EN

WILAmed

Equipment for Professionals

AIRcon Gen2 Respiratory Humidifier

User manual and technical description

www.wilamed.com

CE 0197

Content

1. Intended use

AIRcon Gen2 respiratory gas humidifier is a device for heating and humidifying respiratory gases, such as medical oxygen and/or compressed air or else room air during mechanical ventilation or respiratory therapy in both the clinical and home care environments.

AIRcon Gen2 can be used for invasive as well as noninvasive ventilation/ respiratory therapy for adults, children and newborn babies.

This device may only be operated by trained personnel. User training will be provided by WILAmed or WILAmed authorized agents.

AIRcon Gen2 is always positioned between therapy device and patient. A breathing tube system and a humidifier chamber are always necessary for this connection. This breathing tube system must be matched beforehand to the therapy device being used, to the medical indication and to the respective patient group.

Connect AIRcon Gen2 with approved therapy devices (such as ventilators, bilevel devices, CPAP devices, etc.) only if patient/user safety and the environment are not impaired. The user must make sure that the combination is safe. If in doubt, the manufacturer must be contacted.

Respiratory gas is passed from the therapy device or oxygen source to the humidifier chamber, where it is heated, humidified with water vapor and then passed via the inspiratory tube to the patient. Three different basic modes and the freely adjustable temperatures at the outlet of the humidifier chamber as well as the patient's proximity make it possible to adjust or regulate the moisture output for each application.

AIRcon Gen2 respiratory gas humidifier is not suitable or intended for atomization of medications.

2. Warnings, Cautions and Guidelines

2.1 Warnings

Warnings are indicated by the term **WARNING**. Warnings alert the user when potentially serious consequences for the patient or the user may occur, which can lead to injury with negative consequences including death.

WARNING

Before the patient is connected to the breathing tube system, a check must be made to ensure the breathing gas is flowing unimpeded through the breathing tube system.

WARNING

To avoid penetration of any condensate in the breathing tube system and its flow to the patient, the humidifier should be positioned below the actual level of the patient.

WARNING

Risk of burns!
Under continuous operation, the heating plate and the humidifier chamber can reach temperatures of over 85°C. Before removing the humidification chamber from the respiratory humidifier, the humidification chamber must be allowed to cool down sufficiently.

WARNING

The temperature sensor must be inserted in such a way that the temperature of the respiratory gas is measured in the middle of the breathing tube. Failure to observe this requirement may result in the temperature of the supplied respiratory gas exceeding the critical temperature of 43°C.

WARNING

Do not cover the heated breathing tube system with any insulating material, such as towels or blankets or other materials, because the filament inside the tube will then become overheated at the covered spot. This can lead to deformation of the breathing tube, to the point of melting through.

WARNING

The AIRcon Gen2 respiratory humidifier can be connected to all conventional respirators/therapy devices, provided it is ensured that no danger can occur to the patient, user or environment due to the connection.

WARNING
Risk of burns!
The heated breathing tube system must not touch the patient's skin.

WARNING
The use of this device directly next to other devices or with other devices in stacked form should be avoided, as this could result in a faulty operation. If it is nevertheless necessary to use it in that manner, this device and the other devices should be monitored to ensure that they are working properly.

WARNING
The use of accessories, transformers or lines other than those specified or provided by the manufacturer of your device may result in increased electromagnetic noise emissions or impaired resistance of the device to electromagnetic interference, and result in faulty operation.

WARNING
This device may not be altered without the permission of the manufacturer.

WARNING
The AIRcon Gen2 respiratory humidifier should not be operated near radiators and other heat sources. Sunlight and bright light sources must be avoided.

WARNING
It is important to note that the environmental conditions change after opening a window.

WARNING
Children and pets are to be supervised during operation of the AIRcon Gen2 respiratory humidifier.

WARNING
When used properly, the heating plate and the chamber become hot.

WARNING
The humidity output capacity can be affected if the device is operated outside the specified ambient temperature or ambient humidity range.

WARNING
Portable RF communication devices (radio devices) (including their accessories such as antenna cable and external antennas) should not be used at a distance of less than 30cm (or 12 inches) from the AIRcon Gen2 parts and lines specified by the manufacturer. Failure to comply may result in a reduction in the performance characteristics of the device.

WARNING
Before use, the instructions in this user manual and those for the respective accessory are to be followed!

WARNING
This device may only be operated by trained personnel. User training will be provided by WILAmed or WILAmed authorized agents.

WARNING
The USB interface may be used only for service purposes.

WARNING
Temperatures in operation differ from the storage and transport temperatures. The AIRcon Gen2 may only be operated at an ambient temperature of 18°C to 26°C.

WARNING
If the device is stored or transported at an ambient temperature of -25°C or +70°C, then the device must be acclimatized prior to operation at an ambient temperature of 18°C to 26°C for 30 minutes.

WARNING
Small parts can be swallowed.

2.2 Precautions

Precautions are indicated by the term **CAUTION**. Precautionary measures warn the user of special precautions to ensure safe and effective use of the AIRcon Gen2 respiratory humidifier.

CAUTION
To avoid overheating, a breathing gas flow of at least 2l/min is constantly required in the breathing tube system. If the breathing gas supply is interrupted, the device must be turned off. For applications that require the patient's separation from the humidifier, the device needs to be switched to "treatment interruption" mode.

CAUTION
The water used to fill the humidification chamber must not be warmer than the ambient temperature!

CAUTION
Before any maintenance, inspection or repair work, the device must be disconnected from the mains.

CAUTION
Any intervention in the device – including maintenance and testing – must be performed by trained service technicians in accordance with the applicable legal provisions. For details, please refer to the supplementary

technical description and maintenance and service instructions.

CAUTION
Do not immerse the base unit or its accessories in liquids or sterilize them! Detailed instructions for cleaning and maintaining the device are included in the sections on maintenance and cleaning.

CAUTION
Before each use, check that the base unit, the supplied system parts and the accessories used are free from defects. If the AIRcon Gen2 respiratory humidifier is defective or damaged, it must not be used. In addition, in this situation, please notify the hospital maintenance technician or the customer service department. Remove the damaged system components and do not use them!

CAUTION
Determination of operational shutoff may only be given by a physician or his/her authorized representatives.

CAUTION
This user manual does not replace the physician's instructions or the official instructions for appropriate care of the patient. These medical and official instructions take precedence over this user manual.

2.3 Guidelines

Guidelines are indicated by the term **NOTE**. Guidelines contain important information that should be respected.

NOTE
A change in the room climate (for example, heating, ventilation) or the entry of new ventilation parameters can lead to increased condensation present in the breathing tube system.

NOTE
The AIRcon Gen2 respiratory humidifier and the humidification chamber are not inhalers and neither suitable nor intended for administering drugs, medicinal substances or human blood derivatives.

NOTE
Portable and mobile RF communications equipment (such as mobile phones) can affect the AIRcon Gen2 respiratory humidifier. Further details are included in the manufacturer's EMC declaration in the Appendix.

NOTE
If problems occur during commissioning, use or, where applicable, maintenance or if there is an unexpected operation or incident, the representative is to be contacted.

NOTE
The expected service life of the device is limited to 8 years.

NOTE
Its operation in a potentially explosive and oxygen-rich environment is not allowed.

NOTE
The abbreviation "(i)" means inspiratory the abbreviation "(e)" means expiratory

NOTE
During warming-up period (ca. 30min.) of the humidifier, an activation of the therapy-pause-function (chapter 7.1.2) is not possible.

NOTE
Only WILAmed approved accessories and consumables may be used. Accessories and consumables from third parties may affect the safety of the device

NOTE
The AIRcon Gen2 respiratory humidifier must be set up and taken into operation as described in the user manual.

NOTE
The expected operational life of the accessories is included in the user instructions for the accessories.

NOTE
The AIRcon respiratory humidifier is suitable for reuse. Before each reuse following a change of patient, cleaning and disinfection must be performed according to section 9!

3. Side effects / Contraindications

There are no known adverse side effects.

4. Basic equipment and resources needed

4.1 Delivery

- Basic device AIRcon Gen2 (230V 101200, 115V 101201)
- Heating wire distributor cable ((i) 100942 or (i+e) 100929)
- Temperature probe (160cm 100910 or 180cm 100909)
- Power cord (country-specific)
- User instructions (country-specific)
- Quick Start guide (country-specific)

Basic device

Mains cable

Heating wire distributor cable (i) (100942)

Heating wire distributor cable (i+e) (100929)

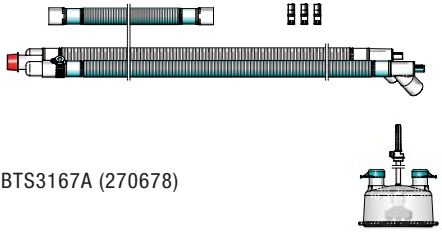
Temperature probe (160cm 100910)

Temperature probe (180cm 100909)

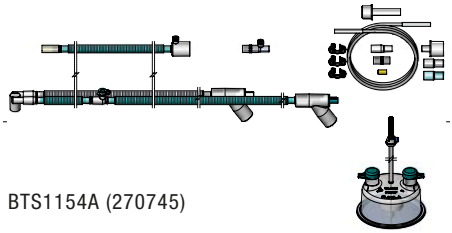
4.2 Consumables

Depending on the specific instance, other accessories are necessary and available from WILAmed. For a complete list of all accessories available, please contact the manufacturer. Examples of accessories and consumables are listed in the following table.

Article number	Accessory
270678	BTS3167A - WILAmed ventilation system with heating (inspiratory + expiratory) for adults (22mm ID) length approx. 150cm with connecting tube 60cm and auto-refill humidification chamber
270745	BTS1154A_double_tube_system for Intensa 10mm 120cm heated (i+e) humidification chamber
500186	WILAqua, sterile water 1000ml bottle
500350	WILAmed C220R humidifier chamber, autoclavable



BTS3167A (270678)



BTS1154A (270745)

WILAqua (500186)

Breathing tube system must be compatible with the treatment device used.

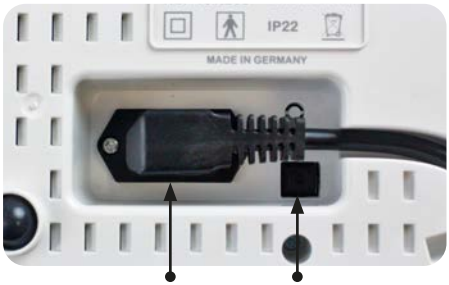
NOTE

Only WILAmed-approved consumables may be used. Consumables from third party providers may affect the safety of the device.

5. Installation and commissioning

5.1 Connecting components

The power cord is inserted under the machine.



Mains cable USB port for service

Connect the power cord to an AC outlet or power strip with the permitted voltage. The connections for the heating wire distributor cable for heating and for the temperature sensor are mounted laterally on the device. These connectors are colored and mechanically coded, being marked with appropriate symbols.

When using a heated breathing tube system, the plug of the heating wire distributor cable is connected with the yellow connector).

The plug of the heated breathing tube system is similarly color-marked (green) and mechanically coded.

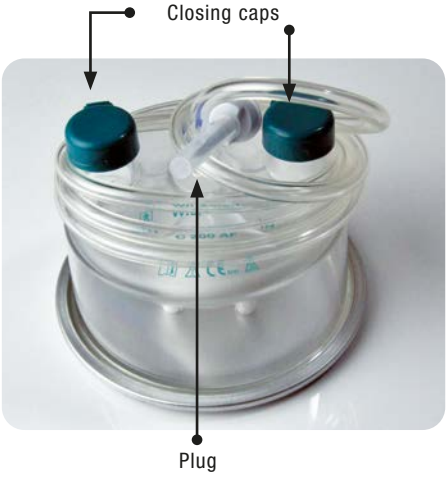
To use the temperature probe, the plug of the temperature probe is connected with the blue connector).

5.2 Installation / Mounting the base unit

The AIRcon Gen2 is equipped with housing feet and can be placed on a flat, solid and level surface. Alternatively, the device can be suspended with the rear retaining tab on a suitable hook.

5.3 Installing the humidification chamber

Unpack the humidification chamber with automatic refill device (for example, C200AF universal) and check it before use for any visible damage.



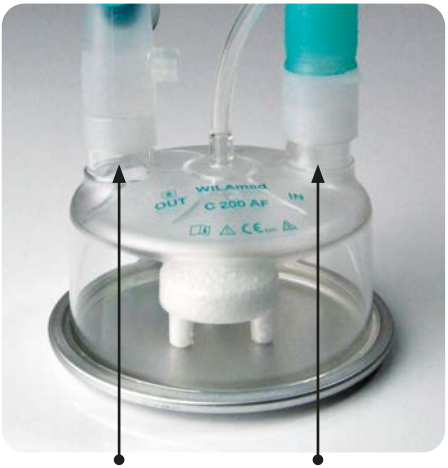
Attention: Use only fault-free humidification chambers.

Attention: Take the device into operation only with the chamber.

Attention: Follow the user instructions for the respective humidification chamber!

Unreel the plug to connect the water bag, pull off colored caps and dispose of appropriately.

Connect the therapy device output with the humidification chamber input - marked with the inscription "IN"; connect the breathing tube (e.g. breathing system 271678) to the patient with the humidification chamber output - marked with the imprint "OUT". The humidification chamber should be oriented so that the and the breathing tube system is not convoluted.



First push the bottom edge of the humidification chamber under the front flap on the base device

and thereafter fix under the movable mounting bracket, which can be pulled back until the bracket audibly clicks into place.

Full-surface heat transfer from the heating plate is only ensured if the humidification chamber is used correctly.

Instruction: When changing the chamber, do not touch the heating plate!

5.4 Connecting the breathing tube system

The T- ensor of the temperature probe must be in the opening of the angle connector,

T sensor in the opening of the angle connector

and the sensor at the end of the cable must be inserted into the patient-side opening at the end of the breathing tube system.

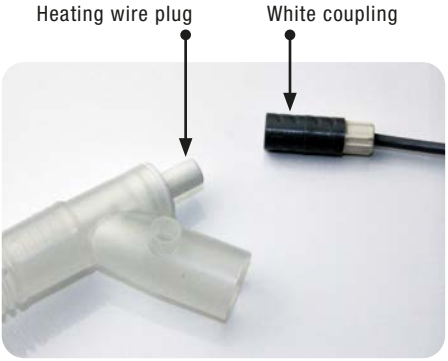
Both sensors must be firmly and securely inserted in the respective opening. The cable of the temperature probe can be fixed in the corresponding hook of the hose brackets.

The green coupling of the heating wire power supply is always connected to the green heating wire plug of the inspiration hose.

Heating wire plug

The basic device AIRcon Gen2 is only ready to operate if the inspiration heating wire is connected.

If the breathing tube system used is equipped with a heated expiration tube, the white coupling of the heating wire power supply is always connected with the white heating filament plug of the expiration tube.

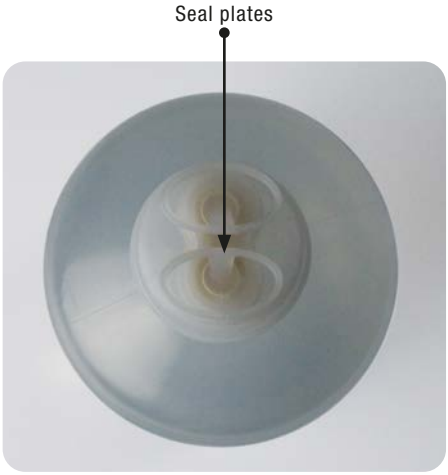


Lines must be routed in such a way that no-one can become tangled up in them.

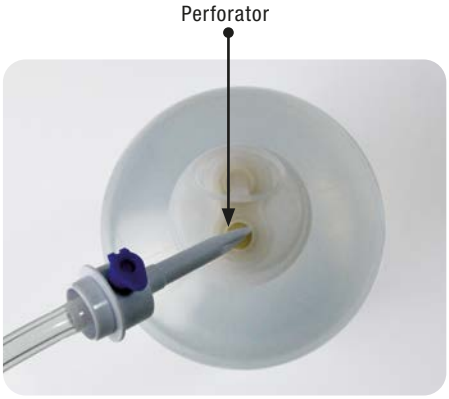
Instruction: Tube clamps and tube retaining brackets are to be used.

It is recommended to use sterile water. However, other water can also be used, as instructed by the physician. However, this water must not contain any mineral additives or drugs.

To ensure the automatic refill device functions, the container with the water (e.g. WILAqua 500186) is suspended at least 0.5 m above the humidifier, after which the seal plate on the bottle neck of the container is removed



and the perforator of the connector instrument is inserted into the rubber membrane.

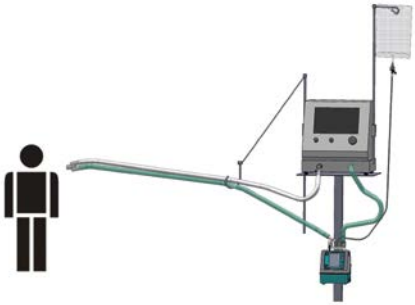


For water bottles, the blue vent cap on the perforator must be opened.

The water gradually fills the humidification chamber and maintains a constant level.

Before the patient is connected to the breathing tube system, make sure that the treatment device is working properly, that the treatment parameters are set correctly and that the breathing gas is flowing freely in the breathing tube system.

The following figure shows the schematic set-up of the device.



5.5 Turning on the base unit

The humidifier is only to be turned on, using the lateral main switch, when the breathing tube system, the humidification chamber and the water reservoir are connected, plugged and punctured correctly.

NOTE

The AIRcon Gen2 respiratory humidifier saves the last setting and uses it for a restart (e.g. after power failure).

NOTE

After switching on, the warm-up phase lasts for no more than 30 minutes. After switching on, the heating and the water vapor saturation of the respiratory gas is steadily increased until an optimum value is reached. Resetting the device to factory settings is described under "7.1 Operation in normal mode".

After switching on, the device first displays the product model and version and performs a self-test. During this initialization, no entries are possible.

NOTE

The version number of the software is for illustration and may differ from the actual version.

WILAmed
AIRcon 2

Version 1.3.2
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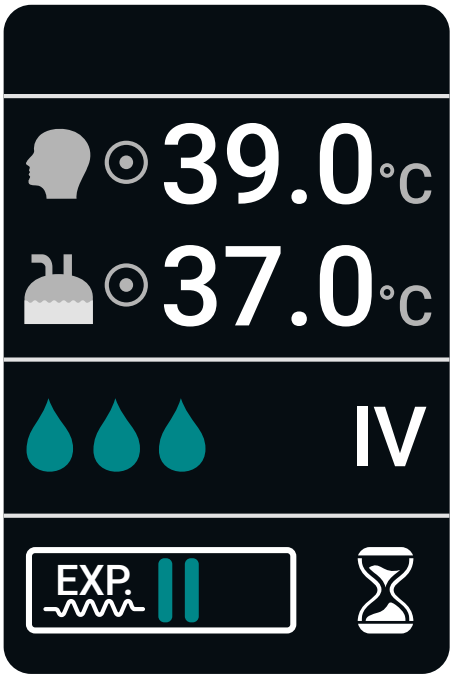
After initialization, the operating display appears.



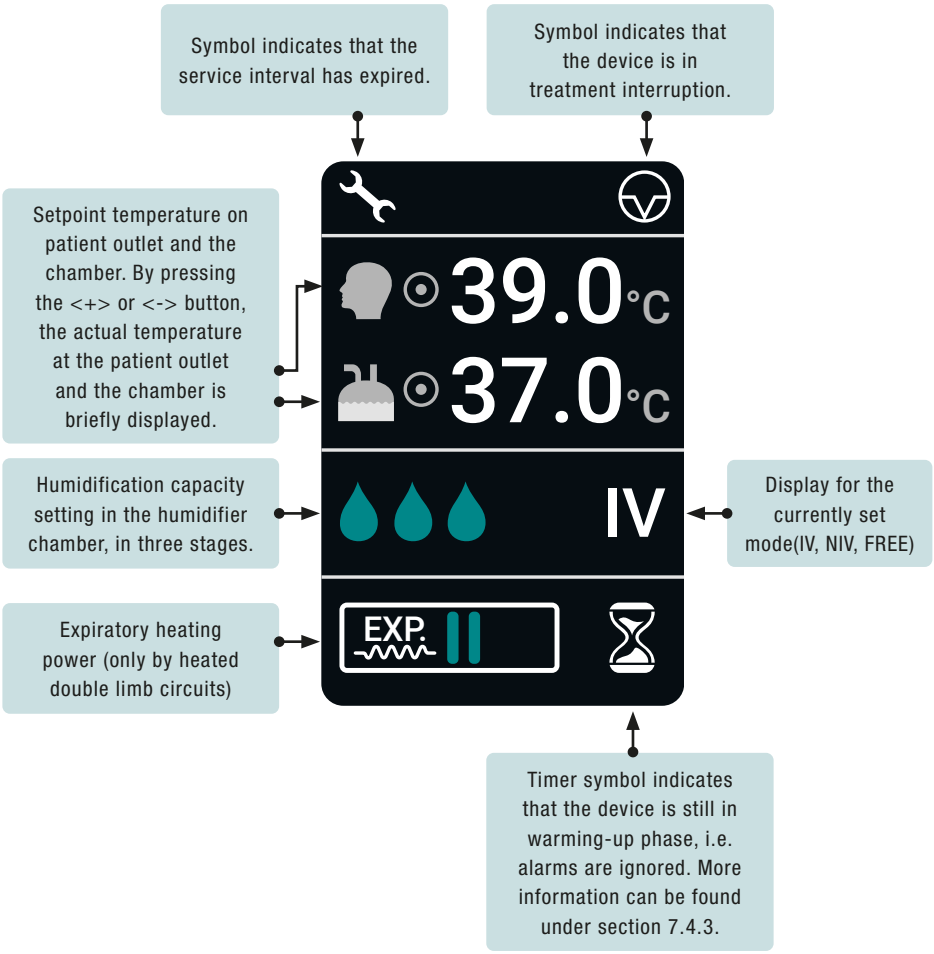
5.6 Turning off the base unit

The respiratory humidifier can be turned off with the power switch after the end of treatment.

After switching off, the device should cool down for at least 30 minutes before it is dismantled, packed or transported, since the heating plate will still be hot.

6. Operation

6.1 Display in normal mode

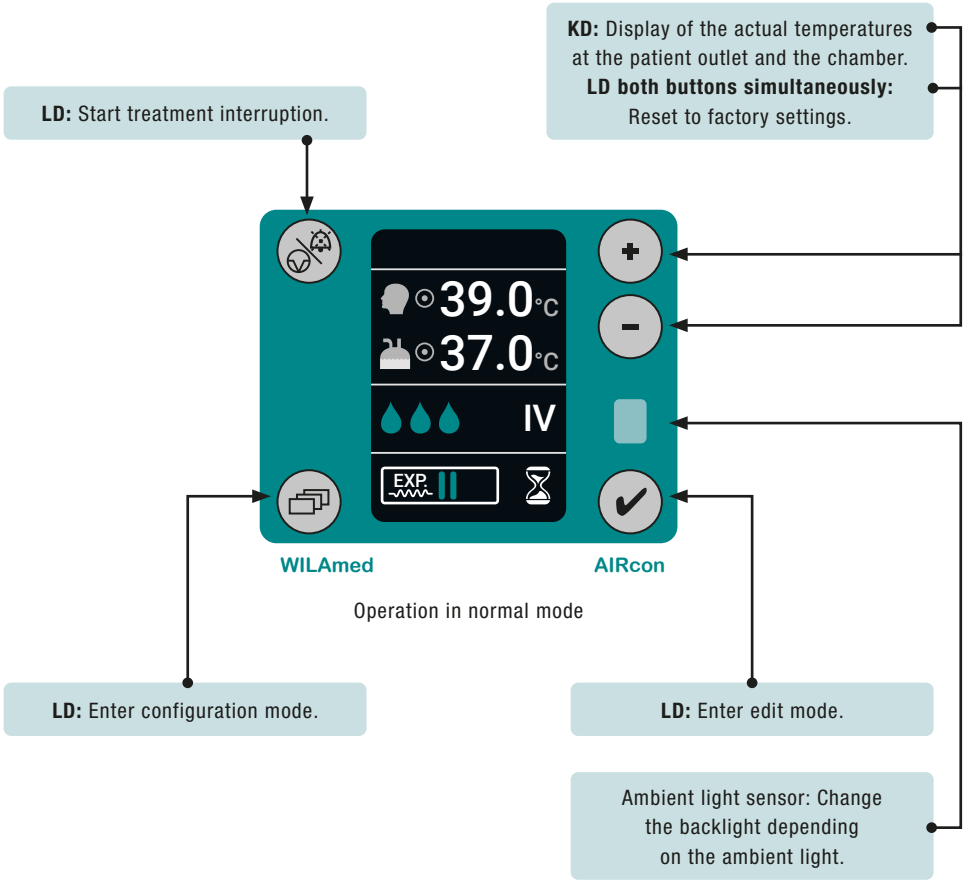


7. Function buttons

In the four different display modes, the keys have partially different functions.
The following illustrations explain how to operate the device.

Key: LD = Long Press **KD** = Short Press

7.1 Operation in normal mode



7.1.1 Reset to factory settings

The device is delivered with the factory setting "IV", i.e.

- Setpoint of the patient-side breathing gas temperature (upper measuring point): 39°C
- Setpoint of the chamber temperature (lower measuring point): 37°C

During operation, the device is reset to factory settings if the button combination ⊕ and ⊖ is pressed simultaneously for 3 seconds. The factory settings loading process is indicated by a black screen with the yellow lettering "FACTORY RESET..." in the lower left corner.

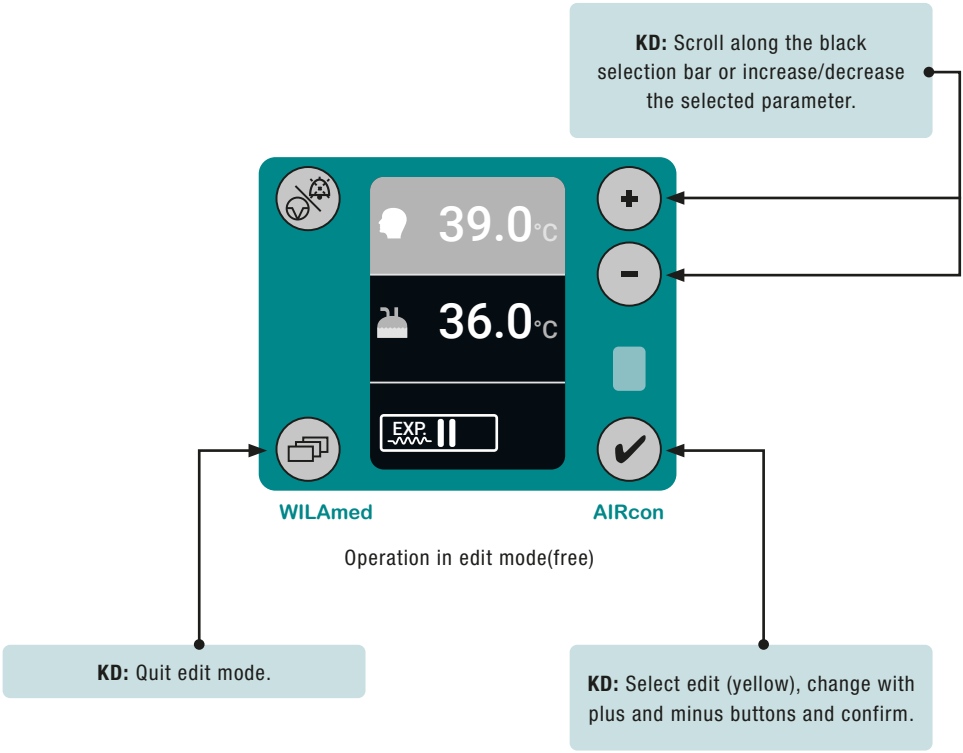
7.1.2 Treatment interruption

Treatment interruption can be activated in normal mode, i.e. when there is no alarm, by pressing the button for 3 seconds. The treatment interruption lasts 3 minutes and can be prematurely terminated at any time by pressing any key. It is indicated by the icon in the upper right corner of the display. During the treatment interruption the heating plate and the heating wire (if connected) are operated at half the power of normal mode.

7.2 Operation in edit mode

By pressing the ✔ fbutton for about 3 seconds in normal mode, the edit mode is called up, and the setpoint temperatures or the expiratory heating capacity can be changed. In the top line, the setpoint for the patient-side temperature can be changed, and below that the setpoint for the chamber temperature. In the bottom line, the heating capacity of the expiratory heating wire can be increased or decreased in 5 stages, indicated in the bar graph display. In order to make a change, select the corresponding line using the cursor keys ⊕ and ⊖. The selected item is initially highlighted in white. The item is highlighted in yellow by pressing the ✔ button. Marked values can be increased or decreased by pressing the buttons ⊕ and ⊖.

Any changes made must be confirmed by pressing the ✔ button. Edit mode is exited by pressing the button.



7.2.1 Reducing condensation in the inspiration tube

To reduce condensation in the inspiration tube, it is recommended that the temperature difference between the patient-side setpoint temperature and the setpoint temperature of the humidification chamber be increased.

7.2.2 Adjusting humidity

The humidity near the patient increases when the setpoint temperature of the chamber is increased.

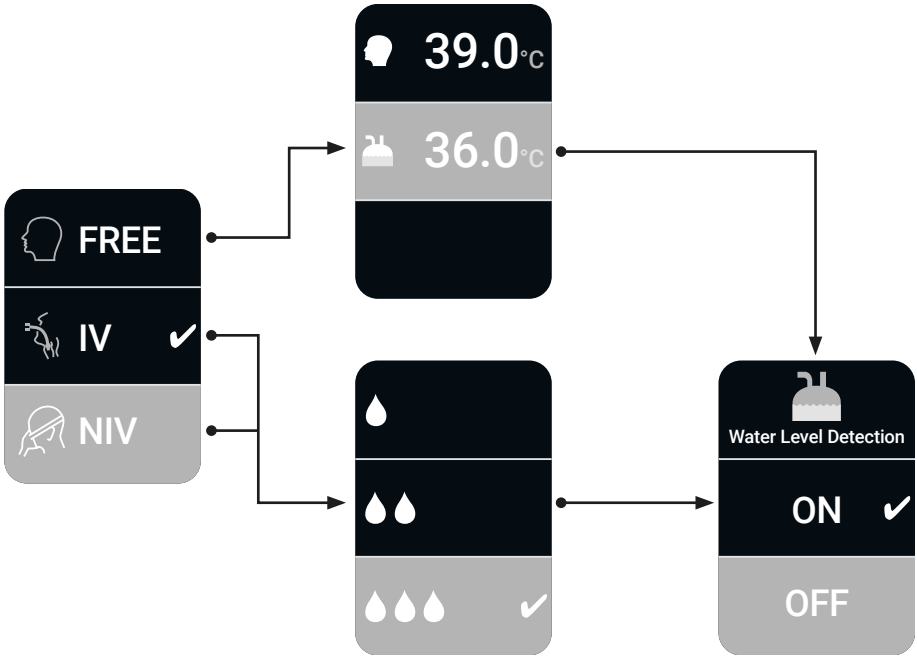
The humidity near the patient decreases when the setpoint temperature of the humidification chamber is reduced.

7.2.3 Reducing condensation in the expiration tube

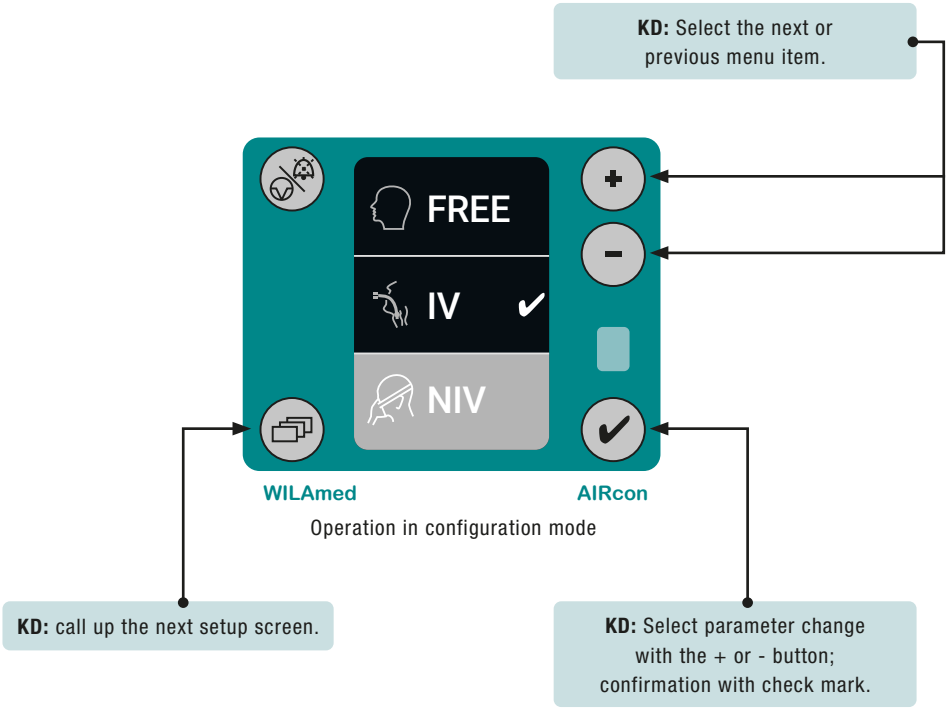
To reduce condensation in the expiration tube, it is recommended that the heat output of the expiratory heating wire be increased.

7.3 Operation in configuration mode

By pressing the ▭ button during normal mode for 3 seconds, the configuration menu is opened. In the configuration menu, it is possible to make individual adjustments. The following diagram illustrates the sequence of menu pages:



The desired function is selected using the cursor keys ⊕ and ⊖. This choice made is automatically marked in yellow and must be confirmed using the ✔ button in order to be adopted. The next menu page, through to operating mode, is opened by pressing the ▭ button.



Operation in configuration mode

7.3.1 Operating mode

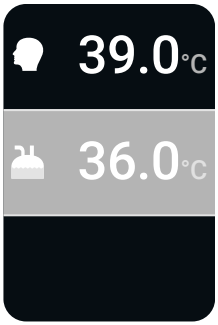
Operating mode	Level	Chamber temperature°C	Patient-side temperature°C
NIV	1	29	34
	2	30	
	3	31	
IV[1]	1	33	39
	2	35	
	3	37	
FREE		28–40.5	28–40.5

[1] In the IV level 3 setting, a minimum humidity of 33mg/l is achieved.

7.3.2 Respiratory flow ranges

Operating mode	Tube diameter (mm)	Respiratory flow range (l/min)
NIV	10	2–15
	15	3–30
	22	4–80
IV	10	2–15
	15	3–30
	22	4–60
FREE	10	2–15
	15	3–30
	22	4–80

7.3.3 Adjusting temperatures

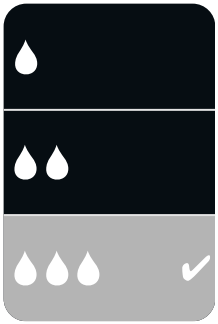


This menu page is only displayed if the user has selected the operating mode "FREE". Notwithstanding the factory setting for invasive and non-invasive ventilation, the user must set the desired patient temperature and chamber temperature manually here.

Note

In any operating mode (including IV and NIV), the temperature can be adjusted to the needs of the patient (e.g. respiratory gas too moist/too dry) if the button is pressed for about 3 seconds, so that the desired setting can be made. When changing the temperature parameters, the device switches automatically to "FREE" operating mode, even with factory settings (IV or NIV).

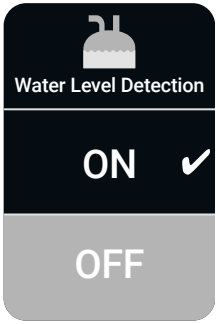
7.3.4 Adjusting humidification capacity



In non-invasive ventilation (NIV) and invasive ventilation (IV) operating modes, the humidification capacity can be adjusted in three steps individually. One drop indicates the minimum humidification capacity, three drops represent the maximum humidification capacity.

This allows the user, depending on the breathing tube system selected and the form of therapy applied, to adapt patient humidification more flexibly; possible condensation in the breathing tube system can be reduced.

7.3.5 Adjusting water fill level detection



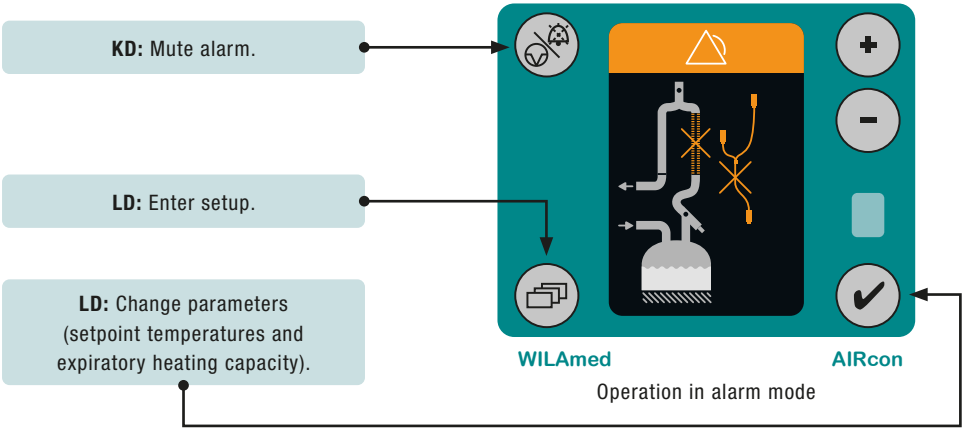
The AIRcon Gen2 active humidifier detects the water level in the humidification chamber autonomously. Should the water level in the humidification chamber exceed the maximum fill level or fall below the minimum fill level, an audible and visual alarm is triggered. The selectable options for automatic water level detection mean:

- „ON“ = Function enabled
- „OFF“ = Function disabled

Note

Correct automatic water level detection function requires the use of unprinted, transparent humidification chambers (e.g. WILAmed C200AF). If the outer wall of the humidification chamber is marked, water level detection must be disabled. The water level should be checked every 2 hours (longer intervals may be possible depending on ventilation parameters) and may not be filled above the maximum marking during operation or run dry.

7.4 Operation in alarm mode



Operation in alarm mode

7.4.1 Alarm muting

The audible alarm can be muted by pressing the button for 120 s and can be terminated prematurely at any time by pressing any key. Then the alarm sounds again. If the cause of the alarm is not resolved within 10 minutes, the unit switches to "OFF" mode.

7.4.2 Alarm delaying

Alarm messages are also suppressed for a certain time if the following conditions are present:

- After completion of treatment interruption, the alarm delay is activated for 3 minutes, because during the treatment interruption period no adjustment has been made. Only the heating power was reduced and the temperatures cannot be immediately achieved after switching to the normal mode.
- After changing the humidification level, the alarm delay is activated for 3 minutes for the same reason.

7.4.3 Warm-up time

During the warm-up time of 30 minutes, certain alarm messages are suppressed. Meanwhile, the icon appears in the lower right corner of the display. These alarms indicate a deviation of an actual temperature from that of the setpoint. The reason for this lies in the fact that the temperatures cannot be achieved immediately after switching on.

7.4.4 Impact on the performance

There are no known adverse effects on the performance of the AIRcon Gen2 due to influences of electrocauterization, electrosurgery, defibrillation, X-rays, infrared rays, transmitted switching pulses, magnetic fields and radio frequency interferences.

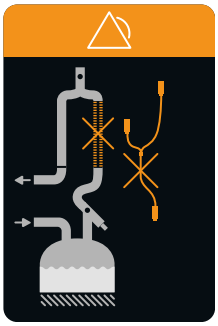
7.4.5 Event list

By pressing and holding the lower right and upper left buttons simultaneously, the event list can be called up. It logs the date, time and the alarm that occurred. Up to 200 entries are can be stored. If the memory is full, the last entry is deleted and the new alarm is added. The content of the event list is retained even after turning off the device.

8. Alarms

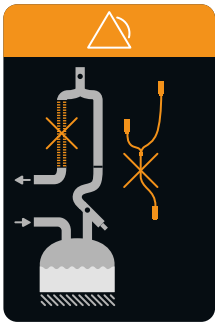
When the device is switched on, it emits an acoustic signal and a visual signal appears in the form of yellow lit LEDs on the display, which verify the functionality of the alarm system. All alarms are assigned to the middle priority.

8.1 Inspiration heating missing/defective



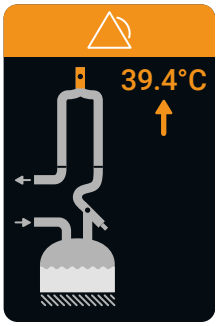
Cause	Remedy
Inspiratory heating wire not connected.	Connect heating wire.
Inspiratory heating wire is defective.	Replace heating wire.
Heating wire distributor cable is defective.	Replace heating wire adapter.
Internal fuses for the heating wire are defective.	Report to customer service.

8.2 Expiration heating missing/defective



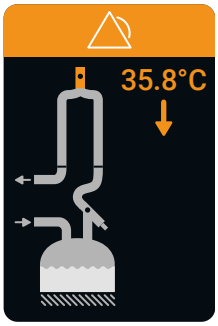
Cause	Remedy
Expiratory heating wire is not connected.	Connect wire filament.
Expiratory heating wire is defective.	Replace heating wire.
Heating wire distributor cable is defective.	Replace heating wire adapter.
Internal fuse for the heating wire is defective.	Report to customer service.

8.3 Breathing gas temperature too high



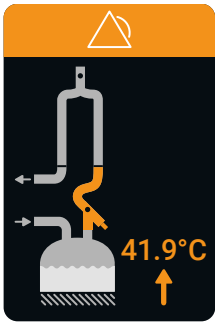
Cause	Remedy
Sudden change in breathing gas flow rate.	Mute alarm and observe whether the temperature reduces to a permissible value.
Temperature probe is defective.	Remove tube system and replace temperature probe.
Breathing gas humidifier is defective.	Remove tube system and report to customer service.

8.4 Breathing gas temperature too low



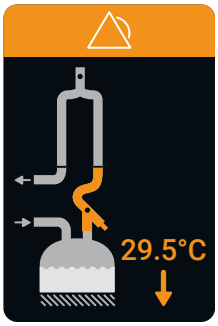
Cause	Remedy
Sudden change in breathing gas flow rate.	Mute alarm and observe whether the temperature increases to a permissible value.
Temperature probe is defective.	Remove tube system and replace temperature probe.
Breathing gas humidifier is defective.	Remove tube system and report to customer service.
Humidification chamber inserted incorrectly.	Correctly insert the humidifier chamber.

8.5 Humidifier chamber temperature too high



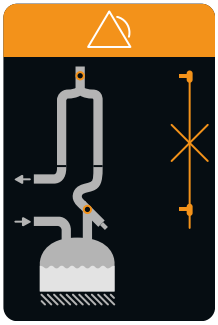
Cause	Remedy
Sudden change in breathing gas flow rate.	Mute alarm and observe whether the temperature reduces to a permissible value.
Temperature probe is defective.	Remove tube system and replace temperature probe.
Breathing gas humidifier is defective.	Remove tube system and report to customer service.

8.6 Humidifier chamber temperature too low



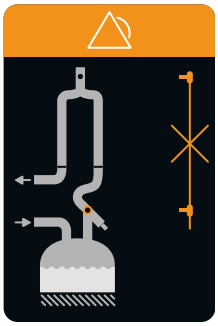
Cause	Remedy
Sudden change in breathing gas flow rate.	Mute alarm and observe whether the temperature increases to a permissible value.
Temperature probe is defective.	Remove tube system and replace temperature probe.
Breathing gas humidifier is defective.	Remove tube system and report to customer service.
Humidification chamber not correctly inserted.	Correctly insert the humidifier chamber.
Temperature fuse has triggered.	Report to customer service.
Bottom of the humidification chamber is uneven.	Replace the humidification chamber.

8.7 Temperature probe missing/defective



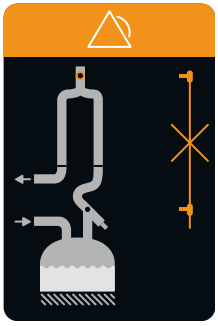
Possible Cause	Measures
Chamber and patient-side temperature probe is not connected to the device or not plugged into the tube.	Switch off device and leave to cool down. Connect chamber and patient-side temperature probe to the device or plug into tube opening and restart. Connection is described in sections 5.1 and 5.4 of the user manual.
Defective temperature probe.	Replace temperature probe.
No ventilation flow.	Check ventilation flow.

8.8 Chamber temperature probe missing/defective



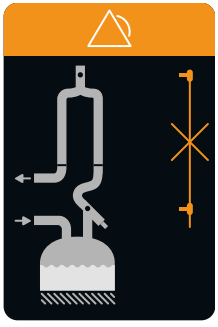
Possible Cause	Measures
Chamber temperature probe is not plugged into the tube.	Switch off device and leave to cool down. Plug chamber temperature probe into tube opening and restart. Connection is described in section 5.4 of the user manual.
Defective chamber temperature probe.	Replace temperature probe.
No ventilation flow.	Check ventilation flow.

8.9 Patient temperature probe missing/defective



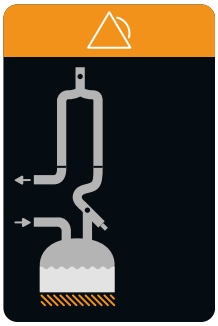
Possible Cause	Measures
Patient-side temperature probe is not plugged into the tube.	Switch off device and leave to cool down. Plug patient-side temperature probe into tube opening and restart. Connection is described in section 5.4 of the user manual.
Defective patient-side temperature probe.	Replace temperature probe.
No ventilation flow.	Check ventilation flow.

8.10 Temperature probe cable defective



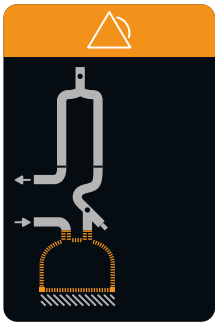
Possible Cause	Measures
Defective temperature probe cable.	Replace temperature probe.

8.11 Heating plate sensor defective



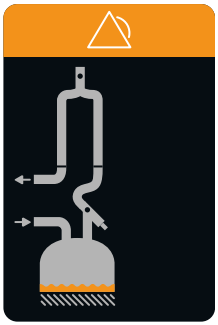
Possible Cause	Measures
Heating element is defective.	Report to customer service.

8.12 Humidification chamber missing



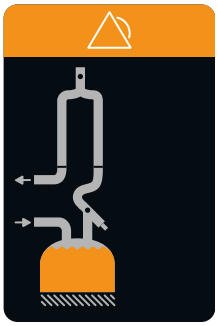
Possible Cause	Measures
No humidification chamber is inserted.	Insert humidification chamber.
Breathing gas humidifier is defective.	Remove tube system and report to customer service.

8.13 Water fill level too low



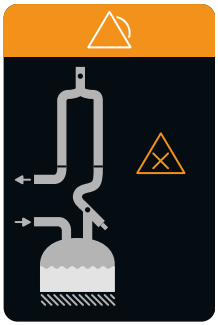
Possible Cause	Measures
Water reservoir is empty.	Replace water reservoir and fill the humidification chamber with water.

8.14 Water fill level too high



Possible Cause	Measures
Float is defective.	Replace the humidification chamber.
Error message due to tilted humidifier.	Place the respiratory humidifier horizontally or disable water level detection.
A labeled humidification chamber is used.	Use non-labeled humidification chamber or disable water level detection.
Sensors for water level detection are dirty.	Remove tube system. Clean sensors with a clean cloth and if necessary contact customer service.
Too much condensate from tube system flowed back into the humidification chamber.	○ Empty the tube system in good time. ○ Reduce excess water in the humidification chamber manually. ○ Disable water level detection temporarily.

8.15 HW alarm

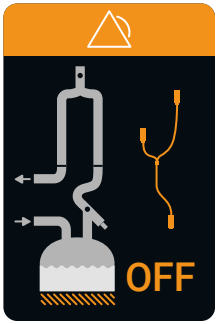


Possible Cause	Measures
	Remove tube system and report to customer service.

8.16 Forced shutdown of the heating wire and the heating plate

Forced shutdown of all heaters.

Depending on the error, this is also displayed in the image.



Possible Cause	Measures
An error has not been corrected within 10 minutes after the alarm report occurring.	Turn off the humidifier device, troubleshoot and turn it on again. If necessary, inform customer service.
Heating plate temperature rises above 108°C.	Turn off the humidifier device and let the heating plate cool down.

8.17 Initialization error

If an error is displayed in orange font on a black background when the device boots up, customer service must be notified.

9. Weekly cleaning

Before cleaning the respiratory humidifier with connected accessories, check to ensure that the AIRcon Gen2 respiratory humidifier is switched off and the power cord is disconnected from the mains connection. Furthermore, it should be ensured that the unit has cooled down.

Do not sterilize or immerse the base unit in liquids! Do not sterilize the temperature probe!

The base unit, temperature probe and heating wire distributor cable can be cleaned with a mild detergent (for example WILAsil). Disinfection is performed by wiping it with any of the following disinfectants:

- Hydrogen peroxide (4%)
- Isopropanol (17%)
- CaviWipes®, METREX® RESEARCH
- Incidin® Plus, Ecolab Deutschland GmbH
- mikrozid® sensitiv liquid, Schülke & Mayr GmbH
- perform®, Schülke & Mayr GmbH
- quartamon® med, Schülke & Mayr GmbH

It is important to ensure that only a damp cloth is used for cleaning! Do not allow any liquids to penetrate the housing. The disinfectant manufacturer's specifications are to be followed. In particular, dilution, exposure times and change in the composition have a major impact on the cleaning process.

For cleaning and disinfecting accessories, the respective instructions for use must be adhered to!

10. Maintenance

The AIRcon Gen2 respiratory humidifier does not need calibration.

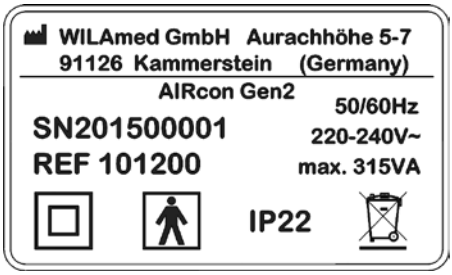
Every 12 months (hospital operation) or every 24 months (domestic care), a safety-related technical check-up and a functional test must be conducted on the AIRcon Gen2. This is performed according to the service and maintenance instructions.

11. Legend

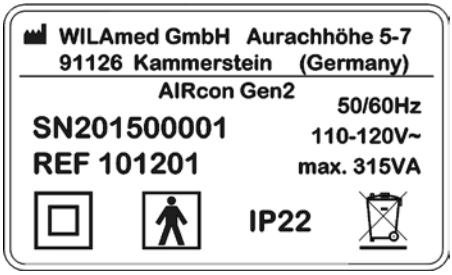
	Application part of type BF (B = Body; F = Floating applied part)
REF 101200	Symbol for Order No.
SN201500001	Manufacturer's serial number. The first four numbers represent the date of manufacture.
	CE mark with designated location
	Manufacturer
	Dispose of the appliance in accordance with the applicable regulations
	Protective insulation; Protection class II
IP22	Protection type
	Follow the instructions
	Warning of hot surface. May cause burns.
	Connection for heating wire distributor cable (imprinted symbol on housing)
	Connection for temperature sensor cable (imprinted symbol on housing)
220–240V~	Operating voltage – 230V version
110–120V~	Operating voltage – 115V version
50/60Hz	Mains frequency

max 315VA	Maximum electric power consumption
2x H 230V 2A F	Fuse for 230V version. H: Breaking capacity 1500A F: Fast-blow fuse
2x H 125V 4A F	Fuse for 115V version H: Breaking capacity 1500A F: Fast-blow fuse

Identification plates depending on the version



Made in Germany



Made in Germany

12. Technical specifications

Before commissioning, check that the voltage corresponds with the operating voltage specified on the identification plate.

Dimensions	Height: Width: Depth:	170mm 145mm 200mm
Weight	AIRcon humidifier:	approx. 2.3kg approx. 2.5kg incl. delivery accessories
Classification	○ Unit (protection class cf. IEC 60601) Class II ○ Application parts of Type BF: - Heated Breathing tube system - Temperature probe ○ Protection category by enclosure IP22 (protected against solid objects with diameter from 12.5mm, protected against access with a finger, protection against falling water drops if the enclosure is tilted up to 15°.)	
Electrical specifications	○ Operating voltage: ○ Mains frequency: ○ Power consumption: ○ Heating plate: ○ Inspiratory tube heater:	*AIRcon Gen2 101200* 220V~ to 240V~ *AIRcon Gen2 101201* 110V~ to 120V~ 50Hz / 60Hz max. 315VA 170W 22V~ , 30W
Operating data	○ Warm-up time: ○ Recommended flow rate: ○ Humidifier system output: ○ Maximum operating pressure: ○ Continuous noise: ○ Sound pressure level of the alarm: ○ Max. volume of water:	max. 30min. 2 to 80l/min >33mg/l in the range of 2–60l/min > 10mg/l in the range of 2–80l/min 200 mbar[1] < 50dB (1m) max. 65dB 200ml

Humidification system	○ Gas leakage at max. operating pressure:	< 10ml/min[2]
	○ Gas leakage at 60mbar:	*Adults* <70ml/min[2] *Children* <40ml/min[2] *Neonates* <30ml/min[2]
	○ Pressure drop:	< 0.02 (mbar*min)/l[2]
	○ Internal Compliance:	*Adults* 0.5 – 5ml/mbar[2] *Children* 0.5 bis 4ml/mbar[2] *Neonates* 0.5 bis 1.5ml/mbar [2]
	○ Flow resistance:	*Adults* < 0.06mbar/l/min bei 30l/min *Children* <0.12mbar/l/min bei 15l/min *Neonates* <0.74mbar/l/min bei 2.5l/min
Environment	○ Temperature	
	- when operating:	+18°C to +26°C
	- during storage and transport:	-25°C to +70°C
	○ Gas inlet temperature:	+18°C to +26°C[3]
	○ Humidity	
	- when operating:	0 – 93% nnon-condensing
	- during storage and transport:	0 – 93% non-condensing
	○ Atmospheric pressure:	
	- in operation	700hPa to 1060hPa
	- during storage and transport:	500hPa – 1200hPa

The humidification decreases if the treatment device delivers breathing gas at a higher temperature!		
Measurement range	Temperature sensor:	9.5°C to 50°C (patient-side) 5°C to 80°C (humidification chamber)
Use area	○ Heated breathing tube system ○ Temperature probe	

[1] Unless the user instructions for the humidification chamber used prescribes lower maximum pressures.

[2] Depending on the humidification chamber used and the breathing tube system used.

[3] The maximum gas outlet temperature of the therapy device at 23°C ambient temperature is 32°C.

13. Storage and disposal

- Clean unit before storing and store it in a plastic bag.
- Loosely wind up the temperature probe and heating wire adapter.
- The permissible storage temperature is from -25°C to + 70°C. Prior to use, the device must be acclimatized and may be put into operation only after reaching the ambient temperature.

To preserve and protect the environment, to prevent environmental pollution, and to enable recycling of raw materials, the European Commission has determined that electrical and electronic equipment shall be taken back by the manufacturer in order to enable their proper disposal. Devices with the symbol "Not for disposal as household waste" may not be disposed in the unsorted municipal waste.

14. Supplement to the technical description

The AIRcon Gen2 measures the breathing gas temperatures at the outlet of the humidification chamber and the patient-side output of the breathing tube system.

The fuses on the primary side are accessible from the bottom side of AIRcon Gen2.
More information can be found in the supplements to the technical description.

15. EMC proof

Guidance and manufacturer's declaration – electromagnetic emissions

The AIRcon Gen2 is intended for operation in an environment as specified below. The customer or user of AIRcon Gen2 should ensure that it is operated in such an environment.

Emission measurements	Conformity	Electromagnetic environment – Guidelines
RF emissions cf. CISPR 11	Group 1	The AIRcon Gen2 uses RF energy exclusively for its internal function. Therefore, RF emissions are very low and it is unlikely that nearby electronic devices will be disturbed.
RF emissions cf. CISPR 11	Class B	The AIRcon Gen2 is suitable for use in residential areas which are directly connected to a public power supply that also supplies buildings used for domestic purposes.
Harmonics cf. IEC 61000-3-2	Fulfilled	
Voltage fluctuations / flicker cf. IEC 61000-3-3	Fulfilled	

Guidance and manufacturer's declaration – electromagnetic immunity to interference

The AIRcon Gen2 is intended for operation in an environment as specified below. The customer or user of AIRcon Gen2 should ensure that it is operated in such an environment.

Checks for immunity to interference	IEC 60601 – test level	Conformity level	Electromagnetic environment – Guidelines
Electrostatic discharge (ESD) cf. IEC 61000-4-2	± 8kV contact discharge ± 15kV air discharge	± 8kV contact discharge ± 15kV air discharge	Floors should be made of wood, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical interferences / bursts cf. IEC 61000-4-4	± 2kV for mains lines 100kHz repetition frequency	± 2kV for mains lines 100kHz repetition frequency	The quality of the supply voltage should be typical for a business or hospital environment
Surges according to IEC 61000-4-5	± 1kV differential mode voltage ± 2kV common mode voltage	± 1kV differential mode voltage ± 2kV common mode voltage	The quality of the supply voltage should be typical for business or hospital environment

Checks for immunity to interference	IEC 60601 – test level	Conformity level	Electromagnetic environment – Guidelines
Voltage dips, short interruptions and voltage variations cf. IEC 61000-4-11	0% U_T; ½ period At 0, 45, 90, 135, 225, 270 and 315 degrees 0% U_T; 1 period and 70% U_T; 25/30 periods Single-phase: at 0 degrees 0% U_T; 250/300 periods	0% U_T; ½ period At 0, 45, 90, 135, 225, 270 and 315 degrees 0% U_T; 1 period and 70% U_T; 25/30 periods Single-phase: at 0 degrees 0% U_T; 250/300 periods	The quality of the supply voltage should be typical for a business or hospital environment
Magnetic field at supply frequency (50/60 Hz) c.f. IEC 61000-4-8	30A/m	30A/m	Magnetic fields at the mains frequency should correspond to the typical values as found in a business and hospital environment

Guidance and manufacturer's declaration – electromagnetic immunity to interference

The AIRcon Gen2 is intended for operation in an environment as specified below. The customer or user of AIRcon Gen2 should ensure that it is operated in such an environment.

Radiation resistance	IEC 60601 – test level	Conformity levels	Electromagnetic environment – Guidelines
Conducted RF interference c.f. IEC 61000-4-6	$3V_{eff}$ 150 kHz to 80 MHz $6V_{eff}$ in ISM and amateur radio frequency bands between 0.15MHz und 80MHz 10V/m	3V 6V	Portable and mobile radio equipment should not be operated in closer proximity to AIRcon Gen2 including power cord than the recommended safety distance, which is calculated according to the equation appropriate to the transmission frequency. Recommended separation distance: $d = 3,5/3 \sqrt{P}$ $d = 3,5/3 \sqrt{P}$ 80 MHz to 800 MHz
Conducted RF interference c.f. IEC 61000-4-3	80 MHz to 2,7 GHz	10V/m 80 MHz to 2,7 GHz	$d = 7/3 \sqrt{P}$ 800 MHz to 2,5 GHz
Radiated RF disturbances in the immediate vicinity of wireless communication devices in accordance with IEC 61000-4-3	Included in table 1	Included in table 1	with P as the rated power of the transmitter in watts (W) according to the transmitter manufacturer and d as the recommended separation distance in meters (m). The field strength of stationary radio transmitters, based on an on-site examination[a] , should be less than the compliance level[b] at all frequencies. In the vicinity of equipment marked with the following symbol, interference is possible. 

Note 1: at 80MHz and 800MHz, the higher frequency range applies

Note 2: these guidelines may not always apply. The propagation of electromagnetic waves depends on absorption and reflection by buildings, objects and people.

[a] The field strength of stationary transmitters, e.g. base stations of radio telephones and mobile radios, amateur radio stations, AM and FM radio and television transmitters, can theoretically not be predetermined precisely. In order to assess the electromagnetic environment with regard to stationary RF transmitters, a study of the electromagnetic phenomena of the site should be considered. If the measured field strength at the site where the AIRcon Gen2 is used exceeds the compliance level above, the AIRcon Gen2 should be monitored in order to demonstrate proper function. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AIRcon

[b] Over the frequency range 150kHz to 90MHz, field strengths should be less than 3V/m.

Test frequency: MHZ	Frequency band [a] MHz	Radio service [a]	Modulation [b]	Maximum power W	Distance m	Interference immunity test level
385	380 up to 390	TETRA 400	Pulse modulation [b] 18Hz	1.8	0.3	27
450	430 up to 470	GMRS 460, FRS 460	FM [c] ± 5kHz range 1kHz sinusoidal	2	0.3	28
710	704 up to 787	LTE band 13, 17	Pulse modulation [b] 217Hz	0.2	0.3	9
745						
780						
810	800 up to 960	GSM 800/900 TETRA 800, iDen 820, CDMA 850, LTE band 5	Pulse modulation [b] 18Hz	2	0.3	28
870						
930						
1720	1700 up to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE band 1,3,4,25; UMTS	Pulse modulation [b] 217Hz	2	0.3	28
1845						
1970						

Test frequency: MHZ	Frequency band [a] MHz	Radio service [a]	Modu-lation [b]	Maximum power W	Distance m	Inter-ference immunity test level
2450	2400 up to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE band 7	Pulse modula-tion [b] 217Hz	2	0.3	28
5240	5100 up to 5800	WLAN 802.11 a/n	Pulse modula-tion [b] 217Hz	0.2	0.3	9
5500						
5785						

NOTE: If necessary, the distance between the transmitting antenna and the ME device or ME system can be reduced to 1 m in order to reach the noise immunity test level. The 1-meter test distance is permitted according to IEC 61000-4-3.

[a] For some radio services, only the frequencies for the radio link from the mobile communication device to the base station (uplink) were included in the table.

[b] The carrier must be modulated with a square wave with 50% duty cycle.

[c] Alternatively to frequency modulation (FM), a pulse modulation with 50% duty cycle with 18Hz can be used, since this, even if not the actual modulation, would thus represent the worst case.

Recommended protective distances between portable and mobile RF communication devices and the AIRcon

The AIRcon Gen2 is intended for operation in an electromagnetic environment in which RF interferences are controlled. The AIRcon Gen2 customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the AIRcon Gen2 - depending on the output power of the communication device, as indicated below.

Rated capacity of the transmitter W	Separation distance depending on transmission frequency in m		
	150KHz to 80MHz $d = 1.2 \sqrt{P}$	80MHz to 800MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters whose rated capacity is not shown in the above table, the distance can be determined using the equation for the respective column, where P is the rated capacity of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: at 80MHz or 800MHz, the separation distance of the higher frequency range respectively applies

Note 2: these guidelines may not always apply. The propagation of electromagnetic waves depends on absorption and reflection by buildings, objects and people.

Notes

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