HOFFRICHTER

VECTOR et BILEVEL ST20

User´s Manual

SERIAL NUMBER

HOFFRICHTER GmbH delivers all its systems with a serial number (Seriennummer) in order to ensure traceability. The serial number is indicated on the type label on the rear of the system. Please always specify the serial number in inquiries and complaints.

CONFORMITY

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

$\mathsf{C}\,\mathsf{E}_{0123}$

CONTENTS

LEGEND OF SYMBOLS

Observe the accompanying documentation

Applied part type BF

Electric safety class II (with protective insulation)

Observe the Operating Instructions

Manufacturer

$C\mathcal{E}_{0123}$ CE Declaration of Conformity

Do not dispose of the device with normal domestic waste.
For information on the proper disposal of the device,
please contact your responsible customer service.

SAFETY INSTRUCTIONS

Before using your respiratory therapy device for the first time, please thoroughly read these Operating Instructions.

Keep these Operating Instructions at a safe place for immediate consultation, if necessary.

For the period stipulated by law, **HOFFRICHTER** GmbH warrants that the product is free from any defects provided it is used as intended.

POWER SUPPLY

VECTOR et BILEVEL ST20 has an external switched mode power supply unit with a wide range input of 100 - 240 V~, 50 - 60 Hz. This allows connection to all energy supply networks in the world.

It is also possible to operate the device with a direct voltage of 24 V DC, e.g. for mobile use in a truck or mobile home. When connecting the device to a DC supply source, please only use the optional connection cable and do not use the device with a PC.

ATTENTION!

HOFFRICHTER GmbH is not liable for any damage and consequential damage nor for any effects on the safety, reliability and performance of the device, if:

• manipulations, modifications, expansions, adjustments, repairs and maintenance measures are carried out by persons not authorized by us to do so.

• use is made of accessories and spare parts which come from other manufacturers and have not been released by us for use with the **VECTOR et BILEVEL ST20** device.

• the device is used in a way that is different from that described in the Operating Instructions.

In order to prevent potential hazards, please follow the instructions below:

- Exclusively use the device for your own therapy, which must have been prescribed by a physician.

- Use accessories only which have been recommended and offered by your specialized dealer.

- Regularly test the alarm function of your device.

- Always ensure that the small hole in the mask or in the adapter between the mask and the tubing is unobstructed so that the exhaled air that is loaded with CO_2 can escape.

- Never set up the device in a compartment of a cabinet nor under your bed.

- Please make sure that air can easily circulate around the device.

- Do not place the device in the vicinity of radiators.

- Ensure that the device is positioned horizontally. This is particularly necessary if a humidifier is connected.

- If you receive oxygen with your therapy, please follow all fire protection and safety regulations with regard to the use of oxygen.

- Mobile use of the device is permitted only in a parked vehicle.

- Immediately see your physician if, while using the device, you develop one or more of the following symptoms: dryness of the mucous membranes in nose and throat, frontal sinus complaints, earache, a running nose, hypersensitivity of the skin, oversensitiveness, loss of voice, disturbances of orientation or memory.

- Immediately notify your specialized dealer if the device fails to function properly.

- Never place the respiration therapy device in the vicinity of other equipment or devices, such as defibrillators, diathermy equipment, mobile phones, microwave, remote-controlled toys, etc. Electromagnetic fields greater than 3 V/m may affect the operation of the device.

To maintain electrical safety, please observe the following instructions:

- Do not put the device into operation if its housing and/or cables are damaged.

- Do not open the housing of the **VECTOR et BILEVEL ST20.** Notify your specialized dealer of any disturbances and failures.

- Protect the device from water and moisture.

- Never operate the device in moist rooms nor in a bathroom.

- Do not place a vessel filled with fluid on the device.

- Be absolutely sure not to seize the device if it has fallen into water.

- Do not set up the device in the vicinity of water vessels (bath tubs).

- Before cleaning the device, always disconnect the power plug.

- Use the supplied power supply pack only.

- When connecting the device to a DC supply source, please only use the optional connection cable listed under optional accessories and do not use the device with a PC.

STANDBY MODE

The device is in the standby mode as long as the turbine is turned off. The standby mode is indicated by the illuminated display showing date and time. If a humidifier is connected with the device, the humidifier as well will be in standby mode. The preset heater level will be displayed. Power consumption in this mode is approx. 5 W.

- In the standby mode, the device may remain continuously switched on without posing any risk.

INTENDED USE

VECTOR et BILEVEL ST20 is intended for treating obstructive sleep apnea in patients with a weight of 30 kg and higher.

The device generates a continuous positive airway pressure in order to keep the upper respiratory tract unobstructed.

The device is not suitable for being used with patients who need artificial respiration. This therapy device is no life-preserving system.

The treatment pressure is applied through a ventilation mask. This ventilation mask must be provided with an exhalation valve in order to ensure that the exhaled air is discharged. Do not wear the ventilation mask while the therapy device is turned off because, otherwise, you might rebreathe exhaled air. Please also follow the manufacturer's instructions on use of the ventilation mask.

CONTRAINDICATIONS

Respiratory therapy may be contraindicated in patients with the following preexisting diseases:

• Bullous lung diseases

• Pneumothorax

• Very low blood pressure

• Air accumulation after open craniocerebral trauma or other head injuries

In case of an inflammation of the paranasal sinuses or the middle ear, it might be indicated to stop the therapy. Please consult your physician.

Devices which have been fitted with an *AquaDROP et* humidifier may not be used with additives such as medication or aroma oils in the humidifier water.

TECHNICAL DESCRIPTION

The device is intended for respiration therapy in adults. It generates two pressure levels in the S-, ST- or T–mode via an electrically controlled turbine.

Switching from one pressure level to another is realized via a quick change of the revolutions of the fitted high-performance blower to keep the stress for the patient as low as possible.

S-mode
Spontaneous trigger – the change from one pressure level to another is triggered by starting respiration of the patient only. A decline in pressure to the set lower pressure level also occurs once the inspiration flow ends.

ST-mode
Spontaneous breathing and **T**ime – as long as the patient is breathing independently the device is operating in the S-mode. Once the patient stops breathing the device automatically switches into the T-mode and provides respiration for the patient in the prescribed safety frequency. The delay time after which the device switches into the T-mode can be set.

T-mode
Time respiration with prescribed, set inspiration time. If the trigger function is deactivated the patient is ventilated according to the set parameters. If the trigger function is activated the device accepts only spontaneous trigger signals in the expiration phase.

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

Trigger device
The respiration trigger detects the patients efforts to breath in and out and signals these efforts to the control device. A flow-based trigger is integrated which can be set separately for inspiration and expiration. In connection with an optimum flank adjustment this results in a ventilation which is very comfortable for the patient and which gives the patient the impression as if the device is following the natural respiration without delay.

To generate the necessary pressure, the device is provided with an electronically controlled blower. In order to keep the stress for the patient as low as possible, the blower has been designed with a high reserve capacity and a quick control response.

The pressure is measured directly in the mask and constantly controlled by the device. Consequently, the breathing work for the patient is a easy as possible. There are two separate tubings in the device. One is for respiratory air and one is for the convection air required for cooling the electronics.

In addition to the mask alarm, the device offers another safety function, the power failure alarm. It automatically restarts the motor after power restoration.

The device contains a built-in microcontroller which controls all of its functions. For added comfort an alarm clock is integrated in the device. Further comfort functions include a soft start ramp, the automatic start-stop function and the adjustable display brightness.

While passing through the device, the air is heated a little, so that it has a higher water absorbency. When indoor air is dry in the heating period, the

mucous membranes in mouth and nose may beco-
me particularly dry. This is unpleasant and may
even cause infections in exceptional cases. For that
reason, a therapy might require air humidification.

AquaDROP et, a clip-on humidifier is available as
accessory for the device. If necessary, just click the
humidifier onto the device. Remove it by pressing
its locking key.

The heater levels are set in the heater menu. The
selected heater level is displayed as a figure in the
display of the device while the humidifier heating is
switched on.

```
BILEVEL ST20
 Press ON/OFF!
 Heating:2   21:45
```
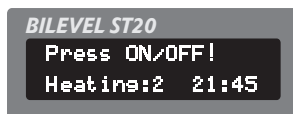
For more information please consult your
AquaDROP et operating instructions or contact
your specialized dealer.

NOTES PRIOR TO FIRST USE

Never turn the device on if you kept it in a very cold
environment. Wait for approx. 1 hour until its tem-
perature compensation is completed.
Regularly check the air filter cassette and regularly
exchange it as described on page 18. Never use
the device without air filter.

Clean your mask system regularly and check all
accessory parts, particularly the therapy tubing, the
mask and the head gear. We recommend that you
wash your face before going to sleep, in order to
remove fat and cosmectics from your skin. This
increases the service life of the mask and helps to
prevent irritations of the skin.

Make sure the measurement tube is unobstructed
at all times. Avoid ingress of water into the measu-
rement tube during cleaning. If water droplets
should have accidentally entered the measurement
tube they must be carefully and thoroughly remo-
ved.

Please strictly observe the following setup
instructions:
• Do not place the device in the vicinity of a
  heating source. Air circulation – particularly
  that below and behind the device – must not
  be impaired by furniture, curtains or cushions

• Set up the device next to your bed. Place it
  on a firm and flat surface of your bedside
  cabinet

• During mobile use, the device must also be
  placed on a firm and flat base, which must
  have an edge to protect the device from fal-
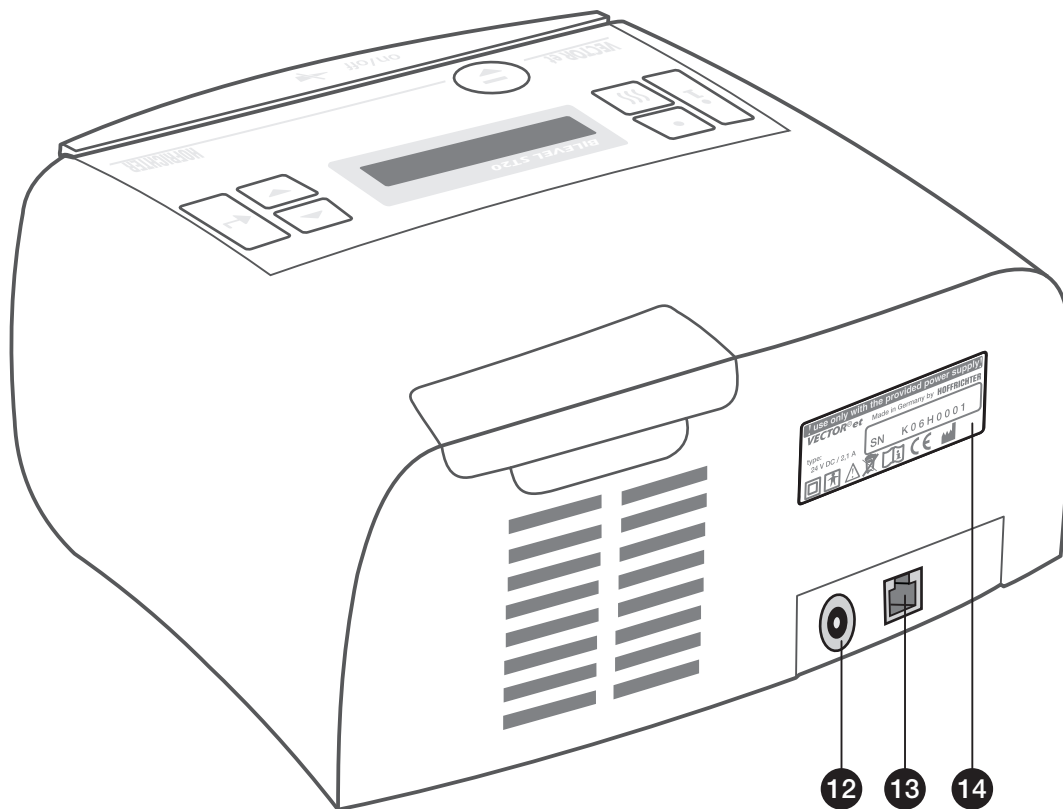 ling off

COMPONENTS OF THE DEVICE

FRONT VIEW

1	Program keys
2	Filter Cassette
3	Display
4	Heater-LED
5	Info key
6	Heater key
7	Release button
8	Measuring tube connection
9	Air outlet
10	Contactors for humidifier
11	Control key (ON/OFF button)
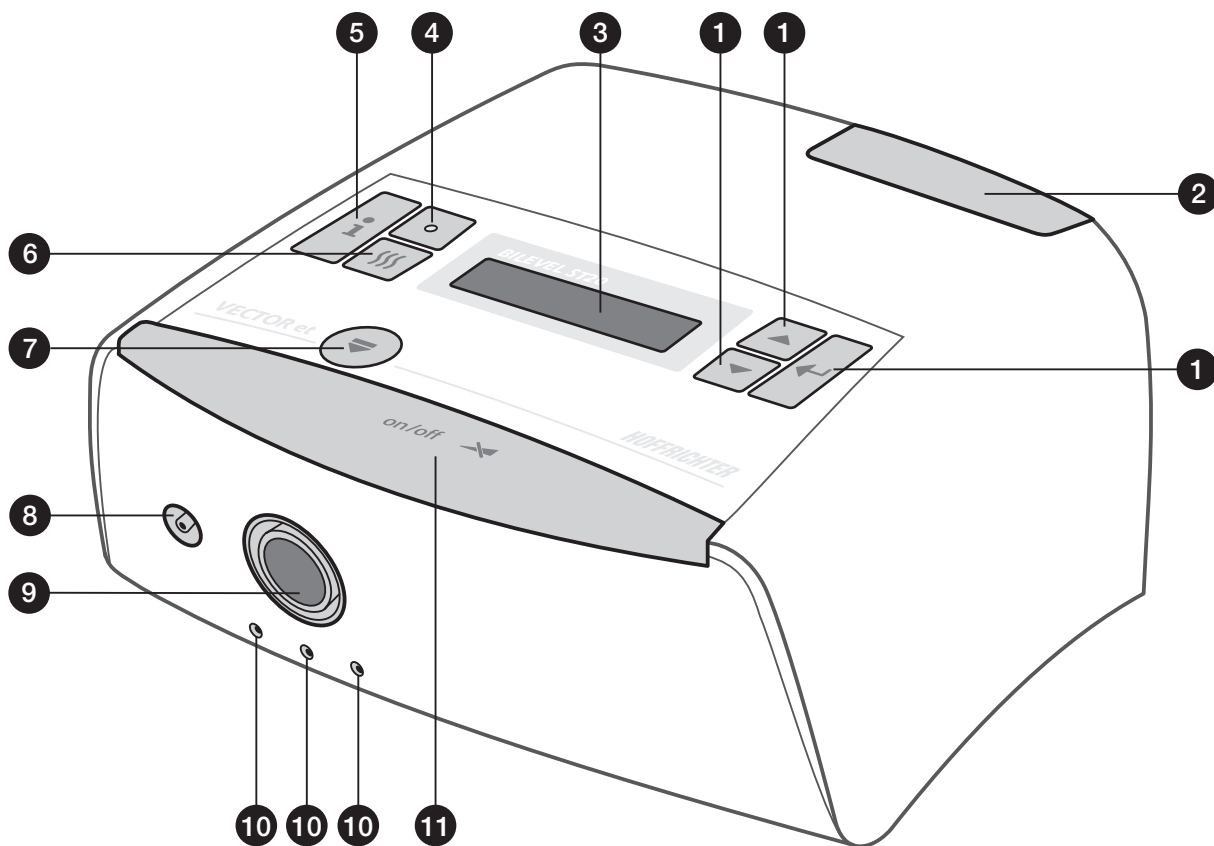
REAR VIEW
12 Power connection
13 RS232 interface
14 Type identification plate

12 13 14

ACCESSORIES

Carrier bag

Air Filter Cassette

Car Cabel

Power Supply Unit

Power cord

Measuring Tube

Stoppers

Therapy Tube
(Length 1,80 m)

Breathing Mask
There are various mask
systems available

Exhalation valve
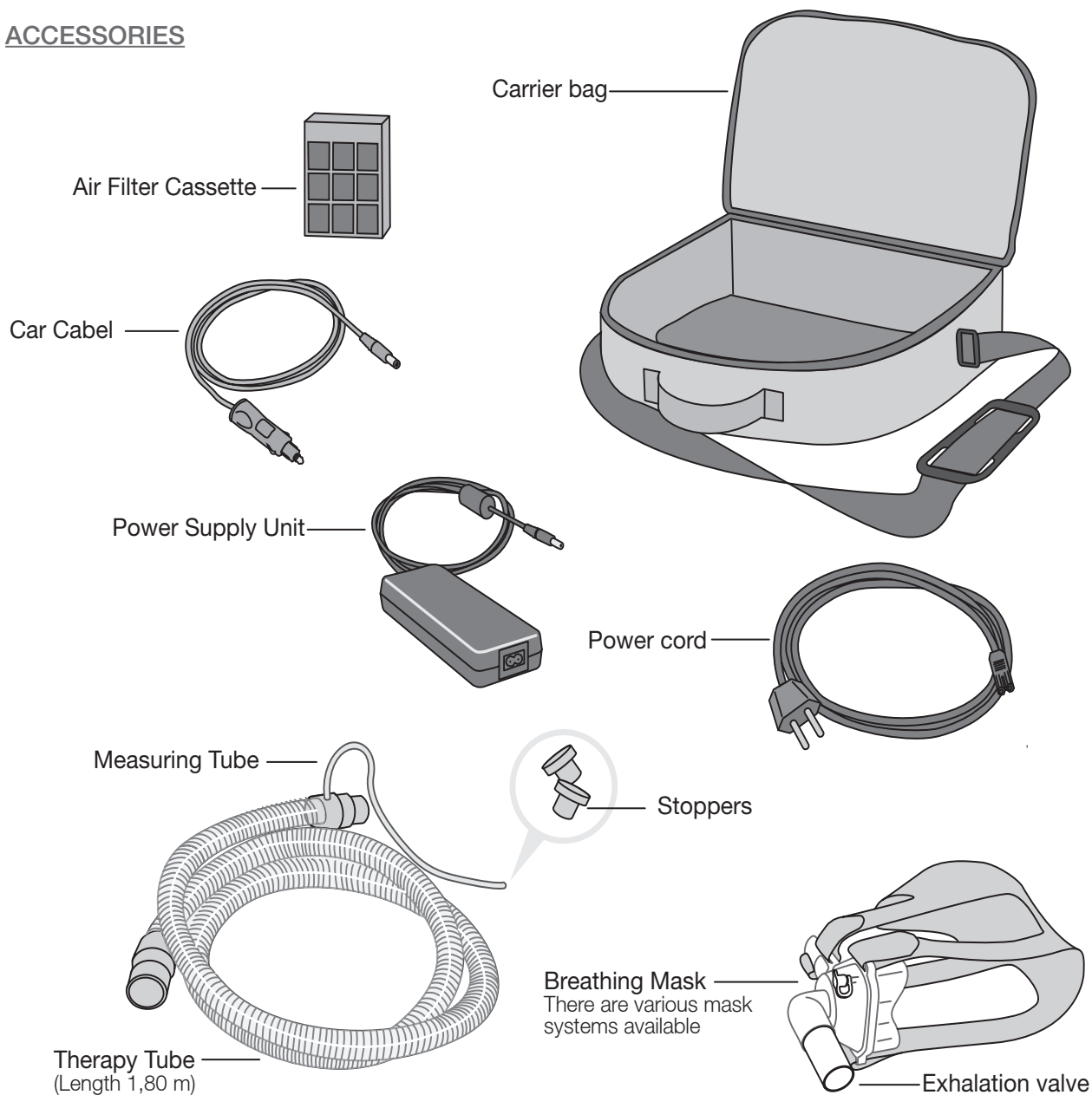
SCOPE OF DELIVERY

	Art.-No.:
VECTOR et BILEVEL ST20	0000 2048
User´s manual	5000 0039
Power supply unit	0000 2020
Power cord	3110 0015
Therapy tube, measuring tube and stoppers	0000 7116
Filter cassette without frame cover	0000 2029
Carrier bag	0000 2080

A ventilation mask that has been specially adjusted for the individual patient is required for start-up and use of the device in the domestic area, in addition to the therapy device with power supply unit, power cord, and therapy tube.

OPTIONAL ACCESSORIES

|	Art.-No.:
AquaDROP et	0000 2015
Car cabel	0000 9212
12 V to 24 V converter	0000 7133
Replacement filter cassette with frame cover	0000 2028

USE OF THE DEVICE

1. After having set up the device properly, connect the power supply unit to the device and, using the supplied power cord, to a grounded outlet.

2. The device displays a welcoming message, the software version and the current number of treatment hours. Thereafter, the display shows the date and time.

3. Connect the therapy tubing
   a) to the air outlet, and
   b) to the mask.

4. Also connect the measuring tube to the measuring tube outlet.

5. Apply the mask. If you have selected the automatic mode, the device will start on your first breath. In the manual mode, press the operator key to start the device.

6. The device will then run through the mask test for the time selected and at the pressure prescribed. You should now properly seat the mask in order to eliminate any potential leaks.

7. Place the tubing such that it does not exert any pulling action on the mask while you are lying down.

8. Breathe deeply and calmly only through your nose. If you have activated the soft start function, the device initially reduces the pressure after completion of the mask test and will then slowly increase the pressure automatically to the prescribed value, allowing you to fall asleep at a lower pressure.
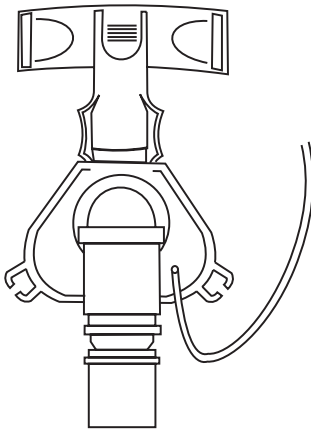
NOTE:
For information on how to adjust the soft start and mask test times to your individual demands, please refer to the section entitled functions of the device.
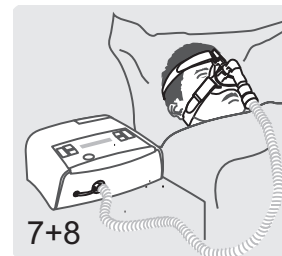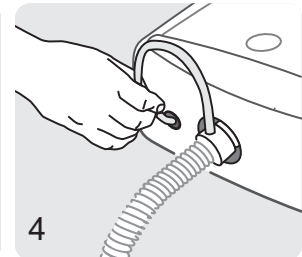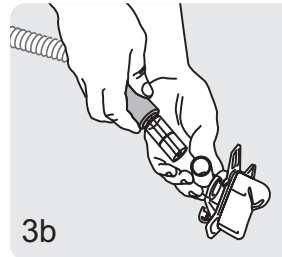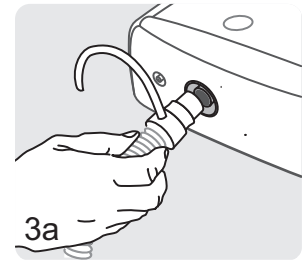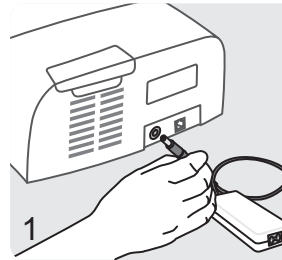
USE OF OXYGEN

If you also have to inhale oxygen during your thera-py, please be absolutely sure to follow the instructi-ons from the manufacturer or the dealer delivering the oxygen to you.

If you supply the oxy-gen directly into the mask, please use a non-kinking tube that consists of a medically approved material.

You can also supply the oxygen through an adapter which is mounted to the air outlet.
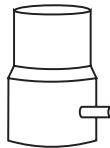
In any case, please be absolutely sure to follow the instructions of your physician.

Please contact your specialized dealer.

ATTENTION!
Oxygen promotes combustion processes. For that reason, please observe the valid fire protecti-on regulations for the use of oxygen. Keep oxy-gen fittings free from fat, do not smoke, and do not handle the device near a naked flame.

ATTENTION!
If you are using oxygen together with the device, the oxygen supply must always be deactivated as long as the device is in the standby mode or while it is turned off.

Always turn on the device first and only then the oxygen supply. Turn off the oxygen supply before turning off the device.
Activate the „Automatic OFF" as described on page 27.
Whenever you use the device, check the tube con-nections for proper seating beforehand.

CLEANING AND CHANGE OF THE FILTER

CHANGE OF THE FILTER

If the filter is polluted or the display shows the message "change filter" the filter cassette must be changed.

BILEVEL ST20
```
IIIII         5.0hPa
Change Filter
```

1. To change the cassette, pull it upwards out of the device.

2. Separate filter cassette and filter frame cover by pulling them apart.

3. Replace the filter cassette.

4. Mount the filter frame cover onto the new filter cassette. Make sure the upper part (slit) and the filter cassette (pin) are in the correct position.
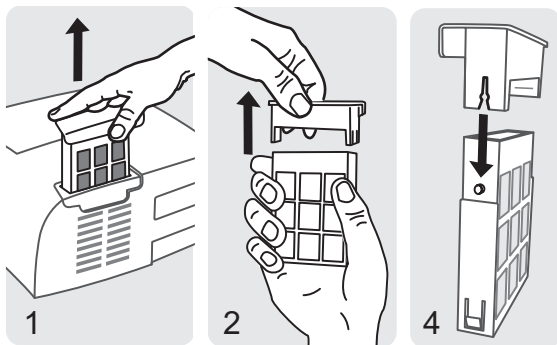
To set back the message proceed as described in the chapter Patient menu (page 24).

NOTE:
Never operate the device without filter cassette. Only and exclusively use original **HOFFRICHTER** filter cassettes. Otherwise, the warranty for the ventilator will become extinct.

CLEANING THE MASK

For reasons of hygiene the mask must be cleaned on a daily basis:
1. Separate the mask from the therapy tubing
2. Clean the mask as described in the mask manufacturer's operating instructions

WEEKLY CLEANING OF THE THERAPY TUBING

Make sure the measurement tube is unobstructed at all times. Avoid ingress of water into the measurement tube during the weekly cleaning. If water droplets should have accidentally entered the measurement tube they must be carefully and thoroughly removed.
1. Close the therapy tubing tightly with the stoppers before cleaning (see page 14)
2. Use mild soapy water for cleaning, thoroughly rinse with clear water, and let the tubing dry in air
3. Remove the two plugs from the measuring tubing after cleaning

CLEANING THE DEVICE

For reasons of hygiene the device must be cleaned on a weekly basis:
1. Disconnect the power plug
2. Wipe the device with a cloth slightly moistened with soapy water. Then use a dry cloth to wipe the device dry

You do not have to disinfect the device or parts of the device chemically or thermally.

CLEANING THE HEAD GEAR

Clean the head gear as required:
1. Disconnect the head gear from the mask
2. Clean the head gear as described in the head gear manufacturer's operating instructions

ALARM FUNCTIONS

POWER FAILURE

If a power faiure at night would go unnoticed as a result the patient would breathe used air from the therapy tubing all night. To avoid this the device is equipped with an alarm mechanism that warns you with a 5 seconds delay if power or a fuse fail at night. You will be woken up with an acoustic signal so you can take the mask off your face and breathe fresh air.
The alarm is turned off by pushing the operating button. After power supply is re-established the motor starts automatically and the display will show the following message:

```
BILEVEL ST20
  Power Failure
  Restart Turbine
```
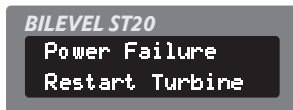
CHECK POWER FAILURE WARNING

NOTE:
To check the power failure alarm, the device must have been connected to the power cord and turned on for at least half an hour.

Use the device with running blower and then pull the power plug out of the wall socket. Now the acoustic warning signal should sound. Check once a month if the signal sounds long enough (reference value: at least 3 minutes).
After pushing the operating button or turning on the power supply again the signal will stop.

MASK ALARM

This alarm function is activated only if the automatic function is turned off. If the mask has slipped off your face or if the tubing is pulled off the device, the device is not turned off automatically, but emits a visual and audible alarm. However, this additional safety function requires that you turn the device on in the evening and off and in the morning with the operating button (ON/OFF).

```
BILEVEL ST20
  Mask Alarm......10s
  Check Mask!
```

CHECK MASK ALARM

Use the device with running turbine in the manual mode (automatic mode OFF). The mask is open but not applied to your face. After a short time, an audible signal is emitted.

PRESSURE ALARM

If during the therapy a hardware error occurs or the pressure becomes too high (e.g. due to a bent measuring tube) the decive will generate an alarm sound and turn off the turbine. The alarm is turned off by pushing the operating button and the therapy can be continued after solving the error.

```
BILEVEL ST20
   Press. too high
  09.May.07  09:42
```
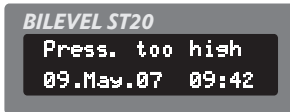
ALARM CLOCK

The device is provided with a comfortable integrated alarm clock. Using the programming keys, you can activate and deactivate this alarm clock at any time, for example on weekends. The alarm clock emits an alarm at the programmed wake time. Press the operator key once to set the alarm for the next 5 minutes (can be set with the help of the computer software) and twice to deactivate it completely.

These functions may have been deactivated through the software. Please contact your speaiclized dealer or service technician for activating these functions.

FUNCTIONS OF THE DEVICE

You can program the functions of the device with the following three keys:

↵ = enter key
▲ = programming key
▼ = programming key

The display has two lines. Using the ▲ and ▼ keys, you can select the line to be displayed. The triangular symbol ▶ preceding the line indicates that this line has been selected.

```
BILEVEL ST20
▶Automatic........OFF
 Exit Menu
```
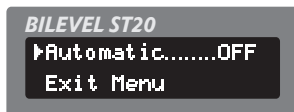
NOTE:
If you do not press any key for 30 seconds while programming, the programming mode is automatically exited for safety reasons.

Unless the changed value is confirmed with the enter key when the programming mode is exited, the original value remains as it is.

If you select the line »exit menu« and then press the ↵ key, programming is ended.

The device has three different menus:

1. Info-Menu:
    In this menu the set parameters can be displayed.

2. Patient-Menu:
    In this menu the patient can change settings.

3. Clinic-Menu:
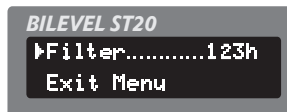   In this menu, only a doctor or service technicians can change settings.

INFO MENU

By pressing the Info button **i** you get to the Info menu. By pressing the buttons ▲ and ▼ you can see the next parameters. To exit the Info menu select the line »exit menu« and then press the ↵ button. If you do not press any buttons for 30 seconds the device will automatically switch back to the operating mode.

The following parameters are shown.

1. Therapy
    Shows the total therapy time of the device

```
BILEVEL ST20
▶Therapy..........123h
 Exit Menu
```
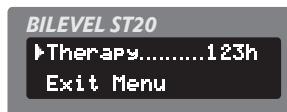
2. Filter
    Shows the time since the last filter change

```
BILEVEL ST20
▶Filter...........123h
 Exit Menu
```

3. Ramp
    Shows the remaining time of the soft start
    ramp

```
BILEVEL ST20
▶Ramp.............50min
 Exit Menu
```

4. P-Ramp
    Shows the ramp start pressure

```
BILEVEL ST20
▶P-Ramp........4.5hPa
 Exit Menu
```

5. Mode
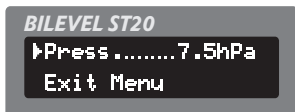   Shows the selected mode

```
BILEVEL ST20
▶Mode........BILEV ST
 Exit Menu
```

The device can be operated in the CPAP-mode
as well as in the BILEVEL-S, BILEVEL-ST and
BILEVEL-T-mode.

6. Pressure
    Shows the selected therapy pressure
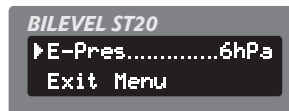
```
BILEVEL ST20
▶Press........7.5hPa
 Exit Menu
```

7. I-Pressure
    Shows the selected inspiration pressure

```
BILEVEL ST20
▶I-Pres..........10hPa
 Exit Menu
```
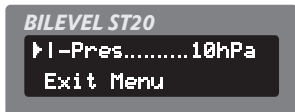
8. E-Pressure
    Shows the selected expiration pressure

```
BILEVEL ST20
▶E-Pres.............6hPa
 Exit Menu
```

9. I-Slope
    Shows the selected inspiration slope

```
BILEVEL ST20
▶I-Slope.............3s
 Exit Menu
```
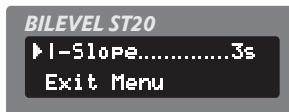
10. E-Slope
    Shows the selected expiration slope

```
BILEVEL ST20
▶E-Slope.............3s
 Exit Menu
```
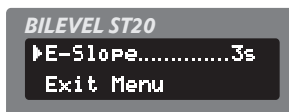
11. Trigger
    Shows the selected trigger status (only in T-
    mode)

```
BILEVEL ST20
▶Trigger............OFF
 Exit Menu
```

12. I-Trigger
    Shows the selected inspiration trigger thres-
    hold

```
BILEVEL ST20
▶I-Trigger............2
 Exit Menu
```
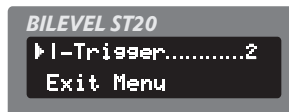
13. E-Trigger
Shows the selected expiration trigger threshold

```
BILEVEL ST20
▶E-Trigger............2
 Exit Menu
```

14. Frequency
Shows the selected number of breaths per minute

```
BILEVEL ST20
▶Frequency....12bpm
 Exit Menu
```
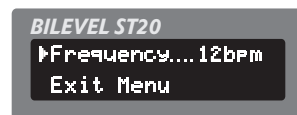
15. Inspiration
Shows the ratio of inspiration time - entire breath

```
BILEVEL ST20
▶Inspiration....33%
 Exit Menu
```

16. Delay Time
Shows the delay for switching from S-mode to T-mode

```
BILEVEL ST20
▶Delay Time........5s
 Exit Menu
```

PATIENT MENU

Press and hold the enter key (at least 1 second) to move to the programming mode. The Patient menu will now appear on the display. In the Patient menu you can set the following parameters:

1. Wake Time
In this menu item you can set and change the wake time.

```
BILEVEL ST20
▶Wake Time...07:00
 Exit Menu
```

After pressing the ↵ key again the hour of the wake time will start flashing. Now you can change it by pressing the ▲ and ▼ keys. After pressing the ↵ key again the minute of the wake time will start flashing. Now you can change it by pressing the ▲ and ▼ keys. Pressing the ↵ button again ends the input and you get back to the menu. Changing the wake time will automatically activate the alarm clock.

```
BILEVEL ST20
 Press ON/OFF!
 Alarm ON   07:00
```
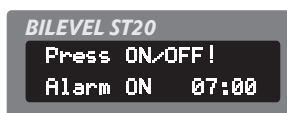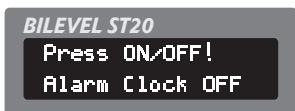
After leaving the menu the alarm clock can be activated and deactivated with the help of the ▲ and ▼ buttons. Press ▲ to activate the alarm function. The display briefly shows the wake time allowing you to verify it.

After that a bell symbol in front of the time display shows that the alarm function is activated.

```
BILEVEL ST20
 Press ON/OFF!
 09.May.07 ⏰09:42
```

Press ▼ to deactivate the alarm function. The bell symbol disappears.

```
BILEVEL ST20
 Press ON/OFF!
 Alarm Clock OFF
```

2. Delete Filter

In this menu item the filter counter can be reset. This function should be used at every filter change so that always a current value is displayed.

```
BILEVEL ST20
▶Delete Filter
 Exit Menu
```

To reset the filter counter, go to the Patient menu (press the ↵ button for approx. 1 second), then select »Reset filter« with the buttons ▲ and ▼. Press the ↵ button.
The system will now ask you if you are sure hat you want to perform a reset.
Press the ↵ key to perform the reset.

```
BILEVEL ST20
 Delete Filter
 Press Reset ↵
```

Now the filter counter is reset to zero.
If you do not want to reset the filter counter, leave the menu by pressing the buttons ▲ and ▼ or wait until the system leaves the menu item automatically.
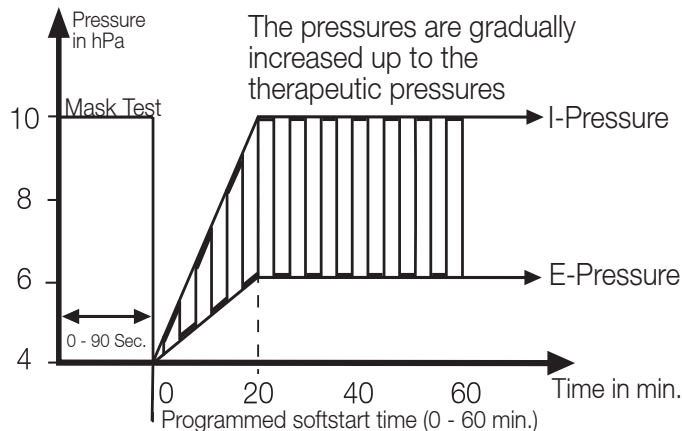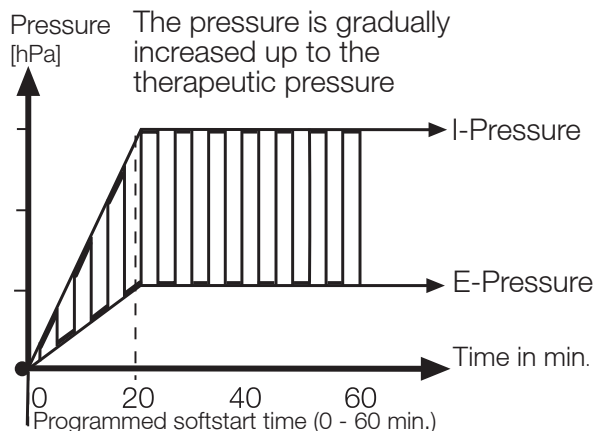
```
BILEVEL ST20
 Filter Counter
 deleted
```

3. Ramp

Whenever the turbine has been started, the microcontroller of the device checks whether a soft start ramp has been programmed. While the programmed time elapses, the soft start function increases the pressure from an adjustable initial ramp pressure (P-ramp) up to the pressure prescribed, thus allowing you to fall asleep more easily.

```
BILEVEL ST20
▶Ramp.............50min
 Exit Menu
```

In particular if you are not yet used to the respiration therapy the soft start can help you get accustomed to the device and fall asleep easily.

The device allows delay times ranging from zero (the prescribed therapy pressure is applied at once) to 60 minutes (the prescribed therapy pressure is built up within 60 minutes).
The initial ramp pressure (P-ramp) can be set by health professionals within a range from 4 hPa to the pressure prescribed.
To set the ramp, first go to the Patient menu (press the ↵ button for approx. 1 second), then select »Ramp« with the buttons ▲ and ▼.
Press the ↵ button. Now select the desired time by pressing the buttons ▲ and ▼.
Press ↵ to confirm.

Pressure [hPa]

The pressure is gradually increased up to the therapeutic pressure

I-Pressure

E-Pressure

Time in min.

0   20   40   60

Programmed softstart time (0 - 60 min.)

Pressure in hPa

The pressures are gradually increased up to the therapeutic pressures

10 Mask Test

8

6

4

I-Pressure

E-Pressure

0 - 90 Sec.

0   20   40   60   Time in min.

Programmed softstart time (0 - 60 min.)

4. **Mask Test**

This parameter determines the time when the device performs a mask test. Put on the mask and start the device.

```
BILEVEL ST20
▶Mask Test........30s
 Exit Menu
```

To ensure that the mask is tight while the pressure slowly increases in the soft start ramp even with higher pressures, you can program a mask testing time of up to 90 seconds in 5-second intervals. This mask test is carried out before the ramp is started. It checks whether the mask is tight even under the maximum therapy pressure.

To set the mask test, first go to the Patient menu (press the ↵ button for approx. 1 second), then select »Mask test« with the buttons ▲ and ▼. Press the ↵ button. Now select the desired time by pressing the buttons ▲ and ▼. Press ↵ to confirm.

5. **Automatic Mode**

This parameter determines if the device starts the therapy automatically as soon as you put on the mask.

```
BILEVEL ST20
▶Automatic........OFF
 Exit Menu
```

To program the automatic mode go th the Patient menu (hold down the ↵ for approx. 1 second) and then select the desired setting with the help of the ↵ button.
If »OFF« is programmed you have to switch the device on and off by pressing the operating button.

If the automatic is set to »ON« you simply have to put on the mask and breathe normally. The device will then start the therapy automatically.

```
BILEVEL ST20
 Put on Mask
 09.May.07  09:42
```

If you want to end the therapy simply take off the mask. After 5 seconds the device will switch off automatically.
In the automatic mode, the device is turned off if the mask or the tubing slip off unnoticed during the night.

```
BILEVEL ST20
  Turbine off......4s
  09.May.07   09:42
```
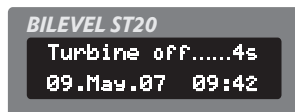
Therefore the device offers you the function »Automatic OFF« with mask alarm. Then you have to switch on the device in the evening and switch it off in the morning by pressing the operation button (ON/OFF) but you also receive an acoustic warning in case of a leakage.

Pressing the ON/OFF button will not end the therapy. You only get the message to take off the mask.

```
BILEVEL ST20
  IIIIIII        7.5hPa
  Take off Mask!
```
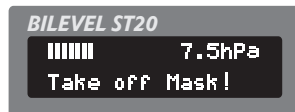
NOTE:
The automatic function can be deactivated via the PC-software TRENDset by a medical assistant.

6. Brightness
    In this menu item you can set the brightness of the display.

```
BILEVEL ST20
 ►Brightness....100%
  Exit Menu
```

To do so go to the Patient menu (hold down the ↵ button for approx. 1 second).
Then select »Brightness« by pressing the buttons ▲ and ▼. Press the ↵ button. After pressing the ↵ button the currently set brightness will flash and can then be adjsted by pressing the buttons ▲ and ▼ in intervals of 10%.
Press ↵ for accepting the selected brightness. If no button is pressed for 15 seconds the device will select the brightness previously set by you. After pressing any button the brightness will automatically switch to 100% for better visibility.

7. Date
    Use this menu item to set the date.

```
BILEVEL ST20
 ►Date......09.May.07
  Exit Menu
```

To do so go to the Patient menu (hold down the ↵ button for approx. 1 second).
Then select »Date« by pressing the buttons ▲ and ▼. Press the ↵ button. After pressing the ↵ button the year will flash and can be set by pressing the buttons ▲ and ▼.
After pressing the ↵ button again the month will flash and can be set by pressing the buttons ▲ and ▼. After pressing the ↵ button again the day will flash and can be set by pressing the buttons ▲ and ▼. Press the ↵ button again to accept the set date.

8. Time
Use this menu item to set the time.

```
BILEVEL ST20
▶Time.............07:00
 Exit Menu
```
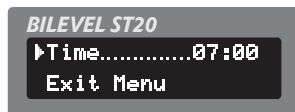
To do so go to the Patient menu (hold down the ↵ button for approx. 1 second).
Then select »Time« by pressing the buttons ▲ and ▼. Press the ↵ button. After pressing the ↵ button the hour will flash and can be set by pressing the buttons ▲ and ▼.
After pressing the ↵ button again the minutes will flash and can be set by pressing the buttons ▲ and ▼. Press the ↵ button again to accept the set time.

With its built-in battery, the internal clock has a reserve power of 8 years without connection to the external power supply.

CLINIC MENU

In addition to the parameters in the Patient menu, in the Clinic menu parameters relevant for the therapy can be set. This menu is used only by health and service professionals. In the Clinic menu the following patient and device relevant data can be shown and changed.

For some parameters you have to enter a PIN first to prevent wrong parameter setting. Your doctor and specialized dealer know this PIN.

Please do not try to find out the PIN. If you are in doubt as to whether the set parameters are correct, please consult your physician.

1. Language
The device can emit display messages in German (DEU), English (ENG), French (FRA), Italian (ITA), Dutch (NLD), and Polish (PLK). Further languages can be implemented at any time.
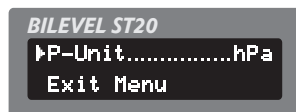
```
BILEVEL ST20
▶Language..........ENG
 Exit Menu
```

For changing the language go to the Clinic menu (hold down the ↵ button for approx. 1 second). Then select »Language« by pressing the buttons ▲ and ▼. Press the ↵ button. Each time you press the button another language will appear.
Leave the menu once the desired language is selected. The device will then save the new language.

2. P-Unit
    The device can show the pressure in the
    pressure units hectopascal (hPa), millibar
    (mbar), and und centimeters of water (cmH$_2$O).

```
BILEVEL ST20
▶P-Unit...............hPa
 Exit Menu
```

For changing the pressure unit go to the Clinic
menu (hold down the ↵ button for approx. 1
second). Then select »P-unit« by pressing the
buttons ▲ and ▼. Press the ↵ button. Each
time you press the button another pressure unit
will appear. Leave the menu once the desired
pressure unit is selected. The device will then
save the new unit.

PLEASE NOTE!
**When changing the pressure unit from hPa or
mbar to cmH$_2$O the pressure will slightly
change.**

Example: 8 hPa = mbar are set.
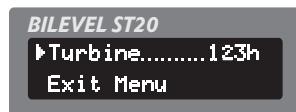At 8 cmH$_2$O the pressure is 7.8456 hPa/mbar.
1 cmH$_2$O = 0.9807 hPa.

3. Turbine
    This menu item shows the total operating time
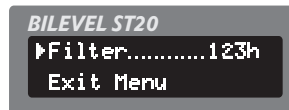   of the turbine, the filter, and the therapy time.

3.1 Turbine
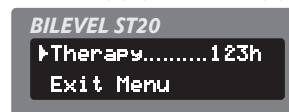   The counter indicates the total turbine running
    time.

```
BILEVEL ST20
▶Turbine.........123h
 Exit Menu
```

3.2 Filter
    The counter indicates the operating hours of
    the filter since the last reset.

```
BILEVEL ST20
▶Filter............123h
 Exit Menu
```

3.3 Therapy
    The counter indicates the operating time with
    the therapy pressure applied.

```
BILEVEL ST20
▶Therapy..........123h
 Exit Menu
```

3.4 Standby
    This counter indicates the time the device was
    in the standby mode.

```
BILEVEL ST20
▶Standby..........123h
 Exit Menu
```

To display the counter go to the Clinic menu
(hold down the ↵ button for approx. 1 second).
Then select »Turbine« by pressing the buttons
▲ and ▼. Press the ↵ button.
Each time you press the button now you see
the next counter.

4. Mode
   The device can be operated both in the CPAP mode and in the Bilevel mode.

   For changing the mode go to the Clinic menu (hold down the ↵ button for approx. 1 second). Then select »Mode« by pressing the buttons ▲ and ▼. Press the ↵ button.

   ```
   BILEVEL ST20
   ▶Mode........BILEV ST
    Exit Menu
   ```

   Now the device will prompt you to enter the PIN. The first digit is flashing. Enter the first digit of the PIN with the help of the ▲ and ▼ buttons.
   After pressing the ↵ button the second digit will flash. Enter the second digit of the PIN with the help of the ▲ and ▼ buttons, and proceed as described for the first digit. Enter the third digit accordingly.

   ```
   BILEVEL ST20
   ▶PIN Code?.....0000
    Exit Menu
   ```

   After entering the last digit of the PIN you can switch between the CPAP- and BILEVEL-mode by pressing the ↵ button. Leave the menu once the desired mode is selected. The device will then save the new language.

5. Pressure

   ```
   BILEVEL ST20
   ▶Press.........7.5hPa
    Exit Menu
   ```

For changing the pressure go to the Clinic menu (hold down the ↵ button for approx. 1 second). Then select »Pressure« by pressing the buttons ▲ and ▼. Press the ↵ button. Now the device will prompt you to enter the PIN. The first digit is flashing. Enter the first digit of the PIN with the help of the ▲ and ▼ buttons. After pressing the ↵ button the second digit will flash.
Enter the second digit of the PIN with the help of the ▲ and ▼ buttons, and proceed as described for the first digit. Enter the third digit accordingly. After entering the last digit of the PIN you can set the pressure by pressing the buttons ▲ and ▼. Then confirm the selected pressure by pressing the ↵ button.

6. I-Pressure
   Pressure during inspiration.

   ```
   BILEVEL ST20
   ▶I-Pres..........10hPa
    Exit Menu
   ```

   For changing the I pressure go to the Clinic menu (hold down the ↵ button for approx. 1 second). Then select »I-pressure« by pressing the buttons ▲ and ▼. Press the ↵ button. Now the device will prompt you to enter the PIN. The first digit is flashing. Enter the first digit of the PIN with the help of the ▲ and ▼ buttons. After pressing the ↵ button the second digit will flash.
   Enter the second digit of the PIN with the help of the ▲ and ▼ buttons, and proceed as described for the first digit. Enter the third digit accordingly. After entering the last digit of the PIN you can set the pressure by pressing the buttons ▲ and ▼. The confirm the selected

pressure by pressing the ↵ button. Next the parameter E-pressure is set.

7. E-Pressure
Pressure during expiration.
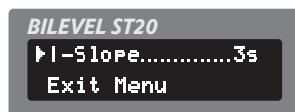
```
BILEVEL ST20
▶E-Pres.............6hPa
 Exit Menu
```
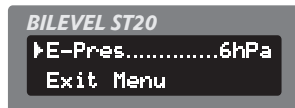
Press the ↵ button. Now select the desired pressure by pressing the buttons ▲ and ▼. Press ↵ to confirm. Next the parameter I-Slope is set.

8. I-Slope
Time of pressure increase from E-pressure to I-pressure (pressure increase rate).

```
BILEVEL ST20
▶I-Slope.............3s
 Exit Menu
```

Press the ↵ button. Now select the desired time by pressing the buttons ▲ and ▼. Press ↵ to confirm. Next the parameter E-Slope is set.

9. E-Slope
Time of pressure decrease from I-pressure to E-pressure (pressure decrease rate).

```
BILEVEL ST20
▶E-Slope.............3s
 Exit Menu
```
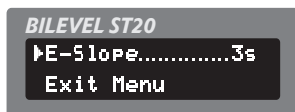
Press the ↵ button. Now select the desired time by pressing the buttons ▲ and ▼. Press ↵ to confirm.

10. Trigger

```
BILEVEL ST20
▶Trigger.............OFF
 Exit Menu
```
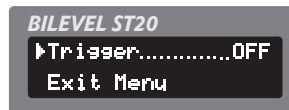
Activate the Clinic menu to set the trigger (only possible in the T-mode). Then select "Trigger" by pressing the buttons ▲ and ▼. Press the ↵ button. Now the device will prompt you to enter the PIN. Pressing the button ↵ again changes the setting from "OFF" to "ON" and vice versa.

11. I-Trigger

```
BILEVEL ST20
▶I-Trigger............2
 Exit Menu
```

The I trigger determines the trigger sensitivity for detecting inspiration. It can be set to three levels.

1	10 ml
2	15 ml
3	25 ml

Go to the Clinic menu to set the I trigger. Then select "I-trigger" by pressing the buttons▲ and ▼. Press the ↵ button. Now the device will prompt you to enter the PIN. Now select the desired level by pressing the buttons ▲ and ▼. Press ↵ to confirm. Next the parameter E-trigger is set.
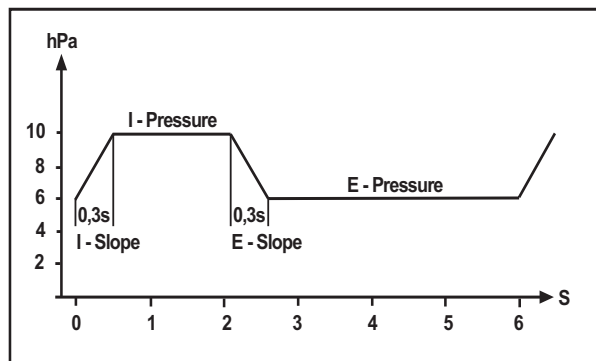
12. E-Trigger

```
BILEVEL ST20
▶E-Trigger............2
 Exit Menu
```

The I trigger determines the trigger sensitivity for detecting expiration. It can be set to three levels.

1	60 % from Peak flow
2	70 % from Peak flow
3	80 % from Peak flow

Press the ↵ button. Now select the desired level by pressing the buttons ▲ and ▼. Press ↵ to confirm.

13. Frequency

```
BILEVEL ST20
▶Frequency....12bpm
 Exit Menu
```

The frequency determines the breathes per minute (in the T-mode or in the ST-mode in case of apnea). Activate the Clinic menu to set the frequency. Then select "Frequency" by pressing the buttons ▲ and ▼. Now the device will prompt you to enter the PIN. After entering the PIN set the desired frequency by pressing the buttons ▲ and ▼. Press ↵ to confirm. You can set values from 5 bpm to 30 bpm in 1-bpm intervals.

14. Inspiration

```
BILEVEL ST20
▶Inspiration....33%
 Exit Menu
```

The inspiration ratio is the inspiration time in relation to the time of the entire breath interval. Activate the Clinic menu to set the inspiration ratio. Then select "Inspiration" by pressing the buttons ▲ and ▼. Now the device will prompt you to enter the PIN. After entering your PIN press the ↵ button again. Set the desired inspiration ratio by pressing the buttons ▲ and ▼.
Press ↵ to confirm. You can set values from 20 % to 80 % in 1 % intervals.

15. Delay Time

```
BILEVEL ST20
▶Delay Time........5s
 Exit Menu
```

The delay time (in the ST-mode only) is the time after which the device switches from S-mode into T-mode in the event of breath failure. Activate the Clinic menu to set the delay time. Then select "Delay time" by pressing the buttons ▲ and ▼. Now the device will prompt you to enter the PIN.
After entering your PIN press the ↵ button two times. Set the desired delay time by pressing the buttons ▲ and ▼. Press ↵ to confirm. You can set values from 0 s to 20 s in 1-s intervals.

MENU OVERVIEW

Info Menu	Patient Menu	Clinic Menu
Therapy	Wake Time	Mode
Filter	Delete Filter	Pressure
Ramp	Ramp	I-Pressure
P-Ramp	Mask Test	E-Pressure
Mode	Automatic	I-Slope
Pressure	Brightness	E-Slope
I-Pressure	Date	Trigger
E-Pressure	Time	I-Trigger
I-Slope		E-Trigger
E-Slope		Frequency
Trigger		Inspiration
I-Trigger		Delay Time
E-Trigger		Ramp
Frequency		P-Ramp
Inspiration		Mask Test
Delay Time		Automatic
		Brightness
		Language
		P-Unit
		Turbine
		Therapy
		Filter
		Standby
		Delete Filter
		Date
		Time
		Wake Time

14

<u>TROUBLESHOOTING</u>

Problem	Possible cause	Remedy
Pain in nose, paranasal sinuses or ears	Inflammation	Stop therapy and contact your physican
Unpleasent feeling of too high pressure	Unwellness with prescribed high pressure values	If you think there is a mistake, consult a physician
	Pressure tolerance not completely acquired yet	Relax, use or alter the soft start function
Dryness and irritation of nose and throat	Air too dry	Device probably without air humidifier; consult a physician and consider prescription of retrofitting a humidifier
Return of original sleep apnea symptoms	Different physical condition and different conditions of living	Inform the attending physician
	Device failure	Return the device to the service to have it checked
Air sensed to be too warm	Filter dirty	Exchange filter
	Air inlet obstructed	Check the device for proper setup
	Radiator in the vicinity of the device	Increase the distance between device and radiator
No air flow	Device defective	Notify the service
	Water in the measuring tube	Remove the water
Very low air flow	Soft start function active	Reduce soft start time
	Air ducts clogged	Check the air inlet

Problem	Possilble cause	Remedy
Blower constantly at maximum speed	Measuring tube not connected or clogged	Check the measuring tube
	Device leaky	Return the device to the service to have it checked
	Water in the measuring tube	Remove the water
Therapy pressure not steady	Water in the measuring tube	Remove the water
	Device defective	Notify the service
	Measuring tube bent	Check for bends
Irritation of the eyes or dry eyes	Air escaping from between the mask and the skin of your face	Check the mask for proper positioning
		Replace the mask if its material has become brittle
Running nose, urge to sneeze	Reaction to the air flow	Increase the air humidity in the room or set the humidifier to a higher level
	Common cold	Consult a physician
Cold nose	Room temperature too low	Increase the room temperature; warm up the tubing under your pillow
Reddening of the skin in the area of the mask; swelling of the skin	Wrong mask size	Inform the attending physician
	Head gear too tight	Head straps loosened
	Allergic reaction	Inform the attending physician

DISPLAY MESSAGES

The sections below describe the most important display messages. All further messages will be clear from their context.

```
BILEVEL ST20
|||||||||      8.0hPa
Mask Test........45s
```
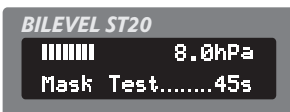
You have 45 sec left for seating the mask properly. Once this time has elapsed, the device starts with the soft start function or the therapy.

```
BILEVEL ST20
|||||      5.0hPa
Ramp.............10:45
```

There will be 10 min and 45 sec left until the full therapy pressure is reached.

```
BILEVEL ST20
Mask Alarm......10s
Check Mask!
```

The mask has slipped off your face or you failed to put the mask on your face while the automatic mode was turned off and the blower was running.

```
BILEVEL ST20
 Press ON/OFF!
 Alarm ON    07:00
```
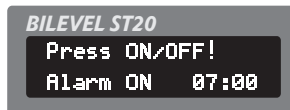
You pressed the ▲ key during operation. There will be a message that you will be wakened at 07.00 hours.

```
BILEVEL ST20
|||||      5.0hPa
Slumber..........1:18
```
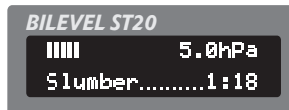
There will be 1 min and 18 sec left until the alarm clock will waken you again.

```
BILEVEL ST20
|||||      5.0hPa
Wake Alarm..07:00
```

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

```
BILEVEL ST20
|||||      5.0hPa
Wake Alarm    OFF
```

You pressed the operator key and stopped the slumber phase.

```
BILEVEL ST20
 Press ON/OFF!
 Alarm Clock OFF
```

You pressed the ▼ key in the normal operating mode. There will be a message that the alarm clock has been turned off.

```
BILEVEL ST20
 Put on Mask
 09.May.07  09:42
```
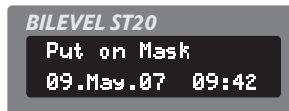
The automatic function is turned on. You are prompted to put on the mask and breath through your nose.

```
BILEVEL ST20
  Put on Mask
  09.May.07  09:42
```

The therapy pressure is too high and the turbine switches off.

```
BILEVEL ST20
IIIIII        7.5hPa
Take off Mask!
```

There was an attempt to turn off the device manually while the automatic function was activated. Please take off the mask. After a few seconds the device will turn off the therapy pressure.

```
BILEVEL ST20
  Power Failure
  Restart Turbine
```

After the line voltage has been restored, the turbine restarts automatically.

```
BILEVEL ST20
  Watchdog defect
```

There has been an error during the system start after switching on the voltage supply.
Contact your dealer.

```
BILEVEL ST20
  Turbine off......4s
  09.May.07  09:42
```

You have taken down the mask or the mask has slipped off your face while the automatic function was activated. The turbine will turn off after 4 seconds.

```
BILEVEL ST20
  Invalid PIN!
```

The PIN you have entered is wrong. Please enter the correct PIN.

```
BILEVEL ST20
  MemoryF defect
```

There has been an error during the system start after switching on the voltage supply.
Contact your dealer.

```
BILEVEL ST20
  Clinic-Menu
      activ
```

The Clinic menu has been activated.

```
BILEVEL ST20
  Patient-Menu
      activ
```

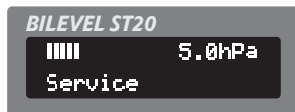The Patient menu has been activated.

```
BILEVEL ST20
IIIII         5.0hPa
Change Filter
```

Change filter.

MAINTENANCE

Although all parts of the device have a very long service life, the device should be maintenanced from time to time.
The device should be maintenanced when the message:

BILEVEL ST20
▮▮▮▮   5.0hPa
Service

apears in the display. We urgently recommend a technical maintenance through our authorized customer service, since only they have the necessary tools and measuring instruments. Even if »Maintenance« appears in the display the device is still fully functional.

ATTENTION!
The display message »Maintenance« must not be removed during checks at non-authorized workshops.

In between maintenance intervals you yourself can contribute to increasing the service life and to maintaining proper and reliable functioning.

1. Please observe the cleaning instructions given on the pages 18 and 19.

2. Check the system at regular intervals.

Proceed according to the following check list:

•   Visually check whether the device is damaged and/or dirty on its outside

•   weekly check of the »Power failure« warning function (see page 20)

•   weekly check of the »Mask alarm« function (see page 20)

Preparing the device for a different patient:
If the patient using the device changes, the device must be hygienically prepared by a specialized dealer or by the manufacturer. The necessary procedure is described in detail in the appropriate hygiene plan.

Disposal of the device:
For information on the proper disposal of the device, please contact your responsible customer service.

Disposal of the packaging:
You can return the packaging to your marketing partner or dispose it separately with your normal domestic waste.

TECHNICAL DATA

Dimensions (W x D x H)	230 x 212 x 107 mm
Weight	ca. 2,0 kg
Power supply	100 V~... 240 V~, 50...60 Hz, 24 V DC / 2,1 A
Pressure range	4 … 20 hPa (mbar)
Max. limit pressure in the event of an error	< 30 hPa (due to engineering)
Power consumption max.	50 W
Power consumption at 12 hPa (without humidifier)	10 W (24 V DC-operation) 12 W (external power supply)
Power consumption at 12 hPa ((with humidifier, level 5)	32 W (24 V DC-operation) 35 W (external power supply)
Power consumption, standby mode	< 5 W
Pressure variance	< 0,3 hPa (mbar) at 20/min according to DIN EN ISO 17510-1
Noise level without mask	< 25 dB(A) at 10 hPa (mbar)
Air delivery volume	> 170 l/min bei 6 hPa therapy pressure > 160 l/min bei 12 hPa therapy pressure > 150 l/min bei 18 hPa therapy pressure > 120 l/min bei 20 hPa therapy pressure
Air warming	2 - 3 °C at 10 hPa
Operating temperature	+ 5 °C ... + 40 °C
Storage temperature	- 20 °C ... + 70 °C
Air humidity	10 ... 95 % rel. humidity (operation and storage)
Operating altitude	- 400 m ... 3500 m (1060 hPa ... 700 hPa) (height above sea level)
Filtration efficiency up to 1 μm	99,5 %

CE mark according to EC Directive 93/42/EEC, device in compliance with MDD, Class IIa

The technical specifications are subject to technical modification

HOFFRICHTER GmbH
Mettenheimer Str. 12/14
D-19061 Schwerin
Germany
Telefon: +49-385-39925-0
Fax   :+49-385-39925-25
www.hoffrichter.de
info@hoffrichter.de