JFR MEDICAL
INSTRUMENTS GMBH

CUBE 30 ATV

VENTILATOR

User Manual

TABLE OF CONTENTS

1. INTRODUCTION

Please read the complete user manual carefully before using the device.

This manual is aimed at users without clinical background. The manual is shortened compared to the clinical manual.

Note *If questions on turning on, operating or maintaining the device remain, please contact your service provider.*

1.1 Intended use

⚠	**Warning**	*The device is not suitable for a ventilator-dependent patient.*

This **Cube 30 ATV** is a device for non-invasive, non-life supporting respiration of spontaneously breathing patients who have a body weight of at least 13 kg and suffer from respiratory insufficiency.
These clinical pictures include:

- Chronic obstructive pulmonary disorder (COPD)
- Neurological, muscular and neuromuscular complaints, such as paresis of the diaphragm
- Restrictive ventilation disorders, e.g. scoliosis, thorax deformities
- Central respiratory regulatory disorders
- Obstructive sleep apnoea (OSA).

The device is suitable for use at home and in clinics (hospitals, sleep laboratories etc.).

It is possible to reuse the device for another patient. In this case the bacterial filter is required (see Page 15).You must follow the hygiene requirements of your physician and medical care provider.

1.2 Contraindication

The **Cube 30 ATV** is **not a life-supporting system** and may therefore not be used by patients that are only able to tolerate short interruptions in ventilation.

The use of the device could also be contraindicated among patients who suffer from the following conditions:

- Pneumothorax or pneumomediastinum
- Risk of aspirating stomach contents
- Hypotension, particularly combined with intravascular volume depletion
- Fluid discharge, short-term cranial operation or trauma
- Acute sinus or middle-ear inflammation
- Dehydration
- Severe bullous pulmonary inflammation.

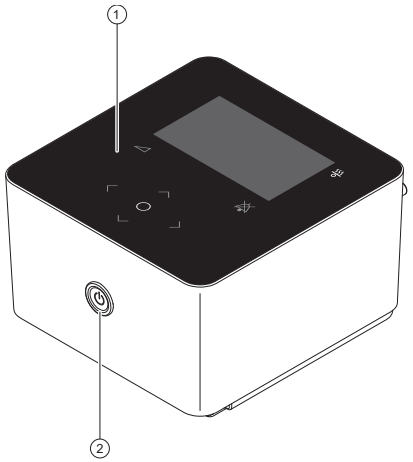
1.3 Side effects

Please contact your doctor immediately if you experienced severe headache, unusual chest pain or shortness of breath.
The following side effects can arise with non-invasive ventilation with this device:

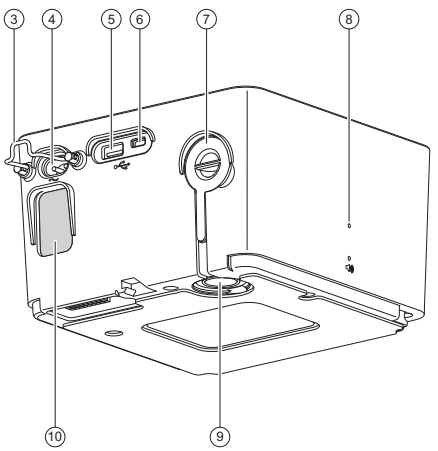
- Irritation of the eye/conjunctiva inflammation
- Ear and nasal cavity symptoms
- Nose bleeds
- Skin irritation or damage
- Dryness of the mouth, throat or nose
- Bloated stomach or feeling of fullness.

2. OVERVIEW OF THE DEVICE

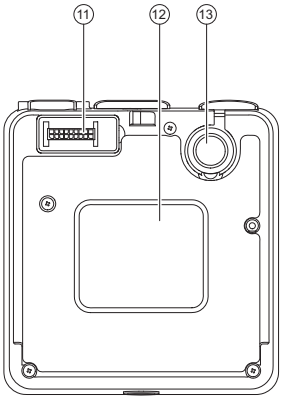
You will find the scope of supply included as standard in section 9.1 on Page 64.



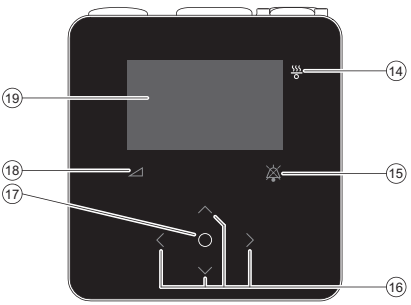
1. Control panel with display
2. Start/stop button



3. Safety clip (mains cable)
4. Mains socket
5. USB A connection
6. Micro USB connection
7. Air outlet (if used without respiratory humidifier) and silicone cover for air outlet
8. Loudspeaker
9. Air outlet (if used with respiratory humidifier)
10. Air inlet and fine or coarse filter



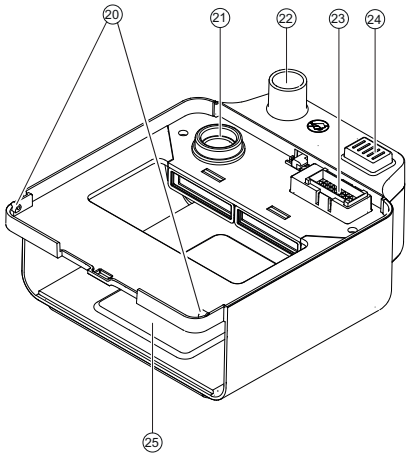
11. Connection socket for respiratory humidifier
12. Type plate
13. Air outlet (if used with respiratory humidifier)



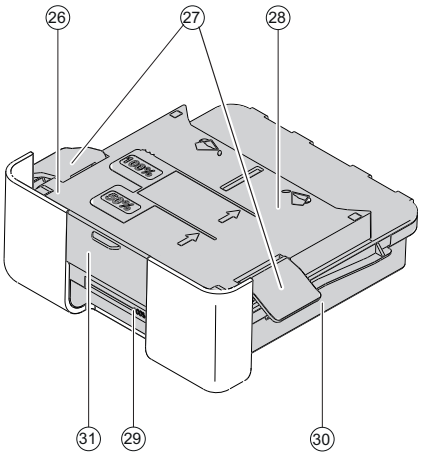
14. LED for respiratory humidifier
15. Audio-pause key
16. Navigation buttons
17. OK key
18. Ramp key
19. Display

2.1 Accessories

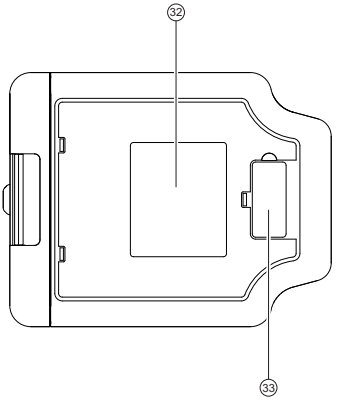
2.1.1 Optional respiratory humidifier P005



20. Holding fence
21. Air inlet of the respiratory humidifier
22. Air outlet
23. Connection socket for respiratory device
24. Release button
25. Heating plate

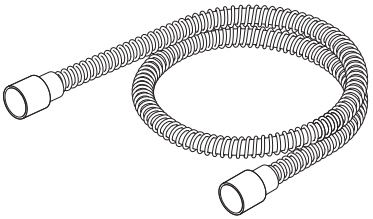


26. Cover for water chamber
27. Locking clamp
28. Heat transfer plate (bottom)
29. Level indicator to the water chamber
30. Water bowl to the water chamber
31. Unlocking handle to the water chamber

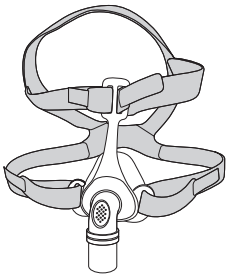


32. Type plate to the respiratory humidifier
33. Storage compartment for the silicone cover of the power connector (if respiratory humidifier is used)

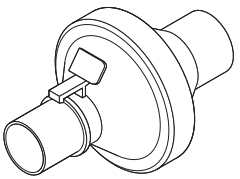
2.1.2 Further accessories



*Tube system
in accordance with ISO 5367

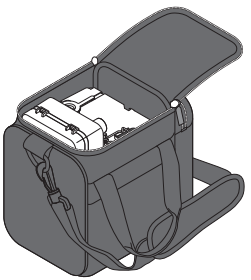


*Respiratory mask
in accordance with ISO 17510
(diagram, not included in the scope of supply)



Bacterial filter
in accordance with ISO 23328-1/ 23328-2
(diagram, not included in the scope of supply)

Power cable (EU type)



Transport bag

*This is the applied part that you will be connecting with.

2.2 Explanation of symbols

Symbols on type plate

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Serial number
	Model number
	Alternating current
	Protection rating II
	Type BF applied part
IP21	Protection from: IP21 + spillage Protection against the ingress of solid foreign bodies ≥ 12.5 mm diameter and larger, and against vertically falling water droplets plus spillage
	Medical device
	CE declaration of conformity

Symbol	Meaning
	The device cannot be disposed of in domestic waste. You can find information about the proper disposal of the device on Page 58.

Symbols on the device

Symbol	Meaning
	Follow user instructions
	Alternating current
	USB connections
	Loudspeaker

Symbols in the clinical manual

Symbol	Meaning
	**WARNING** This symbol designates an extraordinarily dangerous situation. Failure to follow this information can result in serious injuries and even death.
	**CAUTION** This symbol designates a dangerous situation. Failure to follow this information can result in slight or moderate injuries.
	Note This symbol designates information, indications and tips on how to handle the device without any problems.

3. PUTTING THE DEVICE INTO SERVICE

3.1 Setting up the device

⚠ **Warning**	*The device must not be covered or positioned in such a way that the operation or performance of the device is adversely affected. For example, avoid blocking the air inlet on the back of the device with curtains, bedding etc.*

- Ensure that the device is put into service by following the instructions below.
- The responsible organization is accountable for the compatibility of the device and all of the parts and accessories used to connect to the patient before use.
- Place the device a minimum distance of 5 cm from the wall.
- Place the device on a level, dust-free surface, such as a bedside table or on the floor next to the bed.
- Do not place the device on a soft surface, such as a bed or a couch.
- Place the device in such a way that the mains plug can be unplugged at any time without problems.
- Pay attention that the therapy tube cannot strangulate the patient.
- The use of an appropriate coarse air intake filter is necessary.

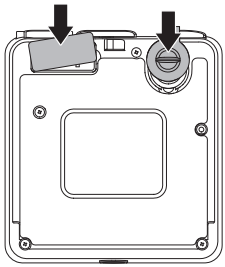
3.2 Connecting the device

The device can be used with or without respiratory humidifier.

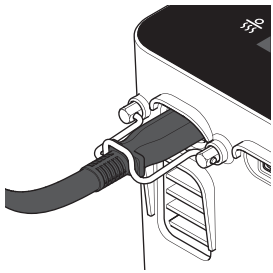
Without respiratory humidifier

1. The openings to the air outlet and the connection socket for the respiratory humidifier can be found underneath the device. Check that the open-

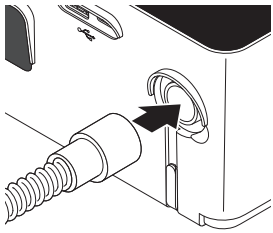
ings are sealed with the silicone covers provided.



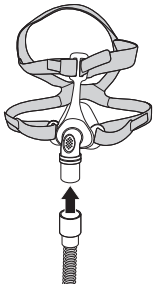
2. Connect the power mains cable to the device. Secure the power cable to the device with the help of the safety clip. Insert the other end of the mains cable into a socket.



3. Connect the respiratory tube on the air outlet on the back of the device.



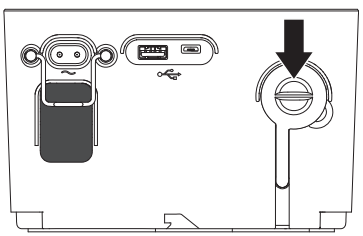
4. Connect the other end of the respiratory tube to the mask.



⚠ **Warning**	*To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.*

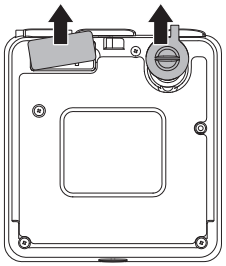
With respiratory humidifier

1. Check that the opening for the air outlet on the back of the device is closed with the silicone cover.

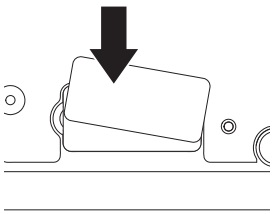


2. Ensure that the silicone cover for the respiratory humidifier's connection

socket under the device has been removed.



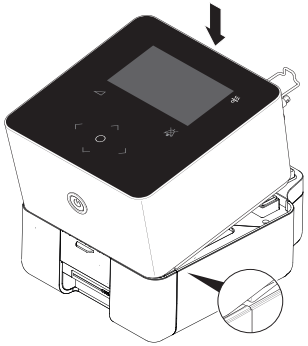
3. There is a storage recess for the silicone cover of the connection underneath the respiratory humidifier. Insert the silicone cover into this storage recess to avoid this getting lost by accident.



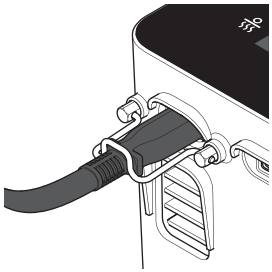
Underside of respiratory humidifier

4. Connect the respiratory humidifier to the device. To do this, place the device on the respiratory humidifier so that it is connected on the front. Ensure that the holding fence of the respiratory humidifier hooks into the

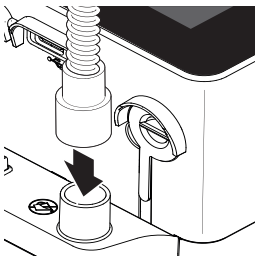
corresponding lugs of the device. Press the back of the device down.



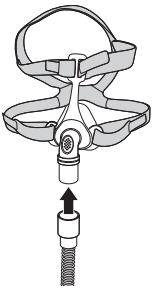
5. Connect the power mains cable to the device. Secure the power cable to the device with the help of the safety clip. Insert the other end of the mains cable into a socket.



6. Connect the respiratory tube to the air outlet on the respiratory humidifier.



7. Connect the other end of the respiratory tube to the mask.



The proper placement and positioning of the mask is critical to the consistent operation of this equipment.

3.3 Fitting the respiratory mask

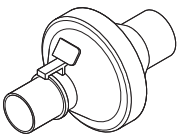
Warning	*The device requires a respiratory mask with integrated air out according to ISO 17510. Otherwise, CO_2 may be reinhaled.*

The device is suitable for use with nasal, oral-nasal, pillow and full-face masks. Please follow the relevant user instructions before fitting the respiratory mask.

Only use masks that comply with DIN EN ISO 17510.

3.4 Connecting bacterial filter

Warning	*If the plan is to use the device with several patients (e.g. in a small clinic), it is necessary to provide the device with a bacterial filter to protect it from contamination with bacteria.*



The bacterial filter is placed between the device's air outlet and the tube system.

Please activate the option in the therapy settings sub-level menu when using a bacterial filter.
Please also note the manufacturer's user instruction.

Please only use bacteria filter which comply to ISO 23328-1/23328-2.

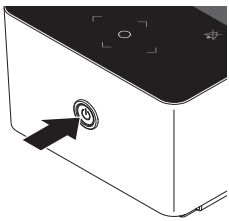
⚠ **Warning**	*When using the humidifier, the bacterial filter will require more frequent replacement to prevent increased resistance or blockage.*

4. USING THE DEVICE DAILY

4.1 Starting therapy

- Put on the respiratory mask. For detailed information on the correct fit of the respiratory mask please refer to the manufacturer information.
- Press the start/stop button to start therapy

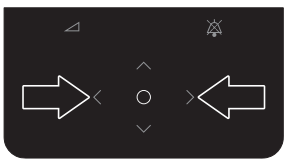
The device provider should periodically reassess the setting(s) of the therapy for effectiveness and ensure that the therapeutic pressure settings were determined for the patient individually with the configuration of the equipment to be used, including accessories.



4.2 Setting the respiratory humidifier

Note *Always leave the device to cool for at least 10 minutes after the end of therapy before you remove the water chamber.*

- Check the water level in the water chamber of the respiratory humidifier.
- Pressing the right/left keys of the navigation buttons on the device allows the required heat level to be set on the standby screen of Patient mode.



- The heat output of the respiratory humidifier can be selected in 6 levels

(off, 1-5, in 1 steps).

- The device saves the step set so that it may be started when it is next used.
- The heating plate can be switched off to use the device with a humidifier connected not using humidification.

⚠ **Warning**	*Use only room temperature distilled water in the chamber. Do not put any chemicals or additives into the water. Possible airway irritation or damage to the water may result.*

⚠ **Warning**	*The height of the device must always be lower than the interface mask during use to prevent water from getting into the mask.*

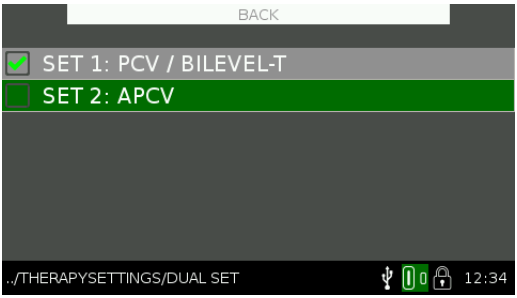
Under normal condition, the humidification can last more than 8 hours with the setting of 10 hPa in CPAP mode, the heating level 5 and the water chamber 100% filled.

In addition to the ambient airflow, the humidification capacity is dependent on the set pressure and the heating level. At the same heating level, the output of the humidifier decreases as the pressure increases.

4.3 Switching therapy sets

The device enables the user to choose one of two therapy sets. This might be useful in case the patient uses different mask configurations or if the patient uses different setups during day and night time.

Through Menu > Therapy settings > Dual set the current set can be changed.

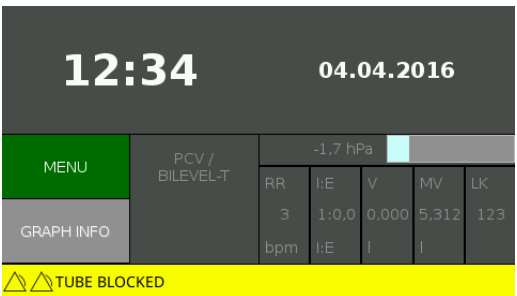


The status bar shows which set is currently enabled.

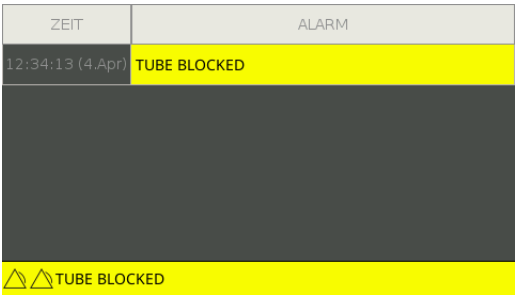
The chosen therapy set is shown in the status bar or the screen which changes the color to purple in case the second set is chosen.

4.4 Handling alarms

The device has different alarms and error messages that can occur during the operation.
If the device is in an active state (i.e. it has been operated during the last two minutes) the alarms and the error messages are notified by an alarm status bar being illuminated in the display and an acoustic signal sounding.
The colour of the alarm status bar varies depending on the alarm's priority that has occurred (yellow for medium priority and turquoise for low priority).



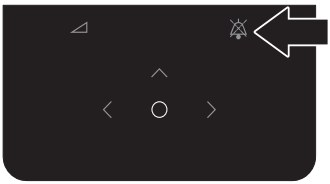
If the device is in the standby state (i.e. has not been operated for at least two minutes) an alarm list that completes the entire display appears and an acoustic signal sounds.
The alarm list shows the 5 prioritised alarms.

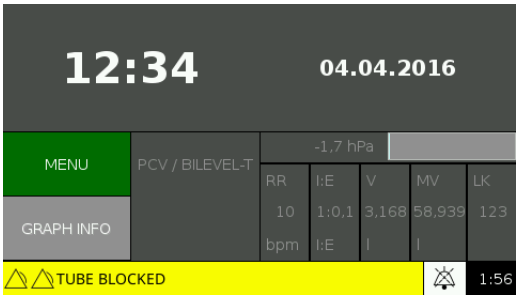


The device changes to the active state after you press any key. The alarms are then detailed in the status bar.

4.4.1 Pausing alarms

- You can switch the acoustic alarm to pause for the duration of two minutes by pressing the "Audio pause" key.





- After a period of two minutes the device reactivates the acoustic signal if the triggering event is still present.
- When you press the "Audio pause" key again during the activated 2-minute counter the duration is reset to two minutes, provided there is still a triggering event. The counter is deactivated if the triggering event has been rectified in the meantime.
- The "Audio pause" key may also be pressed as a matter of precaution if there is a foreseeable condition for an alarm, e.g. before secretion is taken from a patient. At this point the alarms are switched to pause for two minutes.

You can check a more accurate list of the alarms and error messages on Page 49.

4.5 Stopping therapy

- Remove the respiratory mask.
- Press the start/stop button for the period of 3 seconds. Therapy is stopped when you release the button.
  The device signals that therapy has been switched off by notification in the display.

- Pull the tube system out of the respiratory mask.
- Clean the respiratory mask and the tube system. Read a description about this on Page 54.

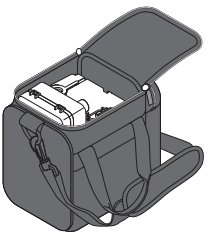
4.6 Switching off the device

The device can remain in standby mode.
However, should you wish to switch it off completely, pull the mains connector out of the socket.

4.7 Travelling with device

Remember to pack the following items:

- Device
- Power cable
- Tube system
- Respiratory mask (including exhalation system if required)
- Respiratory humidifier, if necessary
- Replacement filters and user instructions, if necessary



The **Cube 30 ATV** has a universal power supply that works with mains voltages between 100 and 240 V. It is therefore not necessary to make any changes relating to this on the device. You may need a travel plug adapter to be able to use the power cable in the destination country.

The **Cube 30 ATV** can be used on the plane if the plane is operated via a 100-240 V AC power source.

5. FUNCTIONAL DESCRIPTION

This chapter has only informative character. The therapy settings shall only be adjusted by a doctor and cannot be changed by the patient.

5.1 General function of the device

The device sucks ambient air through the filter system into the device where it is compressed by the blower unit. The compressed air is directed through the therapy tube to the mask of the patient.
The device uses sensors to capture pressure and flow information which are used to get mask pressure as well as breathing phases of the patient. The device uses this information to apply the prescribed therapy.

5.2 Therapy modes

The device has the following therapy modes with the help of which it can be adapted for each individual patient and their individual requirements.
Most of the therapies have two pressure levels (= Bilevel) and differentiate between inhalation and exhalation phase. A breathing cycle starts at the beginning of inspiration and lasts to the end of expiration. Breathing frequency are the number of breathing cycles within a minute.

The doctor can set the following therapy modes on the device: CPAP, PSV-S / Bilevel S, PCV / Bilevel T, PSV / Bilevel ST, APCV.

CPAP

Continuous Positive Airway Pressure.
In CPAP mode a constant pressure level is maintained over the entire respiratory cycle.

PSV-S / Bilevel S

Pressure Support Ventilation Spontaneous.
The patient is respirated with a bilevel mode, at which the pressure support is synchronised with the patient's breathing. When the patient inhales spontaneously the device activates the IPAP (Inspiratory Positive Airway Pressure) and

then returns, released by the patient exhaling into the EPAP (Expiratory Positive Airway Pressure). If the patient does not exhale for a set period (can be set by Ti max), the device switches to EPAP latest after the set period.

PCV / Bilevel T

Pressure Controlled Ventilation.
The patient is respirated with a bilevel mode, at which the pressure support is triggered by the device. The device gives a set, two-stage pressure support, without the patient's respiratory cycle affecting the frequency of the pressure values. The switch from IPAP to EPAP is based on the set inspiration time, the duration of the cycle on the set respiratory rate.

PSV / Bilevel ST

Pressure Support Ventilation.
The patient is respirated with a bilevel mode, at which the pressure support of the breaths is either triggered by the patient himself or the device. The mode is similar to the PSV-S / Bilevel S, only that the device runs at a set respiratory rate and therefore time-controlled respiratory cycles in the absence of any respiratory effort on the part of the patient.

APCV

Assisted Pressure Controlled Ventilation.
The therapy mode is similar to the PCV / Bilevel T, only that the respiratory cycles can also be triggered by the patient. The patient's spontaneous inhalation (trigger) triggers the IPAP and then the device starts the preset respiratory cycle. If no trigger can be found a timed cycle just like on PCV is given.

5.3 Additional therapy functions

The device also offers the following therapy functions.

5.3.1 Ramp

To make the start of therapy more pleasant for the patient, there is the option to set a ramp, through which the pressure level is slowly raised up to the therapy pressure.
The ramp pressure is set as a default by the doctor, the ramp time can be set by the patient.

5.3.2 Target volume

The device offers the option of setting the intended tidal volume that the patient is to reach during the breath. In case the tidal volume is lower the device will increase the support pressure.

5.3.3 Target minute volume

The device offers the option to set an intended air volume that the patient is to achieve over the period of a minute. In case the air volume is lower the device will increase the support pressure.

5.4 Alarms

The device is able to recognise the following fixed and modifiable alarms. Each alarm has a priority which is defined by the possible impact in case no one reacts to the alarm. An detailed description of the different priorities can be found on Page 49. The alarm settings will remain valid after power loss.

Display	Priority
Circuit disconnection	Moderate
Mains failure	Moderate
Tube blocked	Moderate
System error	Moderate
High pressure	Moderate

Display	Priority
Leakage	Low
Non vented mask	Moderate
Low minute volume	Moderate
High respiratory rate	Low
Low respiratory rate	Moderate
Target volume not reached	Moderate
Target minute volume not reached	Moderate

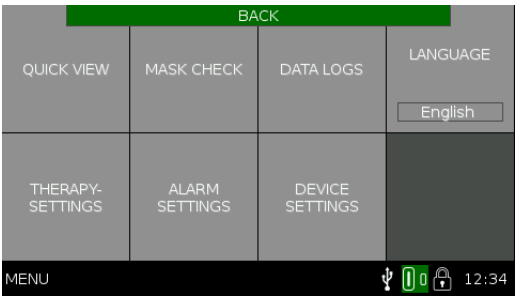
6. SETTING THE DEVICE

6.1 Control panel

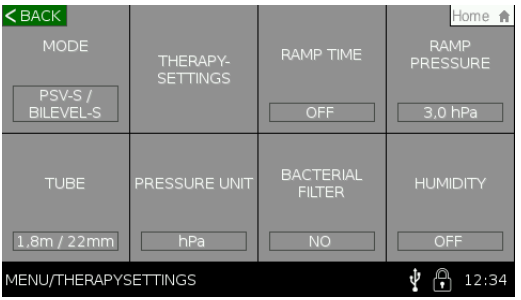
The standby screen appears on the display when you switch on the device. The navigation buttons are underneath the display with the left, right, up and down keys. There is an OK button in the middle of the navigation buttons. Only the keys that currently have a function are lit.

6.1.1 Operating principles

You are able to navigate in the menu using the left, right, up and down keys. The OK key selects the corresponding menu option and confirms the entry.

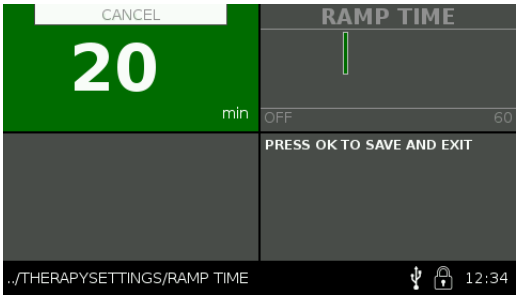


You get back to the previous menu level using the menu option back on the top edge.

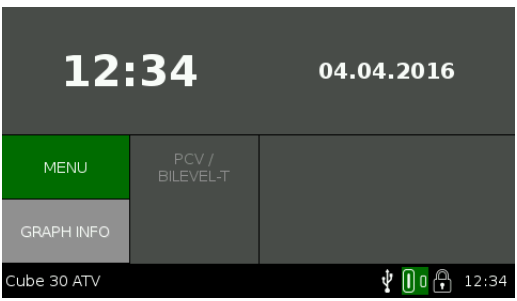


The status bar in the bottom edge shows the menu path you are currently in while you are navigating.

When setting up parameters you are able to change the parameter value by pressing the right/left keys and confirm the set value by pressing the OK key.
To cancel the setting operation and leave the submenu, press the up key until the Cancel field is selected and confirm Cancel with the OK key.



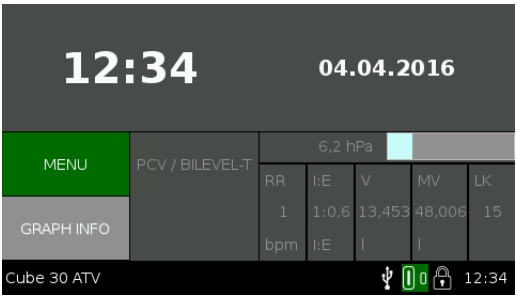
6.2 Standby screen



The standby screen shows the time and date in the top section. If the respiratory humidifier is connected, the set heating performance of the respiratory humidifier is displayed in this area. The heat level then works via the right/left keys.

The menu or a graph of the current therapy can be selected on the left-hand side. The mode currently selected can be found next to it.

With ongoing therapy the current status is displayed on the right-hand side by means of different measured values.



6.2.1 Therapy status range

Parameter	Description
RR	Respiratory Rate. The number of breaths per minute, averaged over the last five breaths.
I:E	I:E ratio. The ratio of inspiration to expiration. Calculated from the last breath.
Vi	Tidal volume. The tidal volume is the integral of the measured patient flow during inspiration.
MV	Breath minute volume. The breath minute volume is the volume of respiratory air that is inhaled and exhaled per minute. The breath minute volume is calculated from the last five tidal volumes with the corresponding breath frequencies.
LK	Leakage. The calculated flow that escapes through the leakage valve and possible leaks at the mask.
Pressure (hPa/cm H_2O)	The current mask pressure is displayed. This is calculated from the measured pressure and the pressure drop via the tube and if necessary respiratory humidifier.

6.2.2 Status bar

The time and the activity of the various device functions including the actual therapy mode are read with the help of the icons in the right-hand area in the status bar next to the currently selected menu option. The icons are hidden if any of the functions is switched off.

Even information about the ramp, provided this has been enabled, can be found in the middle of the status bar.

Status bar in Normal mode

Status bar in Alarm mode

"Audio pause" key has been pressed and the counter of two minutes has been activated.

The alarm priority is indicated: one symbol for low priority, two symbols for moderate priority.

12:34 Time

Connected USB device has been found.

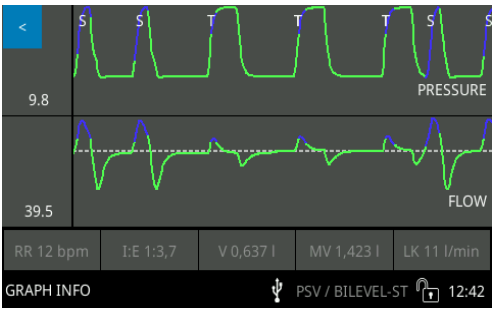
The device is in Patient mode.

The device is in Clinical mode.

The device runs a ramp to reach target pressure. The remaining time is shown besides the icon.

6.2.3 Graph

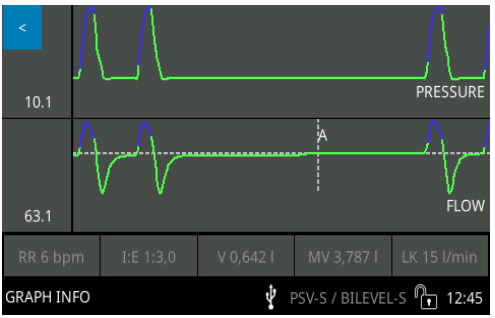
If you select the "Graph info" option, a graphical representation of the last 30 seconds of the mask pressure and the patient flow appears on the display in real time.



The current measured value is displayed on the left-hand side of each of the graphs.

The values of the therapy status area are displayed at the bottom (see Page 30).

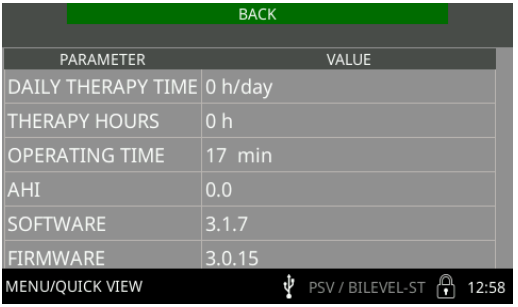
In the Bilevel ST or APCV mode, the inspiration is indicated with S or T.(S) stands for spontaneous inspiration (T) stands for timed mode.



If any AHI events detected by the device, the corresponding event is indicated with A or H. (A) stands for apnea (H) stands for hypopnea.

6.3 Menu

6.3.1 Quick view

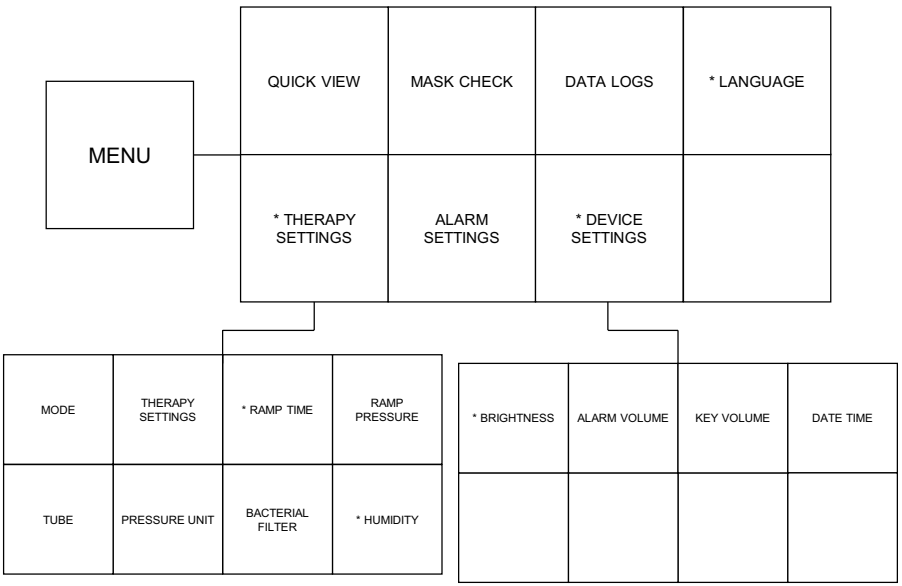


You will find a list of the therapy time used per day, the total usage of the device,the total operating time, the AHI of the current day and the current software/firmware version under Quick view.

⚠ **Warning**	*The AHI values shown in the Quick View is for reference only, cannot be used for diagnosis purpose.*

6.3.2 Menu overview

The device is in Patient mode. The suboptions of the menu, where you are able to change settings yourself, are designated with an *. All further suboptions show the configurations set by the doctor.



6.3.3 Device settings

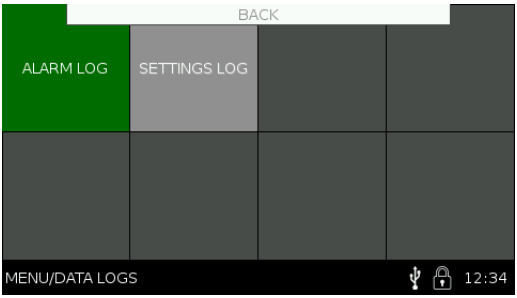
The following parameters can be set for the device.

Parameter	Setting range/ Default	Description
Brightness Display active	Default: 100% Range: 40-100% Step: 10%	Sets the brightness of the display in normal mode.

Parameter	Setting range/ Default	Description
Brightness Display standby	Default: Off Range: Off, 10-100% Step: 10%	Sets the brightness of the display in standby mode.
Brightness Controls active	Default: 100% Range: 40-100% Step: 10%	Sets the brightness of the device keys in normal mode.
Brightness Controls standby	Default: Off Range: Off, 10-100% Step: 10%	Sets the brightness of the device keys in standby mode.
Brightness Humidifier standby	Default: 0% Range: 0-100% Step: 10%	Sets the brightness of the LED that displays if the respiratory humidifier is switched on.
Volume keys	Default: 30% Range: Off, 10-100% Step: 10%	Sets the volume of the keys.
Time	Default set by Service	Sets the time of the device.
Time format	Default: 24 hours Options: 24 hours, 12 hours	Sets the time format.
Date	Default set by Service	Sets the date for the device.
Date format	Default: DD.MM.YYYY Options: DD.MM.YYYY, MM/DD/YYYY	Set the date format.
Language	Default: German Options: The available languages are dependent upon the regional configurations.	Sets the device language.

⚠ **Warning**	*The alarm volume should be set within a range that is not lower than the expected ambient level.*

6.4 Viewing the data logs



6.4.1 Alarm log

To obtain a display of all alarms that occur, you have to select the Alarm log menu option.

- Go to Menu > Data logs > Alarm log and press the OK key to confirm.
- The log appears on the display with the last alarms that occurred.

The following data Date, Time and Alarm type is displayed in the alarm log. The alarm log is sorted chronologically, i.e. the last alarm that occurred is at the top. It includes 50 alarms. After this the oldest alarm is overwritten each time.
The alarm log is retained even after the failure of the device's power supply.

6.4.2 Settings log

To get a display of the previous device settings, you have select the Settings log menu option.

- Go to the Menu > Data logs > Settings log and press the OK key to confirm.
- The log appears on the display with the last settings made.

The following data is displayed in the settings log: Date, Time, Parameters, old and new value.
The settings log is sorted chronologically, i.e. the last setting made is at the top. It comprises 90 setting changes. After this the oldest setting change is overwritten each time.
The settings log is retained even after the failure of the device's power supply.

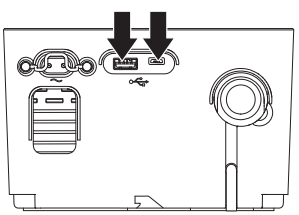
6.5 Data management

⚠ **Warning**	*Do not carry out therapy while the device is connected to the PC via the USB port.*

⚠ **Warning**	*The interconnected equipment must comply with IEC 60601-1, IEC 60950-1 or IEC 60368-1 with safety extra low voltage.*

Note *Ensure that the data has been completely transferred before you remove the USB stick. Otherwise, loss of data and incorrect data may be the result.*

The **Cube 30 ATV** has two USB ports (1x USB-A, 1x Micro USB) on the back of the device. The therapy and device data can be saved via the USB A port with a USB stick. The device can be connected to a PC via the micro USB port.



6.5.1 Backing up patient data

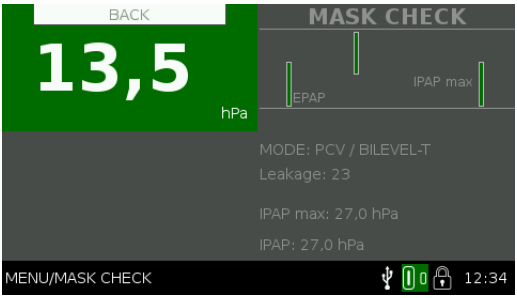
- Connect the USB stick to the USB A connection on the back of the device.
- The device checks the USB stick to see if there is sufficient storage space

available to back up the patient data.

- If the USB stick is suitable, the device starts to back up the therapy data automatically.
- At the end of the data backup a corresponding message will be shown on the display and you can remove the USB stick again.

6.6 Mask check

The mask check function can be used to check that the respiratory mask is fitted correctly on the patient. A constant pressure is given on the respiratory mask, so that the mask fit can be adjusted and any leakages can be corrected.



- Allow the patient to assume the usual position the device is used in, and set up the mask in accordance with the instructions.
- Select Menu > Mask check on the device. Depending on the selected therapy pressure the device starts with the set CPAP/EPAP maximum pressure.
- The pressure is adjusted using the right and left keys.
- Adjust the respiratory mask, the mask cushion and the head harness until the respiratory mask fits well for the patient, and the leakages are significantly reduced.

The device starts automatically with the set therapy after a period of 60 seconds.

6.7 Function test

The device carries out an automatic function test each time it is connected to the power supply, during which important hardware components are checked. The device generates two acoustic signal beeps during the course of the function test that show that the acoustic alarm system is functioning.
If errors are identified during the function test, these are shown in the display. Read the section on operational malfunctions for further information Page 49.

6.8 Testing the alarms

Manual testing of the alarms is not necessary because of the automatic function test of the device. If you still want to check the alarms, follow the instructions regarding alarm simulation.

Alarm simulation

To simulate the alarm, please set up the device as follows:
with a 1.80 m / 22 mm tube, a nasal respiratory mask, without respiratory humidifier and without bacterial filter. Check that the settings have been made accordingly under therapy settings.

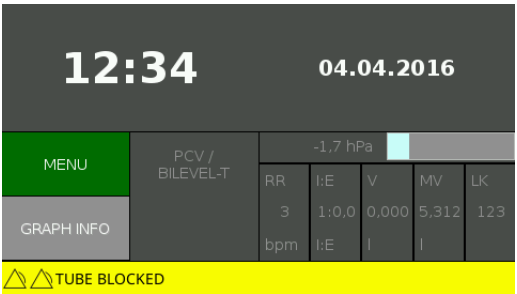
Alarm	Simulation
Circuit disconnection	• Start the therapy. • Pull the tube out of the device. The alarm should sound within 30 seconds.
Mains failure	• Start the therapy. • Pull the power cable out of the socket. The alarm should sound directly.
Tube blocked	• Start the therapy. • Hold the tube with your hand so that no further leakage is possible. The alarm should sound within 20 seconds.
System error	This alarm sounds if the device component is defective. It therefore cannot be tested without damaging the device.

Alarm	Simulation
High pressure	• Start the therapy. • Block the air inlet. • Introduce strong pressure into the device via the air outlet (although not more than 50 hPa; otherwise the device could be damaged). The alarm should sound within 10 seconds.
Leakage	• Ensure that the alarm is activated. • Start the therapy. • Release the respiratory mask partly from your face so that there is no further significant leakage. The alarm should sound within 10 seconds.
Non vented mask	• Ensure that the alarm is activated. • Set the PCV / Bilevel T mode. • Connect an artificial lung without a leak system. • Start the therapy. The alarm should sound within 30 seconds.
Low minute volume	• Ensure that the alarm is activated. • Set the PCV / Bilevel T mode. • Connect an artificial lung with a cubic capacity of 500 ml and leak system. • Set the therapy parameters to the following values: - Respiratory rate to 8 bpm - IPAP to 15 hPa/cm H_2O - EPAP to 5 hPa/cm H_2O - "Low minute volume" alarm to 6 l • Start the therapy. The alarm should sound within 60 seconds.
High respiratory rate	• Ensure that the alarm is activated. • Set the PCV / Bilevel T mode. • Connect an artificial lung with a cubic capacity of 500 ml. • Set the therapy parameters to the following values: - Respiratory rate to 30 bpm - IPAP to 15 hPa/cm H_2O - EPAP to 5 hPa/cm H_2O - "High respiratory rate" to 20 bpm • Start the therapy. The alarm should sound within 5 seconds.

Alarm	Simulation
Low respiratory rate	• Ensure that the alarm is activated. • Set the PCV / Bilevel T mode. • Connect an artificial lung with a cubic capacity of 500 ml. • Set the therapy parameters to the following values: - Respiratory rate to 10 bpm - "Low respiratory rate" alarm to 15 bpm • Start the therapy. The alarm should sound within 5 seconds.
Target volume not reached	• Set the "Target volume not reached" alarm and all other modifiable alarms. • Set the PCV / Bilevel T mode. • Set the therapy parameters to the following values: - IPAP to 8 hPa - EPAP to 6 hPa - Backup rate to 8 bpm - Target volume (parameter) to 1.000 l - Pressure support to 0.5 hPa - Maximum pressure increase per breath to 0.5 hPa • Connect an artificial lung with too low a respiratory volume. The alarm should sound when the set value is not reached despite the maximum pressure increase for 15 seconds.
Target minute volume not reached	• Set the alarm "Target minute volume not reached" and switch all other alarms that can be modified off. • Set the PCV / Bilevel T mode. • Set the therapy parameters to the following values: - IPAP to 8 hPa - EPAP to 6 hPa - Backup rate to 8 bpm - Target minute volume (parameter) to 1.000 l - Pressure support to 0.5 hPa - Maximum pressure increase per breath to 0.5 hPa • Connect an artificial lung with too low a respiratory volume. The alarm should sound if the set value is not reached despite the maximum pressure increase for 1 minute.

7. OPERATING MALFUNCTIONS

7.1 Alarms



The device issues alarms of different priority. These differ in terms of a possible result if the cause of the alarm is not responded to.

Moderate priority

The result of a moderate-priority alarm can be reversible injury to the patient. It is shown in the device display by two yellow △△. An acoustic signal also sounds (see following table).

Low priority

The result of a low-priority alarm can be minor, reversible injuries to the patient or slight damage to the device. It is shown in the device display by a turquoise △. An acoustic signal also sounds (see following table).

Acoustic signals

In addition to the visual signals in the device display the device also issues an acoustic signal. This consists of a sequence of tones that vary depending on the nature of the alarm and priority. The sequence of tones is indicated in the following table by the letters forming each tone pitch (c, a, f, e). The C is an octave above c.

Display	Priority (Display)	Acoustic	Cause	Length of trigger	Measure
Circuit disconnection	Moderate △△	c a f	The device detects a fall in pressure in the exhalation system. The tube system has probably become detached.	30 sec	Checks the tube system's connections.
Mains failure	Moderate △△	Beep (for 2 minutes)	The device no longer has power supply.	Direct	Check the power supply connection.
Tube blocked	Moderate △△	c a f	The device detects an obstruction in the tube system.	10 sec	Check the tube system for any potential blockages. Remove any potential blockages. Restart the therapy.
System error	Moderate △△	C c c	There is an internal error.	Direct	Remove connector, wait 5 minutes and restart device. *Note: The backup alarm will be discharged during the 5 minute wait.* If there is still an error, please contact Service.
	No further display possible	3 second tone (4 kHz), 3 second pause	The hardware for the device possibly failed due to EM disturbances.	Direct	Please disconnect the connector to end the acoustic signal. Please contact Service.

Display	Priority (Display)	Acoustic	Cause	Length of trigger	Measure
High pressure	Moderate △△	c a f	The therapy pressure exceeds the set limit value.	10 sec	Stop the therapy. This alarm cannot occur unless the patient has breathed strongly against the device. Please contact Service department if the alarm still occurs.
Leakage	Low △	e c	The device detects a high system flow (leakage). The respiratory mask has possibly slipped.	10 sec	Check the fit of the respiratory mask.
Non vented mask	Moderate △△	c a f	A respiratory mask is being used without an air outlet, or the air outlet is blocked.	30 sec	Ensure that the patient is using a respiratory mask with an air outlet. Check that the air outlet openings are not blocked.
Low minute volume	Moderate △△	c a f	The respiratory minute volume is lower than the set limit value.	10 sec	The patient's condition should be checked.
High respiratory rate	Low △	e c	The respiratory rate exceeds the set limit value.	5 sec	The patient's condition should be checked.

Display	Priority (Display)	Acoustic	Cause	Length of trigger	Measure
Low respiratory rate	Moderate △△	c a f	The respiratory rate is below the set limit value.	5 sec	The patient's condition should be checked.
Target volume not reached	Moderate △△	c a f	The target volume is not reached despite the maximum indicated inspiration pressure.	Immediately, if not reached despite the maximum additional pressure	The patient's condition should be checked.
Target minute volume not reached	Moderate △△	c a f	The target minute volume is not reached despite the maximum indicated inspiration pressure.	Immediately, if not reached despite the maximum additional pressure	The patient's condition should be checked.

Informative signals

In addition to the alarms there are informative signals. The following signals are for information purposes only:

Reason of the signal	Frequency and interval
System start	261 Hz (for 80 ms) - 80 ms pause - 523 Hz (for 80 ms)
Button strike	220 Hz (for 20 ms)
Therapy stop	880 Hz (for 250 ms) - 100 ms pause - 1760 Hz (for 100 ms)
Accepted	880 Hz (for 750 ms)

Reason of the signal	Frequency and interval
Abort	880 Hz (for 150 ms) - 150 ms pause - 880 Hz (for 150 ms) - 150 ms pause 880 Hz (for 150 ms)

7.2 Handling errors

7.2.1 Error messages (display)

Error message	Possible cause	Measure
"Internal storage error. Settings reset. Code E1"	Software error.	Do not start the therapy. Contact your doctor or your medical advisor to have the settings checked. If the error message appears again, please contact your service partner.
"Internal storage error. Settings reset. Code E2“	Software error.	Do not start the therapy. Contact your doctor or your medical advisor to have the settings checked. If the error message appears again, please contact your service partner.
"Clock not set."	The time on the device is not set.	Please set the time in the menu. If the error message appears several times the clock battery will soon be depleted. Please contact your service partner.
"Clock not calibrated."	The clock on the device has not been calibrated.	Please contact your service partner.
"Clock battery depleted."	The clock battery is depleted.	Please contact your service partner.
"Check humidifier."	The respiratory humidifier has a fault.	Please check the installation of the respiratory humidifier. If everything is installed correctly, contact your service partner.

Error message	Possible cause	Measure
"The set temperature of the humidifier cannot be reached."	If the water filled in the water chamber has a significantly lower temperature than the room air, the heating time may last longer.	Fill in the water with room temperature. If the message persists, contact your service partner.
"Humidifier temperature is too high. Humidifier is deactivated.“	- The heating mattress is defective. - There is no water in the water chamber.	Unplug the device for 5 minutes. Restart the humidifier and check the water level in advance. If the message appears again, contact your service partner.
"The start temperature of the humidifier does not change."	- The heating mattress is defective. - A non-compatible humidifier is connected.	Check if a compatible humidifier is connected. Contact your service partner if necessary.

7.2.2 Troubleshooting

Problem	Possible cause	Measure
Nothing being shown on the display. No running noise.	Device is in standby mode and brightness of the display in standby mode is set to "off".	Press a key on the device. The device should wake up from standby mode. If this does not happen, please investigate other possible causes.
	No power to the device.	Check that the power cable is fitted correctly to the device and to the socket. Ensure there is no general power outage.
Device is running but does not reach the set therapy pressure (CPAP/IPAP).	Filter is dirty.	Check the filters and clean/ change them, if necessary.
	Air outlet is blocked, for example.	Ensure the air inlet to the device is freely accessible.
	There is a leakage in the respiratory mask or tube system.	Check the respiratory mask and tube system are fitted correctly and for potential faults. Replace any relevant components, if necessary.
Air current does not switch on.	Device is in standby mode.	Press the start/stop button to ensure that the device is not in standby mode.
	Tube blocked.	Check condition of the tube system and that there are no blockages.
	Device defective.	Switch the device off and on again. If the problem continues, contact your service partner.

Problem	Possible cause	Measure
Air stream is warmer than usual.	Device is close to the heating/ in sunlight.	Ensure that the device is placed away from sunlight and heating.
	Fluctuations in temperature of the air stream depending on room temperature.	Ensure that the air inlet to the device is not blocked by curtains or bedding. Reduce the room temperature if necessary.
	Respiratory humidifier is connected; water chamber has not been filled up.	Check the settings and the water chamber of the respiratory humidifier. Make any changes to the settings and fill the water chamber of the air humidifier, if necessary.
Dry nasal mucous membrane	Device is being operated without respiratory humidifier	Install a respiratory humidifier to reduce possible symptoms, such as dry nasal mucous membrane, dried out mouth or sore throat by moistening the inhaled air.
	Device being operated with respiratory humidifier and at too low a heat level	Gradually increase the heat level of the respiratory humidifier to increase the air humidity of the respiratory air.

Problem	Possible cause	Measure
Air stream is not warmed/not humidified when the air humidifier is connected.	Respiratory humidifier is not connected correctly.	Check that the respiratory humidifier's LED is illuminated on the device. The respiratory humidifier is connected correctly if the LED is illuminated. If not, detach the device from the respiratory humidifier and reconnect them again.
	Heat level set incorrectly.	Check the set heat level of the respiratory humidifier on the display. Increase the set value if necessary. *Note: After switching on the respiratory humidifier it has a preheating time of approximately 30 minutes to heat the water in the water chamber.*
	Water chamber is empty.	Check that the water chamber for the respiratory humidifier has been filled and fill it with more water, if necessary.
	Respiratory humidifier is defective.	If none of the other possible causes apply, contact your service partner.
Language distorted	Accidental distortion of the device's language, so that the user can no longer operate the device	The menu option for setting the device language can be found in the first menu window (see Page 34).

8. CLEANING AND MAINTAINING THE DEVICE

⚠ **Caution**	*Service and maintenance must not be performed during operation of the device!*

8.1 Intervals

The device and the individual components must be cleaned and maintained at regular intervals. You will find a user guide on how to clean the components from Page 53 onwards.

Components	Interval	Activity
Breathing device **Cube 30 ATV**	When needed	Clean device with damp cloth
Mains cable	When needed	Clean power cable with damp cloth
Respiratory mask	Daily	Clean respiratory mask
	Weekly	Clean respiratory mask thoroughly in accordance with the user instruction
Tube system	Daily	Clean tube system
	Annually	Change tube system
Coarse filter	Weekly	Clean coarse filter
	At the latest after 1500 operating hours	Replace coarse filter, earlier in the case of damage
Fine filter	Every 1000 operating hours	Replace fine filter (do not wash!)
	In the case of contamination	Replace fine filter (do not wash!)
Bacterial filter	In accordance with manufacturer's information	Replace bacterial filter

Components	Interval	Activity
Water chamber of the respiratory humidifier	Daily	Clean water chamber of the respiratory humidifier
Transport bag	When needed	Clean transport bag

8.2 Cleaning

⚠ **Warning**	*After cleaning, ensure that all the device's elements and accessories are rinsed carefully with clean water. Any remaining residues of cleaning agents or descaling agents may harm the patient during therapy.*
⚠ **Caution**	*Do not clean the device and the housing of the respiratory humidifier in the dishwasher. This can result in material damage.*

Note *Only use mild soapy water to clean the components. Do not use any bleach, chlorine, solutions containing alcohol or alkalis, or moisturising or antimicrobial soaps. These agents can harden the materials and therefore significantly shorten the service life.*

The following cleaning steps can be executed as often as required.

Housing

Note *Never submerge the housing in water or rinse off. Protect the openings and filters from ingress of liquids to prevent damage to the device. If, however, liquid should get into the device, please do not continue to use but contact the service department.*

- Disconnect device from the power supply.
- Wipe the device with a damp cloth to remove any dust.
- Allow the housing to dry completely before you use the device again.

Respiratory mask

Note *Please observe the manufacturer's information.*

- Disconnect the respiratory mask from the tube system.
- Clean the respiratory mask with mild soapy water.
- Then rinse the respiratory mask carefully with clean water.
- Allow the respiratory mask to air dry.

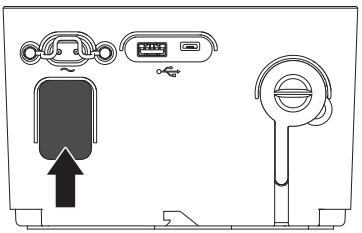
Tube system

Note *Please observe the manufacturer's information.*

- Disconnect the tube system from the device and respiratory mask.
- Wash the tube system with mild soapy water.
- Carefully rinse out the tube system with clean water.
- Allow the tube system to air dry.

Coarse filter

- Remove the dark coarse filter on the back of the device.

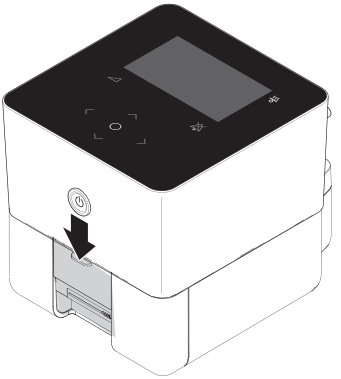


- Wash the coarse filter with mild soapy water.
- Rinse the coarse filter with clean water.
- Allow the coarse filter to dry completely before you use it again.

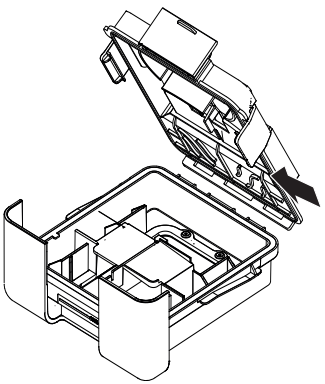
Water chamber of the respiratory humidifier

- Disconnect device from the power supply.
- Pull the water chamber out of the respiratory dehumidifier with the help of the unlocking handle.
- Press the opening lever on the water chamber to separate both halves of

the water chamber.



- Remove the gasket from the lower half of the water chamber.



- Clean all parts of the water chamber with mild soapy water.
- Rinse all parts of the water chamber with clean water.
- Allow the individual parts to dry completely before you put them together again.

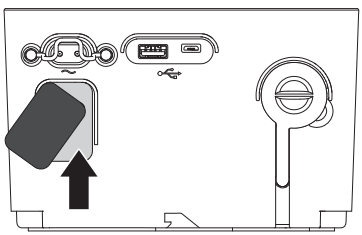
8.3 Maintenance

Replacing the coarse filter

- Remove the dark coarse filter on the back of the device.
- Dispose of the old coarse filter in normal domestic waste.
- Replace the coarse filter.

Replacing the fine filter

- First remove the dark coarse filter on the back of the device.
- Remove the clear fine filter that is located immediately behind the coarse filter.



- Dispose of the old fine filter in normal domestic waste.
- Replace the fine filter.
- Place the coarse filter in front the fine filter again.

Replace bacterial filter

Note *Please observe the manufacturer's information.*

- Detach the bacterial filter from the tube system and device.
- Replace the bacterial filter and connect to the tube system and device again.

Safety checks

The device must be subject to a safety check at the prescribed intervals to ensure operating safety.

To maintain the device, the device must be serviced by an authorised distributor at the following interval as a preventative measure:

- After 20.000 operating hours (shown on the display).

8.4 Disinfection

If necessary, e.g. in the case of severely infectious diseases, you may disinfect the following device components:

- Housing
- Power cable
- Water chamber

Please only use permitted disinfection agents. You will find more detailed information in the hygiene concept that can be obtained from your service partner.

Housing

Disinfect the housing and the air outlet, in particular, using a wipe-down disinfectant, e.g. wet wipe dispenser from Schülke.

Water chamber

- Soak the disassembled components in a hot water bath at 90°C for 1 minute. Take care that no air bubbles are trapped against the components.
- Air dry out of direct sunlight.

Thermal disinfection equivalent water bath parameters:

Process Temperature	Process Time
70 °C	100 minutes
75 °C	30 minutes
80 °C	10 minutes
90 °C	1 minute

8.5 Disposal

Device

The device may not be disposed of in normal domestic waste.
Please contact your authorised collection point or an authorised municipal authority waste disposal company for correct disposal. You can obtain the addresses from your municipal authority. Or send the device back to your service partner.

Packaging

Your can dispose of your device's packaging in normal domestic waste.

Accessories and wear parts

You may dispose of the filters in normal domestic waste.
Please dispose of the tube and mask in accordance with the manufacturer's instructions.

9. SCOPE OF DELIVERY

9.1 Standard scope of delivery Cube 30 ATV

Part	Order number
Cube 30 ATV Device DE	P001G001
Cube 30 ATV Device UK	P001G002
Hose system (Ø 15 mm, length 1.80 m)	P001Z001
EU power cable	P001Z005
Fine filter	P001Z007
Coarse filter	P001Z008
Transport bag	P001Z009
User instruction	P001Z010

9.2 Accessories/spare parts

Part	Order number
Tube system, Ø 22 mm, length 1.80 m	P001Z002
Tube system, Ø 22 mm, length 2.70 m	P001Z003
Tube system, Ø 22 mm, length 3.60 m	P001Z004
UK power cable	P001Z006
Respiratory humidifier	P005
Water chamber	P005E001
Sealing gasket	P005E002
Silicone cover for air outlet	P001E001
Plug lock	P001E012

10. TECHNICAL DATA

10.1 Technical data

Device specification:	
Sizes, W x H x D:	168 x 108 x 182 mm
weight:	1650 g
air outlet:	22 mm cone (in accordance with DIN EN ISO 5356-1)
Service areas:	
Power supply:	100 - 240 V, 50/60 Hz
Max. power consumption:	1 A
Operating conditions:	
Temperature range:	+ 5 °C to + 35 °C
Relative air humidity range:	10 % to 95 % (excluding condensation)
Air pressure range:	800 hPa to 1100 hPa
Transport/storage conditions:	
Temperature range:	- 20 °C to + 50 °C
Relative air humidity range:	10 % - 95 % (excluding condensation)
Air pressure range:	800 hPa to 1100 hPa
Air filter:	
Particle size of coarse filter:	0.2 - 2.5 mm
Mean particle size of fine filter:	3.3µm
Tube system:	Flexible plastic For 22 mm diameter: 1.80 m/ 2.70 m/ 3.60 m length For 15 mm diameter: 1.80 m length
Water Capacity (Humidifier):	To maximum fill line 100%: 380 ml

Sound pressure ranges:	
Sound pressure level in accordance with ISO 80601-2-70:2020-11:	< 32 dB(A)
Sound power level in accordance with ISO 80601-2-70:2020-11:	< 40 dB(A)
Sound pressure level of alarm:	> 50 - 62 dB(A)
Sound power level of alarm:	> 57 - 69 dB(A)
	Note: *The measuring radius is 1 meter away from the measuring equipment.*
Performance features:	
Max. working pressure:	30 hPa (by pressure measurement/ adjustment)
Min. working pressure:	3 hPa (by pressure measurement/ adjustment)
Max. stable limit pressure:	40 hPa
Min. stable limit pressure:	0 hPa
Maximum respiratory resistance in the event of single failure:	
Inspirational pressure on the patient connection opening of the device for a flow of 30 l/min:	1.52 hPa
Expiration pressure on the device's patient connection opening for a flow of 30 l/min:	1.54 hPa
Humidity Output (Humdifier):	
According to ISO 80601-2-74 on 23°C without heated tube:	- 5 hPa (12 l/min) = 18 mg/l - 10 hPa (18 l/min) = 15 mg/l - 20 hPa (28 l/min) = 13 mg/l
Maximum gas temperature:	+ 43 °C
Gas leakage at 30 hPa according to ISO 5367:2023:	< 3 l/min

Inspiration trigger:	Flow-based inspiration trigger Accuracy: ± 20%
Expiration trigger:	The expiration trigger is triggered during the following percentages of the maximum flow during inspiration: 30 - 70% of the IPAP value Accuracy: ± 20%
Pressure measurement:	Integrated pressure converter in the respiratory device Accuracy: ± 0.4 hPa
*Long-term pressure stability in accordance with ISO 80601-2-70:2020-11:	< 0.3 hPa
*Flow at maximum speed in accordance with ISO 80601-2-70:2020-11:	at 3 hPa: 129.3 l/min[1] at 10 hPa: 186.7 l/min at 17 hPa: 167.0 /min at 23 hPa: 145.5 l/min at 30 hPa: 124.8 l/min
Max. operating time/day:	Continuous operating
EMC in accordance with EN 60601-1-2/2015:	CISPR 11, class B
Product category in accordance with Regulation (EU) 2017/745 Annex VIII:	II a
Classification to IEC 60601-1:A2:2020 against electric shock:	BF type class II
The humidifier is classified to ISO 80601-2-74:	Category II

IP protection class:	IP 21 Protection from: IP21 + spillage Protection against the ingress of solid foreign bodies ≥ 12.5 mm diameter and larger, and against vertically falling water droplets plus spillage ***Note:*** *The IP 21 rating for the humidifier will only apply when it is used with the main device.*
Expected operating life of the device:	5 years

All flow and volume values are given in STPD.

[1]Limited by the resistance of the respiratory tube.

*In accordance with ISO 80601-2-70:2020-11, the tolerances of the measuring tool is ± 1.9 % for the flow and ± 1 % for the pressure (Full Scale Output).

10.2 Pressure Accuracy

Maximum dynamic pressure variation according to ISO 80601-2-70:2020-11 in CPAP mode.

The percentages used for the calculation determining the accuracy for inspiratory and exspiratory phase are 40 % to 66.6 % each. The inspiration phase starts, when the flow values become positive, the exspiration phase starts, when the flow values become negative.

Device without humidification and Standard respiratory tubing.

Pressure (cm H_2O)	10 BPM	15 BPM	20 BPM
3	± 0.146	± 0.231	± 0.366
7	± 0.178	± 0.251	± 0.364
12	± 0.22	± 0.301	± 0.346
16	± 0.248	± 0.31	± 0.409
20	± 0.251	± 0.36	± 0.427

Device with humidification and Standard respiratory tubing.

Pressure (cm H_2O)	10 BPM	15 BPM	20 BPM
3	± 0.165	± 0.219	± 0.359
7	± 0.219	± 0.288	± 0.346
12	± 0.252	± 0.315	± 0.369
16	± 0.301	± 0.335	± 0.418
20	± 0.351	± 0.384	± 0.455

Maximum dynamic pressure variation according to ISO 80601-2-70:2020-11 in Bi-Level mode.

Device without humidification and Standard respiratory tubing.

Inspiratory Pressure (cm H_2O)	10 BPM	15 BPM	20 BPM
	(Means, Standard Deviations)		
7	- 0.2973 / 0.4166	- 0.1912 / 0.1074	- 0.0399 / 0.2006
12	- 0.2381 / 0.3586	- 0.2019 / 0.1579	0.0715 / 0.1739
18.5	- 0.3372 / 0.2043	0.2292 / 0.0982	0.2331 / 0.1616
25	- 0.2396 / 0.0896	0.3375 / 0.1139	0.3533 / 0.1698
30	- 0.2961 / 0.1588	0.3844 / 0.1585	0.4209 / 0.1883

Expiratory Pressure (cm H_2O)	10 BPM	15 BPM	20 BPM
	(Means, Standard Deviations)		
3	- 0.00087 / 0.0135	- 0.0217 / 0.0198	0.0110 / 0.0298
8	- 0.0512 / 0.02084	- 0.0546 / 0.0877	0.1323 / 0.0310
14.5	- 0.1142 / 0.1566	0.2137 / 0.0479	0.2599 / 0.0547
21	- 0.1618 / 0.0718	0.3182 / 0.0980	0.3656 / 0.1103
25	- 0.1585 / 0.114	0.3374 / 0.1306	0.4118 / 0.1762

Maximum dynamic pressure variation according to ISO 80601-2-70:2020-11 in Bi-Level mode.

Device with humidification and Standard respiratory tubing.

Inspiratory Pressure (cm H_2O)	10 BPM	15 BPM	20 BPM
	(Means, Standard Deviations)		
7	- 0.3535 / 0.2193	- 0.2846 / 0.1225	- 0.3594 / 0.2207
12	- 0.2814 / 0.0612	- 0.2582 / 0.1168	- 0.3274 / 0.2074
18.5	- 0.2861 / 0.0769	- 0.2974 / 0.1226	- 0.3191 / 0.2010
25	- 0.4179 / 0.6416	- 0.3335 / 0.1342	- 0.3455 / 0.2017
30	- 0.4253 / 0.2072	- 0.3415 / 0.1409	- 0.3473 / 0.1988

Expiratory Pressure (cm H_2O)	10 BPM	15 BPM	20 BPM
	(Means, Standard Deviations)		
3	- 0.0332 / 0.0110	- 0.0165 / 0.0192	- 0.0508 / 0.0309
8	- 0.0870 / 0.0222	- 0.0336 / 0.0271	- 0.0105 / 0.0326
14.5	- 0.1561 / 0.0510	- 0.1473 / 0.0553	- 0.0436 / 0.0501
21	- 0.1268 / 0.6331	- 0.2009 / 0.0874	- 0.1488 / 0.1133
25	- 0.2855 / 0.0855	- 0.2469 / 0.1042	- 0.1760 / 0.1699

Maximum dynamic pressure variation according to DIN EN ISO 80601-2-79:2020-02 in pressure controlled mode.

The inspiratory phase in the set value under leakage condition	± 0.6 hPa
The expiratory phase in the set value under leakage condition	± 0.2 hPa

All flow and volume values are given in STPD.

Tolerances for measuring devices used:
In accordance with ISO 80601-2-70:2020-11 and DIN EN ISO 80601-2-79:2020-02, the accuracy of the measuring tool is ± 1.9 % for the flow and ± 1% for the pressure(Full Scale Output).

10.3 Display values therapy status range

Parameter	Range (step)	Accuracy	Refresh rate
RR	Range: 0-255 bpm Step: 1 bpm	± 1 bpm	Each breath
I:E	Range: 1:0.0 to 1:9.9 Step: 0.01	± 0.01	Each breath
Vi	Range: 0.0-65.535 l Step: 0.001 l	± 150 ml	Start of expiration
MV	Range: 0-65.535 l Step: 0.1 l	± 150 ml (+ mean value formation)	Start of expiration
LK	Range: 0-250 l/min Step: 1 l/min	± 3 l/min (+ mean value formation)	Marginal condition, dependent upon the leakage and leakage change
Pressure (hPa/cm H_2O)	Range: -5-40 hPa/cm H_2O Step: 0.1 hPa/cm H_2O	IPAP: ± 0.4 hPa EPAP: ± 0.4 hPa CPAP: ± 0.4 hPa	2 ms (+ mean average formation)
Flow	Range: -247-247 l/min Step: 1 l/min	± 1.1 l/min or ± 20%	5 ms

10.4 Setting ranges and accuracy of the therapy settings

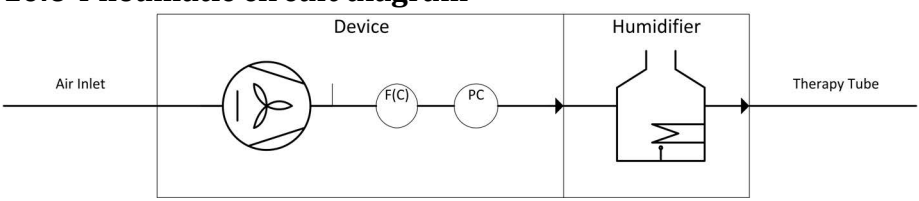
Parameter	Setting range	Accuracy
CPAP	Range: 3-20 hPa/cm H_2O Step: 0.5 hPa/cm H_2O	± 0.4 hPa
IPAP	Range: 5-30 hPa/cm H_2O Step: 0.5 hPa/cm H_2O Dependency: ≥ EPAP + 2 hPa/cm H_2O	± 0.4 hPa
EPAP	Range: 3-25 hPa/cm H_2O Step: 0.5 hPa/cm H_2O Dependency: ≤ IPAP - 2 hPa/cm H_2O	± 0.4 hPa
Target volume	Range: Off, 0.200-2.000 l Step: 0.010 l	± 0.2 Pa
Target minute volume	Range: Off, 2.000-15.000 l Step: 0.100 l	± 0.2 Pa
Pressure support	Range: 0-25 hPa cm H_2O Step: 0.5 hPa/cm H_2O Dependency: ≤ 30 - IPAP	± 0.4 hPa
Maximum pressure increase per breath	Range: 0.1-2 hPa/cm H_2O Step: 0.1 hPa/cm H_2O	± 0.4 hPa
Inspiration slope	Range: Step 1-6 Step: 1	± 0.4 hPa
Expiration slope	Range: Step 1-6 Step: 1	± 0.4 hPa
Inspiration trigger	Range: Step 1-5 Step: 1	± 0.2 Pa
Expiration trigger	Range: Auto, 30-70 % Step: 10 %	± 0.2 Pa
Trigger lock	Range: 0.3-8.0 s Step: 0.1 s Dependency: ≤ (60:respiratory rate)-inspiration time	± 1 ms

Parameter	Setting range	Accuracy
Backup rate	Range: 4-40 bpm Step: 1 bpm	± 1 bpm
Inspiration time	Range: 0.4-5 s Step: 0.1 s Dependency: 20-80% of a respiratory cycle	± 1 ms
Ti min	Range: 0.3-5 s Step: 0.1 s Dependency: < Max. inspiration time	± 1 ms
Ti max	Range: 0.3-5 s Step: 0.1 s Dependency: > Min. inspiration time	± 1 ms
Ramp pressure	Range: 3-20 hPa/cm H_2O, step: 0.5 hPa/cm H_2O Dependency: ≤ CPAP, ≤ EPAP	± 0.4 hPa
Ramp time	Range: 0-60 min Step: 5 min	± 1 ms

10.5 Setting ranges and accuracy of the alarm parameters

Alarm	Setting range	Accuracy
High respiratory rate	Range: Off, 10-60 bpm Step:1 bpm	± 1 bpm
Low respiratory rate	Rate: Off, 4-20 bpm Step: 1 bpm	± 1 bpm
Low minute volume	Range: Off, 2.000-15.000 l Step: 0.100 l	± 0.2 Pa
Leakage	Range: On, off	Not necessary
Non vented mask	Range: On, off	Not necessary
Target volume not reached	Range: On, off	± 0.2 Pa
Target minute volume not reached	Range: On, off	± 0.2 Pa

10.6 Pneumatic circuit diagram



F(C): Flow meter with regulator characteristics if target volume or target minute volume are set.

PC: Pressure measurement with regulator characteristics.

10.7 Protective Distance

Please ensure the protective distances between the device and wireless communication devices such as mobile phones. Otherwise the therapy of the device might be influenced.

Maximum nominal power of sending source in W	Protective distance depending on frequency in m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

10.8 Declarations on Electromagnetic Compatibility

Guidelines and Manufacturer's Declaration - Electromagnetic Emissions

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Emission measurements	Compliance	Electromagnetic environment - Guidelines
Conducted disturbance according CISPR 11	Group 1	The Cube 30 ATV uses RF energy exclusively for its internal function. Its RF emissions are therefore very low and it is unlikely that neighbouring electronic devices will be disturbed.

Guidelines and Manufacturer's Declaration - Electromagnetic Emissions

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Emission measurements	Compliance	Electromagnetic environment - Guidelines
Radiated disturbance according CISPR 11	Class B	The Cube 30 ATV is intended 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.
Oberschwingungen nach IEC 61000-3-2	Class A	
Voltage fluctuations and flicker according IEC 61000-3-3	Matches	

Enclosure - Housing

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines
Electrostatic Discharge (ESD) according IEC 61000-4-2	± 2 kV, ± 4 kV ± 6[a)] kV, ± 8 kV ± 15 kV direct discharge	± 8[a)] kV, ± 15 direct discharge	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
	± 2 kV, ± 4 kV ± 6 kV, ± 8 kV indirect discharge, horizontal coupling plate under the device, vertical coupling plate [b)]	± 8 kV indirect discharge, horizontal coupling plate under the device, vertical coupling plate b)	
	± 2 kV, ± 4 kV ± 6 kV, ± 8 kV contact discharge	± 8 kV contact discharge	
	± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air discharge	± 15 kV air discharge	

Enclosure - Housing

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines
High Frequency Electromagnetic Fields according IEC 61000-4-3	10 V/m 80 MHz - 2,7 GHz 80 % at 1 kHz	10 V/m 80 MHz - 2,7 GHz 80 % at 1 kHz	The quality of the supply voltage should correspond to the environment in professional healthcare facilities and the environment in the home health-care sector.
	385 MHz (18 Hz pulse modulation)	27 V/m	
	450 MHz[c)] 810 MHz 870 MHz 930 MHz (18 Hz pulse modulation)	28 V/m	
	1720 MHz 1845 MHz 1970 MHz 2450 Mhz (217 Hz pulse modulation)	28 V/m	
	2450 MHz (217 Hz Pulsmodulation)	28 V/m	
	710 Mhz 745 Mhz 780 Mhz 5240 MHz 5500 MHz 5785 MHz (217 Hz pulse modulation)	9 V/m	

Enclosure - Housing

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines
Magnetic Field with Power-frequency according IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Magnetic fields at the mains frequency should correspond to the environment in professional healthcare facilities and the environment in the home healthcare sector.
Proximity magnetic field according IEC 61000-4-39	30 kHz	8 A/m	
	134,2 kHz (2,1 kHz pulse modulation)	65 A/m	
	13,56 Mhz (50 kHz pulse modulation)	7,5 A/m	

a Heating plate
b Coupling plates
c Pulse modulation was used as an alternative to FM modulation

Supply - Alternating Voltage

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines
Fast Transients – Burst according IEC 61000-4-4	± 2 kV 100 kHz Repeat frequency	± 2 kV 100 kHz Repeat frequency	The quality of the supply voltage should correspond to the environment in professional healthcare facilities and the environment in the home healthcare sector.
Surge Immunity according IEC 61000-4-5	± 0,5 kV, ± 1 kV Mains line L+N ± 0,5 kV, ± 1 kV, ± 2 kV, Mains L+PE, N+PE (a)	± 0,5 kV, ± 1 kV N/A	
Conducted disturbances, induced by radio-frequency fields according IEC 61000-4-6	3 Vrms 150 kHz bis 80 MHz 6 Vrms ISM- and Amateur radio frequency bands (b) 80 % AM 1 kHz	3 Vrms	

Supply - Alternating Voltage

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines
Power supply drop, Short interruptions according IEC 61000-4-11	0 % UT; 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°	1/2 Period	The quality of the supply voltage should correspond to the environment in professional healthcare facilities and the environment in the home healthcare sector. If the user of the Cube 30 ATV requires continued operation even in the event of interruptions to the power supply, it is recommended that the Cube 30 ATV be powered from an uninterruptible power supply or a battery.
	0 % UT; 0°	1 Period	
	70 % UT; 0°	25/30 Periods (50/60 Hz)	
	0 % UT	250/300 Periods (50/60 Hz)	

Supply - Alternating Voltage

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines

Remark: UT is the AC mains voltage before applying the test levels

a Does not apply to ME devices or ME systems of protection class II.
b The ISM bands (en: Industrial, Scientific and Medical, d. h. the frequency bands used for industrial, scientific and medical purposes) between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz, 13,553 MHz to 13,567 MHz, 26,957 MHz to 27,283 MHz and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz, 50,0 MHz to 54,0 MHz.

Patient Connections

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines
Electrostatic Discharge (ESD) according IEC 61000-4-2	± 2 kV, ± 4 kV ± 6[a)] kV, ± 8 kV ± 15 kV direct discharge	± 8[a)] kV, ± 15 direct discharge	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
	± 2 kV, ± 4 kV ± 6 kV, ± 8 kV indirect discharge, horizontal coupling plate under the device, vertical coupling plate [b)]	± 8 kV indirect discharge, horizontal coupling plate under the device, vertical coupling plate b)	
	± 2 kV, ± 4 kV ± 6 kV, ± 8 kV contact discharge	± 8 kV contact discharge	
	± 2 kV, ± 4 kV ± 8 kV, ±15 kV air discharge	± 15 kV air discharge	
Conducted disturbances, induced by radio-frequency fields according IEC 61000-4-6	3 Vrms 150 kHz bis 80 MHz 6 Vrms ISM- and Amateur radio frequency bands (c) 80 % AM 1 kHz	N/A (d)	

Patient Connections

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines

a Heating Plate
b Coupling plates
c The ISM bands (en: Industrial, Scientific and Medical, d. h. the frequency bands used for industrial, scientific and medical purposes) between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz, 13,553 MHz to 13,567 MHz, 26,957 MHz to 27,283 MHz and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz, 50,0 MHz to 54,0 MHz.
d The Cube 30 ATV has no patient connections into which conducted interference variables can be induced.

Signal Input / Signal Output Parts (SIP / SOP)

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines
Electrostatic Discharge (ESD) according IEC 61000-4-2	± 2 kV, ± 4 kV ± 6[a] kV, ± 8 kV ± 15 kV direct discharge	± 8[a] kV, ± 15 direct discharge	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
	± 2 kV, ± 4 kV ± 6 kV, ± 8 kV indirect discharge, horizontal coupling plate under the device, vertical coupling plate [b]	± 8 kV indirect discharge, horizontal coupling plate under the device, vertical coupling plate b)	
	± 2 kV, ± 4 kV ± 6 kV, ± 8 kV contact discharge	± 8 kV contact discharge	
	± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air discharge	± 15 kV air discharge	
Fast Transients – Burst according IEC 61000-4-4	± 2 kV 100 kHz Repeat frequency	N/A (d)	
Surge Immunity according IEC 61000-4-5	± 2 kV, Mains L+PE, N+PE		

Signal Input / Signal Output Parts (SIP / SOP)

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines
Conducted disturbances, induced by radio-frequency fields according IEC 61000-4-6	3 Vrms 150 kHz bis 80 MHz 6 Vrms ISM- and Amateur radio frequency bands (c) 80 % AM 1 kHz		

a Heating plate
b Coupling plates
c The ISM bands (en: Industrial, Scientific and Medical, d. h. the frequency bands used for industrial, scientific and medical purposes) between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz, 13,553 MHz to 13,567 MHz, 26,957 MHz to 27,283 MHz and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz, 50,0 MHz to 54,0 MHz.
d The Cube 30 ATV does not have any SIP / SOP that are required for its intended use.

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines
Conducted disturbances, induced by radio-frequency fields according IEC 61000-4-6	3 Vrms 150 kHz bis 80 MHz 6 Vrms ISM- and Amateur radio frequency bands (c)	3 Vrms	Portable and mobile radios are used at no closer than the recommended safety distance from the Cube 30 ATV, including the cables, calculated according to the equation appropriate for the transmission frequency. **Recommended safety distance:** $d = 1,2 \sqrt{P}$

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines
High Frequency Electromagnetic Fields according IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	d = 1,2 √P 80 MHz to 800 MHz d = 2,3 √P 800 MHz to 2,7 GHz with P as the rated power of the transmitter in watts (W) as specified by the transmitter manufacturer and (d) as the recommended safety distance in metres (m). The field strength of stationary radio transmitters is lower than the compliance level (b) at all frequencies according to an on-site investigation (a). Interference may occur in the vicinity of devices bearing the following symbol.

Guidelines and Manufacturer's Declaration - Electromagnetic Immunity

The Cube 30 ATV is intended for use in the electromagnetic environment specified below. The user of the Cube 30 ATV should assure that it is used in such an environment.

Immunity Testing	IEC 60601 - Test Level	Matching Level	Electromagnetic Environment - Guidelines

Remark 1 At 80 MHz and 800 MHz, the higher value applies.
Remark 2 These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To determine the electromagnetic environment due to stationary RF transmitters, a site survey is recommended. If the measured field strength in the location in which the Cube 30 ATV is used exceeds the applicable RF compliance level above, the Cube 30 ATV should be observed to verify normal operation in each location. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Cube 30 ATV.
b Over the frequency range from 150 kHz to 80 MHz, the field strength is less than 3V/m.
c The ISM bands (en: Industrial, Scientific and Medical, d. h. the frequency bands used for industrial, scientific and medical purposes) between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz, 13,553 MHz to 13,567 MHz, 26,957 MHz to 27,283 MHz and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz, 50,0 MHz to 54,0 MHz.

⚠ Warning

Use of the Cube 30 ATV immediately adjacent to other devices or stacked with other devices should be avoided, as this could result in incorrect operation. If use in the manner described above is nevertheless necessary, the Cube 30 ATV and the other devices should be observed to ensure that they are working properly.

Warning

Portable RF communications equipment (including accessories such as antenna cables and external antennas) should be used no closer than 30 cm (or 12 inches) to any part or cable of the Cube 30 ATV specified by JFR Medical Instruments GmbH. Failure to do so may result in a reduction in the performance characteristics of the Cube 30 ATV.

11. SAFETY INFORMATION/WARNINGS

11.1 Operating the device

⚠ WARNING

- Do not use the device at an altitude above 2000 m or outside a temperature of + 5°C to + 35°C. Using the device outside of this temperature range or above this altitude can compromise the device performance.
- If there is any damage to the housing do not put your hand or any metallic objects in the housing.
  There is a risk of electric shock.
  Contact your service partner if there are any obvious defect to the housing.
- The power cable may no longer be used if it is damaged in any way.
  There is a risk of electric shock.
  Contact your service partner to obtain a new power cable.
- Covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient.
- The device may not be used by patients with a body weight of less than 13 kg. It has not been tested and approved for this type of application.
  There is a risk of incorrect therapy settings.
  Therefore use an appropriate special device.
- Avoid the device being exposed to high temperatures (above 80°C).
  There is a risk of damage to the device and beyond this injury to the patient during therapy.
- Use of this device adjacent to or stacked with other device should be avoided as it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by JFR Medical could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm(12 inches) to any part of the device, including cables described within the manual. Otherwise, degradation of the performance of the device could result.
- The device has not been evaluated or approved for use near X-ray, CT, or MRI equipment. Do not take the device into a Magnetic Resonance (MR) environment.
- Sources of oxygen must be located more than 1 m from the equipment to avoid the risk of fire and burns.
- Do not add any attachments or accessories to the device that are not intended for use in combination with the device, as the device might not function correctly leading to the risk of degradation or loss of ventilatory support.
- Ensure that there is someone close at all times during therapy who is able to operate the device and react to alarms.
  Otherwise, alarms may be ignored.
- Do not carry out therapy while the device is connected to the PC via the USB port.
  The USB connection is not suitable for remote maintenance of the device.
- Pay attention that the therapy tube cannot strangulate the patient.
- Please ensure the protective distances between the device and wireless communication devices such as mobile phones. Otherwise the therapy of the device might be influenced. Further information on Page 72.
- Please keep the device out of reach of children under 3 years old as it contains small parts that can be swallowed, such as the fine or coarse filter in the air inlet.
- Different alarm settings on the same or similar device within hospital wards might result in endangered patients.

⚠ Caution

- Set up the device in such a way that the air inlet cannot be blocked on the back of the device by curtains, bedding etc.
  This could result in the device overheating and being damaged.

- The heating plate of the respiratory humidifier and the heat transfer plate on the underside of the water chamber may reach temperatures up to 65°C during the normal operation and 74°C if a single failure occurs. There is a risk of burns.
  Leave the device to cool following therapy before you remove the water chamber.

General information

- Please do not use anti-static or electric conducting tubes.
- Please position the device so that the display is visible during the treatment.
- Only use accessories described within the manual.
  The use of other accessories may damage the device or interfere with the therapy. If you are unsure about using accessories please contact your service provider.
- Attaching additional accessories to the device‘s patient interface might result in pressure increase at mask interface during expiration.
- During operation there should always be an alternative ventilation source.

11.2 Transport/maintenance

⚠ WARNING

- If the device is transported in temperature below 5°C or above 35°C, unpack the device and wait for 24 hours until the device temperature reaches room temperature before connecting the device to the power cable.
- The prescribed service intervals (see Page 52 and Page 57) must be observed to guarantee the device runs smoothly.
  Otherwise the quality of the therapy may suffer.
- The device must be hygienically prepared by the manufacturer or the service partner in the event of a change of patient if no bacterial filter was used previously.
  Otherwise, there is a risk of infection for the new patient.
- After cleaning, ensure that all corresponding parts of the device have been

carefully rinsed with clean water.
Any remaining residues of cleaning agents or descaling agents may harm the patient during therapy.

- Any modification of the device is not allowed.

⚠ Caution

- Do not clean the device and the housing of the respiratory humidifier in the dishwasher.
  This can result in material damage.
  Please observe the following cleaning information Page 53.
- Do not transport the device with the respiratory humidifier connected.
  Ensure that the water chamber of the respiratory humidifier has been emptied prior to being transported.
  Any ingress of water into the device may result in damage.

12. INDEX

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