AIR LIQUIDE
MEDICAL SYSTEMS

ALPHA 300

Installation and operation manual **EN**

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I. INTRODUCTION

I.1 ABOUT THIS MANUAL

This manual describes how the following device should be used:

ALPHA 300, equipped with software version 1.0.x and hardware version 1.0

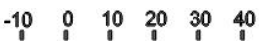
The list of accessories for the ALPHA 300, the correct operation of which has been checked and certified, is available in **Section 9: List of accessories.**

For any questions concerning these accessories, contact the manufacturer, whose details are on the back cover.

The utmost care has been taken over the design of this manual. For any information, suggestion or comment, please contact the authors. Their details are on the back cover.

The manufacturer holds the rights relating to the circuit diagrams, methods used and names quoted in this manual. It also reserves the right to develop and make modifications to the ALPHA 300 in line with technical progress.

I.2 SYMBOLS IN THE MANUAL AND ON THE DEVICE

	Dangerous situation that may arise if the instructions contained in this manual are not observed.
Warning	Situation that may cause injury to the operator and the patient.
Caution	Situation that could cause damage to the system.
	All the warnings and all the precautionary measures should be read and respected.
	Scale of bar graph relating to patient's pressure
	Expiratory valve
	Nebuliser outlet
	Patient connection
	Inspiratory flow rate
	Manual trigger
	Key lock
	Increase
	Decrease

	Nebuliser power
	Insulation; protection class II device
	Keep away from humidity
CE 0123	The ALPHA 300 conforms to the medical device directive 93/42/EEC, when used in accordance with the instructions in this manual. The number "0123" is the approval number of the notified body commissioned by the manufacturer's Quality Department.
	Follow the manual instructions
	The ALPHA 300 must not be disposed of in general household waste. It must be processed separately. To obtain information concerning the disposal of the ALPHA 300, contact the manufacturer.

I.3 ABBREVIATIONS IN THE MANUAL AND ON THE DEVICE

IPPB: Intermittent Positive Pressure Breathing
T. INSP.: Inspiratory trigger (inspiration pressure trigger)
T. EXP.: Expiratory trigger (cut-off pressure)
R. EXP.: Expiratory resistance
P: Pressure
F: Respiratory rate
VT Tidal volume
Serial No.: Serial number
ED: Triggering duration

II. SAFETY

II.1 SAFETY INSTRUCTIONS

Reference:

This manual describes the following product:

ALPHA 300

IPPB respiratory therapy device

Operating safety:

To ensure safety of operation, the ALPHA 300 should only be used as described in this manual. Before using it, the operator must be familiar with the instructions contained in this manual. Only authorised persons may use the ALPHA 300. All the instructions in this manual and all legal provisions relating to the use of this respiratory therapy device must be followed.

Classification:

The ALPHA 300 belongs to Class IIa in accordance with the medical device directive 93/42/EEC, annex IX; section 1.3, article 3; section 3.1, article 9; section 3.2, article 11.

Classification as per standard EN 60601-1 Medical electrical equipment – General requirements for basic safety and essential performance:

CLASS II DEVICE

Duration of operation:

The ALPHA 300 has been designed to be used for a maximum of 30 consecutive minutes. The triggering duration is 50%. Each time it is used, there must be a pause lasting at least as long as the period of use. If you would like to use the device for longer, contact the manufacturer, whose details are on the back cover.

Servicing and maintenance:

The ALPHA 300 must be serviced every year to ensure the safety and proper operation of the device. Repairs, servicing and maintenance should only be carried out by trained, qualified technicians.

Accessories:

The ALPHA 300 is supplied with its original accessories. It should only be used with the accessories listed in **section 9: List of accessories**.

Residual risks:

To minimise the risk of failure of the device, the patient must be conscious and able to breathe spontaneously.

Electrical risks:

Before powering up the device, make sure that the casing is dry. The supply voltage must correspond to the specifications on the ratings plate on the back of the device.

The system must be stored and used only in accordance with the specifications of **section 8: Technical specifications**. If the casing temperature is above or below the specified operating temperature range, switch off the system for approximately an hour, to reduce the temperature differences.

The system must be disconnected from the electricity supply before cleaning, repairs or servicing.

Fire risks:

The ALPHA 300 must not, under any circumstances, be used in areas exposed to explosion risks or in the presence of flammable anaesthetics.

Protection against damage resulting from infiltration of water or foreign bodies:

The ALPHA 300 has no protection against the infiltration of water or foreign bodies. If water does leak into the casing, the device must be switched off immediately. A qualified service engineer should then be contacted.

Risks of electromagnetic interference:

Devices which generate electromagnetic fields of a strength exceeding the specifications of standard EN 60601-1-2 may disrupt the correct operation of the ALPHA 300 and present a danger to the operator.

Devices which generate high-frequency fields and are installed near the system may disrupt the correct operation of the ALPHA 300 and present a danger for the operator.

The use of mobile phones near the ALPHA 300 may disrupt the correct operation of the device and present a danger to the operator.

 **Warning**: The ALPHA 300 must not be used in the immediate vicinity of magnetic resonance devices (MRI, magnetic resonance tomography, etc.).

Electromagnetic compatibility (EMC):

The ALPHA 300 may only be used in an electromagnetic environment if high frequency disturbances are controlled. Operators of the ALPHA 300 may minimise electromagnetic interference by keeping a minimum distance between the ALPHA 300 and portable and mobile high-frequency communication devices (emitters).

Warning: The use of other electrical equipment (e.g. supply cables) may generate excessive high frequency emissions or affect the immunity of the ALPHA 300. This may represent a danger for the operator.

Caution: Connecting other electrical devices to or near the ALPHA 300 may cause interference. It is essential to check that the ALPHA 300 is working correctly before installing it on the patient.

Note

For more information on the electromagnetic compatibility of the ALPHA 300, refer to **section 8.8: Directives and manufacturer's instructions**.

III.GENERAL DESCRIPTION

III.1 USE

The ALPHA 300 is a respiratory therapy device intended for physiotherapists for the periodical inhalation of a medicinal aerosol (physiological serum or hypertonic solution), in combination with intermittent positive pressure breathing assistance (IPPB). In the case of nebulisation of medicines for which the aerosol delivery rate and/or particle size distribution are required to be high, contact the manufacturer of the patient circuit.

The patient on whom the device is used must be conscious and able to breathe spontaneously.

The ALPHA 300 is designed for adults and children of over 10 kg. It may be used for clinical IPPB therapy for resident patients and outpatients; in hospital, at the physiotherapy clinic or at home.

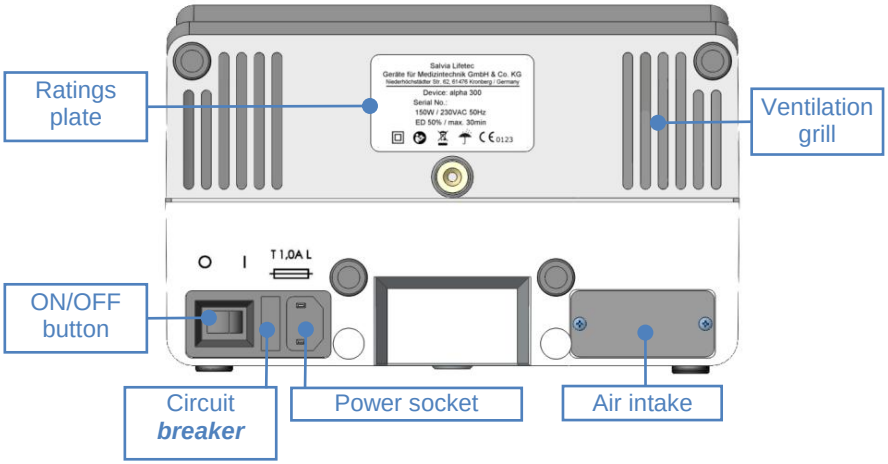
In particular, the ALPHA 300:

- **Facilitates drainage:**
  Offers a larger inspiratory volume to improve the efficacy of expiratory flow rate and cough.
- **Optimises respiratory function:**
  It delivers greater volume than the patient's spontaneous maximum inspiration and improves the vital capacity.
- **Encourages lung recruitment:**
  Assists with the recruitment of poorly ventilated or unventilated lung areas.

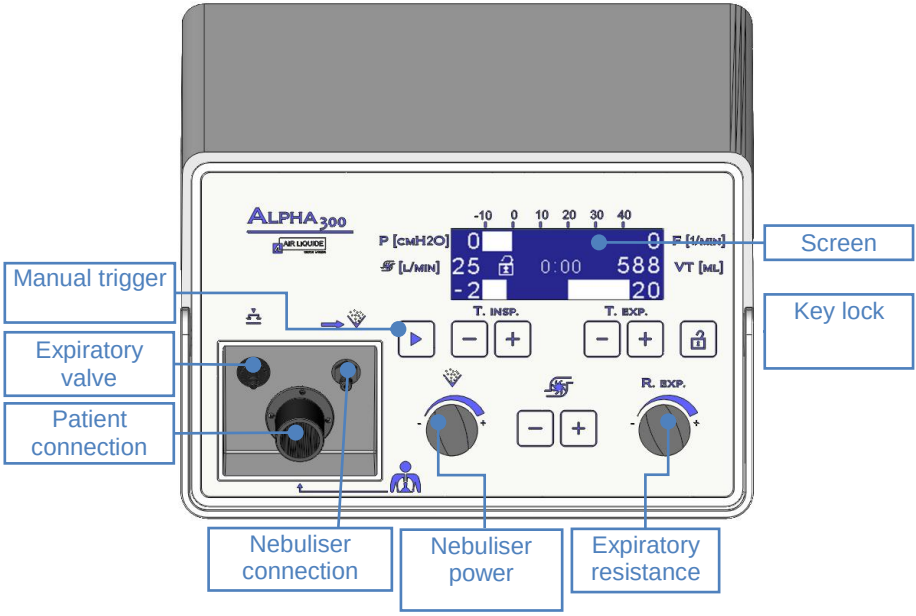
 **Warning**: For safety reasons, respiratory therapy can only be administered to children under supervision.

III.2 MAIN COMPONENTS

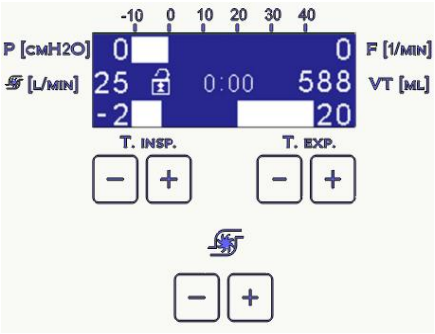
Rear panel:



Front panel:



Display:



III.3 GENERAL INFORMATION ON IPPB AND AEROSOL THERAPY

This inhalation technique, which consists of blowing pressure into the airways, permits the inhalation of medicines combined with intermittent positive pressure breathing (IPPB) assistance. This type of ventilation is used in specific lung diseases, such as chronic bronchitis, emphysema, bronchial asthma, etc.

With the assistance of IPPB, patients with breathing difficulties or limitations can breathe slowly and deeply with minimal effort. Nebulised medicine aerosols can penetrate into and act on the peripheral parts of the lungs.

III.4 OPERATING PRINCIPLE

The ALPHA 300 is a breathing assistance device for patients who are breathing spontaneously. It detects the inspiratory phase by using the pressure drop measured in the device circuit during the inspiratory effort, as a basis. The ALPHA 300 assists the patient's inspiration by supplying a constant inspiratory flow rate until the set cut-off pressure is reached. The set inspiratory flow rate determines the rate of increase in pressure in the respiratory tract. As soon as the set inspiration pressure is reached, the ALPHA 300 switches to the expiratory phase, whereby the air flow is terminated and the expiratory valve - pressure controlled - opens.

If the respiratory therapy requires a certain amount of resistance to expiration, the device can be adjusted accordingly so that the counter-pressure reduces more slowly and the expiratory phase is prolonged.

A medicinal aerosol can be administered to the patient as part of his therapy using the nebuliser.

The combined use of the Alpha 300 will assist this aerosol to penetrate into the peripheral parts of the lungs where it can exert its action.

The ALPHA 300 offers the following functions:

- Recognition of the patient's inspiratory and expiratory phases (triggers).
- Optimised aerosol medication administration due to synchronised inspiration and nebulisation phases.
- Adjustment of inspiratory support to increase alveolar recruitment.
- Display of airway pressure to control the operation of the device.
- Adjustment of inspiratory and expiratory trigger pressures and expiratory resistance for optimum therapy.
- Adjustment of the inspiratory flow rate between 8 and 60 l/min.
- Display of patient's respiratory rate and tidal volume.

IV. PREPARATION FOR START-UP

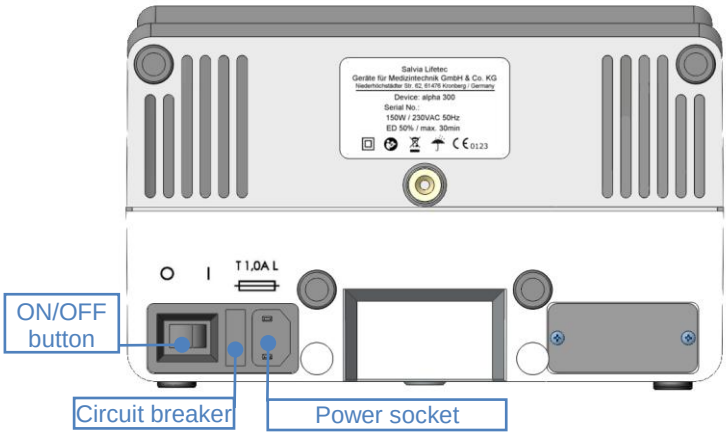
Warning: Before starting up the device, check that there is no visible damage.

For a summary of the information relating to the start-up of the ALPHA 300, refer to **section 11: Check List.**

IV.1 POWER SUPPLY

The ALPHA 300 is designed to withstand a voltage of 230 V AC at 50 Hz.

Warning: Before connecting up the device, check that the supply cable is not damaged. If the supply cable is damaged, it must not be used.



The power cable supplied with the ALPHA 300 must be plugged into the power socket on the back of the device.

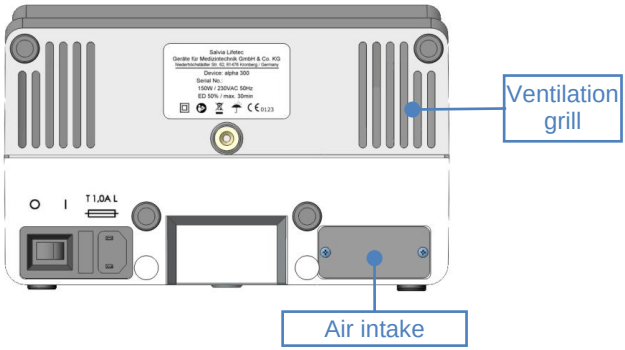
Note: Only the power cable provided should be used.

When the ON/OFF switch is pressed, the ALPHA 300 starts up automatically in standby mode.

IV.2 GAS SUPPLY

The ALPHA 300 comprises a built-in compressor which draws in ambient air at the back of the device and compresses it. This compressor does not require maintenance. The set inspiratory flow rate is obtained from the compressed air from the compressor and a Venturi nozzle.

Rear panel:



Note: The quality of the air used in therapy is the same as that of the ambient air.

Warning: The device should only be used in a clean and dry environment. Any penetration of water, oil or particles in the device could damage it and present a danger to the patient.

IV.3 IPPB CIRCUIT

The ALPHA 300 operates reliably with the IPPB circuits and all the accessories described in **section 9: List of accessories.**

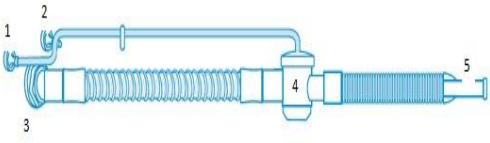
To connect the IPPB circuit without nebuliser (***KG021000***), proceed as follows:

1. Connect the expiratory valve.
2. Connect the patient circuit.
3. Install the expiratory valve.
4. Install the mouthpiece.

Note:

- The circuit without nebuliser (***KG021000***) consists of two tubes. The circuit with nebuliser (***KG020900***) consists of 3 tubes of different diameters. The different tubes can only be connected to the correct adapter, so preventing any connection errors.
- The use of an antibacterial filter on the patient circuit is recommended.
- Refer to the manufacturer's instructions. The components are for single use only and must not be reused.

⚠ **Warning**: Make sure that the circuit tubings are routed directly from the device to the patient, and that they do not compromise patient safety in any way. Eg. they are not wound around the patient's neck (risk of strangling).



IV.4 NEBULISATION

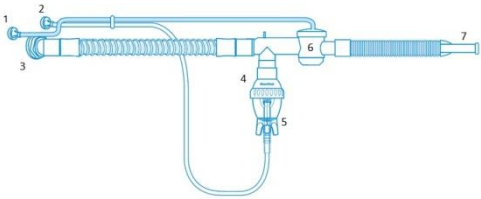
An aerosol medication may be administered to the patient during his therapy, using the nebuliser. The nebuliser operates using compressed air and is only activated in the inspiratory phase to optimise the administration of medicines.

Remarks:

- The nebuliser must be positioned between the device and the expiratory valve on the patient circuit; behind the valve.
- Follow the manufacturer's instructions concerning the minimum and maximum filling volumes of the nebuliser. The components are for single use only and must not be reused.

Proceed as follows to connect the IPPB circuit to the nebuliser (***KG020900***):

1. Connect the expiratory valve.
2. Connect the nebuliser.
3. Connect the patient circuit.
4. Connect the nebuliser head.
5. Connect the medicine reservoir.
6. Connect the expiratory valve.
7. Connect the mouthpiece.



IV.5 INSTALLATION OF THE DEVICE

The ALPHA 300 must be used flat on a horizontal surface. The information contained in **section 2.1: Safety instructions**, and also the environmental conditions described in **section 8.1: General information,** must be observed**.**

 **Warning**: Make sure that the device is fully stabilised. The device should not be moved during use.

 **Warning**:

Make sure that the back panel of the device is never obstructed.

 **Warning**:

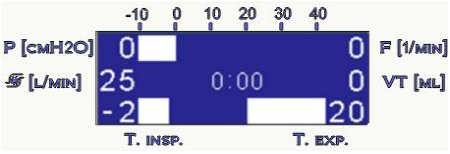
Make sure that the power plug on the ALPHA 300 is always accessible so as to be able to disconnect the device in case of emergency.

V. OPERATION

V.1 STARTING UP AND STOPPING

Starting up

Once the ALPHA 300 is connected to the mains (see **section 4.1: Power supply**), press the ON/OFF switch located on the rear panel of the device. The device starts up in standby mode.



The patient circuit may be connected before turning on the device. For more details, refer to **sections 4.3: IPPB circuit** and **4.4: IV**.4 **Nebulisation**.

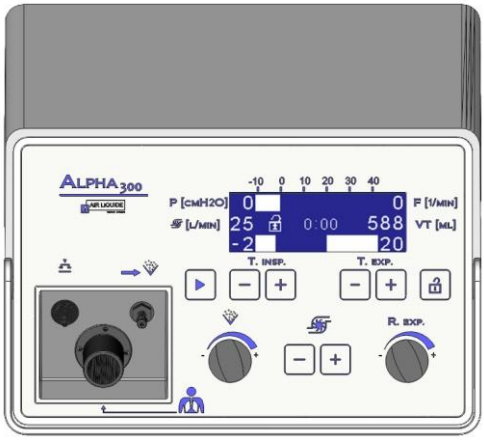
The ALPHA 300 can be stopped at any time using the ON/OFF switch.

V.2 SETTING AND DISPLAY FUNCTIONS

The ALPHA 300 can be configured individually in accordance with the patient's requirements.

V.2.1 SETTING FUNCTIONS

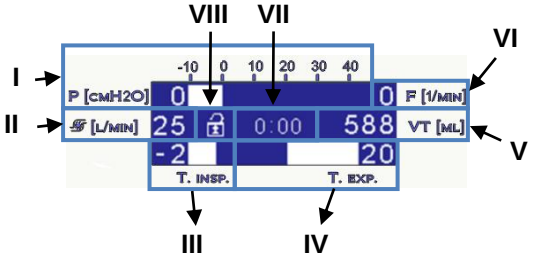
Settings are configured using the [−] and [+] keys and the buttons on the device. All the setting functions of the ALPHA 300 are located on the front panel of the device.



Symbol	Position	Note
	Inspiratory flow rate	The various settings are configured using the − and + keys and are directly visible on the screen. For more details, refer to **section 5.3.1: Inspiratory flow** rate**.**
T.INSP	Inspiratory trigger pressure	The various settings are configured using the − and + keys and are displayed directly on the screen. For more details, refer to **section 5.3.2: T.INSP. Inspiratory trigger.**
T.EXP	Cut-off pressure (expiratory trigger)	The various settings are configured using the − and + keys and are directly visible on the screen. For more details, refer to **section 5.5.3:T.EXP. Expiratory trigger.**
	Manual trigger	The "manual trigger" key allows an inspiratory phase to be activated. The inspiratory phase can be started manually at any time.
	Key lock	By locking the keys, the system can be locked to keep the set parameters; the system can then be unlocked to modify the parameters. For more details, refer to **section 5.3.4: Key locking**.
	Nebulisation power	The nebulisation power can be adjusted using the left knob. For more details, refer to **section 5.3.5: Nebuliser power**.
R.EXP	Expiratory resistance	The expiratory resistance power can be adjusted using the right knob. For more details, refer to **section R.EXP. (expiratory resistance)**.

V.2.2 DISPLAY INFORMATION

The screen on the ALPHA 300 displays the following information:



I. P (Pressure)	The pressure in the patient's airways is indicated both in absolute value and by a bar graph in cmH_2O.
II. Inspiratory flow rate	Displays the set inspiratory flow rate (in l/min.).
III. T.INSP. Inspiratory trigger (inspiratory trigger pressure)	Displays the set value for the **T.INSP**
IV. T.EXP. Expiratory trigger (cut-off pressure)	Displays the set value for the **T.EXP**
V. VT (tidal volume)	Displays the patient's tidal volume in ml. The patient's tidal volume is only displayed when the nebuliser is stopped and the limits specified in **section 8.6: Measurement functions** have been reached.
VI. F (respiratory rate)	Displays the patient's respiratory rate in units of number per minute, 1/min. The first data are displayed after five inspirations.
VII. Duration of treatment	Displays the duration of the therapy. There is an automatic start, stop and reinitialisation function for the display of the duration.
VIII. Key lock display	The key lock icon shows on the screen whether the device is locked or unlocked, and so whether the parameters can be set.

V.3 SETTING PARAMETERS

All the parameters must be set in accordance with the medical prescription issued for the patient.

V.3.1 INSPIRATORY FLOW RATE

The inspiratory flow rate must be set in accordance with the patient's individual requirements and the medical prescription issued. The different settings are adjusted using the [−] and [+] keys and are displayed on the screen. The flow rate determines the rate of increase of the pressure during the inspiratory phase. Its value may be from 8 to 60 l/min.

- Up to 20 litres, the flow rate can be set in 1-litre steps.
- After 20 litres, the flow rate can be set in 5-litre steps.

An excessively high flow rate can cause instability and vortex effects in the airways, and thus affect respiration.

The settings can only be modified after unlocking the keys. For more details, refer to **section 5.3.4: Key locking**.

V.3.2 T.INSP. INSPIRATORY TRIGGER / TRIGGER PRESSURE

The inspiratory trigger is set using the keys under the words T.INSP. [−] and [+] are displayed on the screen. The ALPHA 300 detects the patient's inspiratory phase on the basis of the pressure drop measured in the patient circuit during the inspiratory effort. The inspiratory trigger, the value of which may be from -1 to -9 cmH_2O, determines the triggering threshold for the inspiratory phase.

The settings can only be modified after unlocking the keys. For more details, refer to **section 5.3.4: Key locking**.

V.3.3 T.EXP. EXPIRATORY TRIGGER / CUT-OFF PRESSURE

The expiratory trigger is adjusted using the keys under the words T.EXP. [−] and [+] are displayed on the screen. During the inspiratory phase, the patient receives a constant flow rate until the cut-off pressure is reached. The device then switches automatically to the expiratory phase. The value of the cut-off pressure may be from +5 to +40 cmH_2O.

The settings can only be modified after unlocking the keys. For more details, refer to **section 5.3.4: Key locking**.

V.3.4 KEY LOCK [🔓]

The parameters **Inspiratory flow** rate, **T.INSP. Inspiratory trigger** and **T.EXP. Expiratory trigger** can only be adjusted if the keys are unlocked. Press the [🔓] key to unlock the ALPHA 300 and adjust your settings using the [−] and [+] keys. The set values will then be displayed on the

screen. Once the settings have been completed, press the key again.

V.3.5 NEBULISER POWER

The nebuliser power is set using the knob on the left of the device's front panel. It determines the duration of nebulisation in accordance with the quantity of medicinal solution contained in the nebuliser.

- Turn the knob to the left to close the valve and reduce nebulisation until it stops completely.
- Turn the knob to the right to increase the nebulisation power.

Note: This setting is not affected by key locking.

V.3.6 R.EXP. (EXPIRATORY RESISTANCE)

The expiratory force is set using the knob on the right of the device's front panel. It affects the patient's expiration pressure.

- Turn the knob to the left to reduce the resistance felt by the patient.
- Turn the knob to the right to increase the patient's expiration.

Note: This setting is not affected by key locking.

V.4 CHECK ON THE OPERATION OF THE DEVICE

Before starting therapy, it is essential to check that the device is functioning by manually triggering an inspiration by pressing the button.

Warning:
Always check the current settings of the device before starting therapy. Incorrect values can place the patient in danger.

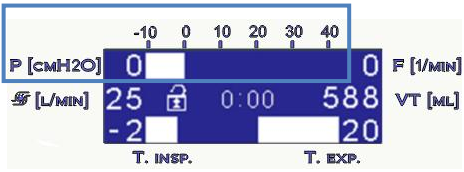
V.5 STARTING THERAPY

After checking the device function, the therapy can begin. For more information on assembling the IPPB circuit, see **section IPPB circuit**.

The therapy starts automatically at the first inspiratory effort of the patient.

V.5.1 PRESSURE DISPLAY (BAR GRAPH)

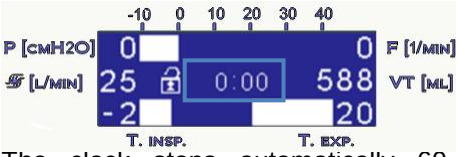
The pressure of the ALPHA 300 is displayed in absolute value and in the form of a bar graph at the top of the screen. The display range extends from -10 to 40 cmH_2O.



Warning Excessive pressures can place the patient in danger. The patient's pressure limits must be set in accordance with the medical prescription.

V.5.2 DURATION OF TREATMENT

The integrated timer in the ALPHA 300 starts when the first inspiration of the therapy is triggered. It is displayed in the middle of the screen and can go up to 99 minutes and 59 seconds. Once this maximum value has been exceeded, the timer starts again at 0 minutes and 0 seconds.

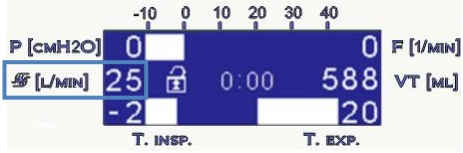


The clock stops automatically 60 seconds after the last triggering. If no inspiration is detected after 120 seconds, the timer reinitialises itself at 00:00.

Warning: The ALPHA 300 has been designed to be used for a maximum of 30 consecutive minutes. If you would like to use the device for longer, contact the manufacturer, whose details are on the back cover.

V.5.3 INSPIRATORY FLOW RATE

The inspiratory flow rate is displayed in litres per minute on the left of the screen.

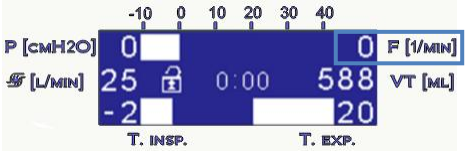


If necessary, the inspiratory flow rate can be adjusted during the therapy:

- between 8 and 20 litres, the flow rate can be adjusted in steps of 1 litre;
- After 20 litres, the flow rate can be set in 5-litre steps.

V.5.4 F (RESPIRATORY RATE)

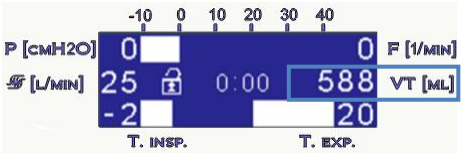
The ALPHA 300 displays the patient's respiratory rate (in number of respirations per minute) at the top right of the screen.



The patient's respiratory rate is calculated from the last 5 respirations.

V.5.5 VT (TIDAL VOLUME)

The ALPHA 300 calculates the patient's tidal volume. The patient's tidal volume is only displayed when the nebuliser is stopped and the limits specified in **section 8.6: Measurement functions** have been reached.



VI. SERVICING

VI.1 SERVICING RECOMMENDATIONS

Important precautions:

- Read the instructions for use and technical data sheets for the cleaning products to be used.
- Wear gloves and protective glasses.
- Do not inhale the vapours.

Warning: To avoid damage to the Alpha 300:

Do not use organic, halogenated or mineral oil solvents, volatile anaesthetic agents, window cleaner, acetone or aggressive or abrasive cleaning products such as steel wool or polishing agents.

Do not allow any liquid to leak into the casing.

Keep electronic components away from any liquid.

For any questions concerning a cleaning product, contact its manufacturer.

Note

If a liquid penetrates into the casing, the ALPHA 300 must be taken out of service. Contact a qualified service engineer to clean the device.

Warning: Avoid patient contamination in clinical use:

Observe the general hygiene rules laid down by the hospital or establishment.

The components are for single use only and must not be reused.

VI.2 CLEANING AND DISINFECTING

VI.2.1 CASING

Switch off the ALPHA 300 and check that the power cable is properly disconnected.

Use a clean cloth and mild detergent to clean the surface of the casing.

To disinfect the surface of the casing, the manufacturer recommends using *Buraton® rapid* by Schülke & Mayr (www.schuelke-mayr.com).

The dust grille located on the rear panel of the casing must also be cleaned regularly.

Before putting the ALPHA 300 into use, make sure that the casing is completely dry.

VI.2.2 PATIENT CIRCUIT

Refer to the manufacturer's instructions. The components are for single use only and must not be reused.

VII. FAULT MANAGEMENT

VII.1 RESOLVING FAULTS

Warning: If a fault is detected, the device must be disconnected and must not be used.

Fault	Origin	Solution
The device does not switch on	No voltage	Contact a qualified service engineer
		Check the supply socket and press the ON/OFF switch again.
The device does not switch off		Disconnect the power cable and contact a qualified service engineer
The device does not start the inspiratory phase	Leak from the circuit or the nebuliser	Check the tubing connections and nebuliser
	Trigger threshold too low	Check the settings or contact a qualified service engineer
The device calculates an incorrect inspiratory flow rate		Disconnect the power cable and contact a qualified service engineer
The device permanently calculates an inspiratory flow rate		Disconnect the power cable and contact a qualified service engineer
The respiratory pressure in the airways is not established	The expiratory valve is faulty	Check the expiratory valve
	The expiratory valve drive line is not connected	Connect the patient circuit correctly
	The patient circuit leaks	Check the tubing connections and if necessary change the hose system

Fault	Origin	Solution
The pressure threshold is not reached		Check the tubing connections and nebuliser Check the settings or contact a qualified service engineer
The nebuliser does not work	Medicine filling level too low	Fill the medicine reservoir
	The nebuliser is blocked	Clean or replace the nebuliser tubing and/or chamber.
	The nebuliser pressure is too low	Increase the nebuliser power
	The nebuliser tubing leaks or is not connected	Check the nebuliser tubing connections
A setting control key is faulty		Disconnect the power cable and contact a qualified service engineer
A knob is faulty		
The screen is blank		
The values displayed are illogical		
"Fault #1" is displayed on the screen		

VIII. TECHNICAL SPECIFICATIONS

VIII.1 GENERAL INFORMATION

Application:

Intended use: see **section 3.1: Use. Applications:** Respiratory therapy, aerosol therapy

Area of Use: Clinical IPPB therapy for in-house patients and outpatients

Patients: Adults and children over 10 kg

Dimensions and weight:

Width x Height x Depth: 265 (W) x 165 (H) x 260 (D) mm

Net weight: 6.7 kg

Environmental conditions:

During operation:

Temperature: +10 to +40°C

Atmospheric pressure: 90 to 106 kPa

Relative humidity: ≤ 99% (without condensation)

Storage and transport:

Temperature: -20 to +70 °C

Atmospheric pressure: 50 to 110 kPa

Relative humidity: ≤ 99% (without condensation)

Electromagnetic compatibility (EMC):

Approved by: CEI/EN 60601-1-2 standard, as per directive 2004/108/EC

Noise emissions:

Noise level: <70 dB(A)

Classification:

Class of the device, as per directive 93/42/EEC, annex IX: IIa

Electrical protection class: II

Duration of operation: ED 50% / max. 30 min.; prolonged use can affect the life of the device.

VIII.2 POWER SUPPLY

AC voltage: 230 V AC, 50 Hz

Power: 150 W

VIII.3 TECHNICAL SPECIFICATIONS OF THE ALPHA 300

Flow rate (inspiratory flow rate): 8 – 20 l/min. (number of steps: 1)

20 – 60 l/min. (number of steps: 5)

T.INSP. (inspiratory triggering pressure): Adjustable from -1 to -9 cmH_2O

T.EXP. (expiratory triggering pressure): Adjustable from 5 to 40 cmH_2O

R.EXP. (expiratory resistance): Adjustable

Display "Respiratory rate" 0 – 99 (1/min)

Display "Treatment duration" 0:00 – 99:59 (min:s)

VIII.4 FACTORY SETTINGS

Treatment duration: 0:00 (min:s)
Inspiratory flow rate: 8 l/min
T.INSP : -1 cmH_2O
T.EXP.: +5 cmH_2O
R.EXP: Not activated
Nebuliser: Not activated

Steps and setting ranges

	Step	Min. value	Max. value
Inspiratory flow rate	1 @ 8 – 20 l/min 5 @ 20 – 60 l/min	8 l/min	60 l/min
Duration of treatment	00:01 (min:s)	00:00 (min:s)	99:59 (min:s)
T.INSP.	1 cmH_2O	5 cmH_2O	40 cmH_2O
T.EXP.	1 cmH_2O	-1 cmH_2O	-9 cmH_2O

VIII.5 MEASUREMENT FUNCTIONS

	Step	Min. value	Max. value	Precision
Patient's pressure	1 cmH_2O	-9 cmH_2O	40 cmH_2O	±(1 cmH_2O + 2 %)
Respiratory Rate	1 /min	0 /min	99 /min	±1 /min
Tidal volume	1 ml	0 ml	2999 ml	± (20 ml + 20%)

VIII.6 SCREEN

Type of screen: LCD - white text on blue background
Screen size: 4.0 po
Screen resolution: 192 x 64 pixels

VIII.7 DIRECTIVES AND MANUFACTURER'S INSTRUCTIONS

Electromagnetic emissions:

The ALPHA 300 must be used in the electromagnetic environments specified below. The operator of the ALPHA 300 must make sure that it is used in this type of environment.

Measurement of interferences	Conformity	Electromagnetic environment - Directive
High frequency emissions CISPR 11	Group 1	The ALPHA 300 only uses high frequency energy for its internal functions. Its high frequency emissions are therefore very low and it is unlikely that they affect electronic equipment situated nearby.
High frequency emissions CISPR 11	Class A	The ALPHA 300 cannot be used in facilities other than residential facilities, connected to the public mains electricity supply also supplying residential buildings.
Harmonic emissions IEC 61000-3-2		
Voltage changes/Flicker 61000-3-3	Non applicable	

Electromagnetic immunity:

The ALPHA 300 must be used in the electromagnetic environments specified below. The operator of the ALPHA 300 must make sure that it is used in this type of environment.

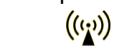
Immunity test	IEC 60601 test level	Level of conformity	Electromagnetic environment - Directives
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV discharge by contact ± 8 kV discharge in air	± 6 kV discharge by contact ± 8 kV discharge in air	Floors must be wood or concrete, or covered with ceramic tiles. If floors are covered with a synthetic material, the relative humidity must be at least 30%.

Rapid/bursts of transient disturbances 61000-4-4	± 2 kV for supply lines ±1 kV for inlet/outlet lines	± 2 kV for supply lines ±1 kV for input/output lines	The quality of the supply voltage must be the same as in a commercial or hospital environment.
Overvoltage, IEC 61000-4-5	±1 kV in differential mode ±2 kV in common mode	±1 kV in differential mode ±2 kV in common mode	The quality of the supply voltage must be the same as in a commercial or hospital environment.

Immunity test	**IEC 60601 test level**	**Level of conformity**	**Electromagnetic environment - Directives**
Immunity to voltage dips, brief power cuts and voltage variations 61000-4-11	< 5 % U_T (> reduction of U_T of 95%) for ½ cycle < 40 % U_T (reduction of U_T of 60%) for 5 cycles < 70 % U_T (reduction of U_T of 30 %) for 25 cycles < 5 % U_T (> reduction of U_T of 95 %) for 5 seconds	< 5 % U_T (> reduction of U_T of 95%) for ½ cycle < 40 % U_T (reduction of U_T of 60 %) for 5 cycles 70 % U_T (reduction of U_T of 30 %) for 25 cycles < 5 % U_T (> reduction of U_T of 95 %) for 5 seconds	The quality of the supply voltage must be the same as in a commercial or hospital environment. If the operator of the ALPHA 300 needs the device to operate continuously, even if there is a power cut, it is recommended to connect the ALPHA 300 to a UPS.

Magnetic fields of the supply frequency. (50 Hz), IEC 61000-4-8	3 A/m	3 A/m	The magnetic fields of the supply frequency must be the same as in a commercial or hospital environment.
Note: U_T is the AC voltage before application of the test level.			

Immunity test	**IEC 60601-1-2 measurement level**	**Level of conformity**	**Electromagnetic environment - Directives**
Portable and mobile high frequency communication devices must not be used near the ALPHA 300 and its connections. The recommended separation distance is calculated from the emission frequency equation.			
High frequency conducted disturbances, IEC 61000-4-6	3 V effective value 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz
High frequency radiated disturbances, IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35\sqrt{P}$ for 800 MHz to 2.5 GHz

			$d = 0.7\sqrt{P}$ where *P* is the nominal power of the emitter in Watts (W) according to the emitter's manufacture, and *d* is the recommended separation distance in metres (m). The intensity of the field of the fixed high frequency emitters – in accordance with a site study [a] – must be lower than the conformity level on all frequencies [b]. Near devices carrying the following symbol, malfunctions are possible. 

The notes and footnotes are explained on the next page.

Note 1 80 MHz and 800 MHz correspond to the maximum values.

Note 2 These directives do not necessarily apply to all situations. The propagation of electromagnetic waves is affected by the absorption and reflection of buildings, objects and persons.

a. The intensity of the fields of fixed emitters – such as base stations of mobile phones and land mobile devices, amateur radio stations or AM/FM radio and television stations - in theory cannot be predetermined precisely. In order to evaluate the electromagnetic environment induced by fixed high frequency emitters, a study on the electromagnetic phenomena of the site in question should be carried out. If the field intensity measured on the site where the ALPHA 300 is used exceeds the above-mentioned level of conformity, the ALPHA 300 needs to be checked to ascertain that it is working correctly. If irregularities are observed, additional measures may become necessary (e.g. re-orientation or move of the system).

b. In the frequency range 150 kHz to 80 MHz, the field intensities must be less than 3 V/m.

Recommended separation distances between the ALPHA 300 and portable and mobile high frequency communication devices

The ALPHA 300 may only be used in an electromagnetic environment if high frequency disturbances are controlled. Operators of the ALPHA 300 can minimise electromagnetic interference by maintaining a minimum distance between the ALPHA 300 and portable and mobile high frequency communication devices (emitters) – depending on the output power of the communication device concerned (see table below).

Power rating of emitter W	**Separation distance depending on emitter frequency (in m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7\sqrt{P}$
0.01	0.12	0.04	0.08
0.1	0.38	0.11	0.22
1	1.2	0.35	0.70
10	3.8	1.1	2.2
100	12	3.5	7.0

For emitters whose maximum rated power is not indicated in the above table, the distance *d* in metres (m) may be calculated using the equation corresponding to this emitter, where P is the rated power of the emitter in Watts (*W*) according to the manufacturer's specifications of the emitter.

Note 1 80 MHz and 800 MHz correspond to the maximum values.

Note 2 These instructions do not necessarily apply in all situations. The propagation of electromagnetic waves is affected by the absorption and reflection of buildings, objects and persons.

IX. LIST OF ACCESSORIES

IX.1 CIRCUIT WITH NEBULISER

ALPHA nebulisation IPPB circuit with nebuliser

Reference: ***KG020900***

ALPHA IPPB circuit without nebuliser

Reference: ***KG021000***

IX.2 FLOOR ROLL STAND

Floor Roll Stand with mounting plate for the ALPHA 300

Reference: ***KC039700***

IX.3 CARRY CASE

Carry Case with shoulder strap and address label for the ALPHA 300 in black

Reference: ***KF007600***

X. MAINTENANCE

X.1 MAINTENANCE FREQUENCY

Warning: All maintenance and repairs must only be performed by authorised trained, qualified engineers.

The ALPHA 300 must be serviced **every year** by a qualified service engineer. A safety check is also conducted on the device.

Note: For more detailed information on the maintenance tasks, refer to the technical Manual.

X.2 LIFESPAN

For safety reasons, all the internal components of the ALPHA 300 are replaced after 12 years.

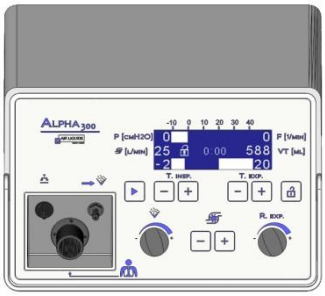
XI. CHECK LIST

Check list for the ALPHA 300 IPPB therapy device.

- It is essential to be familiar with this operation manual.
- When a condition is met, tick the box.

Serial number:

Front:



Rear

Conditions

Visual inspection:	
• Check that the ALPHA 300 does not have any visible damage	❑
• Check that the device is positioned correctly	❑
Preparation of the ALPHA 300:	
• Connect the power cable to the power socket	❑
• Connect the IPPB circuit	❑
• Fill the nebuliser with a medicinal solution if required	❑
Check on operation:	
• Turn on the ALPHA 300 by pressing the ON/OFF button	❑
• Check that the device is working correctly by manually triggering one respiration	❑
• Check all the settings and adjust them according to the patient's requirements	❑
Starting therapy:	
• Therapy starts automatically at the first inspiration	❑
• Respect the maximum duration of continuous use	❑
After one use:	
• Turn off the device	❑
• Respect the required pause stage	❑

Date: **Signature:**

Contact

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