Spire™
INSPIRING RESPIRATORY HEALTH

ZAN200 ProvAir

User Manual

Part Number : 5001002US

Version / Revision : A

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Manufactured for	**nSpire Health Inc** 1830 lefthand Circle, Longmont, Colorado, 80501, USA	Tel: 1.800.574.7374 Email: **sales@nspirehealth.com**
Authorized Representative	**nSpire Health Ltd** Unit 10, Hartforde Court John Tate Road Hertford, SG13 7NW U.K.	Tel: (+44) (0) 1992.526.300 Email: **info@nspirehealth.com**
	nSpire Health GmbH, Schlimpfhofer Strasse 14 D-97723 Oberthulba Germany	Tel: (+49) 097.36.8181.17 (+49) 097.36.8181.27 Email: **zan@nspirehealth.com**

Preface

Thank you for purchasing the ZAN200 ProvAir II system.

The product complies to the newest state of technical development. In order to improve the lifetime of this product, only materials of extremely high quality are used. All materials are environmentally safe and can be recycled.

The manual provides instructions for operating the ZAN200 ProvAir II system.

The instructions in this manual assume the user is familiar with the intended use and application of pulmonary-laboratory systems.

To avoid damage to the devices or incorrect measurement, it is strongly recommended to follow the introductions in the manual and the technical description.

This manual is seen as part of the product, according to DIN EN 60601-1 :1996. It should be kept near to the device. Additional safety hints, according to German Medical Products Law, can be found in chapter 5 "Safety, Maintenance, Service".

nSpire Health GmbH

Documentation Conventions

The following format conventions are used in this document to identify special information:

Warning: statements identify conditions or practices that could result in personal injury.

Caution: statements identify conditions or practices that could result in damage to equipment or loss of data.

Note: The graphical illustrations in this document are for example purposes only and the hardware illustrated may differ from your hardware.

Safety Precautions

a. Connect the power cord for each individual component to a wall source.

b. Do not connect extension cords to the system.

c. Do not use multiple power strips; and only use the power strip that is supplied by nSpire Health.

d. Operate the hardware device only when the power cords are plugged into "U" grounded outlets (3-hole outlets).

e. Unplug the power cords prior to servicing the equipment.

f. Computer, monitor, printer, and testing unit are components fit for use within the patient environment, provided external grounding has been implemented as per instructions.

g. The User/Operator must not touch any non-medical device (that is, any device other than the testing unit) and the test subject at the same time.

h. The ZAN hardware (ZAN100 USB) has been tested and meets the latest EMC requirements for immunity and emissions of IEC 60601-1-2. However, electromagnetic interference may still be encountered. If the device is behaving erratically due to electromagnetic interference, contact nSpire Health customer support.

i. Do not connect items that are not specified as part of the ZAN hardware (ZAN 100)

j. Do not operate the ZAN hardware (ZAN100 USB) or other system components on any voltage other than that specified.

k. All flammable materials must be kept away from the equipment and “No Smoking” signs must be prominently displayed in the testing area.

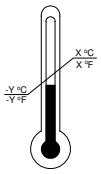
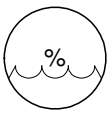
l. Oil and grease must be kept away from oxygen equipment.

m. Oxygen-approved regulators must be used for O_2 tanks.

n. The equipment is a Type IIA device that requires the use of a 3-wire Type I cord-set.

o. According to good hygiene practices, filters and/or mouthpieces that came into direct contact with the subject's mouth or aerosolized droplets from the subject's effort should not be touched. Dispose of filters and mouthpieces as ordinary waste, or as specified by your institution.

Labeling Glossary

Glossary of Common ISO Symbols[1]			
	High Voltage		Item for single use (do not use more than once).
	This symbol indicates that the user must read and understand all instructions and warnings prior to use.		Acceptable Ambient Temperature Range: Indicates the upper and lower temperatures allowed for transport and storage.
	Protective earth ground		Indicates the date by which the product must be used, in the format Year.Month.Date (e.g., 2005.02.19)
	Type B Equipment: Equipment providing a particular degree of protection against electric shock, particularly regarding: allowable leakage current and reliability of the protective earth connection (if present).		Heavy weight.
	Alternating current		Fragile.
	Direct current		Keep Dry.
	Power on		Transport and storage humidity conditions.

[1] International Standard, CEI IEC 417P, Graphical symbols for use on equipment, first edition, 1973

Glossary of Common ISO Symbols[1]	
CE 0535 This symbol indicates that this Class IIA equipment complies with the guidelines concerning medical devices 93/42/EEC of the council from 14.Jun 1993.	Power off.
Fuse	This symbol indicates that the associated jack is for a USB (Universal Serial Bus) connection.

CONTENTS

1 Preparation

1.1 General Information about the ZAN200 *ProvAir II*

The medical product ZAN 200 ProvAir II is a current based compressor in a compact desktop case with respiration recognition and remote control. A nebulizer nozzle is connected to the compressor for provocation testing.

The DeVilbiss 646 nebulizer is used as a standard nebulizer. nSpire Health GmbH will adjust it to a defined nebulization capacity in order to guarantee the comparability of the provocation results as it has been proved in international studies.

The recommended standard provocation method according to Chai 1975 is easy to perform using this device. The automatic respiration recognition and a assured nebulization period of 0,6 sec help to get best results.

The preferred usage of ZAN200 ProvAir-II is clinical lung function diagnostics in pulmological offices and clinics. It can be used both for in-patients and out-patients.

Particular advantages of the ZAN200 *ProvAir II* are:

- It can be used both for in-patients and out-patients.
- The device is ready for operation with 6 seconds after power on.
- The automated inspiration recognition allows defined nebulization during the inspiration.
- The remote control with a counter makes provocation easier.
- The calibrated nebulizers control exactly the doses of nebulized provocation medication.
- The compressor is integrated in a compact desktop case.
- The nebulizer/dosimeter system is designed as plug in components, which provides easy disinfection and quick exchange of replacement parts.

1.2 Safety Precautions

Warning

A doctor or qualified and experienced physiologist must be available during every provocation test.

We strongly recommend that medication and equipment to treat even severe bronchospasm are to hand.

Provocation solutions are drugs which have the potential to trigger hyperreaction and allergic reactions. A successfully performed provocation test in the past allows no prediction about the course of the current test.

In no event will nSpire Health LLC be liable for any damages, harm or other consequences by the use of medications or the correctness of the delivered protocols.

1.3 Operating environment

Following requirements for operating and storage should be observed:

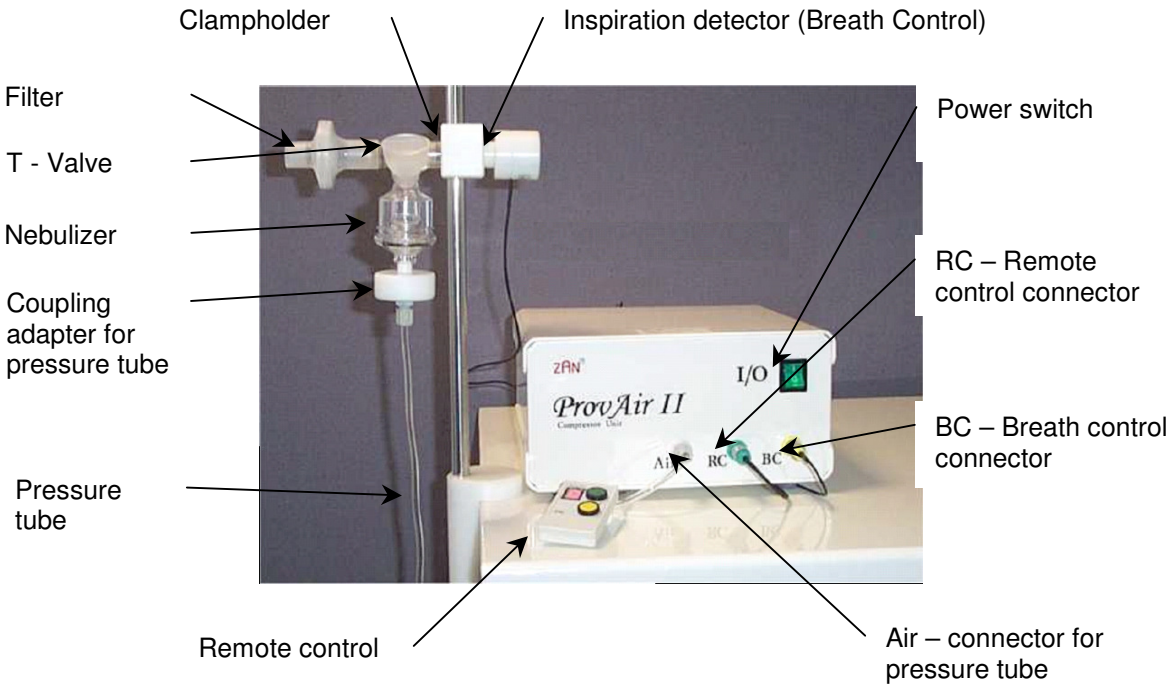
- Room temperature between + 10° and + 35 °C
- Relative humidity between 20% and 80 % without condensation
- Stable environmental conditions, no sudden temperature or humidity changes
- Do not expose the parts to direct sunlight, chemical products or vibration
- Never operate the devices outdoors or in an environment which is endangered by explosions.

2 Start-up

2.1 Selecting the Location

The ZAN200 device needs a solid base to be mounted on. It has to be placed in a way that vibrations created by the compressor should be damped and can not cause damage or irritations to other equipment. The device should not be placed close to other devices, which are sensitive to vibrations.

2.2 Overview



2.3 Assembling the Device

1. Mount the stand on the desktop plate with a clamp
2. Put the inspiration recognition unit into the compatible hole on the side of the moveable clamp adapter. Push the t-valve IN-EX into the other side of the adapter so that the arrows point away from the clamp.
3. Connect the filter to the t-valve; make sure that the arrow shows towards the filter.
4. Connect the respiration recognition unit to the BC socket of the compressor unit.
5. Plug the remote control unit into the *RC* socket of the compressor..
6. Connect the pressure tube to the front panel of the compressor unit.
7. Connect the coupling adapter for the pressure tube to the bottom of the nebulizer.
8. Connect power supply to the back of the compressor unit and plug it into a socket that complies with the electrical specifications.

Warning **The current voltage must comply with the voltage indicated on the device plate.**

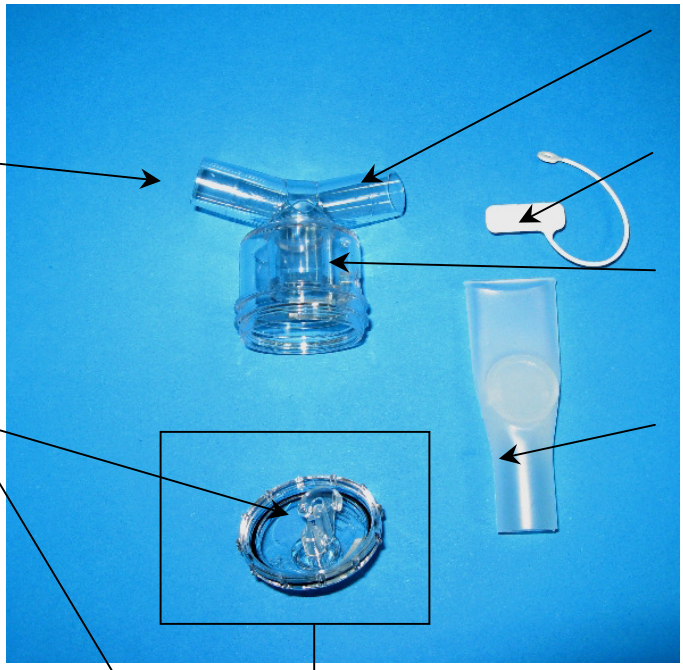
Attention All plugs and socket connectors are color coded for ease of assembly. Please pay attention to the particular color markings.

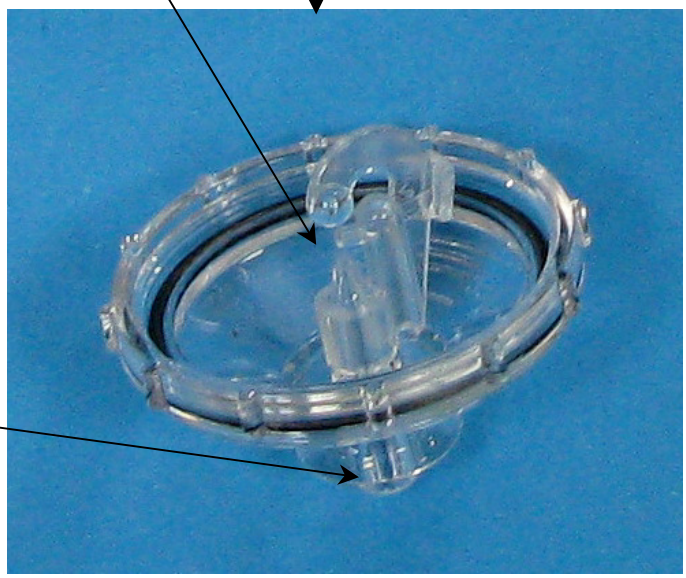
2.4 Assembling the DeVilbis 646 Nebulizer

The DeVilbiss 646 nebulizer consists of two parts; upper and lower. It can be screwed apart.

The upper part provides connections for the mouthpiece, the T- valve and the VENT opening. If left open, the nebulizer draws additional air through this opening. The nebulization capacity will be reduced to about 5 µl when the vent is closed.

Disassembled nebulizer





Bottom part

Complete assembled nebulizer with locked Vent

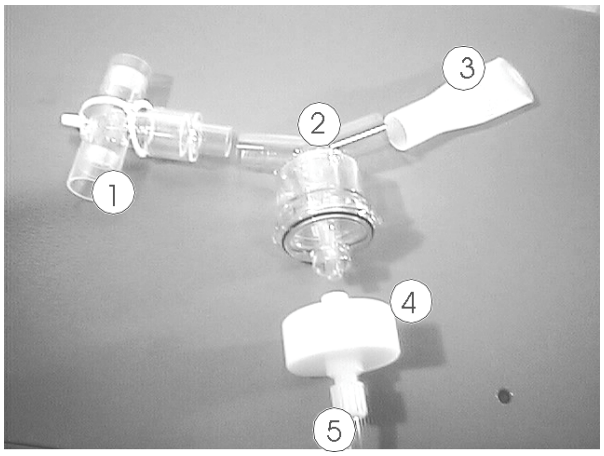
In the bottom part, there is a reservoir for liquid, a nebulization nozzle and a pressure adapter connection.

Note Please use only a calibrated nebulizer. You can identify a DeVilbiss 646 nebulizer calibrated for the ZAN200 ProvAir by the yellow label on the nebulizer top. The nebulizer is calibrated to provide an output of 14mg/ml

Be sure to maintain and carefully clean the nebulizer so that correct delivery of doses is continued.

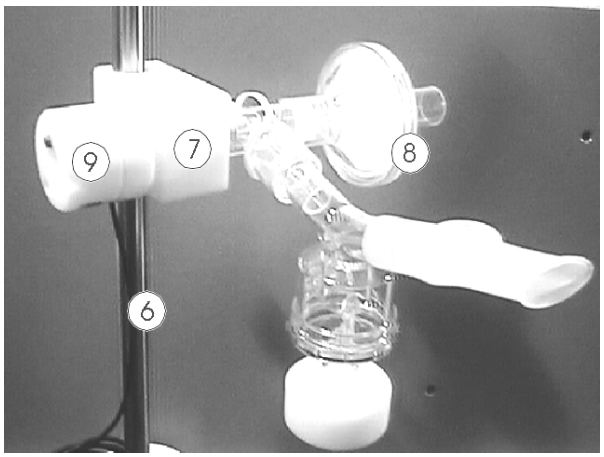
2.5 Assembling the Provocation System on the Stand

1 T-valve
2 DeVilbiss 646 Nebulizer
3 Mouthpiece
4 Coupling adapter for pressure tube
5 Pressure tube



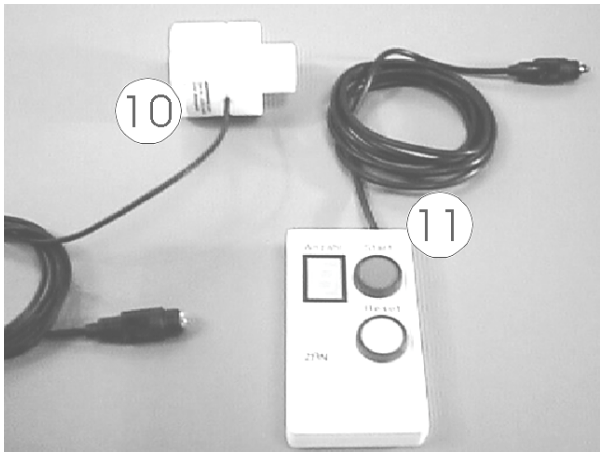
Picture 1

6 Stand
7 Clamp holder
8 Filter
9 Inspiration detector



Picture 2

10 Inspiration detector
11 Remote control



Picture 3

Assemble the separate parts according to the Picture 1.

Note **The arrow on the T- valve must show towards the respiratory filter.**

- Fix the assembled nebulizer to the stand (Picture 2)
- Plug the remote control into the 'RC' socket of the device.
- Plug the respiration recognition into the 'BC' socket of the device.
- Connect the other end of the pressure tube to the 'Air' socket of the device.

2.6 Start up

The device is turned on with the '0/I' switch on the front plate. When the switch is illuminated, the device is running. The remote control display shows a '0' (zero).

The compressor will first build up the appropriate pressure for nebulization, which usually takes 6 seconds after which the compressor is ready for use.

Note: If the compressor is turned off and turned on again in a very short time, it may not start up again. If so, disconnect nebulizer and press reset on the remote control. This releases air to reduce the pressure and the compressor will restart.

Once it has started, press the reset button again to stop the pressure falling any further.

Reconnect the nebulizer

Wait for 6 seconds for the operating pressure to again be reached before continuing with nebulizations.

2.7 Controls

On the remote control is a green 'Start' button, a yellow 'Reset' button and the numeric display.

Start Button: This button triggers the nebulization. Once pressed, the nebulizer is activated during the next inspiration for 0.6sec. After the nebulization, the counter increments by one.

Reset Button: Use this button to reset the counter.

Numeric Display The display shows the count of the nebulizations.

It is a single digit display with numbers from 0 to 9. The next count after 9 is zero. If another nebulization is triggered, the display will turn off.

It is possible to carry out further nebulizations but when using the DeVilbisss 646 nebulizer but they will no longer be precise for reasons outlined in chapter 4.2

3 Nebulization

3.1 General Information about Provocation Tests

The ZAN200 allows a simple course of provocation tests like that described by H. Chai (1975). Numerous national and international authors describe this method as standard and as a reliable method of provocation testing.

Another commonly used protocol is the 5 breath dosimeter protocol. In this protocol the patient takes 5 breaths (from FRC to TLC) of known concentrations of a provocation agent. At certain time points, 30s and 90s after the end of the fifth breath, the FEV_1 is recorded. If the FEV_1 has not dropped from baseline by 20% an increased concentration of provocation agent is used for the next 5 breaths. For consistency, there should be 5 minutes between delivery of the provocation agent. See appropriate literature for protocols.

3.2 Loading and Handling the DeVilbis 646 Nebulizer/Dosimeter

The DeVilbiss nebulizer is calibrated by nSpire Health so that it consistently delivers 14mg of isotonic NaCl solution on every nebulization (which is equivalent to a volume of 14µl of a liquid with the same density and viscosity) . This is based on a particular quantity of solution, 2ml, being used each time. A deviation from 2ml leads to either a decreased or increased nebulization capacity. 2ml is enough for 10 nebulizations, after 10 the nebulizer must be refilled.

The solution is held in the lower half of the nebulizer. First, unscrew the nebulizer, fill with 2ml of solution and then screw the top and bottom pieces together.

The nebulizer with the mouthpiece in place should be pressed into the T- valve. The pressure tube with the coupling adapter can then be fixed to the connector on the bottom of the nebulizer.

Remark: Although only 14 µl of liquid is administered to the patient on each nebulization, 1ml of liquid is lost after 10 nebulizations. The rest of the liquid is spread over the inside of the nebulizer housing. This condensation is not longer available for neblisation but can reach the mouth of the test person if the amount gets to much. It is therefore

3.3 Respiratory Maneuver

Note **The use of noseclips is strongly recommended.**

The patient should form a tight seal around the mouthpiece with his or her lips and breathe tidally.

When ready for the nebulization, press the Start button. On the next breath the nebulizer will deliver for 0.6s and the counter will be increased by 1.

Repeat until the desired number of nebulizations has been reached then wait until the required time has elapsed before performing measurements.

If necessary, repeat this process.

4 Security and Maintenance

4.1 Security Advice

Note This manual conforms to EN 60601-1. According to these regulations, the operator of the ZAN200 ProvAir II is fully responsible for the maintenance and condition of the device.

Note Warranty by nSpire Health is restricted and depends on:

- only authorized personnel making changes, extensions, repair and other installations on the device;
- the device being used according to its functional purpose;
- regular maintenance being carried out;
- the electrical installation in the room in which the device is operated complying to requirements of VDE0107;
- User manual and technical manual being observed.

Attention

Please read the following carefully. It provides important information about security, use and maintenance of this device.

- Do not wash or submerge the device in water or cleaning fluids.
- Do not touch electrical contacts or stand alone parts. Do not insert objects into openings which are not declared as plugs or connectors.
- Do not hang wires over edges.
- The device may only be connected and operated according to this User Manual.
- Do not operate or power devices with obvious damage.

4.2 Type Plate of ZAN 200 ProvAir-II Compressor Unit

4.2.1 Assembly of the Serial Number:

- 1. Digit denotes the year.(e.g. 9 for 1999)
- 2-4. Digits designate a product specific tag (e.g. 201)
- 5-7. Digits built a sequence number (e.g. 100)

4.2.2 Explanation of All Symbols and Warning Advices

This symbol indicates the patient applied part is type BF.
It is isolated from the mains supply according to the standard EN 60601-1.

Caution! Read and understand associated documentation.

IPX0 No protection against condensed water

0535 This symbol indicates that the product complies with the European Union Medical Device Directive.

This number is the identification number of the institute that checked this device. In this case it is the Institute Eurocat Company, Arheiliger Weg 17, D-64380 Roßdorf by Darmstadt. The corresponding Certificate that legitimates using such a sign on our products can be produced on request.

2 X 0,8AT

Fuse parameters = 0,8 Ampere, slow(in both fuse cartridges of the line filter).

ZAN
nSpire health GmbH
97723 Oberthulba
Ser.Nr.: 204 - 9001

4.3 Type Template of the ZAN200 ProvAir II Nebulizer Type: DeVilbis 646

The DeVilbiss 646 nebulizers, adjusted by nSpire Health have this label.

204 is ZAN article number for the DeVilbiss 646 nebulizer
9 is the year of production (Here 1999, 0 is for 2000 etc.)
001 is the serial number.

4.4 Electromagnetic c

- The EMC test is based on a noise immunity level of 3V/m. The device must not be operated in an environment with a higher level.
- The device must not be operated near high power installation.
- Powerful transmitting equipment must not be present in the proximity of the device.

4.5 Calibration / Maintenance

4.5.1 Compressor Unit ZAN 200 with Flow Sensor and Remote Control

ZAN 200 ProvAir II (directly connected to main current, metal case, SK1 device)

Lifetime: The compressor unit is designed for appr. 3000 hours operating time.

Since remote control and breath sensors do not contain mechanical parts, their lifetime is limited by the endurance of their electronic parts as well as the lifetime of the compressor pump only. Assuming appropriate use and maintenance a lifetime of 10 years and more can be expected..

Recommended Calibration: after 1 year
(assumed appropriate use)

The compressor provides a defined pressure according to its technical data, as well as a defined output and nebulization time. During calibration all the parameters are tested and adjusted if necessary. Additionally the overall condition of the device is tested and adjusted if necessary.

Maintenance: once every year

All medical products should be checked for function and safety within appropriate intervals

nSpire Health recommends a check of the compressor unit, the breath sensor and the remote control at least once a year.

During the maintenance all the technical as well as the functional, safety and measuring properties of the ZAN200 Prov Air-II will be checked and adjusted if necessary.

Important parameters are, for example, operating pressure, output, insulation resistance, protective conductor resistance and discharge current.

Only nSpire Health is able to perform the maintenance for measurement.

The proper nebulization capacity requires a calibrated nebulizer as well as correct compressor pressure and nebulization period. Incorrect parameters will lead to wrong measurement results.

4.5.2 ZAN200 Nebulizer Type DeVilbis 646

Lifetime:

nSpire Health calibrates every DeVilbiss 646 nebulizer before delivery in a way, that 14 mg +-1 mg isotonic NaCl solution will be nebulized on every actuation. The straw and baffle of each nebulizer are securely fixed during the calibration.

If used correctly, this device works virtually without any loss.

However, the position of the baffle over the straw may change during use (mechanical stress etc.). Also, the nebulization capacity could be reduced if the nebulization nozzle is obstructed. For those reasons, nSpire Health recommends calibrating the DeVilbiss nebulizer regularly.

Calibration:

Calibration is recommended after approximately 100 measurements or one year (assuming proper usage).
Calibration makes sure that the required nebulizer output of **14 mg** isotonic NaCl solution will be created on every nebulization process (which **is equivalent to a volume of 14µl of a liquid with the same density and viscosity**) with open vent.

A standard method must be used to carry out the reproducible calibration. 10 nebulization cycles with 0.9% sodium chloride solution will be performed according to the method used by nSpire Health. The nebulizer will be weighed on a precision scale before and after the nebulization. This infers the nebulized quantity of every nebulization.

This quantity must be 14 mg +-1 mg.

Since there is no way to adjust the output of the nebulizer once the straw and baffle have been fixed, the device must be exchanged if the nebulized quantity is more or less than specified.

Important: Calibration is strongly recommended.
If the nebulizer output has changed, for example because of damage, precise doses will not be delivered and the accuracy of the measurement will be compromised.
Calibration is the only way to ensure the nebulizer is functioning correctly.

5 Consumer Parts, Spare Parts

Part Name	Art.No.
Stand ZAN200	1300205
ZAN200 ProvAir II compressor unit	1300220
Power cable	9300497
Remote control	1300222
Respiration recognition	1300221
Tube coupling	1100004
Pressure tube	1300563
T- Valve IN-EX with reducer	9300411
Calibrated nebulizer top DeVilbis 646 with mouthpiece	1300204
Breath filter	9300410
User Manual ZAN200 ProvAir-II	1300000
Technical Description ZAN200 Prov Air II	

6 Technical Data

Model Type	ZAN 200 ProvAir II
Electrical Specifications	
Protection class	SK1
Classification	IIa
Typ (IEC 601-1)	BF
Power supply	230V AC 50Hz
Current reception	0,6A max. (recommended 0,5A)
Protection type	IPX0
Environmental Conditions	
Operating conditions	Temperature: +10°C to +35°C Humidity: 20% to 80% (no condensation)
Storage conditions	Temperature: 0°C to +35°C Humidity: 20% to 80% (no condensation)
Physical Specifications	
Operating pressure	2,0bar ± 5 %

Flow by operating pressure	7 l/min ± 5%
Inspiration recognition	automatic
Nebulizing time	0,6sek
Nebulizer type (standard)	DeVilbiss 646
Average particle size of the standard nebulizer	5 µm
Nebulizing capacity	14 +- 1mg/shot calibrated for 10 nebulizations with phys. NaCl
Weight	5,5 kg
Dimensions in mm (w / h / d) (Compressor unit)	280(b) 150(h) 270(d)

7 Disinfection

7.1 Nebulizer, Mouthpieces, T- valve

Caution: **To avoid cross contamination with medical devices, directly contaminable parts must be disinfected after each patient.**

Nebulizer pots, mouthpieces and T-valves will be contaminated by patients' breath and test drugs. They must be cleaned after every use. The recommended method of cleaning is cold sterilization.

Deposits on the nebulizer, particularly on the nozzles, can affect the nebulizer output. Therefore it is prudent to use only cleaning agents and disinfectants that do not leave deposits. (It is possible to clear such depositions in an ultrasound bath.)

Do not use substances that may cause damage to the plastic parts.

Always rinse all parts in demineralized water after disinfection

Caution : **Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.**

Note : **Visible dirt must be removed before immersion in disinfectant.**

7.2 Expiration Filter

The expiration filter is in a one-way circuit and will be disposed after usage.

7.3 Compressor Unit

The electrical parts are safely enclosed in the case. The devices and their components (remote control, inspiration recognition) must not be immersed in any solution nor exposed to spray water.

The modules can be cleaned with a piece of cloth that has been moistened in soapy water. Make sure that no moisture gets inside or on the contacts of the device. This could lead to short circuits or shock hazards and the contacts may oxidize.

Dirt on the stand can be cleaned the same way, followed by use of a disinfecting spray.

Dirt on the stand can be cleaned the same way, followed by use of a disinfecting spray.

Warning: **The ZAN electronic modules are not protected against harmful ingress of moisture. Before cleaning the surface, please unplug the device.**

Important: **Make sure that no moisture can enter the device. This could lead to short circuits or shock hazards and the contacts may oxidize.**

There is a outlet faucet on the back of the compressor unit to release water. Please open the faucet every 4 weeks and drain the water. Close the faucet carefully.

8 Provocation Course

8.1 Standard Procedure according to Chai and Al

- Metacholin concentration from 0,1 to 8mg/ml
- Doubling of the concentration between the stages
- 5 inhalations per stage
- Wait 2 min between each stage

Lit.: ChaiH, Farr RS, Froelich LA, Mathison DA, Mc Lean JA, Rosenthal RR, Scheffer AL, Spector SL, Townley RG, Standardization of bronchial inhalation challenge procedures. J

Allergy Clin Immunol 1975; 56 : 323-327

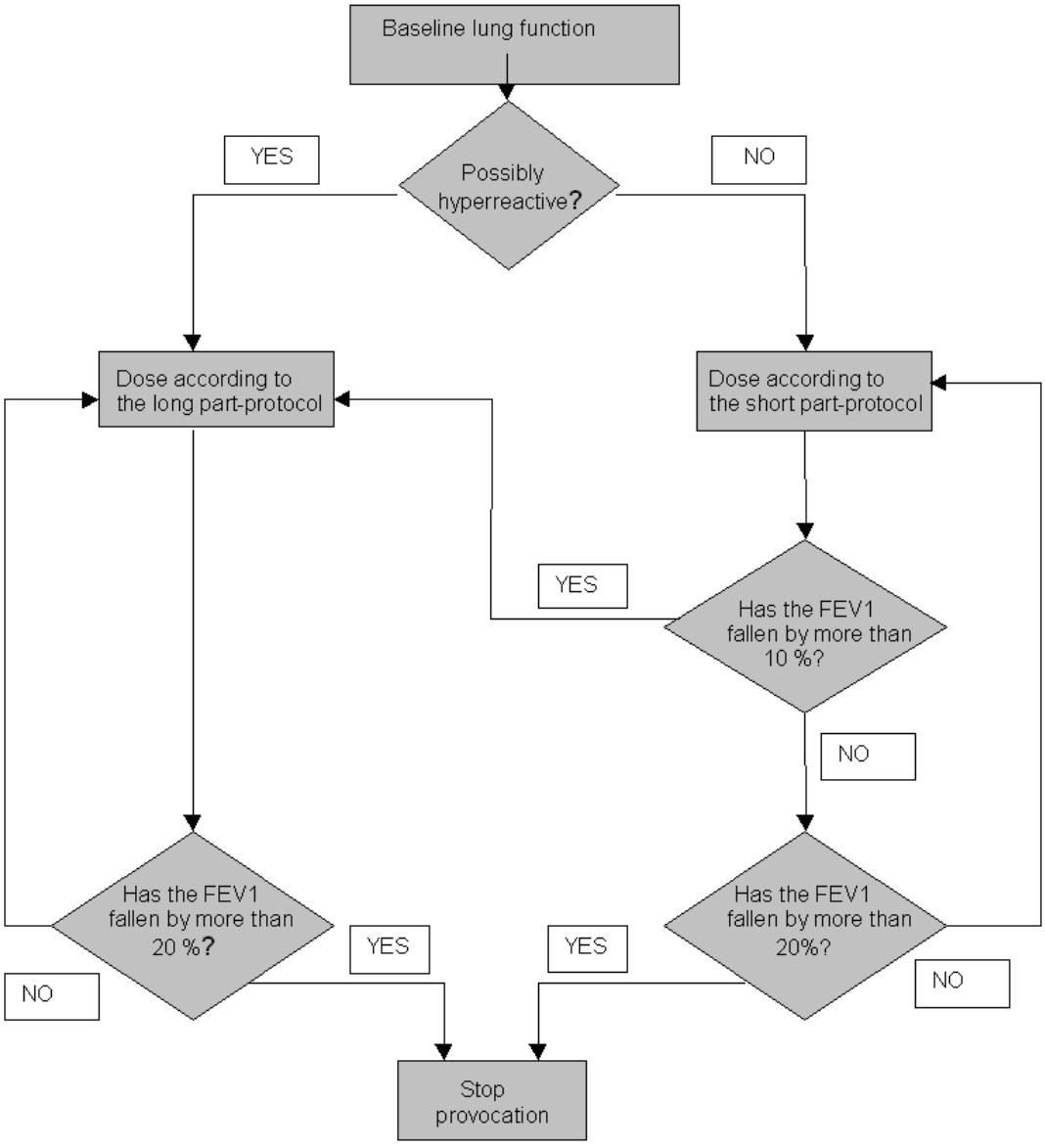
8.2 Short Procedure of Metacholine Provocation

- Metacholine concentrations 0,04 to 10,67 mg/ml
- Double (or quadruple) of the concentration between the stages
- 5 inhalations per stage
- Wait 2 min between each stage

Lit.: L. Grönke, D. Nowak, R. Jörres, H. Magnussen: Entwicklung und Validierung eines Kurzprotokolls zur inhalativen Metacholinprovokation bei epidemiologischen Studien.

Atemwegs- und Lungenkrankheiten 21, 320-321 (1995)

8.3 Flow Chart for Provocation Course



8.4 Metacholine Provocation Check List

1	Have you, in the last 12 months, been out of breath when at the time, you still had a cold, a whistle or a drone in your chest?	Y	N
2	Have you, in the last 12 months, been short of breath during the day while resting?	Y	N
3	Have you, in the last 12 months, been woken up by coughing?	Y	N
4	Have you, for 3 or more months during the last year, had a productive cough (i.e. a cough that produces phlegm)?	Y	N

8.5 Analysis for Metacholine – Provocation

ID:_____

Date of birth: _____ Name: _____

1. Carry out the basic measurement FEV1 through.

N°	FEV1[l]		
1	,		
2	,		

2. Measure the FEV1 after the inhalation of 3 inspirations NaCL solution.

N°	FEV1 [l]		
1	,		
2	,		

3. Calculate the theoretical value of the FEV1.

Theoretical value of the FEV1 [l]	,		

4. Calculate the FEV1 as per cent of the theoretical value.

Best FEV1 [l]	,		
Theoretical value of the FEV [l]	,		
FEV1 is/ FEV1 theo[%]	,		

5. Transfer the questionnaire.

Every question answered with “yes” has a certain value in column 4.

Question	No	Yes	Valuation
FEV1< 90 % theo			1
FEV1 < 75 % theo			1
1			1
2			1
3			1
4			-2
Sum			

When the total value is 2 points or more, carry out the provocation according to the long part-protocol.

6. Calculate the 80 % FEV1 value and with a short part-protocol provocation - the 90 % FEV1 value.

80 % of FEV1	,		
90 % of FEV1	,		

	Short part-protocol	Long part-protocol	1. FEV1			2. FEV1		
1	-	2 AZ from conc. 1	,			,		
2	6 AZ from conc. 1	4 AZ from conc. 1	,			,		
3		2 AZ from conc. 2	,			,		
4	6 AZ from conc. 2	4 AZ from conc. 2	,			,		
5		2 AZ from conc. 3	,			,		
6	6 AZ from conc. 3	4 AZ from conc. 3	,			,		
7		2 AZ from conc. 4	,			,		
8	6 AZ from conc. 4	4 AZ from conc. 4	,			,		
9	6 AZ from conc. 5	2 AZ from conc. 1	,			,		

conc. x: concentration in accordance to mixing instructions.

When the FEV1 falls to 90% of the baseline value in short protocol, carry out the further provocation from the next stage of the long protocol.

When the FEV1 falls to 80 % of the basic value or application of the 9th dose, the provocation should be stopped.

7. When the FEV1 falls to 80 % or less, give 2 puffs salbutamol and 20 mins repeat the measurement. The FEV1 should return to baseline.

1. FEV1 [l]	,		
2. FEV 1 [l]	,		

8. Calculate the PC20 FEV1

8.6 Mixing Instructions

Mix 800 mg metacholine with 30 ml isotonic NaCL solution. This volume is enough for ca. 10 provocations.

This main solution corresponds the concentration number 5. Mix now 0,7 ml in 2,1 ml solution and you will get the concentration number 4.

Proceed in the same way until you get all five concentrations.

Concentration number	Isotonic NaCL solution	
5	-	2 ml main solution
4	2.1 ml	0,7 ml of main solution
3	2.1 ml	0,7 ml of the concentration 4
2	2.1 ml	0,7 ml of the concentration 3
1	2.1 ml	0,7 ml of the concentration 2

Table 1: Instructions to producing Metacholine solution.

Only 2ml of each concentration is needed for the nebulizer.

8.7 Overall view of the concentrations for the calculation of the PC20 FEV1

Step	Concentration [mg/ml]	Breathing Part-protocol		Concentration [mg/ml] calculated for 5 breaths Part-protocol		Doses Cumulated Doses [µg]	
		short	long	short	long	short	long
1	0,104	-	2	-	0,04	-	2,9
2	0,104	6	4	0,125	0,08	8,7	8,7
3	0,42	-	2	-	0,17	-	20,5
4	0,42	6	4	0,5	0,34	44,0	44,0
5	1,67	-	2	-	0,67	-	90,8
6	1,67	6	4	2	1,34	184,3	184,3
7	6,67	-	2	-	2,67	-	371,1
8	6,67	6	4	8	5,34	744,6	744,6
9	26,67	2	2	10,67	10,67	1491,3	1491,3

8.8 Calculation of the PC20 FEV1

To calculate the PC20 FEV1 you need the values of FEV1 before and after reaching a 20% fall of the FEV1 as well as the concentration of Methacholine of the corresponding stages, which you can take out of the Table 2.

$$PC20 = antilog\left[logC1 + \frac{(\log C2 - logC1)(20 - R1)}{R2 - R1}\right]$$

where

C1 = second to last methacholine concentration

C2 = final concentration of methacholine

R1 = percent fall in FEV1 after C1

R2 = percent fall in FEV1 after C2

Example:

A patient reacts between 6 breaths of concentration 1 and 2 breaths of concentration 2.
So C1 is 0.125 mg/ml and C2 is 0.17mg/ml.
The baseline FEV1 is 5 l, 80% of which is 4 l.
The FEV1 is 4.2 l after 6 inhalation breaths (i.e. at C1), the value after 2 inspirations of concentration 2 the FEV1 is 3.6 l(i.e. at C2).

1 The quotient of the concentration is: $\frac{0.17 mg/ml}{0.125 mg/ml} = 1.36$

The logarithm is equal to 0.134.

2 The difference between 80% of the FEV1 value and the FEV1 at C1 is: 4 l – 4.2 l =- 0.2 l

3 The difference between the FEV1 values is: 3.6 l – 4.2 l = -0.6 l

4 The quotient of differences is: $\frac{-0.2\ l}{-0.6\ l} = 0.33$

0.33 multiplied by the quotient of the concentration is: 0.33 x 0.134 = 0.045

5 The inverse logarithm of this value is: 1.11; being multiplied by C2 (0.125 mg/ml) gives the value 0.14 mg/ml for the PC20 FEV1.

9 Reduction, Recycling

9.1 Electronic Components

Some products contain electronic components. To avoid environmental risks or hazard, waste management of these components is based on particular regulations depending on local laws. These regulations may vary widely from place to place.

9.2 Mechanical Components

Wherever possible, only recyclable materials are used inside the mechanical units and accessories of ZAN devices.

The most common materials used are coated aluminum and POM (Polyoxymethylen, Ultraform H2320 from BASF). Refer to the waste management regulations of your region when disposing of these products. There is no need to send these products back to ZAN, the customer may dispose of them in a suitable manner.

nSpire Health avoids single use components where ever possible. Only parts which can be separated and disinfected easily when contaminated, are used.

In principal only unbleached paper and cardboard is used for packing.

Packing material can be disposed of as ordinary waste or recycled.

10 Customer support

nSpire Health works closely with local dealers. We aim to always provide the best customer support and service.

10.1 Support from your Dealer

Your local dealer will be your first contact for assistance. They will know precisely how to fulfil your particular needs. nSpire Health will closely support your dealer.

10.2 Direct Support from nSpire Health:

Of course you may directly contact nSpire Health in the UK, Germany or USA for advice and support.

11 Warranty

11.1 One Year limited Warranty

nSpire Health grants a one year warranty on manufacturing and material.

During this period, the nSpire Health declares itself ready to replace or repair the products that have proved defective.

The warranty gives you defined rights, which may differ from country to country.

11.2 Exclusions

The warranty does not cover damages caused by the following:

Negligent handling of the device
Improper or inadequate maintenance by customers
Connection to unauthorized hardware
Unauthorized changes or misuse
Usage outside advised environmental conditions
Improper installation and on-site servicing
Incorrect voltage or current supply
Mechanical damage of the flow sensor
Use of disinfectants not recommended

The warranty starts either on the delivery date or on the date of installation.

11.3 Limitations

The warranty above is exclusive. No further written or verbal warranty will be granted.

Every legitimate warranty regarding to the usual quality or suitability to a given purpose is limited in this warranty for one year.

Some local authorities do not allow the limitation or exclusion or liability for incidental or consequential damages so the above limitation or exclusion may not apply to you.

11.4 Maintenance during Warranty Time

The devices must be sent in original packaging in order to avoid transport damage.

The customer is responsible for any damage during transportation caused by using improper packaging.

12 Pneumatic Scheme