User Manual

smart pft® nebulizer

Nebulizer system for pulmonary challenge testing

It is obligatory to read this manual before using the device

CE 0123

Date of issue: 19.09.2016 UM / NEBULIZER-05-01-01

Preface

We want to thank you for your confidence into our company and products.
We also want to inform you, that our company always tries to keep production standards and product quality as high as possible.
This document is a part of the product according to DIN EN 60601-1 and has to be located near to the device.

Disclaimers

To avoid patient and / or users injury, we point out, that the device may only be used for the specified purpose and only by trained and experienced persons.
We accept no liability for any damage caused by misuse of the device, caused to write and / or semantic errors in this document. Similarly, we assume no liability for personal injury or property damage incurred by use of the device. Any potential liability is limited to the refund of the purchase price.
Contractual pictures, technical specifications and information contained in this manual are furnished for informational use only and are subject to change at any time without a notice.

Copy right

Warranties

The manufacturer offers a warranty of 12 months from the date of purchase for damage to the device on production and / or material defect.

Trademarks

smartPFT, is a registered trademark of Medical Equipment Europe GmbH

Table of Content

Important information for the use of this manual

The information shown in a red window rimmed by the solid line is taken to prevent serious injury or death of patients and / or users.

The information shown in a red window rimmed with a dotted line is observed to prevent patient injury and / or users and / or serious damage to the equipment

Important safety advices

Explosion hazard: The device is not suitable for use in hazardous locations

At all time of the challenge test, the patient has to be under observation and a physician has to be available at any time if necessary.

Standardized protocols

To avoid severe obstruction during the test it is recommended to use only accepted challenge testing protocols. At a minimum it is required that the technician knows the guidelines and is experienced in doing challenge testing. He should know contraindications of challenge testing and should be familiar with safety and emergency procedures.

Before the daily use, the device itself, all connectors, cables and tubes have to be checked. If there is any damage recognizable, the defective parts have to be substituted before using the device again. In case of any questions or uncertainties, a trained and authorized person has to check the device before further use.

At a minimum it is required that the technician knows the guidelines and is experienced in doing challenge testing. He should know contraindications of challenge testing and should be familiar with safety and emergency procedures. The technician also must be aware of the required testing procedures.
It is important to respect, that any kind of provocation drug like Histamine, Methacholine can also affect persons who are located next to the device during the nebulization procedure.

It is not allowed to refill the nebulizer above the device. The housing has an IPX 0 protection class so no liquid may run over it.

ISO Symbols

	A product with this label, is part of the application in accordance with DIN EN 60601-1, type BF
	Attention! Accompanying documents!
IPX0	No protection against dropping water !
	Don`t dispose in domestic waste !
CE 0123	Das so gekennzeichnete Produkt ist konform mit den Richtlinien für Medizinprodukte 93/42/EWG des Rates vom 14.Juni 1993 und dem MPG (1994). Die Nummer ist die Kennnummer der benannten Stelle, welche dies überprüft hat. Dieses Institut ist in diesem Fall TÜV-SÜD Product Service GmbH, Ridlerstraße 65, 80339 München ID N° 0123 / ID 0123 Entsprechende Dokumente erlauben uns, unsere Produkte entsprechend mit dieser Nummer zu kennzeichnen

	This product is produced by: Medical Equipment Europe GmbH Dr. Gerog-Schäfer-Str. 14 97762 Hammelburg Germany

CE marking

Our smart PFT CO nebulizer unit is declared as a class **IIa** device in relation to directives 93/42/EEC annex I.

The following standards are met.

The device fulfill the standards.

EN 60601-1 part I	for electronic safety
EN 60601-1-2 :	for electromagnetic compatibility

The CE product certification was performed by

TÜV-SÜD Product Service GmbH, Ridlerstraße 65, 80339 München
ID N° 0123 / ID 0123

The CE marking includes exclusively the device- and spare- parts listed in the annex.

Magnetic and electric fields can affect function and/or functionality of the device.
When you operate the product, ensure that all third-parties operated devices in the vicinity meet their relevant EMC requirements. X-ray, MRI, radio equipment, cell phones, etc. can interfere with other devices, because they may have approval pursuant to higher electromagnetic interference. Keep a safe distance from such equipment and check the device functions prior to the use in case of such interferences.

The device is suitable for continuous operation.

Manufacturing and service by:

Medical Equipment Europe GmbH
Dr. Georg-Schäfer-Str. 14
97762 Hammelburg
Germany

Setup advices

This device includes a compressor which causes vibrations when running. The device must be placed on a stable table or surface to avoid the risk of falling down during running and to reduce noise caused by vibrations. The device also has to be protected from dropping water IP0 housing class.

Electrical connection

When positioning the device make sure, the power supply cable can be disconnected at any time if necessary to take electrical voltage from the device. The power supply cable may only be substituted by an equivalent one with certificate of approval that fulfills the necessary norms.
Electrical safety class I

Attention: To avoid any risk of an electrical shock, THE CABLE TO LOCAL POWER SOURCE MUST BE EARTHED. Use only cables with valid approval.

Electrical fuses

Fuses required: 1,6 AT.

System changes

No changes are allowed

Storage conditions

Temperature	-20°C to +40°C
Humidity	10%rel. to 90% rel. not condensing
Ambient pressure	700hPa to 1200 hPa

Working conditions

Temperature	10°C to +30°C
Humidity	10%rel. to 90% rel. not condensing
Ambient pressure	700hPa to 1200 hPa

How to dispose the package

We are only using package material that can be recycled. Depending on the country, this kind of material can be given for recycling at the public waste collection. In case of any question, ask your local supplier.

How to dispose the device

Feed the media under the rules applicable to the local waste rules. The equipment, including accessories and empty batteries / batteries do not belong in the garbage, because they are made of quality materials that can be recycled and reused. The European Directive 2002/96/EC (WEEE) required to detect separately the electrical and electronic equipment from unsorted municipal waste, then to feed them to a recycling. The symbol with the crossed out wheeled bin indicates the need for separate collection.

Decommissioning

Special provisions for decommissioning are not to be considered.

Technical data

voltage:	230V AC / 50 Hz
physical dimensions	
length	250 mm
widths	250 mm
height	145 mm
weight	2,9 kg
housing material	steel and aluminum
maximum operating pressure of compressed air chamber	7 bars
minimum operating pressure of compressed air chamber	3,5 bars
compressed air chamber volume	0,6 l
nebulization pressure	2 bars
nebulization time	0,6 seconds
dose per 0,6 seconds nebulization period	10 ± 2 µL Vent. has to be closed !

Scope of supply

N°	article description	quantity
1	Compressor and control unit	1
2	stand with cross arm	1
3	DeVilbiss 646 nebulizer	2
4	mouth piece for nebulizer	2
5	T- valve	2
6	adapter for exhalation filter	1
7	adapter for mouth piece	2
8	power supply cable	1
9	stand for 3 nebulizers	1
10	unser manual	1
11	6mm pressure tube transparent	1
12	3mm silikon tube for inhalation phase recognition	1

Intended use

The device is designed to nebulize a precise dose of liquid provocation products using a standardized nebulizer type to have a particular particle size spectrum for pulmonary challenge testing.

Indications

A history of breathlessness which is not detectable either by physical examination or by a pulmonary function test
Unclear cough after exclusion of other causes for Inadequate shortness of breath during exercise
Expert questions
Occupational health issues Scientific questions epidemiological issues

Contraindications

Moderate or severe airway obstruction

Severe cardiac disorders, especially bradycardic arrhythmias, use of parasympathomimetics

Spirometry induced obstruction

Exacerbations of asthma bronchiale

Severe hypertension

Pregnancy

Missing patient consent

Particular caution is also advised when in the medical history of the patient a status of asthmaticus or anaphylactic shock is given.

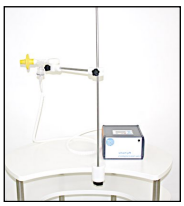
Special advices

Carrying only a doctor's orders
Patient must be informed in detail
Consent of the patient must be given
An experienced physician in emergency medicine must always be near
Emergency medications must be always at hand
Patient must never go unnoticed during the investigation
Be aware of late reactions

How to assemble the device

Remove the packaging carefully and verify no parts are missing or damaged.
Assemble the device step by step using this instruction manual.

1 Place the compressor unit on a stable surface……



2 Fix the clamping piece on a table plate……..……..

3 Mount cross arm and nebulizer adapter to the stand bar……..……

4 Press pressure tube into quick connector of the cross arm from below……..……

5 Press nebulizer potty firmly on top of the quick connector……

Nebulizer connection version I

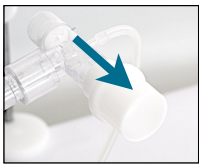
6 connect the mouth piece to one end of the nebulizer……

7 connect the adapter piece to the other end of the nebulizer……

8 connect middle arm of T-valve to the adapter ……

9 connect thinner silicon tube to the tube connector of the T-valve ……..……

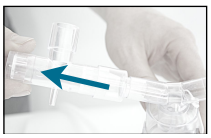
10 set the filter adapter to the end of the T-piece, which is in the direction of arrow.
The arrow can be seen on one side of T-adapter……



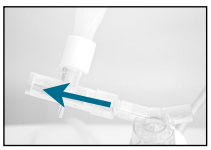
11 connect filter on adapter……

Nebulizer connection version II

6 stuck T-Valve with the arrow pointing away from the nebulizer via the appropriate adapter to one end of the nebulizer.
The arrow can be seen imprinted on one side of the T-adapter.



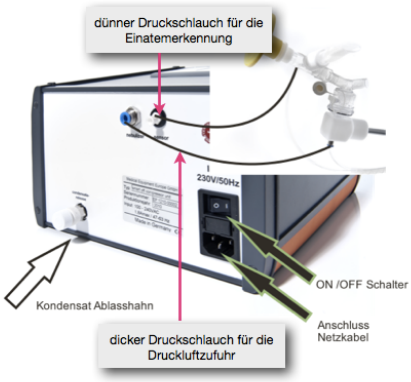
7 connect a mouth piece via a white mouth piece adapter to the middle bar of the T-Valve



8 plug the filter onto the open T-valve end via a filter adapter

9 connect thinner silicon tube to the tube connector of the T-valve

Connect the thicker 6 mm compressed air tube to the correlating fitting at the backplane of the compressor and control unit. Connect in the same way the thinner silicon tube.



Connect power supply cable

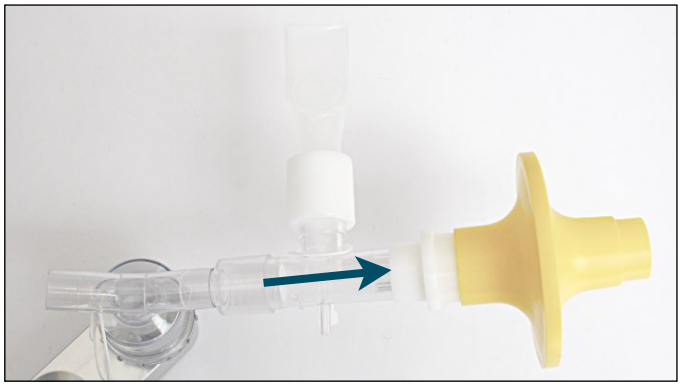
Caution: Do To avoid the risk of electric shock, the device can be connected only to a supply network with protective conductor

Switch device on

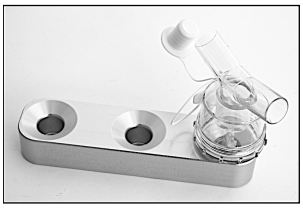
Make sure there is always a filter connected to the exhalation path of the nebulizer system to reduce exposition of the provocation mean.

picture of connection version I

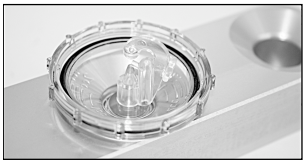
picture of connection version II



The nebulizers can be placed in a massive table holder



The nebulizer can be separated by a thread, the movable fan in the center must be pressed tightly onto the rod.



The literal opening of the nebulizer has to be closed by the white square plug

Marks inside the nebulizer characterize the height tabs for filling.
The nebulizer should not be filled above the compressor unit so that no liquid can be spilled over the device. The device complies with protection class IPX0.

How the device functions

The smart PFT nebulizer system is a microprocessor controlled device with a built in compressor unit in order to allow challenge testing independent from local compressed air sources.

To achieve always a constant nebulization pressure, a built in compressed air chamber is pressurized with a pressure range between 3,5 bars and 7 bars. The pressure is automatically controlled.

This compressed volume allows approximately 7 nebulization steps without switching on the compressor. The system allows nebulization steps also during refilling the chamber.

To keep the output pressure constant at 2 bars, an additional pressure regulator is located at the output flow.

The functionality of the system is based on the Rosenthal Chai dosimeter method to allow international comparisons of test results.

Provocation protocol

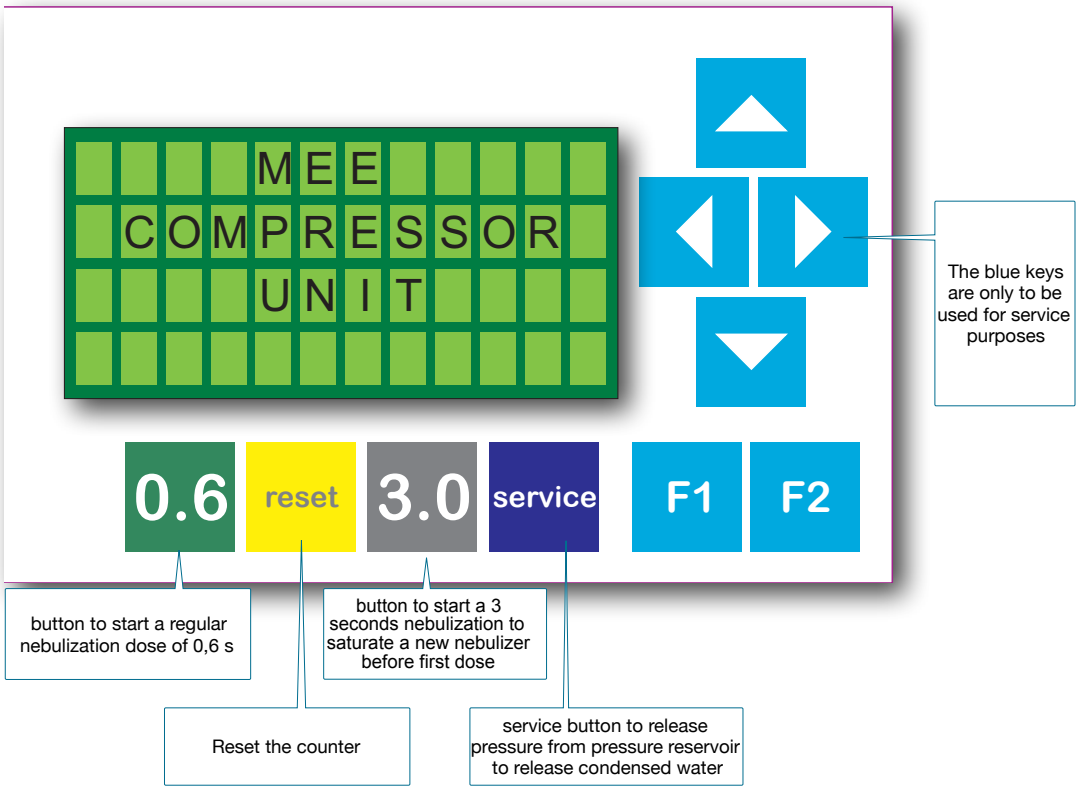
For the procedure of performing a non specific challenge testing the correlating national or international guidelines have to be respected.

References:

Guidelines for Methacholine and Exercise Challenge Testing - 1999
American Thoracic Society :

Leitlinie für die Durchführung bronchialer Provokationstests mit Allergenen
Deutsche Gesellschaft für Allergologie und klinische Immunologie
und Deutsche Gesellschaft für Pneumologie

Device display and control unit

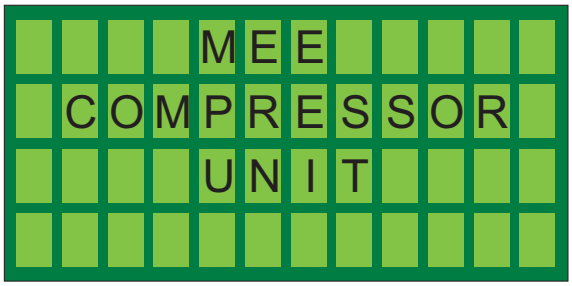


How to use he device

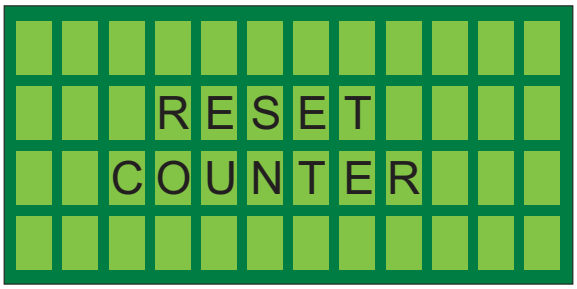
First, a De Vilbiss 646 nebulizer has to be filled with the required concentration of the provocation liquid. Fill in 2 ml to 3 ml solution using an injection syringe

After switching on the device, the init routine takes a few seconds. The device displays the ready conditions.

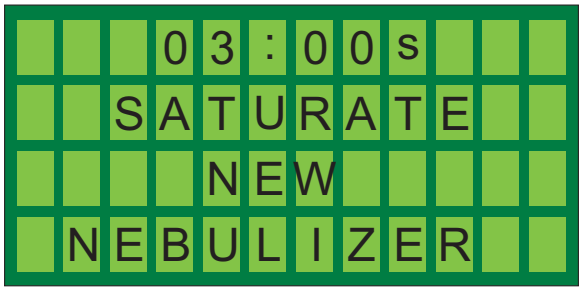
Display after power on



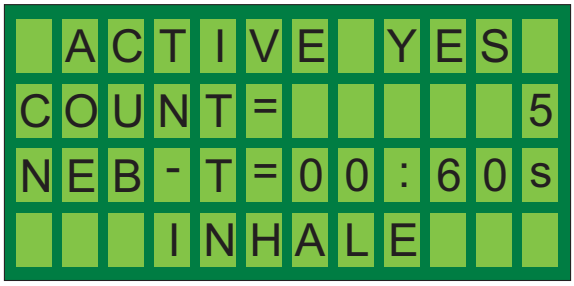
Press the yellow RESET button to reset the counter.



After plugging on a new nebulizer, the gray button named 3.0 has to be pressed to start a 3 seconds saturation procedure.



To initialize a regular 0,6 second nebulization period the green button named 0,6 has to be pressed.



After pressing the green button, the device will start a nebulization after beginning of next inhalation for a time period of 0,6 seconds.

To perform the maneuver correctly, we recommend to advice the patient to exhale deeply first, than the technician presses the green button, advice the patient now to enclose the mouthpiece with the mouth tightly around and inhale slowly up to the maximum. After an air stopping time of approximately 2 seconds the patient should exhale slowly remaining on the device to exhale via the filter.

Thereafter, the patient can leave the mouthpiece and relax with a few breaths in order to inhale the next dose.

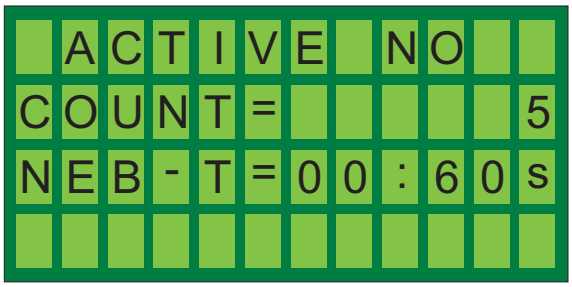
This procedure will be repeated as often the protocol requires.

Please verify when the nebulizer reaches the lower fill mark to refill it again.

Please note, if the patient does not inhale within a time period of 20 seconds after pressing the green button, the nebulization process is deactivated automatically and the button has to be pressed again.

When the required dose is reached, the reaction has to be controlled by either a Flow/Volume and/or a Resistance test.

The display ACTIVE NO indicates, the nebulization trigger is deactivated



After every nebulization, the counter is increased by one to show the number of doses achieved
You can reset this counter by pressing the yellow RESET button

As soon as the pressure in the chamber goes below 3,5 bars, the compressor starts automatically refilling

As soon as the maximum chamber pressure of 7 bars is reached again, the compressor switches off and the display shows system ready conditions.

During the period of compressing air it is possible to continue with nebulization. The pressure is always high enough.

Maintenance, cleaning and disinfection

DGHM approved products tested on the MEE Products for compatibility

product name	PZN	Producer	Comment
SAGROTAN® Desinfektionstücher	4041906	Reckitt Benckiser Deutschland GmbH	
SAGROTAN med Sprühdesinfektion	3911624	Reckitt Benckiser Deutschland GmbH	
Korsolex extra	963678	Bode Chemie	
Endo Star	1291554	Laboratorium Dr. Deppe GmbH	aldehyd free and phenol free

The use of disinfectants influences the material consistency, so a regular calibration and inspection is required.

It is important to ensure that tubes and / or holes are checked after each disinfection treatment. Make sure, there are no water pearls in the tubes. Likewise all tube connectors must be verified. Condensed water in the thicker pressure tube does not influence the system.

When dealing with disinfectant solutions and contaminated parts it is important to follow the guidelines for working protection. Use protecting clothes.

Disinfection of particular components

To avoid cross infections, all part contaminated by patient´s air must be disinfected or substituted after a single patient use. Only cold disinfections are allowed. See the list of approved products in the list above.

It is not allowed to put tubes into the liquid. If there is water in the tubes, blow it out by dry air.

Visible dirt on system components have to be removed mechanically or chemically prior to the disinfection.

The complete system should be disinfected after each daily use preferably by use of disinfection wipes.

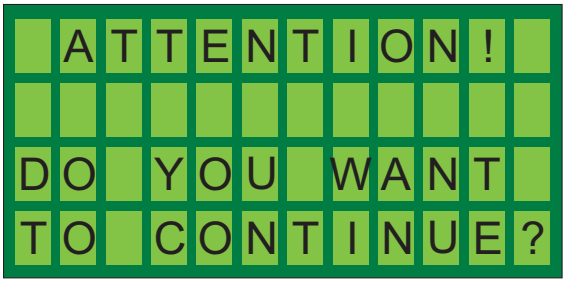
When choosing the disinfection mean please note, the nebulizers are made from sensitive plastic and require soft cleaning and disinfection. Nevertheless all plastic treatments destroy the material after a wile. Check the material after each treatment if there is any damage recognizable and substitute the parts when necessary.

For cleaning of the De Vilbiss 646 nebulizer, the manufacturer recommends only the use of soap water. For disinfection, use a microwave steam sterilizer at 600 watts for minimum 5 mins. Before removing the parts wait until it cooled down for minimum 5 minutes.

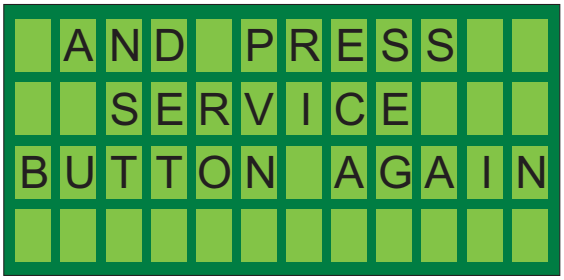
Please avoid the use of alcohol for disinfection of the nebulizer, it destroys the plastic.

Important maintenance and trouble shooting

The system includes a compressor having a pressure vessel. At the end of a working day, the compressor must be depressurized to drain the condensate by pressing the blue colored button „service“. After the button is pressed the following display appears

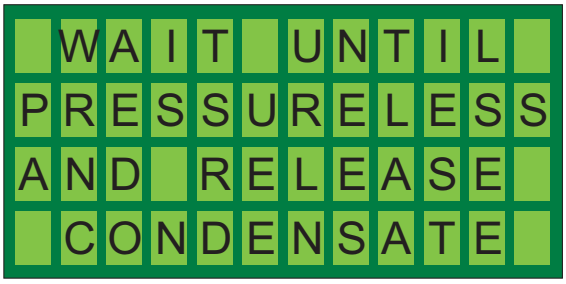


To continue press again the blue colored button



Once the device is without pressure, open the screw on the stopcock to drain the pressure chamber. Please collect the flow of condensed water in a cup. Then close the stopcock again and press the blue colored button again.

Turn off the system at the end of the working day



The system requires qualified service procedures each 24 months.

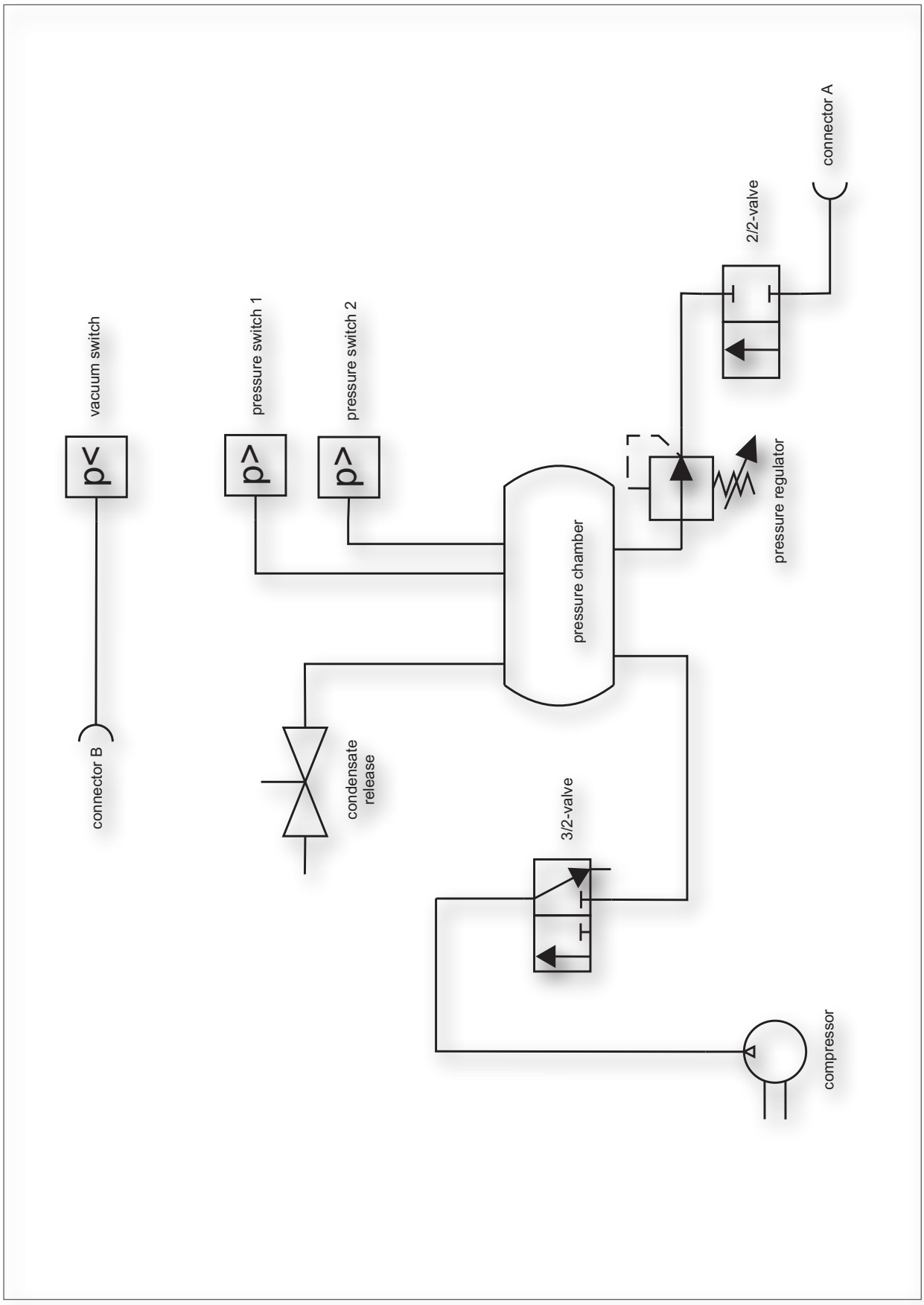
Possible faults and their elimination

error description	cause	how to check	fixed by
Device don´t start	no electrical energy	check power supply source	by qualified in house technician
	device is switche off	check if power lamp on device front penal is lightning	user
	fuse of net filter is defect	replace fuse by equivalent type and size	qualified in house technician
	power supply plug not connected	check if power supply line is tightly connected at both ends	user
	other reasons	by manufacturer or qualified service partner	by manufacturer or qualified service partner
after pressing the 0,6 seconds button, the system does not nebulize during inhalation	the thin silicon tube is not connected either to the T-valve or the backplane of the compressor unit	check connection at both sides of the silicon tube	user
	there are water pearls in the silicon tube	optical check of tube, replace tube if necessary	user
	the patient inhales too slowly	instruct patient	user
	T. Valve direction wrong	check direction of arrow on t-Valve and change if necessary	user
	pressure sensor disadjusted	if all other reasons are not relevant	by manufacturer or qualified service partner
The compressor is always running	the stopcock for draining the compressed air chamber is opened	close the screw on the stopcock of the pressure chamber on the backside of the device	user
	leakage in the system	by manufacturer or qualified service partner	by manufacturer or qualified service partner
unknown defect	unknown	by manufacturer or qualified service partner	by manufacturer or qualified service partner

Maintenance, STK, MTK

maintenance plan smartpft nebulizer				
kind of task	performed by	maintenance period	obligatory	only with certificate
release condense water	user	1 x per month	x	nein
cleaning and disinfecting the system	user	after every use	x	nein
optical control of compressor unit	user	1x per 3 months		nein
check if tubes are damaged	user	1 x per month		nein
check tube connectors	user	1 x per month		nein
check electrical connectors and wires	user	1 x per year	x	nein
check De Vilbiss nebulizer for cracks or damage	user	before every refilling		nein
STK	qualified service person	1 x per 2 years	x	ja
MTK	qualified service person	1 x per 2 years	x	ja

Pneumatic Diagram



Electronic Diagram