MED-121
MED-125

B.Well
Caring for everyone

COMPRESSOR NEBULIZER
APARAT DE AEROSOLI CU COMPRESOR
NEBULIZATOR SPRĘŻARKOWY
ΝΕΦΕΛΟΠΟΙΗΤΗΣ ΣΥΜΠΙΕΣΗΣ
МЕДИЦИНСКИ ИНХАЛАТОР
ИНГАЛЯТОР МЕДИЦИНСКИЙ

B.WELL SWISS CONTROLLED

EN Instruction for Use

1. INTRODUCTION

Thank you for purchasing the Compressor Nebulizer MED-121 / MED-125 B.Well.
The B.Well Nebulizer* is a reliable device. It creates a stream of air that travels through clear tube to the nebulizer. When air enters the nebulizer, it will convert the prescribed medication into aerosol mist for easy inhalation.
The B.Well company guarantees this device was made of high-quality materials and meets national and international safety standards.
The Nebulizer is a medical device therefore it should be used under the supervision of a licensed physician and/or a respiratory therapist.
Please, read this Instruction for Use carefully before use and follow the recommendations.

2. INTENDED USE

Your nebulizer is intended for use in treatment of asthma, COPD and other respiratory ailments in which an aerosolized medication is required during therapy. Please consult with your physician and/or pharmacist to determine if your prescription medication is approved for use with this nebulizer. For type, dose, and regime of medication follow the instructions of your doctor or respiratory therapist.
It is a compact medical device designed to effi ciently deliver physician prescribed medication to the bronchial lung passages.
The particle size is less than 5 μm that allows treating lower respiratory tracts.

3. CONTRAINDICATIONS AND USE LIMITATION

The following is strictly forbidden to use as nebulizer therapy medicine:

- substances and solutions containing suspended particles (herbal infusions, suspensions, extracts, etc.) Suspended particles are signifi cantly larger than the particles of respirable fraction. Using it in nebulizer can bring harm to health;
- oil-containing solutions (including ester oils). Oil particles form the fi nest fi lms when entering lower respiratory tract and this increases the risk of the so called "oil pneumonia";
- anaesthetic mixture infl ammable with air, oxygen or nitrogen protoxide;
- fl avoring substances.

Use the device only as described in this Instruction for Use and therefore as an aerosol therapy system, following the indications of your doctor.

⚠ **Cautions.** Please use general safety precautions when operating your nebulizer. This unit should be used only for its intended purpose as described in this guidebook and with medications only under the supervision and instruction of your physician. Do not use the device in anesthetic or ventilator breathing circuits.

ⓘ MEDICAL DISCLAIMER:

This Instruction for Use and product are not meant to be a substitute for advice provided by your doctor or other medical professionals. Don't use the information contained herein or this product for diagnosing or treating a health problem or prescribing any medication. If you have or suspect that you have a medical problem, promptly consult your doctor.

4. PRECAUTIONS

Read this Instruction for Use carefully before use. Keep it for future reference during the life cycle of the device. Use the device only as described in this Instruction for Use and therefore as an aerosol therapy system, following the indications of your doctor. Any use different from the intended one is to be considered improper and hence dangerous. The manufacturer cannot be held liable for any damage caused by improper, incorrect and/or unreasonable use, or if the equipment is connected to electrical installations which do not comply with current safety regulations.

Rules of use the Nebulizer

For the B.Well Compressor Nebulizer MED-121 and MED-125 can be used all the medicines allowed using with common aerosol therapy systems. Use this device only with medicines prescribed by your doctor and according to his instructions. Make the treatment using only the accessory recommended by your doctor depending on the pathology; Check in the medicine package leafl et for possible contraindications for use with common aerosol therapy systems.

⚠ Cautions:

- Closely follow the shelf-life instructions of the solutions which are allowed for use. Do not use solutions with expired shelf-life.
- For greater hygienic safety, we recommend you to avoid using the same accessories for more than one person.
- If you use the accessories for the fi rst time, after long period of storage, and/or after every use cleaning and disinfection of the accessories should be performed! Make sure that all the components are properly disinfected and dried, and after that store it in clean place.
- Components and device have to be cleaned according to the point. 9 Cleaning, Maintenance and Storage of current instruction for Use.

Product cautions

⚠ READ THE FOLLOWING BEFORE USING

1. To avoid electrical shock: keep unit away from water.
2. Do not immerse the unit in liquid.
3. Do not use while bathing.
4. Do not reach for a unit that has fallen into water immediately unplug the unit.
5. Do not use the unit if it has any damaged parts (including plug), if it has been submersed in water or dropped. Promptly send the unit for examination and repair.
6. The unit should not be used where fl ammable gas, oxygen or aerosol spray products are being used.
7. Keep the air vents open. Do not place the unit on a soft surface where the openings can be blocked.
8. If the medication cup is empty, do not attempt to operate the unit.
9. If any abnormality occurs, discontinue using until the unit has been examined and repaired.
10. The unit should not be left unattended while plugged in.
11. Do not tilt or shake the unit when in operation.
12. Disconnect the unit from the electrical outlet before cleaning, fi lling and after each use.
13. Do not use attachments unless recommended by the manufacturer.
14. Do not plug or unplug the AC adapter into the electrical outlet with wet hands. Unplug the AC adapter from the electrical outlet after using the device.
15. Do not disassemble or attempt to repair the unit.
16. Do not use the device in anesthetic or ventilator breathing circuits.

Operating cautions

1. Close adult supervision is highly recommended when the unit is used by children or invalids.
2. Keep your eyes away from the output of medication mist.
3. The maximum capacity of the medication cup is 5 ml and should not be overfi lled.
4. Do not use this unit while operating a vehicle.
5. If any discomfort or abnormality occurs, stop using the unit immediately.
6. Do not use the device if the air tube is bent.
7. Pentamidine is not an approved medication for use with this device.

Storage cautions

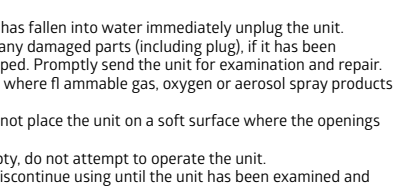
1. Do not store the unit in direct sunlight, high temperature or humidity.
2. Keep the unit out of reach of small children.
3. Always keep the unit unplugged while not in use

Cleaning cautions

1. Check air fi lter, nebulizer, mouthpiece and any other optional component before each use. Dirty or worn parts should be replaced.
2. Do not immerse the unit in water. It may damage the unit.
3. Disconnect the unit from the electrical outlet before cleaning.
4. Clean all necessary parts after each use as instructed in this instruction for use.
5. Always dispose of any remaining medication in the medication cup after each use. Use fresh medication each time you use the device.
6. Do not store the air tube with moisture or medication remaining in the air tube. This could result in infection as a result of bacteria.

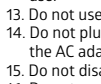
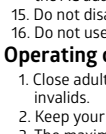
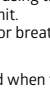
The correct functioning of the equipment can be affected by electromagnetic interferences which exceed the limits indicated by the European standards in force. In case this device interferes with other electrical devices, move it and plug it to a different power socket. In case of failure and/or malfunction, read the section «11. Table of possible problems». Do not handle or open the compressor housing.
Before plugging in the device, make sure that the electrical rating, shown on the rating plate on the bottom of the unit, corresponds to the mains rating. In case the power plug provided with the device does not fi t your wall socket, address to qualifi ed personnel for the problem solving. In general, the use of extension cables is not recommended. If their use is indispensable, it is necessary to use types complying with safety regulations.
The installation must be carried out according to the instructions of the manufacturer.
An improper installation can cause damage to persons, animals or things, for which the manufacturer cannot be held responsible. If you decide not to use the device any longer, it is recommended to dispose of it according to the current regulations. Do not position the equipment so that it is diffi cult to operate the disconnection device.

5. COMPONENTS

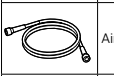
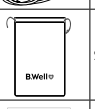
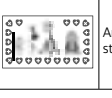


1. Compressor housing
2. Power switch
3. Air outlet
4. Filter case
5. Nebulizer kit holder
6. AC adaptor Jack

Complete set

	Description	Set MED-121	Set MED-125		Description	Set MED-121	Set MED-125
	Compressor nebulizer	1 pcs.	1 pcs.		Infant mask	–	1 pcs.
	Nebulizer kit Basic	1 pcs.	1 pcs.		Air filters	5 pcs.	5 pcs.

* Hereafter referred to as "nebulizer" and "inhaler" consider the same.

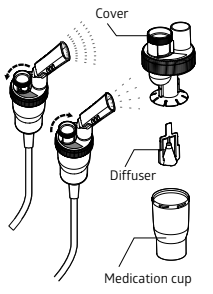
	Description	Set MED-121	Set MED-125		Description	Set MED-121	Set MED-125
	Air tube	1 pcs.	1 pcs.		AC adapter	1 pcs.	1 pcs.
	Mouthpiece	1 pcs.	1 pcs.		Storage bag	1 pcs.	1 pcs.
	Child mask	1 pcs.	1 pcs.		Instruction for Use	1 pcs.	1 pcs.
	Adult mask	1 pcs.	–		Animal stickers	–	1 pcs.

Nebulizer kit

Nebulizer kit Family:

Valve Adjustable Technology

The proprietary adjustable valve is able to deliver medications of different viscosity level according to every user's conditions and needs at ease. Our VA technology allows users to adjust different levels of nebulization rate ranging from 0.08 – 0.3 ml/min at consistent particle size. The nebulization rates can be adjusted by the user in a very easy way without exchanging parts. Higher nebulization rate/fully open is for higher viscosity medications and higher breathing capacity user while lower nebulization rate with closed valve will be more appropriate for kids / infants with lower breathing capacity.



6. PREPARATION FOR USE

The device must be checked before each use, in order to detect possible functioning anomalies and/or damages due to transport and/or storage. During inhalation, sit upright and relaxed at a table and not in an armchair, in order to avoid compressing your respiratory airways and impairing the treatment effectiveness.
The accessories must be used only with a single patient, it is not recommended to use them with several patients.

- Wash your hands carefully before using the device.
- After unpacking the device, check it for visible damages or defects; pay particular attention to cracks in the plastic housing, which may expose electrical components. Check for accessories integrity.
- Before using the device, proceed with the cleaning operations as described in the "9.Cleaning, maintenance and storage" section.
- Place the device on a stable and horizontal surface so that you can easily reach the Nebulizer, accessories and ON/OFF switch when you do the inhalation.

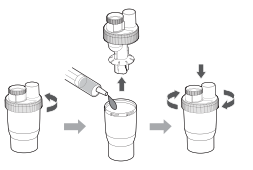
Before using of the device make sure that:

- all the components are properly assembled;
- air fi lter is inside of the fi lter cap;
- air fi lter is clean (if air fi lter has changed the color or has been used for a long period of time, replace it with a new one).

Nebulizer kit preparation for use

Follow the cleaning instructions in this guidebook under "9.Cleaning technique" prior to using your nebulizer for the fi rst time or after it has been stored for an extended period of time.

1. Gently twist and pull straight up on the lid of the nebulizer to separate into two parts (medication cup and cover).
2. Add the prescribed amount of medication to the medication cup.
3. Reassemble the nebulizer by carefully twisting the medication cup and cover together. Make sure that the two parts fi t securely.

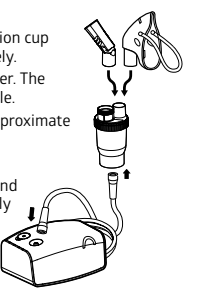


Make sure that the nozzle is properly installed on the upper cover. The stem inside the medication cup inserts into the tube of the nozzle.

⚠ **NOTE:** there is a scale on the medication cup. It is used for approximate assessment of the medical capacity.

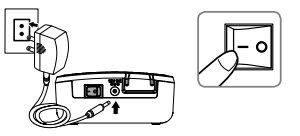
Air tube connection

Connect one end of the air tube to the nebulizer and the other end to the air outlet on the device. Make sure that air tube is properly attached in order to avoid air leakage.



⚠ **WARNING!** Hold the nebulizer strictly vertically, do not spill the drug when attaching the air tube. Insert the mask or mouthpiece directly onto the nebulizer.

- Check that the power switch is in the "OFF" position.
- Connect the AC adapter with the AC adapter jack in the back of the unit.
- Plug the AC adapter into the socket (use only the authorized AC Adaptor with this nebulizer).
- Press the power-switch to the "ON" position.



7. OPERATING

Hold the nebulizer strictly vertically.

⚠ **WARNING!** Do not incline the nebulizer at more than 45 degrees. If the angle is greater than 45 degree, no aerosol will be generated.

To start the treatment, set the switch into the "I" position. The compressor will start working and a nebulizing will begin.

Do the treatment in accordance with your doctor's instructions. Inhale the aerosol solution using the prescribed accessory.

⚠ **WARNING!** The temperature of inhaled aerosol depends on the temperature of the ambient atmosphere and the temperature of the drug solution. If the solution was stored in refrigerator for a long period of time, it is recommended to raise the temperature to 16-20C°.

Use of mouthpiece:

Take the mouthpiece to your mouth and breathe smoothly during the inhalation. Using of mouthpiece is recommended in treatment of lower respiratory tract in grownups and children above 5 years old.

Use of masks:

Put on a mask in the way that it will close your nose and mouth, and conduct inhalation of the drug. Inhale and exhale through the mask.
Using of mask is recommended in treatment of upper respiratory tract. It allows for irrigation of the whole nasal and pharynx cavities, and also larynx and trachea. Child mask is recommended for use for children aged from 1 to 5 years old. Infant mask for children under 1 year old. When the treatment has been completed, switch the unit off by setting the switch into the "O" position and disconnect the plug from the wall socket.
Wash the nebulizer and its accessories as described in the section "9. Cleaning, maintenance and storage". Condensate can form in the air tube. In this case detach the air tube from the nebulizer, turn on the compressor and dry the air tube till the elimination of all the liquid.

⚠ **WARNING!** Do not store the air tube if there is condensate or liquid inside. It can lead to bacterial infection.

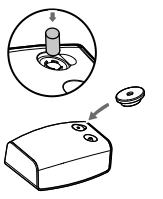
Switch off the device from the socket.
Rinse your mouth with boiled water of the ambient temperature after the procedure. If you used mask – rinse your eyes and face with water.

⚠ **WARNING!** The device can work for 30 min without a pause, than you should let the device to cool down for 30 min.

8. REPLACEMENT OF THE AIR FILTER

The Air fi lter must be replaced in case of damage or severe contamination. In normal usage conditions, It is recommended to change air fi lter every 60 days of usage. It is recommended to periodically check the air fi lter (10 – 12 treatments) and, if the fi lter shows a grey or brown color or is wet, replace it.

1. Remove the air fi lter cover by gently pulling forward.
2. Discard the gray fi lter with the help of tweezers
3. Replace with a new, clean air fi lter.
4. Securely re-attach the air fi lter cover to the unit.



⚠ **WARNING!** The use of dirty fi lter or fi lter made of another material, for example, cotton, may lead to device damage. Use original fi lters only.

- Do not use the device without fi lter.
- Do not try to clean the fi lter for reusing it. If the fi lter is wet replace it.
- The air fi lter shall not be serviced or maintained while in use with a patient.
- To avoid the air fi lter cover obstruction clean it regularly.

⚠ **WARNING!** Air fi lters cannot be cleaned or washed.

9. CLEANING, MAINTENANCE AND STORAGE

Cleaning the device and the accessories

The cleaning of the device must be carried out by using a soft and dry cloth and nonabrasive cleansers.

- Make sure that the power-switch has been turned to the "OFF" position
- Disconnect the air tube from the nebulizer device

⚠ **ATTENTION!**

- During cleaning operations, make sure the internal parts of the unit are not in contact with liquids and that the power plug is disconnected.
- Any other form of cleaning or cleaning agents may damage the fi nish of the unit.

Follow carefully the cleaning and disinfection instructions of the accessories as they are very important for the device performances and the therapy success.

⚠ **ATTENTION!** Before fi rst using of the device and after each treatment it is necessary to clean all the accessories according to the following instructions:

Nebulizer kit and mouthpiece disinfection:

- Disassemble the nebulizer by turning counterclockwise the top and remove the medicine conduction cone.
- Wash the components of the disassembled nebulizer and the mouthpiece by using tap water; dip in boiling water for 5 minutes.
- Reassemble the nebulizer components and connect it to the air-outlet , switch the device on and let it work for 10-15 minutes or put on the clean paper towel for drying on the air.

Air tube and mask disinfection:

The masks and air tube must be washed with warm water till 40C with neutral soft cleanser, approaching to PVC material.

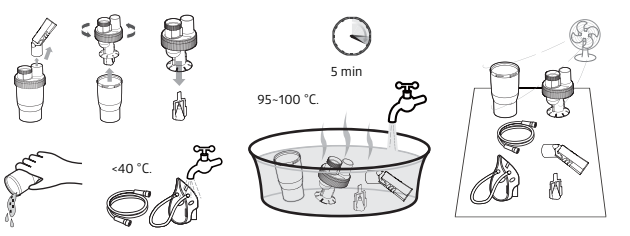
Do not boil or autoclave the air tube and masks!

Rinse the components in warm running water for 30 sec in order to eliminate washing agent. For sterilization use cold disinfecting liquids following the instructions of the sterilization liquids' manufacturer.

- wash your hands and take the components out from disinfection solution, wash in warm running water, lay the components on paper towel and dry.
- do not wipe disinfected parts of the device with a towel; do not use hair dyer, microwave oven or other household appliances for drying. The outer surface of wet parts can be wiped with a clean dry cloth.

⚠ **Caution:** In order to avoid spread of infections it is recommended to conduct disinfection of device components before fi rst and after every use. Use for treatment only the drugs prescribed by your attending doctor and strictly follow his/her indications.

Opening of the device is prohibited. Repair of the device should be conducted only in technical service centers recommended by B.Well company.



ⓘ **Note:** B.Well recommends replacing the nebulizer kit after 6 months.

The nebulizer must be replaced after a long period of inactivity, in case it shows deformations or breakings, or when the nebulizer nozzle (diffuser) is obstructed by dry medicine, dust, etc.
Use original B.Well nebulizer kits only.

Maintenance and storage

If you want your device to serve you for years, follow the following indications:

- Do not store the device at extremely high or low temperatures, high humidity or under direct sunlight;
- Do not bend or wrap the air tube.

Operation and storage conditions – please see section "12. Technical specifi cations"
Utilization of the device and any of its components should be performed in accordance with the local regulations.

10. DISPOSAL

The unit must be disposed in accordance with current standards separately from domestic wastes.
For disposal it is necessary to contact special organizations licensed to make utilization.

11. TROUBLESHOOTING

Contact an authorized Customer Service Centre in case you need help about the use and the maintenance of the equipment.
In case of any malfunction look at the table and try to eliminate it.

Problems	Solutions
The device does not switch on	· Check the adaptor connection to the outlet; · Make sure that the device has been operating within operating limits indicated in this Instruction for Use (30 min ON / 30 min OFF).
The device does not nebulize or nebulizes weakly	· Check the main unit if there is any physical damage. · Make sure that air tube and other components are properly attached. · Check that there is medication in the nebulizer cup. · Check the position of the nozzle (diffuser) inside the nebulizer. · Check the air fi lter and replace if necessary.

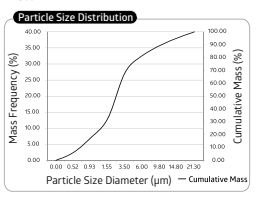
In case of the device not start working properly again, address to authorities Service center.

Maintenance and repairs

In case of failure, address to qualifi ed personnel authorized by B.Well. Do not open the device in any case. The unit has no user-serviceable parts within and does not need internal maintenance or lubrication.

12. SPECIFICATIONS

Power supply:	Input: DC 12V, 1A
Adaptor:	AC 100-240 V, 50/60 Hz
Power consumption:	≤12 W
Compressor Pressure Range:	110 kPa
Operating Pressure Range:	55 kPa
Operating Flow Range:	≥ 2.0 L/m
Sound Level:	≤ 46 dBA (1 meter away from device)
Weight:	0.303 kg (without accessories) 0.660 kg (in the gift box with accessories)
Dimension (L x W x H):	102 x 140 x 61 mm
Working conditions: 30 min ON / 30 min OFF	
Nebulizer kit Family	
Medication capacity:	2-5 ml
Particle Size (MMAD):	≤3.0μm (microns)
% of particle less than 5 μm (FPD):	≥70%
Average Nebulization Rate (0.9% Saline Solution)	0,08-0,3 ml/min (depending on the valve position and the medicine used)
· Subject to technical modifi cation without prior notice.	
· Performance may vary with drugs such as suspensions or high viscosity. See drug supplier's data sheet for further details.	



Operating conditions:	Operating Temperature Range 10°C to 40°C Operating Humidity Range ≤ 90% RH Operating Atmospheric Pressure Range 700-1060 hPa
Storage conditions:	Storage Temperature Range –20°C to 60°C Storage Humidity Range ≤ 90% RH Storage Atmospheric Pressure Range 700-1060 hPa

Durable periods:

Durable periods are as follows, provided the product is used to nebulize 2ml of medication 2 times a day for 6 minutes each time at room temperature (25°C).
Durable period may vary depending on usage environment.
Compressor (main unite) ≥ 5 years (or ≥ 400 hours)
Nebulizer kit, air tube, mouthpiece, masks – 1 year
Adapter – 6 months
Air fi lter – 60 days

- Class II device as regards protection against electric shocks.
- Nebulizer, mouthpiece and masks are type BF applied parts.
- Protection against harmful ingress of water and particulate matter: IP21
- Degree of safety in the presence of fl ammable anesthetics or oxygen: No AP/APG (not suitable for use in the presence of fl ammable anesthetics or oxygen).
- Device for intermittent use (30 min ON / 30 min OFF)
- Device not suitable for use in an aesthesia or lung ventilation systems.

The manufacturer may change technical specifi cations and design of the device due to improvement without prior notice.

13. APPLIED STANDARDS

Electric Safety Standards EN 60601-1. Electromagnetic Compatibility according to EN 60601-1-2. Class IIa Medical Device according to the 93/42/EEC European Directive on Medical Devices.
This device fulfi ls the provision of the EC directive 93/42/EEC (Medical Device Directive) and the European Standard EN 13544-1:2007+A1:2009 Respiratory therapy equipment – Part 1: Nebulizing systems and their components.

14. WARRANTY

Warranty period is 3 years from the date of purchase.
This warranty doesn't cover any damages caused by improper using, and also protective cover and storage bag, packaging and the accessories supplied with the device (nebulizer kit, air tube, mouthpiece, masks, adapter, air fi lters) and those parts subject to normal wear and tear. The warranty does not apply to damage caused by using adapters not recommended by the B.Well company and the overvoltage. When a manufacturing defect is revealed during the warranty period a faulty unit would be repaired or, if repairing is impossible, replaced with another one. The manufacturer may change units partially or completely if necessary, without prior notice.
Manufacturing date of the device is encoded in the SN number at the bottom of the device: Two fi rst numbers are numbers of the week; two other numbers are last numbers of the year.
Manufacturing date of the spare parts, which can be bought separately from the device is encoded in the LOT number on the sticker:
Two fi rst numbers are numbers of the week; two other numbers are last numbers of the year.

15. SYMBOL INFORMATION

	READ INSTRUCTIONS BEFORE USE	LOT	LOT NUMBER
	DISPOSAL FOR SEPARATE COLLECTION	REF	ARTICLE NUMBER
			MANUFACTURER'S NAME
	TYPE BF EQUIPMENT	IP21	PROTECTION AGAINST HARMFUL INGRESS OF WATER AND PARTICULATE MATTER: IP21
	CLASS II EQUIPMENT		KEEP DRY
CE 0044	CE MARK	10°C ~ 40°C OPERATION CONDITION	OPERATING CONDITION, TEMPERATURE 10°C ~ 40°C
SN	SERIAL NUMBER	-20°C ~ 60°C STORAGE CONDITION	STORAGE CONDITION, TEPERATURE -20°C ~ 60°C

ELECTROMAGNETIC COMPATIBILITY INFORMATION

Guidance and manufacturer's declaration-electromagnetic emissions

The MED-121 / MED-125 is intended for use in the electromagnetic environment specified below. The customer or the user of the MED-121 / MED-125 should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The MED-121 / MED-125 use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The MED-121 / MED-125 are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Compliance	

Guidance and manufacturer's declaration-electromagnetic immunity

The MED-121 / MED-125 is intended for use in the electromagnetic environment specified below. The customer or the user of the MED-121 / MED-125 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV differential mode Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	<5% UT(>95% dip in UT) for 0,5 cycle 40% UT(60% dip in UT) for 5 cycles 70% UT(30% dip in UT) for 25 cycles <5% UT(>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MED-121 / MED-125 requires continued operation during power mains interruptions, it is recommended that the MED-121 / MED-125 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The MED-121 / MED-125 power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration-electromagnetic immunity

The MED-121 / MED-125 is intended for use in the electromagnetic environment specified below. The customer or the user of the MED-121 / MED-125 should assure that it is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the MED-121 / MED-125 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1,2 √P, d = 1,2 √P 80MHz to 800 MHz, d = 2,3 √P 800MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: ((•))
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2,5 GHz	3 V/m	

NOTE1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MED-121 / MED-125 is used exceeds the applicable RF compliance level above, the MED-121 / MED-125 should be observed to verify normal operation. If abnormal performance is observed, additional measures my be necessary, such as re-orienting or relocating the MED-121 / MED-125.
b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the MED-121 / MED-125

The MED-121 / MED-125 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MED-121 / MED-125 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MED-121 / MED-125 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter, (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz / d=1,2√P	80MHz to 800MHz / d=1,2√P	800MHz to 2,5GHz / d=2,3√P
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

B.Well Swiss AG, Bahnhofstrasse 24,
9443, Widnau, Switzerland
www.bwell-swiss.ch

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