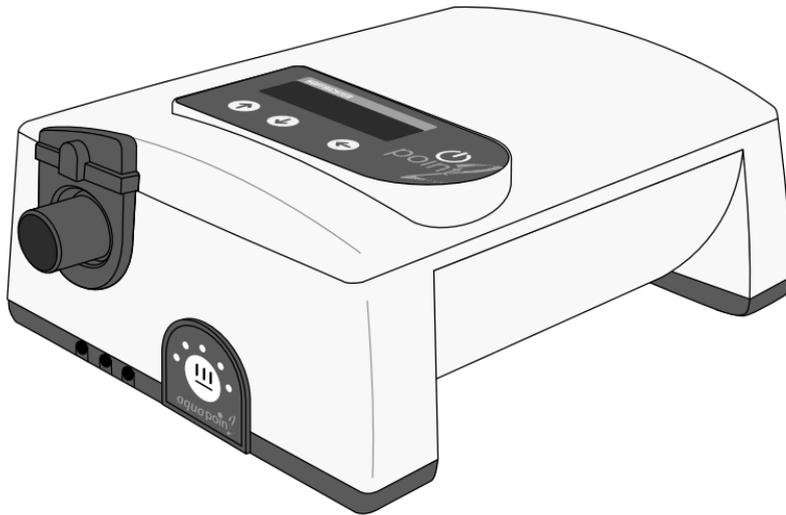


HOFFRICHTER
Quality makes the Difference ■■■■

point



User's Manual
Respiratory Therapy Device BILEVEL S20
as of device software 5.000

SERIAL NUMBER

Every HOFFRICHTER GmbH device is supplied with a serial number for traceability purposes.

Please enter your device's serial number here. You will find the serial number on the rating plate on the back of the device.

SN

Please always quote the serial number for all queries and complaints.

CONFORMITY



The device complies with the requirements of Directive 93/42/EEC.

CONTENTS

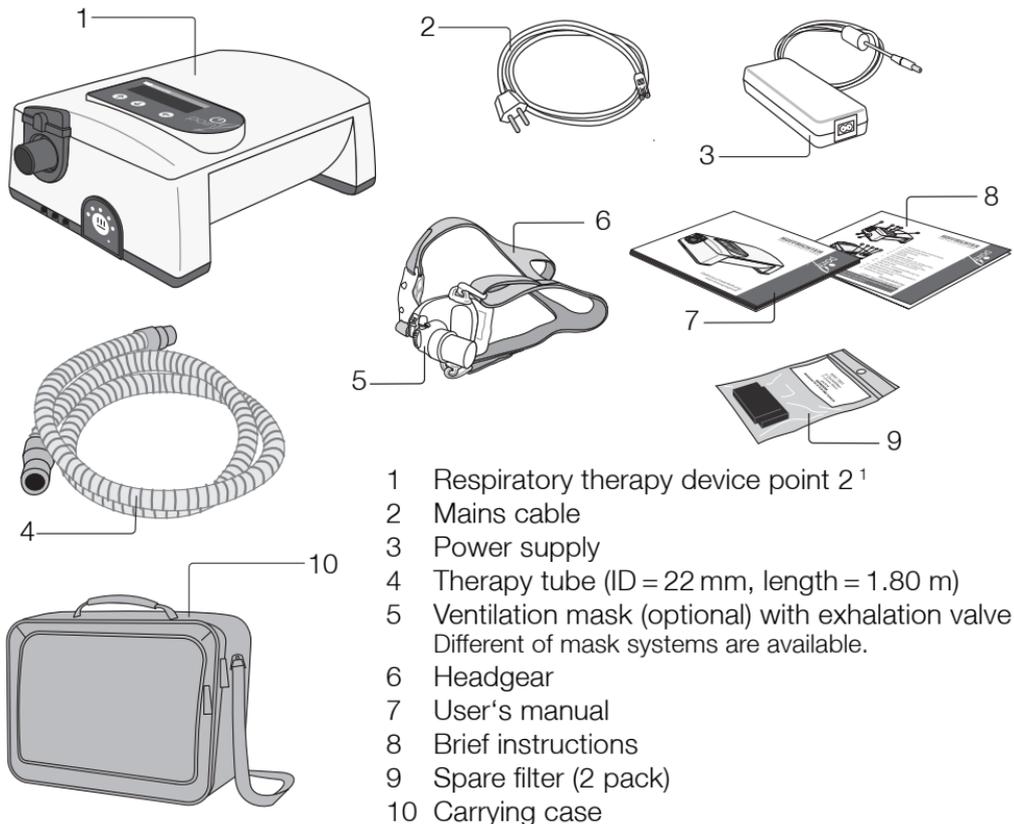
Scope of delivery	7
General.....	8
Information on this user's manual.....	8
Symbols used in this manual.....	9
Symbols on the packaging.....	10
Symbols on the rating plate.....	11
Safety Information.....	12
General safety instructions	12
Electrical safety.....	14
Installation requirements and transport	15
Before commissioning.....	17
Using oxygen.....	18
Intended use.....	19
Contraindications.....	21
Side effects.....	22
Device description	23
How the device works.....	24
General.....	24
Power supply.....	25
Therapy modes.....	27
CPAP.....	27
BILEVEL S.....	31

Using the device	33
Commissioning	33
Turning on and off in battery mode	35
Standby mode	35
Automatic zero point correction	36
Power failure.....	38
Using oxygen.....	38
Device functions	40
Parameter.....	43
Language	45
P-Unit.....	45
Operating times	46
Date	47
Time	48
Wake up time.....	49
Mode	50
Pressure	51
IPAP	52
EPAP	53
I-Slope.....	53
E-Slope	54
Backup freq.....	56
I-FLEX.....	57
E-FLEX	58
Calibration	59

Ramp	61
Mask Test	63
Automatic	64
Display Vt	65
Bact.Filter	67
Brightness	68
Parameter settings.....	69
Alarm functions of the device	70
Mask alarm.....	70
Pressure alarm.....	70
Wake up alarm.....	71
Important display messages.....	72
Using an SD card.....	74
General information.....	74
Inserting the SD card	75
Removing the SD card	76
Error messages.....	77
Storage of therapy data	79
Internal device memory	79
SC card	79
Changing the filter, cleaning.....	81
Cleaning the mask	83
Cleaning the therapy tube	83
Cleaning the device.....	84
Cleaning the headgear	85

Cleaning the humidifier	85
Preparing the device for a patient change.....	86
Using bacterial filters	87
Troubleshooting	88
Maintenance	90
Disposal.....	91
Device	91
Packaging.....	91
Accessories	91
Accessories	92
Technical data.....	94
Manufacturer's declaration on electromagnetic compatibility	98
Disclaimer	103

SCOPE OF DELIVERY



1 optional equipment variant for use with humidifier

GENERAL

INFORMATION ON THIS USER'S MANUAL

Read this user's manual through carefully before using your therapy device for the first time.

Follow the safety and cleaning instructions in particular.

Keep the manual in a safe place close to the device so that you can refer to it immediately if necessary.

SYMBOLS USED IN THIS MANUAL

Important information is denoted by symbols in this user's manual. Be sure to follow these instructions in order to avoid accidents, personal injury and material damage.



This symbol denotes general safety instructions. Follow these instructions to avoid accidents, personal injury or material damage.

DANGER

This symbol denotes hazardous situations that lead to serious injuries or death.

WARNING

This symbol denotes hazardous situations that may lead to serious injuries or death.

CAUTION

This symbol denotes hazardous situations that may lead to moderately severe injuries.

ATTENTION

This symbol denotes situations that may lead to material damage or damage to the device.

NOTICE

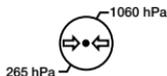
This symbol denotes information, tips and instructions for efficient, error-free use of the device.

In addition, the local accident prevention regulations and general safety regulations in force in the area of use must be observed.

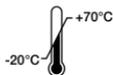
SYMBOLS ON THE PACKAGING



Range of humidity for storage and transport



Range of ambient air pressure for storage and transport



Range of temperature for storage and transport

SYMBOLS ON THE RATING PLATE



Observe the warning and safety instructions in the user's manual.



BF application part



Protection class II (protective insulation)



CE conformity declaration



Manufacturer



Serial number



Follow the user's manual.



Do not dispose of the device in the household waste. Please contact the relevant customer services department to find out how to dispose of the device properly.

SAFETY INFORMATION

GENERAL SAFETY INSTRUCTIONS



- Only use the device for your own CPAP therapy prescribed by the physician.
- Only use accessories and spare parts approved by us for use with the device.
- Only use the mask and therapy tube for your own therapy.
- Observe the mask manufacturer's usage instructions.
- Check that the exhalation opening in the mask is not obstructed.
- Make sure you use an exhalation valve if the mask has no exhalation opening.
- Inform your specialist dealer immediately if the device is not working properly.



- Please see your physician immediately if dryness of the mucous membranes in the nose and throat, sinus discomfort, ear ache, runny nose, over sensitive reactions of the skin, irritabilities, loss of voice, orientation or memory impairment occur when using the device.

ELECTRICAL SAFETY



- Do not use the device if its housing, cables or power supply are damaged.
- Do not open the device housing under any circumstances. Inform your specialist dealer if the device develops a fault.
- During therapy, do not connect any other line-powered devices via the RS232 interface at the rear of the device.
- Protect the device from water and dampness.
- Always unplug the device from the mains before cleaning.
- Empty and thoroughly clean any optional humidifier if you do not plan to use it for a lengthy period of time.

INSTALLATION REQUIREMENTS AND TRANSPORT



- Place the device near your bed on a firm and level surface. A bedside cabinet is ideally suited for this.
- During therapy, the device must not be operated in a drawer, on a closet shelf or behind a partition.
- It must be ensured that the air inlet at the rear of the device is accessible at all times and not obstructed. Drapes, curtains, paper or other objects must not be located behind the device.
- Do not place the device on the floor or under the bed in order to maintain low dust exposure levels.
- Do not put the device close to a source of heat.
- Avoid setting up the device at locations where it will be exposed to direct sunlight.



- Make sure you operate the device at a sufficient distance from other equipment which could emit electromagnetic waves such as diathermy devices, cell phones, remote-controlled toys and microwave appliances.
- Empty the humidifier (optional accessory) before packing it away in the carrying case.

BEFORE COMMISSIONING



- Do not switch the device on if it has previously been in a very cold environment. Wait for about one hour for the temperature to balance out.
- Check for proper setup and proper condition of the device.
- Check the condition of the breathing tube, mask, humidifier and air filter. Special attention should be paid to the maintenance instructions.

USING OXYGEN



- Oxygen supports combustion. Therefore, observe the fire protection regulations applicable for using oxygen.
- Ensure that there is no grease on the oxygen fittings. Do not smoke and do not handle naked flames.
- Before using any oxygen equipment for the first time, you must receive instruction from your specialist dealer in your home environment.
- Be sure to observe the user's manual of the manufacturer or distributor from whom you obtain the oxygen.
- Have your distributor advise you about the use of oxygen.
- In any case, follow your physician's instructions.

INTENDED USE

DANGER

The device must not be used for patients weighing less than 30 kg. An improper use may result a lung damage.

The point 2 is a respiratory therapy device designed for the treatment of sleep-related breathing disorders in patients weighing 30 kg or more. With increased demand of pressure and/or forms of respiratory insufficiency, the point 2 BILEVEL S20 offers the classical non-invasive S-Bilevel therapy.

In CPAP mode (CPAP = Continuous Positive Airway Pressure) the device applies a continuous positive airway pressure to the patient.

In BILEVEL S mode (S = Spontaneous) the device adapt two independently adjustable pressure levels depending of inspiration and expiration.

The device generates positive airway pressure which keeps the patient's airways open whilst asleep. The therapy pressure is administered via a respiratory mask (nasal, nasal cushion or full-face mask), which must be fitted with an exhalation valve to ensure that the exhaled air is discharged.

The point 2 is designed for use at home, in hospitals and for portable operation.

The device is not suitable for use with patients in need of artificial respiration.

 **DANGER**

This therapy device is no life-support system.

CONTRAINDICATIONS

WARNING

Respiratory therapy may be contraindicated for certain pre-existing conditions. Therefore, always talk to your treating physician before starting the therapy.

Contraindicating pre-existing conditions include:

- bullous lung diseases
- pneumothorax
- very low blood pressure
- pneumocephalus after open craniocerebral injury or other head injuries

Inflammation of the paranasal sinuses or the middle ear may be an indication to stop the treatment. Please speak to your physician about this.

SIDE EFFECTS

There is the possibility of undesirable side effects occurring with respiratory therapy. Reasons for side effects occurring could be unsuitable therapy settings, not using the device properly or not following the cleaning instructions. Normally the side effects disappear when their causes have been eliminated.

You will find suitable counter measures for some side effects in the section „Troubleshooting“ from page 88.

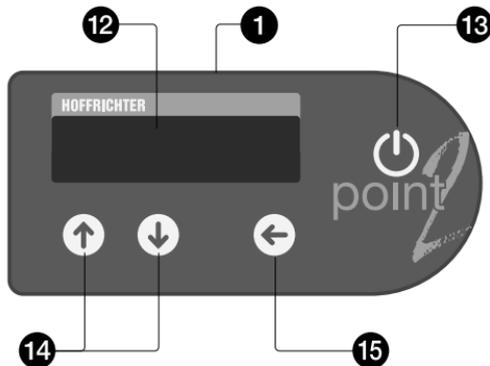
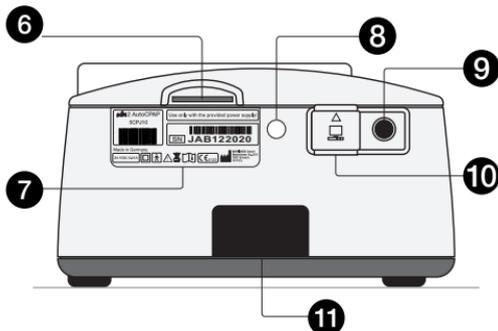
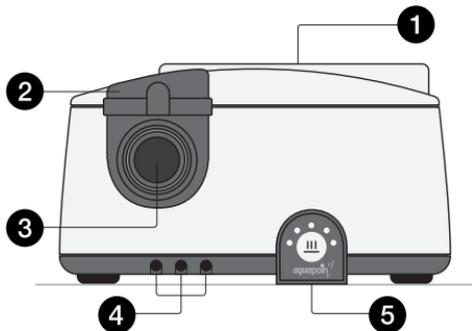
The following side effects may occur during therapy:

- Pain in the nose, paranasal sinuses and ears
- Dryness and irritation in the nose and throat
- Nose bleeds, runny nose, sneezing, colds
- Irritated or dry eyes
- Reddening of the skin, swelling of the skin and pressure points in the mask area
- Difficulty in breathing, claustrophobia
- Stomach problems caused by air accumulating in the stomach

CAUTION

If you experience side-effects continuously, contact your treating physician to clarify the causes.

DEVICE DESCRIPTION



- 1 Control panel and display
- 2 Humidifier lock
- 3 Therapy tube connection
- 4 Contact socket for humidifier¹
- 5 Control panel for humidifier¹
- 6 SD card slot
- 7 Rating plate
- 8 Air inlet for baro sensor
- 9 DC power connection
- 10 RS232 interface
- 11 Filter or connection port for the **filtersystempoint 2**
- 12 Display
- 13 ON/OFF key
- 14 Selection keys
- 15 Enter key

¹ optional equipment variant for use with humidifier

HOW THE DEVICE WORKS

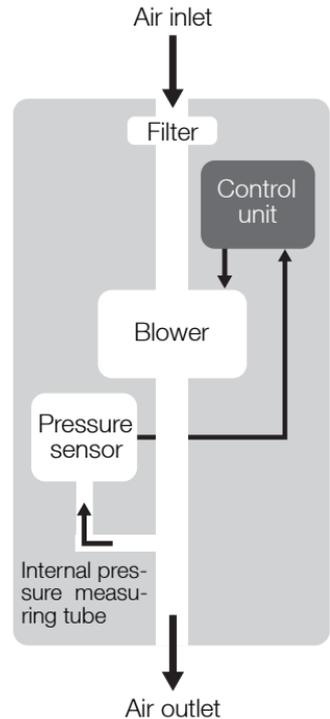
GENERAL

The point 2 has an electronically controlled blower to create the air pressure. In order to keep impositions to the patient at a minimum, the blower has been fitted with high power reserve capacity and a rapid control response.

The point 2 has an inbuilt microcontroller to control all its functions. Further comfort functions include a soft start ramp, automatic start / stop and adjustable display brightness.

Air going through the device is warmed slightly and therefore gains a higher water absorption capacity. The mucous membranes in the mouth and nose can dry out, particularly in winter when the ambient air is dry. This is unpleasant and in some cases may also lead to infections. Therefore, a respiratory air humidifier may be necessary in conjunction with a treatment. The plug-in **aquapoint 2** humidifier is available as an accessory to humidify respiratory air.

For more information on the humidifier read the **aquapoint 2** user's manual or contact your specialist dealer.



POWER SUPPLY

The point 2's power can be supplied from one of three sources:

- 1 External switched-mode power supply (included in scope of delivery)
- 2 DC vehicle cable (optional)
- 3 *powerpackpoint 2* battery pack (optional)

External switched-mode power supply

For mains operation the point has an external switching power supply with a wide input range of 100 - 240 V alternating current (AC), 50 - 60 Hz. Thus it is possible to connect it to an energy supply anywhere in the world.

DC vehicle cable

For mobile use of the point 2, e.g., in a truck or a caravan, it is possible to operate it with a 24 V direct current (DC). For this you will need the optionally available DC vehicle cable.

WARNING

Only use the optional DC vehicle cable to connect the device to a DC power supply.

Battery pack

To use point 2 while travelling and when mains current fails, the device can be operated with the optionally available *powerpackpoint 2* battery pack. With the battery pack, point 2 BILEVEL S20 can be used at least 7 hours is possible (at IPAP = 12 hPa, EPAP = 6 hPa, 12 bpm, 300 ml tidal volume).

ATTENTION

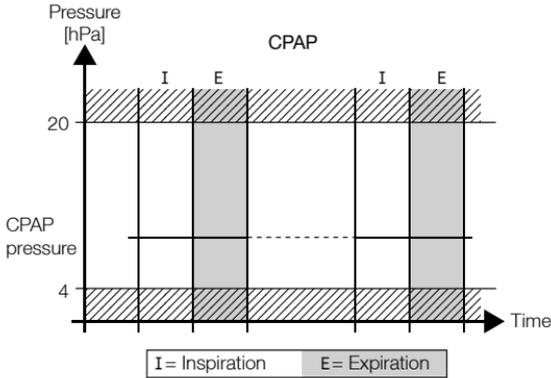
Before using the battery pack, ensure that you have read the *powerpackpoint 2* user's manual.

THERAPY MODES

The point 2 BILEVEL S20 has the CPAP and BILEVEL S modes.

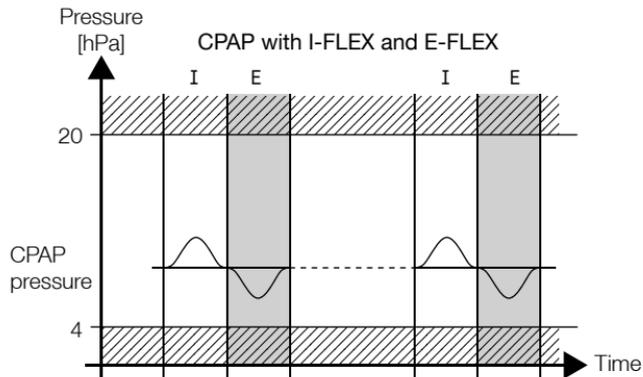
CPAP

In CPAP mode (Continuous Positive Airway Pressure), the point 2 supplies continuous positive pressure.

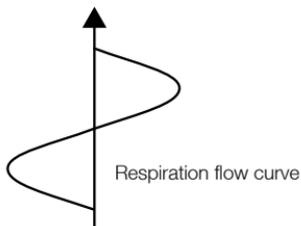
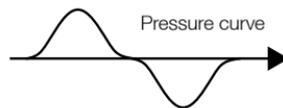
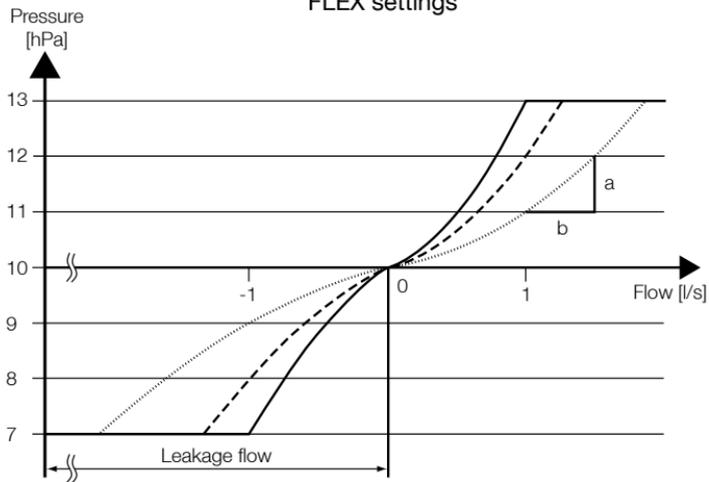


FLEX settings

Breathing compressed air results in an increased burden for the respiratory muscles. FLEX controls ease this burden on the respiratory muscles by reducing the effect of the flow resistance in the airway. To this end, the therapy pressure needs to be increased during inspiration and reduced during expiration. The degree of pressure control can be individually selected for inspiration and expiration at four levels (0, 1, 2, 3). The level selected is identical to the airway resistance value in hPa/(l/s) by which the effort for the patient's respiratory muscles is relieved. The specified curves of the FLEX transfer characteristics correspond to the prevailing pressure and flow behavior of the airways. Changes in pressure are only possible within the adjustable pressure range of the point 2 and are additionally limited to ± 3 hPa. FLEX settings are not activated until after the third breathing period, as the point 2 takes a short period of time to calculate the leakage flow.



FLEX settings



$$\frac{a}{b} = \frac{\text{hPa}}{\text{l/s}} = \text{Flow resistance}$$

- 3 hPa/ (l/s)
- - - 2 hPa/ (l/s)
- 1 hPa/ (l/s)

BILEVEL S

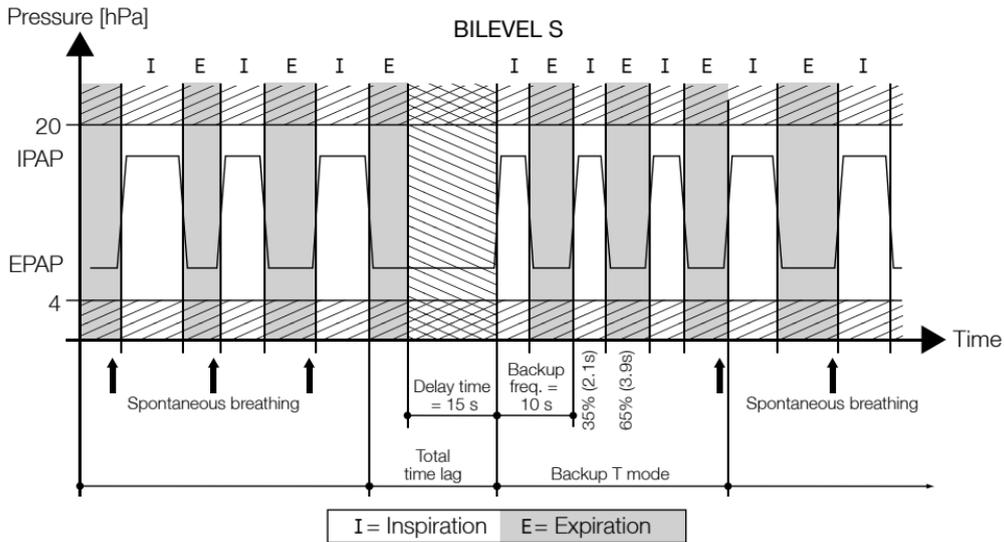
In BILEVEL S the transition from inspiration pressure (IPAP) to expiration pressure (EPAP) is triggered once the patient starts to breath. When the inspiration flow ends, the pressure drops to the EPAP. In addition, a backup frequency (Backup freq) can be activated. In the event of an apnea patients ventilation will be continuously restored at fixed parameters:

- IPAP, EPAP
- I-Slope, E-Slope
- Backup frequency

The parameters will be set by the physician.

NOTICE

During the expiration phase a negative pressure (vacuum) will not be created.

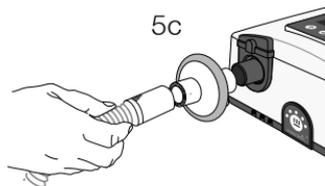
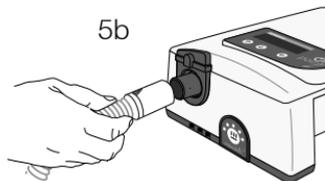
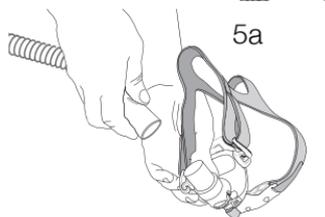
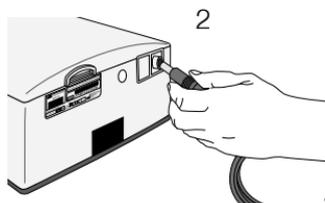


USING THE DEVICE

COMMISSIONING

⚠ CAUTION

Before commissioning the device, read section „Safety Information“ (starting from page 12).



1. Set up the device according to the installation requirements (see page 15).
2. Connect the power supply to the device.
3. Connect the mains cable to the power supply and its plug to a power socket.
4. The device starts up and successively displays a welcome text, the device type, its software version and the current number of therapy hours and then switches to the date and time display (standby mode).
5. Connect the therapy tube to the mask (5a) and the unattached end of the tube to the air outlet (5b). If you are using a bacterial filter, fit it between the tube and air outlet (5c).
6. Calibrate the device as described in the chapter „Calibration“ from page 59.

7. Put the mask on. If automatic mode has been selected (see page 64), the device is turned on by the patient's breathing. If automatic mode has been set to „OFF“, the device is started by pressing the ON/OFF key.
8. The device first of all runs (for the time selected by you for the mask test) at the prescribed pressure. You should now ensure the mask's correct positioning to avoid potential leakages.
9. Place the tube in such a way that it does not exert any strain on the mask when you lie down.
10. Now breath deeply and calmly, just through your nose. If the soft start function (Ramp) has been selected (see page 61), the device reduces air pressure after the mask test has been performed. It then increases pressure automatically gradually up to the prescribed value while you can go to sleep under reduced pressure.



NOTICE

Read how you can adapt the time settings for mask test and ramp to suit your personal requirements in section „Device functions“ (starting page 40).

TURNING ON AND OFF IN BATTERY MODE

If the device is powered by the optional available *powerpackpoint 2*, press and hold the ON/OFF key for approx. 3 seconds to switch it on or off.

NOTICE

In standby mode the device automatically switches itself off after 1 minute.

STANDBY MODE

If the blower is switched off, the device switches to standby mode (discernible on the lit display with date and time).

The point 2 can be kept in standby mode permanently. This does not harm it.

If the *powerpackpoint 2* is fitted on the device, the batteries are charged in standby mode. The charging process is indicated by a flashing battery symbol on the display.



Press ON/OFF!
25.Jan.12 11:45

AUTOMATIC ZERO POINT CORRECTION OF PRESSURE SENSOR

Automatic zero point correction ensures the uniformly high precision of the pressure measurements and takes account of aging effects. Therefore the electric and electronic components are maintenance-free.

Sensors are normally temperature-compensated before being installed in CPAP devices. This process requires certain compensation tools, which are used solely by trained staff. Unfortunately, the selected values are not permanent as they vary over time due to aging, vibrations or constant changes in climate. This means that these values need to be checked for correctness at prolonged intervals and possibly readjusted.

HOFFRICHTER's technicians have however developed a new method in which the necessary compensation tools are, so to speak, permanently „on board“ the point 2. It is thus no longer necessary to check measurement accuracy.

To allow this method to function, the point 2 has to be put on standby from time to time. Here it is sufficient to run the device in this mode for just a few seconds before and after each starting up of the blower to allow the software to collect and apply the necessary data.

We also recommend running the device on standby for a longer period, e.g. for a day, once a month.

NOTICE

In order to determine an applicable correction factor, the device requires a certain amount of time in standby mode. We therefore recommend that the device is left in standby mode at least once a month between nightly therapies.

The zero-point correction is particularly recommended if the device is used in a new location (e.g., when travelling) or if there are significant temperature fluctuations in the room.

For the patient the automatic zero-point correction system means that the device is always optimally adjusted, leading to even better therapy.

POWER FAILURE

After a power failure during therapy, the motor re-starts automatically and you will see a message on the display about the power failure and the blower re-start.

Power Failure
Restart Blower

NOTICE

If you are using the optionally available *powerpackpoint 2*, the batteries provide the power for the device in the event of a power failure.

USING OXYGEN

⚠ WARNING

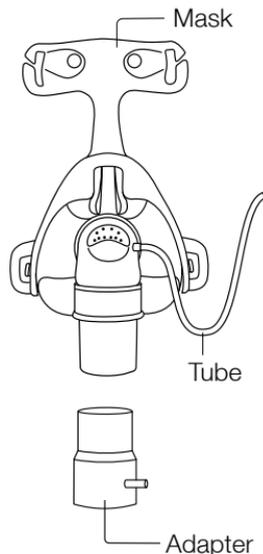
Before using oxygen, it is essential to read the safety information on page 18.

When feeding oxygen directly into the mask, please use a kink-resistant tube made of a medically approved material.

Oxygen can also be fed in via an adapter fitted onto the air outlet.

⚠ DANGER

If oxygen is using directly at the air outlet the therapy setting must be set, that no backflow of oxygen takes place into the device.



Proceed as follows when using oxygen:

WARNING

If the device is in standby mode or switched off, the oxygen supply must always be switched off.

1. Before starting the treatment, check that the tube connections are fitted correctly.
2. Switch the device on first and then start the oxygen supply.
3. Check whether the automatic mode is set to „Auto OFF“. If not, program it as described on page 65.
4. Switch off the oxygen supply before switching off the device.

NOTICE

Using oxygen influences the therapy pressure. Therefore we recommend to include oxygen in the therapy pressure determination / titration process, for every patient who's therapy is intended to include an oxygen supply.

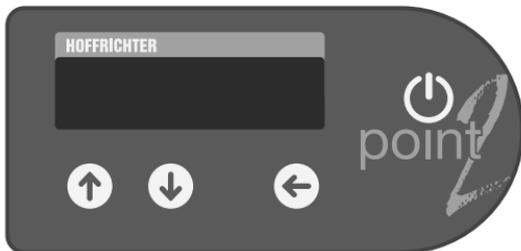
DEVICE FUNCTIONS

There are three keys for programming point 2's functions:

⬆ = Selection key

⬇ = Selection key

⬅ = Enter key



If the enter key ⬅ is pressed for a prolonged time, you enter the programming mode and the menu appears on the display.

The device display has two lines. By pressing ⬆ and ⬇ you can select the top or bottom row. A triangle symbol ▶ in front of a row means that this row has been selected.

```
▶Wake Time..07:00
Exit Menu
```

Example: Wake Time

The point 2 has two different menus:

- Standard menu
- Complete menu

The standard menu contains the menu items relevant to patients. The complete menu contains all menu items of the standard menu as well as all menu items required for setting the therapy. This menu is primarily intended for physicians and trained medical staff.

To switch between the menus, first press the enter key . Then hold both the selection keys  and  down at the same time for a prolonged period. The display shows the message:



NOTICE

If during programming you have not pressed a key for 30 seconds, the standard or complete menu exits automatically for security reasons. If a modified value is not confirmed by pressing the enter key and the standard or complete menu has exited, the original value is retained.

To access a menu, hold down the enter key for longer than 1 s. You can access the menu items within menus by pressing the selection keys  or . To activate a parameter, press the enter key .

Some parameters may only be set by physicians or trained medical staff. These parameters are protected by a PIN code.



▶PIN Code? 0000
Exit Menu

CAUTION

Please do not try to crack the PIN code. Speak to your physician if you doubt the correctness of the pressure prescription.

PARAMETER

Parameter	Standard menu		Complete menu	
	CPAP	BILEVEL S	CPAP	BILEVEL S
Language	-		•	•
P-Unit	-		•	•
Power 				
Blower 				
Filter 	-		•	•
Therapy				
Date	•		•	•
Time	•		•	•
Wake Time ¹	•		•	•
Mode ²	-		•	•
Press. ²	-		•	-
IPAP ² 				
EPAP 				
I-Slope 	-		-	•
E-Slope				
Backup Freq. ²	-		-	•
I-FLEX ²	-		•	-
E-FLEX ²	-		•	-
Calibration	•		•	•
Ramp 				
P-Ramp	-		•	•
Mask Test	-		•	•

Parameter	Standard menu		Complete menu	
	CPAP	BILEVEL S	CPAP	BILEVEL S
Auto	-		•	•
Display Vt	•		•	•
Bact.Filter	-		•	•
Brightness	-		•	•
<p>← next parameter is displayed by pressing the enter key</p> <ul style="list-style-type: none"> • present, - not present 				
<p>¹ only present, if the alarm clock function is enabled (see page 49)</p>				
<p>² PIN code protected</p>				

```
▶Language.....ENG
Exit Menu
```

LANGUAGE

The device can display messages in German (DEU), English (ENG), Greek (ELL), Spanish (SPA), French (FRA), Italian (ITA), Dutch (NLD), Turkish (TUR), Polish (PLK), Portuguese (POR) and Czech (CZE).

Setting the language

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **Language**.
3. Set the desired language by pressing the enter key .

```
▶P-Unit.....mbar
Exit Menu
```

P-UNIT

The device can show the pressure in the pressure units hectopascal (hPa), millibar (mbar), and centimeters of water (cm = cmH₂O).

Setting the pressure unit

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **P-Unit**.
3. Set the desired pressure unit by pressing the enter key .

OPERATING TIMES

Under this menu item you will find the total operating time including standby mode of the device, the blower running time, the operating time of the filter and the therapy time.



```
▶Power.....250h
Exit Menu
```

Checking the device's operating times

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **Power**. The total operating time including standby is now displayed.
3. Press the enter key . The total running time of the blower is now displayed.
4. Press the enter key  again. The operating time of the filter is now displayed.
5. Press the enter key  again. The therapy time is now displayed.

```
▶Date...25.Jan.12
Exit Menu
```

DATE

The day (1 - 31), the month (Jan. - Dec.) and the year (00 - 99) can be set.

Setting the date

1. Press the enter key  for 1 second.
2. Use the selection keys  and  to select **Date**.
3. Press the enter key  and then use the selection keys  and  to set the year. Confirm your setting by pressing the enter key .
4. Use the selection keys  and  to set the month. Confirm your setting by pressing the enter key .
5. Use the selection keys  and  to set the day. Confirm your setting by pressing the enter key .

TIME

The device has an internal clock. In the event of a power failure, the clock operates on inbuilt battery power. The hour (00 - 23) and minutes (00 - 59) can be set.



```
▶Time.....13:00
Exit Menu
```

Setting the time

1. Press the enter key  for 1 second.
2. Use the selection keys  and  to select **Time**.
3. Press the enter key  and then use the selection keys  and  to set the hour. Confirm your setting by pressing the enter key .
4. Use the selection keys  and  to set the minutes. Confirm your setting by pressing the enter key .

```
▶Wake Time..07:00
Exit Menu
```

```
Press ON/OFF!
25.Jan.12 *12:20
```

```
Press ON/OFF!
Slumber.....4:45
```

WAKE UP TIME

NOTICE

Ex factory, the alarm clock function is not enabled. But it can be unlocked by the physician or dealer with TRENDset PC software.

To activate the wake up alarm, press . For checking purposes, the programmed wake up time is displayed for a short time. To deactivate the alarm, press . The activated alarm is indicated by a bell symbol on the display.

When the wake up alarm sounds, there are two options:

1. Press the ON/OFF key once to stop the alarm for the next 5 minutes (Slumber mode) and twice to deactivate it completely.
2. Press  to end the alarm.

Setting the wake up time

1. Press the enter key  for 1 second.
2. Use the selection keys  and  to select **Wake Time**.
3. Press the enter key  and then use the selection keys  and  to set the hour. Confirm your setting by pressing the enter key .

4. Use the selection keys  and  to set the minutes. Confirm your setting by pressing the enter key .

MODE

Selection of mode by the physician

1. Press the enter key  for 1 second.
2. Use the selection keys  and  to select **Mode**.
3. Press the the enter key  and if necessary, input the PIN code with the selection keys  and . Press the enter key  after every digit.
4. Use the selection keys  and  to select the desired mode. Confirm your setting by pressing the enter key .



```
▶Mode.....APAP
Exit Menu
```

▶ Press 7.5hPa
Exit Menu

PRESSURE (only CPAP mode)

Selection of pressure by the physician

NOTICE

When the pressure parameter is changed during therapy/titration, the device adapts to the new setting slowly (25 Pa/s). This pressure ramp can be deactivated using the TRENDset PC software.

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **Mode**.
3. Press the the enter key  and if necessary, input the PIN code with the selection keys  and . Press the enter key  after every digit.
4. Use the selection keys  and  to select the **CPAP** mode.
5. Press the selection key . The menu item **Press.** is now displayed.
6. Press the enter key  and then use the selection keys  and  to set the desired value. Confirm your setting by pressing the enter key .

IPAP

(only in mode BILEVEL S)

Selection of inspiration pressure (IPAP) by the physician

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **IPAP**.
3. Press the the enter key  and if necessary, input the PIN code with the selection keys  and . Press the enter key  after every digit.
4. Press the enter key  and then use the selection keys  and  to set the desired value. Confirm your setting by pressing the enter key .

The parameter EPAP is set next.



```
▶ IPAP.....10.0hPa
Exit Menu
```

```
▶EPAP.....6.0hPa
Exit Menu
```

EPAP
(only in mode BILEVEL S)

Selection of expiration pressure (EPAP) by the physician

1. First set IPAP.
2. Use the selection keys  and  to set the desired value. Confirm your setting by pressing the enter key .

The parameter I-Slope is set next.

```
▶I-Slope.....2
Exit Menu
```

I-SLOPE
(only in mode BILEVEL S)

The I-Slope determines the time of pressure increase from EPAP to IPAP.

- Level 1 = 10 hPa/s
- Level 2 = 20 hPa/s
- Level 3 = 40 hPa/s

Selection of I-Slope by the physician

1. First set IPAP and EPAP

2. Use the selection keys \uparrow and \downarrow to set the desired value. Confirm your setting by pressing the enter key \leftarrow .

The parameter E-Slope is set next.

Calculation of the I-Slope time:

Settings:

IPAP = 10 hPa I-Slope = 2 Frequency = 12 bpm
EPAP = 6 hPa E-Slope = 2

$$\text{I-Slope time} = \frac{\text{IPAP} - \text{EPAP}}{\text{I-Slope}}$$

$$\text{I-Slope time} = \frac{10 \text{ hPa} - 6 \text{ hPa}}{20 \text{ hPa/s}} = 0.2 \text{ s}$$

E-SLOPE

(only in mode BILEVEL S)

The E-Slope determines the time of pressure decrease from IPAP to EPAP.

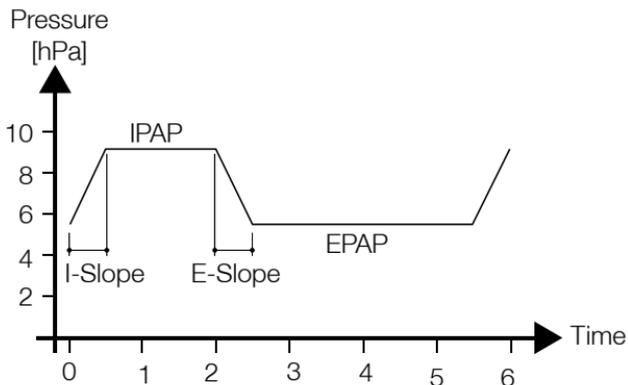
- Level 1 = 10 hPa/s
- Level 2 = 20 hPa/s
- Level 3 = 40 hPa/s



```
▶E-Slope.....2
Exit Menu
```

Selection of E-Slope by the physician

1. First set IPAP, EPAP and I-Slope.
2. Use the selection keys \uparrow and \downarrow to set the desired value. Confirm your setting by pressing the enter key \leftarrow .



The E-Slope time is calculated as the I-Slope time (see page 54).

BACKUP FREQ

(only in mode BILEVEL S)

By activating the backup frequency ventilation will be automatically restored if patient suffers from a persistent apnea (> 15 s). Evolving mandatory ventilation is characterized by following fixed parameters:

- $f = 10$ bpm
- $I:E = 35:65$ %.



```
▶Backup freq...ON
Exit Menu
```

Selection of backup frequency the physician

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **Backup freq.**
3. Press the the enter key  and if necessary, input the PIN code with the selection keys  and . Press the enter key  after every digit.
4. Press the enter key  and then use the selection keys  and  to select **ON** or **OFF**. Confirm your setting by pressing the enter key .



▶ I-FLEX.....3
Exit Menu

I-FLEX

(only in mode CPAP)

Inhaling under therapy pressure is always more difficult as the lungs are already partly filled and thus also prestressed. Such additional stress from therapy can be reduced by means of a personalized I-FLEX setting. FLEX settings will only work if spontaneous respiration is actually present. FLEXLINE is not a form of artificial respiration, but merely a way of supporting the respiratory effort of the patient.

Selection of I-FLEX by the physician

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **I-FLEX**.
3. Press the enter key  and if necessary, input the PIN code with the selection keys  and . Press the enter key  after every digit.
4. Press the enter key  and then use the selection keys  and  to set the desired value. Confirm your setting by pressing the enter key .

E-FLEX

(only in mode CPAP)

Although the point 2 is equipped with an excellent pressure control system, an E-FLEX setting can help make expiration easier. This should however be adjusted individually for each patient. Once again, FLEX settings will only work if actual respiratory effort is present.



▶E-FLEX.....3
Exit Menu

Selection of E-FLEX by the physician

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **E-FLEX**.
3. Press the enter key  and if necessary, input the PIN code with the selection keys  and . Press the enter key  after every digit.
4. Press the enter key  and then use the selection keys  and  to set the desired value. Confirm your setting by pressing the enter key .

▶ Calibration
Exit Menu

CALIBRATION

NOTICE

Calibration guarantees an optimum performance of the automatic function and mask test. It must be performed when:

- the device is used initially,
- the mask has been changed,
- there is a change within the therapy system.
If a bacterial filter or a humidifier is added/ removed the calibration has to be redone.

Ex factory, the point 2 is pre-calibrated for using with a Cirri Comfort nasal mask (size M) without humidifier and without bacterial filter.

Calibration is only possible during mains operation not in battery mode.

Calibrating the device

1. Connect the mask, the therapy tube and, if applicable, the humidifier or bacterial filter to the device.

NOTICE

Ensure that the air and exhalation openings in the mask are clear and the tube is not kinked. Do not put the mask on.

2. Press the enter key  for 1 second.
3. Use the selection keys  and  to select **Calibration**.
4. Press the enter key .
5. **Start** appears on the display. Press the enter key . If you do not press the key within 5 s, the display jumps back (see point 3).
6. The blower starts and calibration begins. **Calibration active** appears on the display. Calibration takes 20 - 70 s. The blower switches off after calibration is finished.
7. If calibration has been successful, **Successful** appears on the display and if it has failed, **Failed** appears on the display.
8. In both cases press the enter key .

NOTICE

The old values will be retained if calibration has failed. Start calibration again.

```
▶ Ramp.....20min  
Exit Menu
```

```
▶ P-Ramp.....4.5hPa  
Exit Menu
```

RAMP

After every blower start, the device's microcontroller checks whether a soft start ramp has been programmed. The soft start function slowly increases the pressure over the time programmed by you, starting with a programmable initial ramp pressure (P-Ramp) up to the prescribed pressure (CPAP) or IPAP/EPAP (BILEVEL S) in order to make it easier for you to get to sleep. The soft start can bring relief particularly if you are not quite used to the respiratory therapy yet.

The device offers delay time settings from zero (prescribed therapy pressure starts immediately) to 45 minutes (prescribed therapy pressure is gradually built up within 45 minutes). The initial ramp pressure (P-Ramp) can be set between 4 hPa and the prescribed pressure.

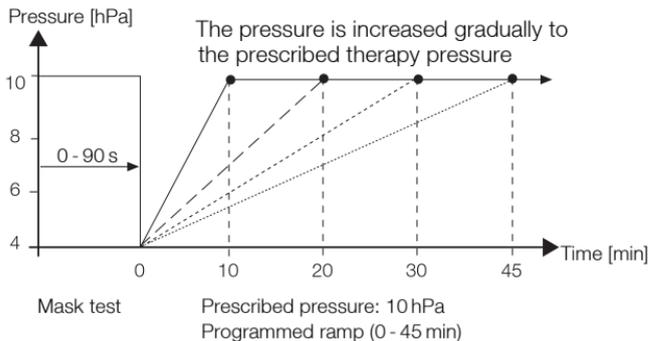
Setting the ramp

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **Ramp**.
3. Press the enter key  and then use the selection keys  and  to set the minutes (Ramp). Confirm your setting by pressing the enter key .
4. Use the selection keys  and  to set the desired value for the initial pressure (P-Ramp).

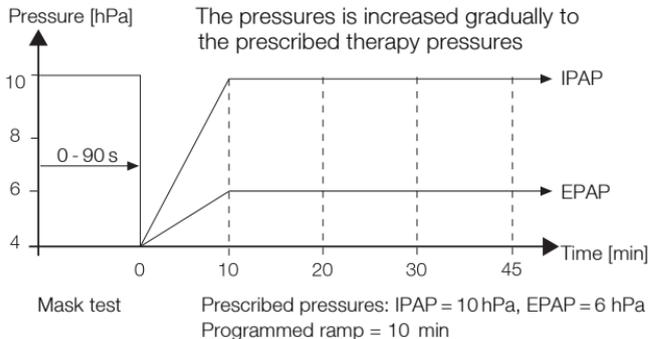
Confirm your setting by pressing the enter key



CPAP mode



BILEVEL S mode



```
▶Mask Test.....30s  
Exit Menu
```

MASK TEST

This ensures that the mask is airtight, not only during the slow pressure increase during the soft start ramp, but also at higher pressures. The mask test can be programmed to last from 5 to 90 seconds in 5 second increments. The mask test is performed before the ramp starts and tests the tightness under maximum therapy pressure (see figures on page 62).

Setting the mask test

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **Mask Test**.
3. Press the enter key  and then use the selection keys  and  to set the seconds. Confirm your setting by pressing the enter key .

AUTOMATIC

The automatic mode has three settings:
OFF, Start/Stop, Start

1. Auto OFF (with mask alarm)

With the „Auto OFF“ setting, you must switch the device on with the ON/OFF key when therapy starts and off with the same key when therapy ends. Should the mask slip from your face or should a leak occur that cannot be compensated for, you will be given an acoustic and visual warning.



▶Auto.....OFF
Exit Menu



Mask Alarm.....10s
Check Mask!

2. Auto Start/Stop

With the „Auto Start/Stop“ setting, you only have to put the mask on. As soon as you begin breathing, the point 2 blower switches on. When you take the mask off, the blower switches off automatically after a 5 second delay. The blower also switches off when the mask slips off your face or a leak that cannot be compensated for occurs.



▶Auto..Start/Stop
Exit Menu

3. Auto Start (with mask alarm)

With the „Auto Start“ setting, you only have to put the mask on. As soon as you begin breathing, the point 2 blower switches on. If you take the mask off or the mask slips off your face or a leak occurs which cannot be compensated for, the blower does



▶Auto.....Start
Exit Menu

```
Mask Alarm.....10s  
Check Mask!
```

not switch off but you receive an acoustic and visual warning. The blower can only be switched off by pressing the ON/OFF key.

Setting automatic mode

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **Auto**.
3. Press the enter key  to set the desired automatic mode.

The device can be switched on or off in any automatic mode by pressing the ON/OFF key.

```
►Display Vt.....ON  
Exit Menu
```

DISPLAY VT

When the function „Display Vt“ is activated, the tidal volume is displayed in ml during therapy. The value displayed is the arithmetic mean of the inspired air volume from the last four breathing periods. The value is recalculated after each breathing period and shown on the display. The leakage air flow must be calculated before display is possible. This is generally the case after about three breathing periods.

Activating/deactivating the display of the tidal volume

1. Press the enter key  for 1 second.
2. Use the selection keys  and  to select **Display Vt**.
3. Press the enter key  to set „ON“ or „OFF“.

NOTICE

During the therapy the display of the tidal volume replaces the display of the date.

Possible displays states

Display of tidal volume in ml.



No valid value for the tidal volume is available yet.



If the display shows the value 0 ml for the tidal volume, an apnea has occurred.



▶Bact.Filter..Yes
Exit Menu

BACT.FILTER

As pressure measurement is influenced by the connection of a bacterial filter, it must be specified on the device whether or not a bacterial filter has been connected.

Select whether a bacterial filter is connected (by the physician)

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **Bact.Filter**.
3. Press the the enter key  and if necessary, input the PIN code with the selection keys  and . Press the enter key  after every digit.
4. Press the enter key  and then use the selection keys  and  to set **Yes** or **No**. Confirm your setting by pressing the enter key .

NOTICE

Whenever a bacterial filter is connected to or removed from the device, it is necessary to calibrate the device (see page 59).

BRIGHTNESS

You can set the brightness of the display from 0 % to 100 %.

This value determines the brightness of the display 30 seconds after the last key was pressed. When a key is pressed, the display brightness is always 100 % (50% during battery operation).



▶Brightness..100%
Exit Menu

Setting the brightness

1. Select the complete menu (see page 41).
2. Use the selection keys  and  to select **Brightness**.
3. Press the enter key  and then use the selection keys  and  to set the desired brightness.
4. Confirm your setting by pressing the enter key .

PARAMETER SETTINGS

Parameter	Settings range	Dependency	Setting steps
Language	DEU, ENG, ELL, SPA, FRA, ITA, NLD, TUR, PLK, POR, CZE	-	-
P-Unit	hPa, mbar, cmH ₂ O	-	-
Press. ¹	4 – 20 hPa	-	0.5 hPa
IPAP ²	EPAP – 20 hPa	≥ EPAP, ≤ 20 hPa	0.5 hPa
EPAP ²	4 hPa – IPAP	≥ 4 hPa, ≤ IPAP	0.5 hPa
I-Slope ²	1 – 3	Frequency, I:E	1 Level
E-Slope ²	1 – 3	Frequency, I:E	1 Level
Backup freq ⁵	ON, OFF	-	-
I-FLEX	0 – 3 hPa/ (l/s)	-	1 hPa/ (l/s)
E-FLEX	0 – 3 hPa/ (l/s)	-	1 hPa/ (l/s)
Ramp	0 – 45 min	-	5 min
P-Ramp	4 hPa – 20 hPa	≤ Press. ¹ , ≤ EPAP ²	0.5 hPa
Mask Test	0 – 90 s	-	5 s
Auto	OFF, Start/Stop, Start	-	-
Display Vt	ON, OFF	-	-
Bact.Filter	Yes, No	-	-
Brightness	0 – 100 %	-	10 %

¹ only in mode CPAP

² only in mode BILEVEL S

ALARM FUNCTIONS OF THE DEVICE

MASK ALARM

If the mask slips off your face, the tube is pulled out or any other leak occurs that cannot be compensated for, the device does not switch off automatically but emits an acoustic and visual alarm.

The mask alarm is only active in the „Auto OFF“ and „Auto Start“ automatic modes.

Testing the mask alarm

Start the device in „Auto OFF“ mode. The mask should be open, not on the face. After a short time an acoustic signal sounds.

A black rectangular LCD display with white text. The top line reads "Mask Alarm.....10s" and the bottom line reads "Check Mask!".

Mask Alarm.....10s
Check Mask!

PRESSURE ALARM

Should an excessively high pressure occur during the treatment due to a hardware error or other circumstance, the device emits an alarm sound and switches the blower off. The alarm is turned off by pressing the ON/OFF key.

A black rectangular LCD display with white text. The top line reads "Press. too high" and the bottom line reads "25.Jan.12 21:33".

Press. too high
25.Jan.12 21:33



||||| 5.0hPa
Wake Alarm 07:00

WAKE UP ALARM

NOTICE

Ex factory, the alarm clock function is not enabled. But it can be unlocked by the physician or dealer with TRENDset PC software.

If enabled, you can activate or deactivate the alarm clock with the selection keys  and . Pressing the ON/OFF key once mutes the alarm for the next 5 minutes and pressing it twice stops it completely.

IMPORTANT DISPLAY MESSAGES

The most important display messages are listed below. All further messages will be clarified from the given context. The values shown here are examples.

You still have 15 seconds to ensure that the mask is fitted correctly. When the time is up, the device starts the soft start function or the therapy.

There are still 8 minutes and 40 seconds until full therapy pressure is reached.

You have activated the display of the tidal volume as well as the wake up alarm.

The mask has slipped off your face or a leak that cannot be compensated for has occurred or you have not put the mask on in the „Auto OFF“ or „Auto Start“ automatic modes while the blower is running.

In normal mode you have pressed the selection key  and get the message that you will be woken up at 7 a.m.

In normal mode you have pressed the selection key  and get the message that the alarm clock has now been switched off.



||||| 8.5hPa
Mask Test.....15s



||||| 8.5hPa
Ramp.....8:40



||||| 8.5hPa
642ml +05:30



Mask Alarm.....10s
Check Mask!



||||| 8.5hPa
Alarm ON 07:00



||||| 8.5hPa
Alarm Clock OFF

||||| 5.0hPa
Wake Alarm 07:00

The wake alarm has been triggered. Press the ON/OFF key once to initiate the slumber phase. Press the key once again to turn off the alarm completely.

||||| 5.0hPa
Slumber.....1:18

You still have 1 min and 18 s until the alarm clock will sound again.

||||| 5.0hPa
Wake Alarm OFF

You have pressed the ON/OFF key and ended the slumber phase.

||||| 5.0hPa
Change Filter

The filter must be changed (see page 81). To reset the message, hold the enter key (↵) down and, while you are doing this, insert the DC power supply plug into the device's DC power connection.

Power Failure
Restart Blower

After the mains voltage is restored, the blower re-starts automatically.

Complete Menu
is inactive

The complete menu has been deactivated by the PC software TRENDset and cannot be displayed.

NOTICE

Ex factory, the alarm clock function is not enabled. But it can be unlocked by the physician or dealer with TRENDset PC software.

USING AN SD CARD

GENERAL INFORMATION

The use of an SD card during therapy enables the most important therapy data to be saved long-term and detailed. The physician can readout and evaluate this data via the TRENDset PC software. Furthermore, the physician may set up new therapy parameters using TRENDset and send them to the patient to update its therapy requirements. As soon as the SD card is inserted, the device imports the modified therapy parameters.

NOTICE

Only SD cards with the specification $1.x \leq 2$ GB can be used. The SD card must be formatted with TRENDset before use.



Do not remove
the SD card

New Parameters
were accepted

INSERTING THE SD CARD

1. Ensure that the device is in standby mode (see page 35).
2. Insert the SD card into the SD card slot (see picture).
3. The device starts initializing while the message “Do not remove the SD card” is displayed. Finally the symbol  is shown at the display. The time required for initialization depends on the device settings.

ATTENTION

During the initialization process do not remove the SD card at any time! This could lead to loss of data or damage the SD card.

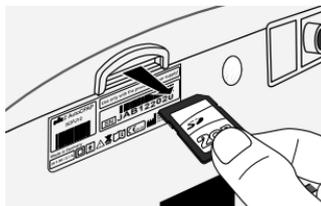
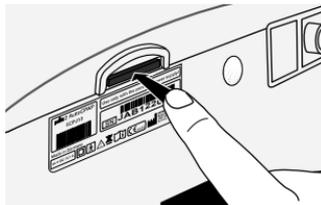
4. After successful initialization, the message disappears. If the SD card contains valid new therapy parameters, the device is going to import them. Finally “New Parameters were accepted” indicates initialization to be successful.
5. By pressing the enter key  or after 10 s the message will be disappear automatically.

REMOVING THE SD CARD

ATTENTION

Only remove the SD card in standby mode. Otherwise data may be lost or the SD card might be damaged.

1. Ensure that the device is in standby mode (see page 35).
2. Carefully push the SD card into the card slot.
3. Remove the SD card.



A screenshot of a device's LCD display. The text is in a pixelated, monospaced font. The top line reads "Press ON/OFF!" and the bottom line reads "SD-Error E02".

Press ON/OFF!
SD-Error E02

ERROR MESSAGES

Two different types of error can be distinguished: errors with data loss and errors without data loss.

The display “Exx” denotes errors in which data may have been lost. The display “Wxx” denotes errors in which data has not been lost.

To hide an error message, press the enter key .

ATTENTION

If error messages occur frequently, we recommend that the device is examined by a service technician.

The following table shows all error codes that can occur in connection with the use of the SD card.

Error code	Meaning	Remedy
E00	Writing data has failed. Possible causes are power failure, removal of card during writing or a faulty SD card.	The SD card is probably faulty. Remove the SD card and then insert it into the device again. If the error continues to occur, send the card back to the physician.
E01	The SD card is faulty.	Obtain a new SD card from your physician or specialist dealer.
E02	File system or folder structure is faulty or cannot be read.	The SD card must be formatted by the physician using TRENDset.
E03	New files cannot be created or the SD card is full.	The SD card must be formatted by the physician using TRENDset.
E04	The device cannot adopt the therapy data.	The SD card must be returned to the physician to check the therapy.
E05	The SD card was removed.	Insert the SD card again.
	The SD card has fallen out of the card slot.	If this occurs frequently, the device should be examined by a service technician.
E06	The SD card or the device is faulty.	Change SD card. If this occurs frequently, the device should be examined by a service technician.
W00	The device is attempting to repair the SD card. But you have inserted a new SD card into the device.	Confirm with key. The old SD card is defective. Continue to use the new SD card.
W05/06	see error code E05/E06	see error code E05/E06

STORAGE OF THERAPY DATA

Therapy data is stored internally in the device and alternatively on an SD card. The data from the device and the SD card can be readout by the physician using the TRENDset PC software.

INTERNAL DEVICE MEMORY

The internal device memory is limited to 30 days¹.

SC CARD

In contrast to the internal device memory the SD card offers a capacity of more than one year^{1, 2}. In addition to the therapy data the last 100 device events are saved on the SD card. Events are changes of parameters such as therapy settings, resetting counters (e.g., filter counters) etc. The parameters changes are saved with the date and time they were changed, as well as the old and new value. All alarms that occurred are also being saved with date and time.

1 depending on the operating time and number of events

2 when using a 2 GB SD card

Therapy data	Internal device memory	SD card
Frequency	-	•
Mode	•	•
Adjustment	•	•
Leakage	•	•
Average System Flow	•	•
Therapy Pressure (low resolution) no Bilevel pressure changes visible	•	-
Therapy Pressure (high resolution) Bilevel pressure changes visible	-	•
Respiratory Flow	-	•
Relative Respiratory Volume	-	•
- not saved		
• saved		

CHANGING THE FILTER, CLEANING

The filter prevents dust, insects and airborne particles from entering the device. Over time such substances would cause heavy soiling of the ducts inside the device and the blower parts. As a result, the device would no longer satisfy the hygiene requirements. In extreme cases, unpleasant odors might result after a while. To ensure that the filter remains permeable to air, it needs to be cleaned or replaced at certain intervals.

The standard filter is only designed to offer a certain level of protection from bacteria and allergens. Here, we recommend using the optional *filtersystempoint 2*, an attachable filter cassette with replaceable filter layers. The large filter area means that a much denser filter material can be used here without there being any significant pressure loss.



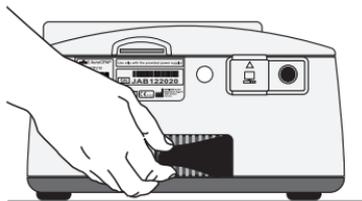
When the filter is soiled or the display reads **Change Filter**, the filter must be either replaced or rinsed out.

Changing the filter

Pull out the filter on the back of the device and replace it with a new or cleaned one.

NOTICE

Always use the device with the filter element inserted and clean the filter element regularly. If the filter element is heavily soiled or not inserted, this may damage the device and result in unpleasant odors.



Removing the filter

Cleaning the filter

1. Clean the filter with mild soapy water. Do not use any other agents!
2. Rinse the filter thoroughly with clear water.
3. Let the filter dry completely.
4. Insert the cleaned filter into the device.

If the device is run with the optionally available **filtersystempoint 2** according to the cleaning instructions in the filter system user's manual.

Resetting the display message

1. Disconnect the DC power supply plug from the device.
2. Hold the enter key  down and, while you are doing this, reconnect the DC power supply plug to the device's DC power connection.
3. **Filter Counter Reset** appears on the display. Press the enter key  to confirm.
4. **Filter Counter deleted** appears on the display.

CLEANING THE MASK

For hygienic reasons, clean the mask every day. To do so, proceed as follows:

1. Disconnect the mask from the therapy tube.
2. Clean the mask with mild soapy water. Do not use any other agents!
3. Rinse the mask thoroughly with clear water.
4. Let the mask dry completely.

CLEANING THE THERAPY TUBE

For hygienic reasons, clean the therapy tube weekly. To do this, proceed as follows:

1. Disconnect the therapy tube from the mask and the device.
2. Clean the therapy tube with mild soapy water. Do not use any other agents!
3. Rinse the therapy tube thoroughly with clear water.
4. Let the vertically suspended therapy tube dry completely.

CLEANING THE DEVICE

Clean the device once a week. To do this, proceed as follows:

1. Unplug the mains plug.
2. Wipe the device with a cloth slightly dampened with soapy water.
3. Rub the device dry with a cloth.

ATTENTION

Chemical cleaning products or solvents should not be used to clean the surface of the device under any circumstances. They might damage the high gloss finish of the device.

CLEANING THE HEADGEAR

You only need to clean the headgear if it is necessary. To do this, proceed as follows:

1. Remove the headgear from the mask.
2. Clean the headgear according to the manufacturer's instructions.

CLEANING THE HUMIDIFIER

NOTICE

When using a humidifier, the cleaning instructions in its user's manual must be observed.

PREPARING THE DEVICE FOR A PATIENT CHANGE

WARNING

Before every change of patient a hygienic preparation must be carried out in accordance with the HOFFRICHTER's hygiene concept.

When being given to another patient, the device must be prepared hygienically by the specialist dealer or the manufacturer. If reuse of the mask and the therapy tube is planned, they must also be prepared by the specialist dealer or the manufacturer.

The preparation procedure is described in detail in the corresponding hygiene plan.

USING BACTERIAL FILTERS

If the device is intended for use by more than one patient (e.g., operation in clinics), a suitable bacterial filter (e.g., MEDISIZE BARR-VENT S) must continuously be used to protect the device from contamination by human pathogens.

NOTICE

Change the bacterial filter daily and follow the manufacturer's user's manual.

If the optionally available humidifier *aquapoint 2* is used with the device, a bacterial filter must not be used.

On a change of patient, carry out the following steps:

- Replace the bacterial filter.
- Disinfect all the parts of the housing and the connections with a suitable agent, e.g., Mikrozid® Liquid.
- Change the filter or if you are using the optionally available ***filtersystempoint 2***, either change its coarse and fine filter and disinfect the surface of the filter system or replace the entire filter system with a new one.

NOTICE

If there is any doubt, it should be assumed that the device is contaminated and it should be hygienically prepared according to the hygiene concept.

TROUBLESHOOTING

Problem	Possible cause	Remedy
Pain in the nose, the paranasal sinuses or the ears	Inflammation of the paranasal sinuses or the middle ear	Stop the treatment and contact your physician
Unpleasant feeling because of the high pressure	Malaise with prescribed high pressure values	If you suspect an error, please ask your physician for help
	Acclimatization phase to the pressure not yet completed	Try to relax. Use or vary the soft start function
Dryness and irritation in the nose and throat	Air is too dry	Device probably does not have an air humidifier. Speak to your physician about retrofitting an aquapoint 2 humidifier
Original symptoms of sleep apnea come back	Physical condition or life circumstances have changed	Inform your physician
Irritated or dry eyes	Air escapes between mask and the skin of the face	Check the positioning of the mask
		Replace the mask if the material has become chapped
Cold nose	Room temperature too low	Increase room temperature. Warm up the tube under the pillow

Problem	Possible cause	Remedy
Runny nose, sneezing	Reaction to the air flow	Either increase the humidity in the room or the temperature of the humidifier
	Normal cold	Contact your physician
Reddening of the skin in the mask area, skin swelling	Incorrect mask size	Inform your physician
	Headgear too tight	Loosen the headgear
	Allergic reaction	Inform your physician
Feeling that the air is too hot	Heater close to the device	Move the device and the heater further apart
No air flow	Device is defective	Inform customer services
Very little air flow	Soft start function has been selected	Reduce soft start time
	Air channels are blocked	Check air inlet
Blower is running constantly at maximum speed	Leak in the device	Have the device checked by customer services

MAINTENANCE

ATTENTION

Do not try to open the device. Maintenance and repairs may only be performed by personnel authorized by us.

⚠ CAUTION

Do not try to open the power supply. Maintenance and repairs may only be performed by personnel authorized by us.

You yourself can help to increase the service life of the device and ensure that it continues to work safely.

- Follow the cleaning instructions from page 81.
- Check the system regularly:
 - Conduct a visual check for external damage and dirt
 - Check the mask alarm function once a week (see page 70)

DISPOSAL

Proper disposal saves natural resources and prevents harmful substances being released into the environment.

DEVICE

The device must not be disposed of with the household waste. Please contact the relevant customer services department to find out how to dispose of the device properly.



PACKAGING

The packaging is taken back by the distributor but it can alternatively be recycled.



ACCESSORIES

The accessories such as the tubing, mask, filter cassettes, etc. should be disposed of according to the manufacturer's instructions, or with normal household waste.

ACCESSORIES

For ordering of accessories, please contact a HOFFRICHTER service partner.

Scope of delivery	Article number
Carrying case	0000 2080
Power supply	0000 2133
Mains cable	3110 0029
Filter	0000 2110
Spare filter (2 pack)	0000 7801
Therapy tube (inner diameter = 22 mm, length = 1,80 m)	0000 7875
User's manual	5000 0606
Brief instructions	5000 0519

Optional	Article number
Standard masks	
CPAP nasal mask, size S	0000 3440
CPAP nasal mask, size M	0000 3434
CPAP nasal mask, size L	0000 3435
CPAP full face mask, size S	0000 3441
CPAP full face mask, size M	0000 3436
CPAP full face mask, size L	0000 3437
Cirri Comfort Mini masks	
Cirri Comfort Mini nasal mask, size XXS	0000 3498
Cirri Comfort Mini nasal mask, size XS	0000 3497

Optional	Article number
Cirri Comfort masks	
Cirri Comfort nasal mask, size S	0000 3486
Cirri Comfort nasal mask, size M	0000 3487
Cirri Comfort nasal mask, size L	0000 3488
Cirri Comfort full face mask, size S	0000 3483
Cirri Comfort full face mask, size M	0000 3484
Cirri Comfort full face mask, size L	0000 3485
Pillow mask	
Nasal Pillow, 4in1 size (XS, S, M, L)	0000 3499
Other Accessories	
SD card, formatted with TRENDset	1120 0010
ComfortTube System (heated tubing system)	0000 3479
Tube cover sleeve	0000 7161
Humidifier aquapoint 2	0001 2949
Electronics for humidifier aquapoint 2	0001 2286
Battery pack powerpackpoint 2	0001 2846
AKKUPACK uni BASE "Respiratory therapy"	0001 1101
filtersystempoint 2	0001 2847
Fine filter for filtersystempoint 2	0000 2109
Coarse filter for filtersystempoint 2	0000 2108
Bacterial filter MEDISIZE BARR-VENT S	0000 4932
24 V DC vehicle cable	0000 2295
12 V to 24 V converter	0000 7133

TECHNICAL DATA

	point 2	point 2 with <i>aquapoint 2</i>
Dimensions (WxDxH)	170 x 220 x 95 mm	180 x 350 x 110 mm
Weight	1.5 kg	approx. 1.9 kg (without water)
Power supply		
Mains power	100 ... 240 V AC, 50 ... 60 Hz	
DC power	24 VDC / max. 2.01 A	
Battery power (per battery)	11.1 V / 2200 mAh	-
Operating time under battery power ¹		
CPAP mode	> 8 hours (at 10 hPa, 12 bpm, 500 ml tidal volume)	-
BILEVEL S mode	> 7 hours (at IPAP = 12 hPa, EPAP = 6 hPa, f = 12 bpm, 300 ml tidal volume)	-
Running reserve of internal clock	up to 8 years	
Pressure range	4...20 hPa (mbar)	
Max. pressure limit in the event of a fault	≤ 30 hPa	
¹ The operating time is depending on the device settings and the age and stage of charge of the batteries.		

	point 2					point 2 with <i>aquapoint 2</i>				
Power consumption	DC power		Mains power			DC power		Mains power		
Standby (battery charging)	< 26 W		< 35 W			-		-		
Standby (without batteries)	< 3 W		< 5 W			-		-		
Operation at 20 hPa	< 14 W		< 17 W			< 38 W		< 42 W		
Operation at 12 hPa	< 10 W		< 12 W			< 34 W		< 38 W		
Operation at 6 hPa	< 6 W		< 9 W			< 30 W		< 35 W		
Short term pressure variation	4hPa	8hPa	12hPa	16hPa	20hPa	4hPa	8hPa	12hPa	16hPa	20hPa
10 bpm	< 0.26 hPa					< 0.49 hPa				
15 bpm	< 0.39 hPa					< 0.73 hPa				
20 bpm	< 0.50 hPa					< 0.91 hPa				
Long term pressure variation	< 0.1 hPa									
Pressure reading accuracy	0.5 hPa									
Average sound pressure level (operating at 1 m distance)	≤ 30 dB(A) at 10 hPa (equivalent to a sound power level of ≤ 38 dB[A])									
Air flow rate										
4 hPa	> 200 l/min					> 170 l/min				
8 hPa	> 185 l/min					> 160 l/min				
12 hPa	> 175 l/min					> 145 l/min				
16 hPa	> 160 l/min					> 135 l/min				
20 hPa	> 145 l/min					> 125 l/min				

	point 2	point 2 with <i>aquapoint 2</i>
Operating temperature	+ 5 °C ... + 38 °C (Ambient temperatures up to 40°C does not harm the device function at all.)	+ 5 °C ... + 35 °C (Ambient temperatures up to 40°C does not harm the device function at all.)
Storage/Transport temperature	- 20 °C ... + 70 °C	
Therapy air heating at air outlet at end of tube	0.3 K/ hPa via compression 0.2 K/ hPa via friction <0.3 K/ hPa at 10hPa; 0,5l/s	
Relative humidity	15 % ... 95 % for operation, storage and transport	
Ambient air pressure range		
Storage/Transport	1060 hPa ... 265 hPa (approx. - 400 m ... 10000 m)	
Operation	1060 hPa ... 800 hPa (approx. - 400 m ... 2000 m) ¹	
Filter	Polyurethane foam on polyester basis, 80 ppi, 30 kg/m ³	
Therapy tube connection	22 mm, cone (as per ISO 5356-1)	
Product class according to 93/42/EEC	IIa	
Classification according to EN 60601-1	Protection class II (protective insulation)	
¹ With increasing altitude, the air flow rate decreases.		

Factory settings

Parameter	
Menu	Complete menu
Language	ENG
P-Unit	hPa
Mode	BILEVEL S
IPAP	10 hPa
EPAP	6 hPa
I-Slope	2
E-Slope	2
Backup freq	OFF
Ramp	0 min
Mask Test	0 s
Auto	OFF
Display Vt	OFF
Bact.Filter	No
Brightness	50 %
Alarm clock	OFF ¹

¹ It can be unlocked by the physician or dealer with TRENDset PC software.

CE marking as per EC directive 93/42/EEC.

The manufacturer reserves the right to make technical changes without notice.

MANUFACTURER'S DECLARATION ON ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions

The point 2 is intended for use in the electromagnetic environment specified below. The user of the point 2 should assure that it is used in such an environment.

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

Guidance and manufacturer's declaration – electromagnetic immunity

The point 2 is intended for use in the electromagnetic environment specified below. The user of the point 2 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient (Burst) IEC 61000-4-4	± 2 kV power supply lines ± 1 kV input / output	± 2 kV power supply lines ± 1 kV input / output	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode not applicable	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p>> 95 % clip in $U_T/0.5$ cycles 60 % clip in $U_T/5$ cycles 30 % clip in $U_T/25$ cycles > 95 % clip in $U_T/5$ s</p>	<p>> 95 % clip in $U_T/0.5$ cycles 60 % clip in $U_T/5$ cycles 30 % clip in $U_T/25$ cycles > 95 % clip in $U_T/5$ s</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the point 2 requires continued operation during power mains interruption, it is recommended that the (Equipment or System) is powered from an UPS or a battery.</p>
<p>Magnetic field power frequency (50/60) Hz magnetic field IEC 61000-4-8</p>	<p>3 A/m</p>	<p>3 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>Conducted RF IEC 61000-4-6</p>	<p>$V_1 = 3$ V 150 kHz – 80 MHz</p>	<p>3 V</p>	<p>Portable and mobile communications equipment should be used no closer to any part of the point 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter:</p> <p>$D = 1.17 \sqrt{P}$ for $V_1 = 3$ V</p>

Guidance and manufacturer's declaration – electromagnetic immunity

Radiated RF
IEC 61000-4-3

$E_1 = 3 \text{ V/m}$
80 MHz – 2.5 GHz

3 V/m

$d = 1,17 \sqrt{P}$
80 MHz - 800 MHz
 $d = 2,33 \sqrt{P}$
800 MHz - 2.5 GHz

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol^b.



Note 1 At 80 MHz and 800 MHz the higher frequency range is essential.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the location in which the point 2 is used exceeds the compliance level, the point 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating or using another location of the point 2.

^b Over the frequency range from 150 kHz to 80 MHz the field strength should be lower than 3 V/m.

Recommended separation distances between portable and mobile RF communication equipment and the point 2

The point 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the point 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the point 2 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz – 80 MHz $d = 1.17 \sqrt{P}$	80 MHz – 800 MHz $d = 1.17 \sqrt{P}$	800 MHz – 2.5 GHz $d = 2.33 \sqrt{P}$
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	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz the higher frequency range is essential.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

DISCLAIMER

HOFFRICHTER GmbH is not liable for consequences in terms of safety, reliability and performance of the product where:

- interventions, modifications, extensions, adjustments, repairs and maintenance are carried out by persons not authorized by us,
- other manufacturers' accessories and spare parts are used that have not been approved by us for use on the product,
- the product is used other than as described in the user's manual or
- the hygiene and cleaning instructions described in the user's manual have not been complied with.

Statutory guarantee rights remain unaffected by this.

HOFFRICHTER GmbH
Mettenheimer Straße 12/14
19061 Schwerin
Germany
phone: +49 385 39925-0
fax: +49 385 39925-25
e-mail: info@hoffrichter.de
web: www.hoffrichter.de