jet function the parameters for the second Jet are displayed at the bottom right of the main screen, and can also be adjusted from there.

In this case the parameters for bypass and humidification are no longer available. With Double-Jet activated these settings can also be made through the menu.





Вура	SS
In Single-Jet mode the bypass can be adjusted directly on the main screen.	21         Min         Aus-Flow         NV         12 lpm           0         5 lpm         70         www.www.www         EFP         8 mbar
MONSOON Basic features a constant flow of 15 lpm.	etcop 0 min 0 kPa
MONSOON+ features a flow range of 0 - 70 lpm, which can be adjusted in 5lpm increments.	0,9 DP [bar] F [cpm] O, [%] 50 IT [%] PP [mbar] PP [mbar] 0 Humidity
In Double-Jet mode the bypass must be adjusted through the menu.	Strings Language Maintenance Disconnection





There are 8 humidification settings (see table at the right).

#### Caution:

When using the MONSOON for long-term applications, e.g. the ICU or longer than 30 minutes in the operating theatre, humidification must be used to avoid damage to the respiratory tracts. During humidification the respiratory tracts must be routinely monitored for proper humidification.

Only use sterile water. Never use NaCl for humidification to avoid damage to the vaporiser unit inside the apparatus.

Setting	RH[%] at 37°
0	0
1	30
2	40
3	50
4	60
5	70
6	80
7	90
8	100

#### Preparation





#### Dehumidification





Settings			
The "Settings" menu allows the following to be adjusted:			
- etCO <sub>2</sub> module ON / OFF			
<ul> <li>etCO<sub>2</sub> interval measurement: measurement automatically starts at the selected intervals during Jet operation</li> </ul>	SIPL Double Jet Aux-Flow Humidity ? etCO <sub>2</sub> etCO <sub>2</sub> interval etCO <sub>2</sub> -unit		
- etCO2 measuring unit	ON OFF kPa		
- Manual oxygen sensor calibration	Calibration O <sub>2</sub> type of application		
<ul> <li>Application selector (MONSOON+):</li> <li>OR mode -&gt; SIPL not available</li> <li>ICU mode -&gt; SIPL available</li> </ul>	Contrast Laser O <sub>2</sub> -Level Beeper Volume 25 % 40 % 1 Level Settings Language Maintenance Disconnection		
- Display contrast			
<ul> <li>Laser O<sub>2</sub> level:</li> <li>O<sub>2</sub> value default for "Laser on/off" key</li> </ul>			
- Alarm volume			

Language			
Set the desired language.	LPSI Doppio Jet Flusso-Aux Umidità Deutsch Hungarian English Russian Français Italiano Svenska Polska Impostazioni Lingua Manutenzione Disconnessione		

### Maintenance

The "Maintenance" menu is password protected. Only ACUTRONIC Medical Systems AG trained staff will have the password to access:

- Calibrations
- Time / Date
- Factory settings
- Demo mode





## Disconnection

With the "Disconnection" function activated pressure changes in the respiratory tract are measured<br/>via the proximal tube.Image: Control of the control of the



The desired oxygen concentration for laser procedures can be adjusted under settings (21% to 40%).

Pressing the "*Laser on/off*" key to activate regulating the oxygen concentration at the default. Once the oxygen concentration is reached **inside the blender** a notification "*Laser Ok*" will appear. Once the function is deactivated the blender will automatically return to the last 0, setting.

The notification "*Laser Ok*" merely refers to having reached the default oxygen concentration in the blender. An increased oxygen concentration may still be present in the respiratory tracts of the patient as the ventilation parameters or constricted respiratory tracts results in a decreased depletion of the oxygen.







## etCO, - Measurement (Optional)

The  $et\text{CO}_{\scriptscriptstyle 2}$  module is activated through the "Settings" menu.

In addition, times for interval measurements and units can be set.

With an interval measurement time set etCO, measurement is automatically triggered in the set intervals. The interval measurement time proceeds once "start/stop" key is pressed to start the Jet.

Connect Sample Line H (P/N 7715) to the front of the MONSOON. Please allow up to 20 seconds for calibration.

#### **IMPORTANT:**

Calibration must be performed against atmosphere!

Pressing the "etCO2" key with the Jet on will trigger the measuring cycle. The MONSOON automatically switches to 5 long inhalations followed by the measurement over a period of 10 seconds with the Jet switched off. Following measurement the apparatus will continue with the previous parameter settings.

The right of the graph (1) displays the graphic and numerical real time measurement. The elapsed time (2) is displayed below the etCO, key, the peak measurement from the last measurement at the left of the graph (3). The graph also indicates measurements as a trend (4).



etC02

(2) 9 min

(4)

(1)



## Video Camera (Optional)

Press the *"Video"* key to activate the video camera.

#### Focusing the image

To focus the image, turn the optical focusing ring (2) on the camera head.

#### Adjust white balance

Proceed as follows:

Aim the endoscope at a white object, e.g. sterile gauze.

Briefly press the white balance button (3) and keep the endoscope aimed at the white object for 5 sec.

The image will now change to pure white. This process allows true colour rendering for all colours.

#### Window function

The "Window" button (3) will select a preset window. Only the part of the camera chip containing image information will be used to control sensitivity. This function allows black edges of e.g. thin optics with small working diameters to be removed, thus optimizing the images.

The window function is deactivated in the factory settings. Hold button 3 (min. 3 sec) to activate the Window function. This setting can be recognised by images now being displayed without brightness artefacts when using thin endoscopes. To deactivate this function press key 3 again (min. 3 sec).





## **Remote Control (Optional)**

The function of the remote control is identical to the Start/Stop key function on the control panel. The remote cable is 2 metres long.

Connect the remote to the jack at the back of the apparatus labelled "Start/Stop". The jet may now be controlled via remote control or control panel.





## Automatic – Manual Operating Mode

The MONSOON features two operating modes:

#### Automatic mode

To select automatic mode press the "a*u-to/manual"* key until the yellow LED next to the key lights.

Pressing the "start/stop" key will start the MON-SOON. The Jet valve open and close based on the set parameters (frequency, inspiration time) and is monitored by the activated limits (PIP, PP and SIPL).

Pressing the *"start/stop"* key again will stop the MONSOON.

#### Manual Mode

In this mode the Jet valve is only open as long as the *"start/stop"* key is pressed and the PIP limit has not been reached.



The proximal pressure sensing line must be connected in manual mode! Pressure monitoring is not active without connected pressure sensing line! Monitor thorax

movement!

To select manual mode press "a*uto/manual*" until the blue LED next to the key lights.

When switching to manual mode the notification "Manual mode – PIP monitoring recommended" will appear. This notification will be displayed until the apparatus returns to automatic mode.







## **CLINICAL APPLICATIONS**

## Patient Data

The patient data menu allows information pertain- ing to treatment/application type and patient condi- tion to the entered. MONSOON will recommend parameter settings based on this information. Press the <i>"Patient Data" key to</i> access the menu. Data can now be entered. Tap the respective tab to select it and browse with the rotary pulse encoder. Now confirm the selection.	Image: state stat
MONSOON will now recommend settings which will automatically be applied when confirmed. CAUTION: The recommended settings are mere- ly intended as a guide.	Patient settings Jet frequency 1 200 (cpm) Inspiration time 1 50 (%) Oriving pressure 1 0.9 (bar) Oxygen 100 (%) Humidity 8 Level



## **CPAP Ventilation Set for MONSOON**



Figure 7: CPAP ventilation set

#### <u>Legend:</u>

- 1. 2 litre breathing bag
- 2. Patient connecting tube (part number 1004)
- 3. Swivel adapter with Jet cannula or Luer Lock adapter (part number 1010)
- 4. Standard T-piece with 22 mm connections
- 5. Standard PEEP valve with 22 mm connection (part number 1000-8014)

#### <u>Set-Up:</u>

- 1. Connect swivel adapter to endo- or transtracheal tube.
- 2. Secure breathing bag and 22 mm ventilation tube to T-piece. The tube from the swivel adapter to the T-piece should be no longer than 50 cm. The length of the tube from the T-piece to the PEEP valve is less critical and can be approx. 1 m long.

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3. Connect patient connection tube to swivel adapter.

#### Apparatus settings:

- 1. Frequency approx. 100 CPM
- 2. Inspiratory time 30%
- 3. Driving pressure 1 bar
- 4. PIP alarm 40 mbar.
- 5. Pause pressure alarm (PP-Alarm) 40 mbar
- 6. SIPL limit OFF

Press the "start/stop" key to start the ventilator.

#### Humidification:

To prevent the trachea from desiccating the humidifier should be set to 100% output (=Level 8). When in doubt occasionally check the trachea using a fibre optic bronchoscope.

#### <u>Remarks:</u>

Occasionally perform blood gas analysis to ensure sufficient oxygen saturation and CO2 elimination and modify settings based the results. The CO2 elimination efficiency increases with increased driving pressure.

The breathing bag should periodically be checked for proper mixed gas filling from the Jet ventilator. Do not allow the breathing bag to collapse as this would result the patient being insufficient supplied with mixed gas for spontaneous respiration.

#### <u>Diagram:</u>

The following pressure-time diagram shows the pressure pattern with CPAP superimposed Jet ventilation. However, this curve will only be displayed on the Jet ventilator monitor with the proximal pressure sensing line connected.



Figure 8: CPAP ventilation



## Infraglottic Catheter Jet Ventilation

## "Kleinsasser" technique:

- Laryngotracheal diagnosis and microsurgery
- Laser surgery
- Removing foreign objects



Figure 9: Principle of infraglottic Jet ventilation



## Supraglottic (Catheterless) Jet Ventilation

#### "Aloy" technique:

- Laryngotracheal diagnosis and microsurgery
- Laser surgery
- Airway stenosis



Figure 10: Principle of supraglottic Jet ventilation



## Rigid Bronchoscopy Infraglottic Jet Ventilation

#### "Sanders" technique:

- Laryngotracheal diagnosis and microsurgery
- Laser surgery
- Removing foreign objects



Figure 11: Principle of rigid bronchoscopy



## Transtracheal Jet Ventilation

#### "Ravussin" technique:

- Laryngotracheal diagnosis and microsurgery
- Laser surgery
- Emergency oxygenation



Figure 12: Principle of transtracheal Jet ventilation



#### **ALARMS AND ERROR CODES**

The MONSOON features a complex notification concept. There are 3 levels with different visual and audible indication:





Figure 13: Alarm LEDs

LED1: Patient alarm LED2: System alarm

**Patient** and **System** alarms can be muted for two minutes. If the error persists after this period the alarm will again sound.

If another error type is detected while the alarm is muted the silencing will instantly be cancelled.

Alarms automatically mute if the error no longer exists or has been resolved. However, the error notification will remain until cancelled by the user with the "alarm reset" key.

If multiple alarms are active the highest priority alarm is displayed. With multiple inactive alarms the notification for the last active superimposes prior notifications. The user must cancel these one after another via the "alarm reset" key.

**Notices** are silent and merely provide the user with information or reminders for certain processes. Notices will only appear with a specific process active and cancel automatically.



## **Patient Alarms**

Patient alarms are alarms triggered with (pressure) limits exceeded or disconnected water supply for the humidification and must and can be checked by the user.

Error	Cause	Instructions
No drops detected	Drop counter defective or disconnected	Check drop counter connection and function
	Bottle empty	Check IV bottle
	TV Set closed, kinked of disconnected	Check IV set
	Bottle empty	Check IV bottle
Naturatan	IV set closed, kinked or disconnected	Check IV set,
No water	Air in humidifier	Press "Alarm reset" to flood humidi- fier CAUTION: ventilation may stop for up to 15 seconds
		Check airways
PIP high	Excessive airway pressure	Proximal tube blocked / kinked?
		Adjust ventilation parameters
		Patient connected to Jet outlet?
PIP disconnect- ed	No pressure change detected in proximal tube for more than 15 seconds	Jet tube connected to system?
		Proximal pressure sensing line connected?
		Check airways
		Jet tube blocked / kinked?
PP high	Excessive pause pressure	Adjust ventilation parameter
		Catheter too small for driving pres- sure?



## System Alarms

System alarms are alarms caused by disconnected energy supply or faulty hardware. To some extent these can be checked and resolved by the user.

Error	Cause	Instructions
DP Sensor defect	Driving pressure sensor de- fective or disconnected	Contact ACUTRONIC service
Auxiliary flow valve error	Bypass valve defective or disconnected	Contact ACUTRONIC service
Auxiliary flow sensor defective	Bypass flow sensor defective or disconnected	Contact ACUTRONIC service
Low air supply pressure	AIR supply pressure too low < 2bar	Check AIR gas supply
Low air supply pressure, do not use laser	Oxygen saturation setting for laser cannot be reached due to low /missing air supply	Check AIR gas supply
Error LED defective	Defective LED on control unit or main unit	Contact ACUTRONIC service
CO2 device failure	Exhaust pump overheated CO2 module defective or disconnected	Reactivate CO2 module in settings menu Contact ACUTRONIC service
FiO <sub>2</sub> failure	O2 setting cannot be reached within 3 minutes	Check gas supply and start manual calibration Contact ACUTRONIC service
Main-processor unit error	Discrepancy between main and slave processor	Contact ACUTRONIC service



Heater failure	Temperature too low	Contact ACUTRONIC service
Internal temper- ature measuring defective	Temperature sensor defec- tive or disconnected	Contact ACUTRONIC service
Jet valve error	Jet valve defective or dis- connected	Contact ACUTRONIC service
Jet flow sensor defective	Flow Sensor defective or disconnected	Contact ACUTRONIC service
No communica- tion between MMI and main unit	MMI unplugged defective cable between MMI and main unit	Check connection Contact ACUTRONIC service
Power switch turned OFF, system not de- humidified	Residual water in humidifica- tion system	Press power switch and start dehumidification cycle (see section: <u><i>Humidification</i>)</u>
Power switch is turned OFF. Push 'alarm mute' to shutdown	Power switch on back panel was pressed	To switch off apparatus press "Alarm mute" or press power switch to continue operation
O2 calibration failed	Gas supply disconnected	Check gas supply and start manual calibration
O2 sensor weak	02 sensor worn, weak signal	Replace O2 sensor or contact ACUTRONIC ser- vice
PIP measuring electronic error	Measurement discrepancy between Main and Slave processor	Contact ACUTRONIC service
PIP Sensor de- fective	Proximal pressure sensor defective or disconnected	Contact ACUTRONIC service



PP measuring electronics error	Measurement discrepancy between Main and Slave processor	Contact ACUTRONIC service
PP sensor de- fective	Pause pressure sensor de- fective or disconnected	Contact ACUTRONIC service
PP sensor pneumatically disconnected	No pressure measurement by sensor with Jet on	Contact ACUTRONIC service
Real Time Clock unit error	Undefined time measurement	Contact ACUTRONIC service
Low oxygen supply pressure	O2 supply pressure too low < 2bar	Check O2 gas supply
Beeper error	Buzzer defective or loose contact	Contact ACUTRONIC service
Ventilator error	Ventilator defective or dis- connected	Contact ACUTRONIC service



## Notices

Notices are silent and merely provide the user with information or reminders for certain processes. Notices will only appear with a specific process active and cancel automatically.

Error	Cause	Instructions	
Humidifier is turned off	Safety switch-off due to mul- tiple subsequent <i>No Water</i>	Use alternate apparatus Contact ACUTRONIC service	
Check CO <sub>2</sub> - filterline if occluded or kinked	CO2 module pump overload- ed	Check filter line for kink or clog, exchange filter line if necessary	
CO <sub>2</sub> measuring in progress	CO2 measurement triggered	Measurement takes approx. 20 seconds, ventila- tion continues at prior parameters once complet- ed	
CO <sub>2</sub> zeroing	Automatic calibration once filter line is plugged into CO2 module	<b>Do not connect filter line to patient</b> Must be calibrated to atmosphere	
Disconnect monitoring ac- tive	SIPL activated Disconnection activated	Connect proximal tube to patient	
Heater and Humidifier is turned off	Message triggered by <i>Internal temperature meas- urement defective</i> or <i>Heater error</i>	Use alternate apparatus Contact ACUTRONIC service	
Laser ok	Appears once the oxygen saturation preset for laser applications is reached	Laser may be switched on	



Manual mode PIP monitoring recommended	No pause pressure monitor- ing during manual inspiration	Connect proximal tube to patient Set PIP limit
Only use distilled water	Message appears when hu- midification active	Message can be cancelled
PIP monitoring recommended	At frequency ≤ 80 CPM insuf- ficient measurement through pause pressure	Connect proximal tube to patient
Pump-system priming in progress	Message triggered by <i>No</i> <i>water</i> alarm	Message disappears once water is added to the humidification system
Service due	Annual safety control re- quired	Apparatus may continue to be used Inspection and service by trained technician highly recommended



#### ACCESSORIES

P/N	Description	
7720	Jet tube MONSOON III, Jet 1, length 1.6m	
7721	Jet tube MONSOON III, Jet 2, Length 1.6m	
7722	Bypass flow tube MONSOON III, length 1.6m	
7723	Proximal pressure tube MONSOON III length 1.6m	
1011	Test lung for ACUTRONIC Jet ventilator	
7715	etCO2 sample Line for MONSOON III Box of 10	
7716	etCO2 measurement Y-piece MONSOON III	
7717	Drop counter MONSOON III	
7718	Water supply set MONSOON III	
7731	Connection cable MONSOON III to Control Panel Length 30 cm	
7732	Connection cable MONSOON III to Control Panel Length 250 cm	
7733	Retainer DIN-bar/IV bar for MMI	
7734	Bottle holder MONSOON III	
7703	Video camera incl. TV adapter MONSOON III	



1002	Jet medication nebulizer	
1008	Transtracheal jet catheter, paediatric 14 G	
1009	Transtracheal jet catheter, adult 13 G	
1010	Jet ventilation swivel adapter, female Luer Lock	
1539	ACUCATH, double-lumen Jet catheter for non-laser ENT proce- dures, 40 cm, 12 CH Box of 5	
1938	LaserJet 40, double-lumen Jet catheter, Biro type, for ENT laser procedures, 40 cm, 12 CH Box of 5	
1939	LaserJet 70, double-lumen jet catheter, Biro type, for ENT laser procedures, 70 cm, 12 CH Box of 5	
1393	Swivel Jet, swivel connector with Jet cannula	
1189	Double Jet injection needle for standard Kleinsasser laryngo- scope	
1057	Metal laser needle for laser procedures of the upper respiratory tract, with laryngoscope Adults, 240 mm, ID 2.5 mm, AD 3.5 mm	
1058	Metal laser needle for laser procedures of the upper respiratory tract, with laryngoscope Paediatric: 200 mm, ID: 1.4 mm, OD: 2.2 mm	
1059	Metal laser needle for laser procedures of the upper respiratory tract, with laryngoscope Infant: 140 mm, ID: 1.4 mm, AD: 2.2 mm	
1060	Needle holder for laryngoscopes for securing the laser needle	
misc.	. Laryngoscopy Set REMACLE	

#### **TREATMENT, DISINFECTING / CLEANING**

Treat the apparatus and tube set after each patient.

#### Never sterilise the actual apparatus. Only surface disinfect e.g. with Buraton 10 F or Terralin (by Schülke & Mayr, Norderstedt).

Always follow the manufacturer instructions for use.

**Recommendation:** 

Circuit as well as Jet tube, pressure tube and bypass flow tube **must** always be changed and treated to avoid contaminating the next patient. The following methods may be used.

Sterilising the circuit:

ltem no.	Description	Sterilisation method	
7720	let tube 1	Gas sterilisation,	
1120		autoclavable at 134°C / 18 minutes	
7721	Jet tube 2	Gas sterilisation,	
		autoclavable at 134°C / 18 minutes	
2222	where flow tube	Gas sterilisation,	
1122	bypass now tube	autoclavable at 134°C / 18 minutes	
202	Process tube	Gas sterilisation,	
1123		autoclavable at 134°C / 18 minutes	
After a maximum of 20 starilisations the tubes must be replaced and are no longer usable.			

After a maximum of 20 sterilisations the tubes must be replaced and are no longer usable!

Sterilising accessories:

ltem no.	Description	Sterilisation method
1002	Medication nebuliser	Autoclavable at 134°C
1008	Transtracheal Jet catheter 14 G	Single use only
1009	Transtracheal Jet catheter 13 G	Single use only
1010	Swivel adapter for Jet ventilation	Autoclavable at 134°C
1011	Test valve for Jet ventilator	Surface disinfect
1393	Swivel adapter with Jet cannula	Autoclavable at 134°C
1539	Jet catheter Acucath	Single use only
1938	Teflon catheter for laser surgery	Single use only
1939	Teflon catheter for laser surgery	Single use only
7715	etCO2 sample line	Single use only
7716	Y-adapter etCO2	Single use only
7717	Drop sensor	Surface disinfect
7920	Remote button	Surface disinfect



### ABBREVIATIONS AND SYMBOLS

SYMBOL

#### Description



Follow instructions for use. Important



Apparatus type BF



Caution - voltage. Unplug apparatus before opening. Only to be opened by skilled service personnel.



Potential equalisation port

01	OFF / ON	0 = 0FF	I = 0N	
AD	Driving pre	ssure or emission pr	essure of Jet pulse	
PP	Pause pres next Jet pu	ssure = pressure m lse is applied.	easured inside the Jet	tube, 10 ms before the
PIP	Peak inspir tube	ratory pressure me	asured inside the airw	vay pressure measuring
SIPL Limit	Adjustable ceeds this this limit. N Jet ventilat ventilation.	limit. If pressure ir value the Jet halts o alarm is triggered ion. This does not o However, this incre	nside the airway press pulsation until the pres as this function is desi cause the peak pressur ases the median airway	ure measuring tube ex- sure has dropped below rable with superimposed e to increase during Jet pressure.
PIP Limit	Peak inspir cally interru triggered.	atory pressure limit upted if this limit is r	, which must be set. J eached and a visual as	et pulsation is automati- well as audible alarm is

#### ABOUT ELECTROMAGNETIC COMPATIBILITY

#### Note:

"MONSOON" is a MEDICAL APPLIANCE subject to specific precautionary measures with regard to EMC and must be installed and started up according to the notices according to the instructions in this manual.

#### Warning:

Portable and medical HF communication devices could impact MEDICAL APPLIANCES!

#### Warning:

Never use "MONSOON" directly adjacent to, or stack with other apparatuses. If unavoidable, be sure to monitor the equipment for proper operation with this set-up.

#### Warning:

The use other accessories, cables or converters with the "MONSOON" may result in increased electromagnetic interference and reduce the immunity of "MONSOON".

#### Note:

The key performance characteristics of the "MONSOON" ventilator are:

- MONSOON must operate within the defined specifications and the medical purpose. Failure to meet these specifications will result in respiration being stopped.
- For this reason a second, stand-alone ventilation unit must always be available, e.g. resuscitation bag.

#### Guideline and manufacturer declaration – electromagnetic emission

The device "MONSOON" is intended for operation in the environment described below. The customer or user of the "MONSOON" apparatus should ensure it is operated in this type of environment.

EMI measurement	Compliance	Electromagnetic environment - guideline		
HF emission CISPR 11	Group 1	The device "MONSOON" uses HF energy solely for internal operat Its HF emission is thus very low and interference with adjacent ap ratuses is unlikely.		
HF emission CISPR 11 Class A Emission of harmonics IEC 61000-3-2 Class A		The device "MONSOON" is suitable for use in all other areas except		
				Emission of voltage fluctuations / flickers IEC 61000-3-3



## Guideline and manufacturer declaration – electromagnetic immunity

The device "MONSOON" is intended for operation in the environment described below. The customer or user of the "MONSOON" apparatus should ensure it is operated in this type of environment.

Immunity testing	IEC60601	Compliance level	Electromaanetic environment – quideline
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	±6 kV contact ±8 kV air	Floors should be wooden or concrete or tiled with ceramic tiles. For flooring made from synthetic materials the relative air humidity must be no less than 30%.
Quick electric transi- ents/burst IEC 610004-4	± 2kV for power cords ± 1kV for in-/output cables	± 2kV for power cords ± 1kV for in-/output cables	The mains quality should correspond to typical business or hospital environments.
Surges IEC 61000-4-5	± 1 kV lead to lead ± 2 kV lead to ground	± 1 kV lead to lead ± 2 kV lead to ground	The mains quality should correspond to typical business or hospital environments.
Voltage drops, temporary power failures and fluctua- tions IEC 61000-4-11	$<\!\!5\% \ U_{\tau} \\ (>\!95\% \ drop \ of \ U_{\tau}) \\ for \\ \frac{1}{12} \ period \\ 40\% \ U_{\tau} \\ (60\% \ drop \ of \ U_{\tau}) \ for \\ 5 \ periods \\ 70\% \ U_{\tau} \\ (30\% \ drop \ of \ U_{\tau}) \ for \\ 25 \ periods \\ <\!5\% \ U_{\tau} \\ (>\!95\% \ drop \ of \ U_{\tau}) \\ for \\ 5 \ seconds \\ \end{cases}$	<5% $U_{\tau}$ (>95% drop of $U_{\tau}$ ) for ½ period 40% $U_{\tau}$ (60% drop of $U_{\tau}$ ) for 5 periods 70% $U_{\tau}$ (30% drop of $U_{\tau}$ ) for 25 periods <5% $U_{\tau}$ (>95% drop of $U_{\tau}$ ) for 5 seconds	The mains quality should correspond to typical business or hospital environments. If the operator of the "MONSOON" requires continued use in the event of a power failure we recommend connecting the "MONSOON" to an uninterruptible mains supply or a battery.
Magnetic field at supply frequency (50/60 Hz)	3 A/m	3 A/m	Magnetic fields at the mains frequency should correspond to typical values in business and hospi- tal environments.
IEC 61000-4-8			
Remark $U_{\rm r}$ is the mains alter	ernating voltage prior	to applying the test level.	



## Guideline and manufacturer declaration – electromagnetic immunity

The device "MONSOON" is intended for operation in the environment described below. The customer or user of the "MONSOON" apparatus should ensure it is operated in this type of environment.

Immunity testing         IEC60801 test level         Compliance level         Electromagnetic environment – guideline           HF interference cur- rotts         3 V. 150 kHz to 80 MHz beyond ISM bands <sup>1</sup> 10 V         Recommended safety distance eluvated distance eluvated using the equation applicable to the transmission frequency.           HF interference cur- rotts         3 V. 150 kHz to 80 MHz beyond ISM bands <sup>1</sup> 10 V         Recommended safety distance d = 0.35P           HF interference radia- tion         10 V/ 150 kHz to 80 MHz beyond ISM bands <sup>1</sup> 10 V/ 10 V         d = 1.2-P         80 MHz to 800 MHz d = 2.3-P         80 MHz to 2.5 GHz d = 2.3-P         Notes (intercent the compliance level <sup>-</sup> on all frequencies as the compliance level <sup>-</sup> on all frequencies as				
HF interference cur- rents IEC 6100-4-6       3 V <sub>a</sub> 150 kHz to 80 MHz byood ISM bads*       10 V       d = 0.35+P         HF interference cur- rents IEC 6100-4-6       10 V, 10	Immunity testing	IEC60601 test level	Compliance level	Electromagnetic environment – guideline
HF interference currents       I N - 10 V       I O V         IEC 61000-4-6       I N - 150 KHz to 80 MHz       I D V         HF interference radia- tion       I D V - 150 KHz to 80 MHz       I D V/m         HF interference radia- tion       I D V/m       I D V/m         IEC 61000-4-3       ID V/m       I D V/m         BD MHz to 25 GHz       ID V/m       I = 1.2*P         ME interference radia- tion       ID V/m       I = 1.2*P         ME interference may occur in proximity of apparatuses       Interference may occur in proximity of apparatuses         ME interference may occur in proximity of apparatuses       Interference may occur in proximity of apparatuses         *       The ISM bands (industria), scientific and medical) between 150 KHz and 80 MHz are 6.765 MHz to 6.795 MHz to 15.753 MHz to 13.67 MHz to 25.68 JT MHz to 27.80 MHz; and 40.66 MHz to 40.7 MHz.         *       The ISM bands (industria), scientific and medical) between 150 KHz and 80 MHz are 6.765 MHz to 6.795 MHz to 15.753 MHz to 13.67 MHz to 25.68 JT MHz to 72.80 MHz; and 40.66 MHz to 40.7 MHz.         *       The ISM bands (industria),				Never use portable or mobile radio devices closer to the "MONSOON", including cables, than the recommended safety distance calculated using the equation applicable to the transmission frequency.
HF interference cur- rents       3 V, + 50 kHz to 80 MHz bands       10 V       d = 0.35-P         HF interference radie- tion       10 V/m       10 V/m       d = 1.2-P         HF interference radie- tion       10 V/m       d = 1.2-P         B0 MHz to 2.5 GHz       10 V/m       d = 1.2-P         HF interference radie- tion       10 V/m       d = 1.2-P         B0 MHz to 2.5 GHz       10 V/m       d = 1.2-P         ME interference radie- tion       10 V/m       d = 1.2-P         REMARK 1       At 80 MHz to 2.5 GHz       10 V/m         REMARK 1       At 80 MHz to 2.5 GHz       10 V/m         REMARK 3       These quidelines may not apply to all case. The propagation of electromagnetic quantities is influenced by absorption         REMARK 3       These quidelines may not apply to all case. The propagation of electromagnetic quantities is influenced by absorption         *       The Compliance levels in ISM frequency bands between 150 kHz and 80 MHz and 5.765 MHz to 6.795 MHz; 13.553 MHz to 2.567 MHz to 2.758 MHz; 23.573 MHz to 2.561 MHz; 28.577 MHz to 2.783 MHz; and 40.66 MHz to 40.7 MHz.         *       The compliance levels in ISM frequency transmitters, as e.g. base units of radio telephones (mobilers) and mobile or detatily brought in to the vicinity of the patient. For this reason an additional factor of 10.313 used when calculating the reasonmended safety distance of transmitters, as e.g. base units of radio telephones (mobileroders) and mobile or detatily brouo				Recommended safety distance
HF interference radie- tion       10 V       d = 1.2*P         HF interference radie- tion       10 V/m       d = 1.2*P 80 MHz to 800 MHz within ISM bands         IEC 61000-4-3       10 V/m       d = 1.2*P 80 MHz to 2.5 GHz         IB MHz to 2.5 GHz       10 V/m       d = 1.2*P 80 MHz to 2.5 GHz         Pbeing the transmitter's nominal rating in Watts (W) per- manufacturer specifications and / being the recom- mended safety distance 'in metres (m).         The field strength of stationary radio transmitters should be below the compliance level 'on all frequencies as tasted on site '.         REMARK 1       At 80 MHz the higher frequency range applies.         REMARK 2       Thes guidelines may not apply to all case. The propagation of electromagnetic quantities is influenced by absorption and reflexion of buildings, objects and people.         *       The ISM bands (industi), scientific and medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 28.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.         *       The compliance levels in ISM frequency bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 28.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.         *       The compliance levels in ISM frequency bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 28.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.         *       The compliance levels in ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz are defined as such as as to decrease the probb	HF interference cur- rents IEC 61000-4-6	3 V <sub>eff</sub> 150 kHz to 80 MHz beyond ISM	10 V	d = 0.35•P
HF interference radie- tion IEC 61000-4-3       10 V/m 80 MHz to 2.5 GHz       10 V/m       10 V/m       d = 1.2-P 80 MHz to 800 MHz d = 2.3-P 800 MHz to 2.5 GHz         HE interference radie- in IEC 61000-4-3       10 V/m 80 MHz to 2.5 GHz       10 V/m       d = 1.2-P 80 MHz to 800 MHz d = 2.3-P 800 MHz to 2.5 GHz         Pressentities and performed and the stationary radio transmitter's nonimal rating in Watts (W) per manufacturer specifications and <i>J</i> being the recom- mended safety distance 'in metres (m).       The field strength of stationary radio transmitters should be below the compliance level 'on all frequencies as tested on site '.         REMARK 1       At 80 MHz and 800 MHz the higher frequency range applies.         REMARK 2       These quidelines may not apply to all case. The propagation of electromagnetic quantities is influenced by absorption and reflexion of buildings, objects and people.         *       The Compliance levels in ISM frequency bands between 150 KHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz; 26.957 MHz; 26.957 MHz; 26.957 MHz; 13.553 MHz; and 40.66 MHz to 40.7 MHz.         *       The compliance levels in ISM frequency bands between 150 KHz and 80 MHz and between 80 MHz and 2.5 GHz are defined to a such as a as decrease the probability of mobile/portable transmitters: causing interference in the event they are a cal- dentally brought in to the vicinity of the patient. For this reason an additional factor of 10/3 is used when calculating the recommended safety distance of transmitters, as e.g. base units of radio telephones (mobile/cordless) and mobile indical devices, amateur radio stations, AM and MH radio stations and television stations cannot be pred		bands <sup>ª</sup>	10 V	d = 1.2•P
HF interference radia- tion IEC 61000-4-3       10 V/m 8 MHz to 2.5 GHz       10 V/m       d = 1.2-P 80 MHz to 800 MHz d = 2.3-P 800 MHz to 2.5 GHz         Ability of the compliance of the patient of the pat		10 V <sub>eff</sub> 150 kHz to 80 MHz within ISM bands		
tion IEC 61000-4-3       B0 MHz to 2.5 GHz         d = 2.3-P       800 MHz to 2.5 GHz         // Debing the transmitter's nominal rating in Watts (W) per manufacturer specifications and J/being the recom- mended safety distance 'in metres (m).         The field strength of stationary radio transmitters should be below the compliance level 'on all frequencies as tested on site '.         Interference may occur in proximity of apparatuses bearing the following symbol:         Willings, objects and people.         *         The compliance levels in ISM frequency bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 20.573 MHz; to 27.283 MHz; and 40.66 MHz to 40.7 MHz.         *       The compliance levels in ISM frequency bands between 150 kHz and 80 MHz and 25 GHz are defined as such so as to decrease the probability of mobile/portable transmitters causing interference in the event they are acci- dentally brought in to the vicinity of the patient. For this reason an additional factor of 10/3 is used when calculating the recommended safety distance of transmitters in this frequency range.         *       In theory the field intensity of stationary transmitters, as e.g. base units of radio telephones (mobile/cordless) and mobile land radio devices, amateur radio stations, AM and FM radio stations and television stations cannot be predefined precise- ty. A study of the location should be conducted to determine the electromagnetic environment with regard to stationary transmitters. If the field intensity at the location where the "MONSOON" is used exceeds the above compliance levels, "MONSOON" should be monitored for proper function. If unusual performance characteristics are observed, add	HF interference radia-	10 V/m	10 V/m	d = 1.2•P 80 MHz to 800 MHz
Pheing the transmitter's nominal rating in Watts (W) per manufacturer specifications and <i>d</i> being the recom- mended safety distance <sup>5</sup> in metres (m). The field strength of stationary radio transmitters should be below the compliance level <sup>4</sup> on all frequencies as tested on site <sup>5</sup> . Interference may occur in proximity of apparatuses bearing the following symbol:	tion IEC 61000-4-3	80 MHz to 2.5 GHz		d = 2.3•P 800 MHz to 2.5 GHz
*       The field strength of stationary radio transmitters should be below the compliance level <sup>1</sup> on all frequencies as tested on site <sup>2</sup> .         *       Interference may occur in proximity of apparatuses the propagation of electromagnetic quantities is influenced by absorption and reflexion of buildings, objects and people.         *       The ISM bands (industrial, scientific and medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.         *       The ISM bands (industrial, scientific and medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.         *       The compliance levels in ISM frequency bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; and 2.5 GHz are defined as such so as to decrease the probability of mobile/portable transmitters causing interference in the event they are accidentally brought in to the vicinity of the patient. For this reason an additional factor of 10/3 is used when calculating the recommended safety distance of transmitters; as e.g. base units of radio telephones (mobile/cordless) and mobile recommended safety distance of transmitters. Be and to be adveced the electromagnetic environment with regard to stationary transmitters, as e.g. base units of radio telephones (mobile/cordless) and mobile recommended safety distance of transmitters. The tiel intensity of stationary transmitters, as e.g. base units of radio telephones (mobile/cordless) and mobile recommended safety distance of transmitters. If the location should be conducted to determine the electromagnetic environment with regard to stationary transmitters. If the field intensity at the location where the "MONS00N' is used exceeds the above compliance leve				P being the transmitter's nominal rating in Watts (W) per manufacturer specifications and d being the recommended safety distance <sup>b</sup> in metres (m).
a       Above a frequency range of 150kHz to 80MHz the field intensity should be below 10 V/m.				The field strength of stationary radio transmitters should be below the compliance level <sup>d</sup> on all frequencies as tested on site <sup>e</sup> .
REMARK 1 At 80 MHz and 800 MHz the higher frequency range applies. REMARK 2 These guidelines may not apply to all case. The propagation of electromagnetic quantities is influenced by absorption and reflexion of buildings, objects and people. The ISM bands (industrial, scientific and medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz. The compliance levels in ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz are defined as such so as to decrease the probability of mobile/portable transmitters causing interference in the event they are accidentally brought in to the vicinity of the patient. For this reason an additional factor of 10/3 is used when calculating the recommended safety distance of transmitters in this frequency range. In theory the field intensity of stationary transmitters, as e.g. base units of radio telephones (mobile/cordless) and mobile land radio devices, amateur radio stations, AM and FM radio stations and television stations cannot be predefined precise-ly. A study of the location should be conducted to determine the electromagnetic environment with regard to stationary transmitters. If the field intensity at the location where the "MONSOON" is used exceeds the above compliance levels, "MONSOON" should be monitored for proper function. If unusual performance characteristics are observed, additional measures may be required, as e.g. changing the direction or location of the "MONSOON".				Interference may occur in proximity of apparatuses bearing the following symbol:
<ul> <li>REMARK 1 At 80 MHz and 800 MHz the higher frequency range applies.</li> <li>REMARK 2 These guidelines may not apply to all case. The propagation of electromagnetic quantities is influenced by absorption and reflexion of buildings, objects and people.</li> <li><sup>a</sup> The ISM bands (industrial, scientific and medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.</li> <li><sup>b</sup> The compliance levels in ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz are defined as such so as to decrease the probability of mobile/portable transmitters causing interference in the event they are accidentally brought in to the vicinity of the patient. For this reason an additional factor of 10/3 is used when calculating the recommended safety distance of transmitters, as e.g. base units of radio telephones (mobile/cordless) and mobile land radio devices, amateur radio stations, AM and FM radio stations and television stations cannot be predefined precise-ly. A study of the location should be conducted to determine the electromagnetic environment with regard to stationary transmitters. If the field intensity at the location where the "MONSOON" is used exceeds the above compliance levels, "MONSOON" should be monitored for proper function. If unusual performance characteristics are observed, additional measures may be required, as e.g. changing the direction or location of the "MONSOON".</li> </ul>				(((•)))
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<sup>d</sup> Above a frequency range of 150kHz to 80MHz the field intensity should be below 10 V/m.	In theory the field land radio devidence ly. A study of the transmitters. If "MONSOON" she measures may	eld intensity of statior ces, amateur radio st e location should be the field intensity at t nould be monitored fo be required, as e.g. c	ary transmitters, as e.g. bas ations, AM and FM radio sta conducted to determine the he location where the "MON r proper function. If unusual hanging the direction or loc	e units of radio telephones (mobile/cordless) and mobile tions and television stations cannot be predefined precise- electromagnetic environment with regard to stationary ISOON" is used exceeds the above compliance levels, performance characteristics are observed, additional ation of the "MONSOON".
	<sup>d</sup> Above a freque	ncy range of 150kHz	to 80MHz the field intensity s	should be below 10 V/m.



#### Recommended safety distances between portable and mobile HF communication devices and the device "MONSOON"

"MONSOON" is intended to be operated in an electromagnetic environment with controlled HF interferences. The operator of the "MONSOON" can help avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the device "MONSOON" – depending on the output rating of the communication device, as listed below.

	Safety dis m	tance depo	ending on	frequency
Maximum transmitter power output W	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz within ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	d = 0.35•P	d = 1.2•P	d = 1.2•P	d = 2.3•P
0.01	0.04	0.12	0.12	0.23
0.1	0.13	0.38	0.38	0.73
1	0.40	1.2	1.2	2.3
10	1.3	3.8	3.8	7.3
100	4.0	12	12	23

For transmitters with a maximum power output not listed in the above table the recommended safety distance d in metres (m) can be determined using the equation from the corresponding column, with P being the transmitter's maximum power output Watts (W) per the transmitter's manufacturer specifications.

REMARK 1 At 80 MHz and 800 MHz the safety distance of the higher frequency applies.

ANMERKUNG 2 The ISM bands (industrial, scientific and medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.7 MHz.

REMARK 3 An additional factor of 10/3 is used when calculating the recommended safety distance for transmitters within the ISM frequency between 150KHz and 80 MHz and between 80MHz and 2.5GHz to reduce the probability of mobile/portable transmitters causing interference if accidentally brought into the vicinity of the patient.

REMARK 4 These guidelines may not apply to all case. The propagation of electromagnetic quantities is influenced by absorption and reflexion of buildings, objects and people.



## TECHNICAL SPECIFICATION

	Settings and Ranges
Jet frequency	Jet 1: 12 – 1600 pulses/min ( <u>+</u> 2%) Jet 2: 1 – 100 pulses/min( <u>+</u> 2%)
• Inspiratory time	15- 75 % ( <u>+</u> 2%)
<ul> <li>Alarms: <ul> <li>Pause pressure</li> <li>Airway pressure</li> <li>Disconnection</li> </ul> </li> <li>Driving pressure</li> <li>Oxygen concentra</li> <li>Minute volume meas</li> <li>Tidal volume meas</li> <li>Bypass Flow</li> <li>Max. water flow</li> </ul>	e Jet 1: OFF - 100 mbar ( $\pm$ 2%) Jet 2: 1 - 100mbar ( $\pm$ 2%) re 1 - 100 mbar ( $\pm$ 2%) On - Off 0.1 - 3.5 bar ( $\pm$ 2%) tion 21 - 100% ( $\pm$ 3%) asurement 0 - 200 l/min ( $\pm$ 10%) surement 0 - 10,000 ml ( $\pm$ 10%) 0 - 70 l/min 6 ml/min
Max. heater output	t 200 Watt
	Dimensions
Main unit: • W x H x D • Weight:	42 cm x 19 cm x 39 cm Basic:approx. 13.5 kg PLUS:approx. 14.0 kg PLUS Double jet: approx. 15.8 kg
Control panel: • W x H x D • Weight:	27 cm x 8 cm x 21 cm approx. 1.5 kg
	Connections / Ports
<ul><li>Air supply</li><li>Oxygen supply</li></ul>	4.0 to 6.5 bar 4.0 to 6.5 bar
<ul><li>Power supply</li><li>Average power c</li></ul>	100 to 240 VAC 50/60 Hz onsumption: 100 W
Ethernet port	LAN connection / HL7



## **Environmental Conditions**

Operation:

•	Temperature	15 to 40°C
	romporataro	

- Barometric pressure 700 to 1060 hPa • 0-90%
- rel. humidity

Storage and transport:

- Temperature •
- Barometric pressure 500 to 1060 hPa •
- rel. humidity •

- 20 to 60°C

0 to 100%

## Disposal

Disposal of batteries and O2 sensors:



Do not throw batteries into fire; do not charge batteries → Risk of explosion!



Do not force open → Risk of chemical burn!



Dispose of batteries and O<sub>2</sub> sensors according to local waste management ordinances. Please contact your local environmental or regulatory authority and appropriate waste management companies.



## **Rear View / Connections**



Figure 14: MONSOON - rear view

#### Legend:

- Element 1: AIR input (NIST)
- Element 2:  $O_2$  input (NIST)
- Element 3: Fan
- Element 4: Nurse Call connection
- Element 5: Drop counter connection
- Element 6: Remote control connection
- Element 7: LAN / HL7 port
- Element 8: Mains switch
- Element 9: Mains connector (100 240V)
- Element 10: Earthing connector
- Element 11: Nameplate
- Element 12: 0, bleed
- Element 13: CO, bleed
- Element 14: Bottle mount priming



## **Replacing Fuses**

#### Principle:

Always replace fuses with fuses of identical rating. We recommended having fuses replaced by training service staff.

The mains fuses are located inside the MONSOON's mains input socket at the back of the device.

#### Procedure:

Unplug. Use a screwdriver to loosen the locking mechanism marked with arrows and open drawer. Remove fuse and replace with a fuse of identical rating (T3.15A H). Push drawer into mains input socket. Be sure the locking mechanism catches.



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