EN Instructions for Use with devices as of serial number 65,000

SOMNO*vent* auto-S/ST

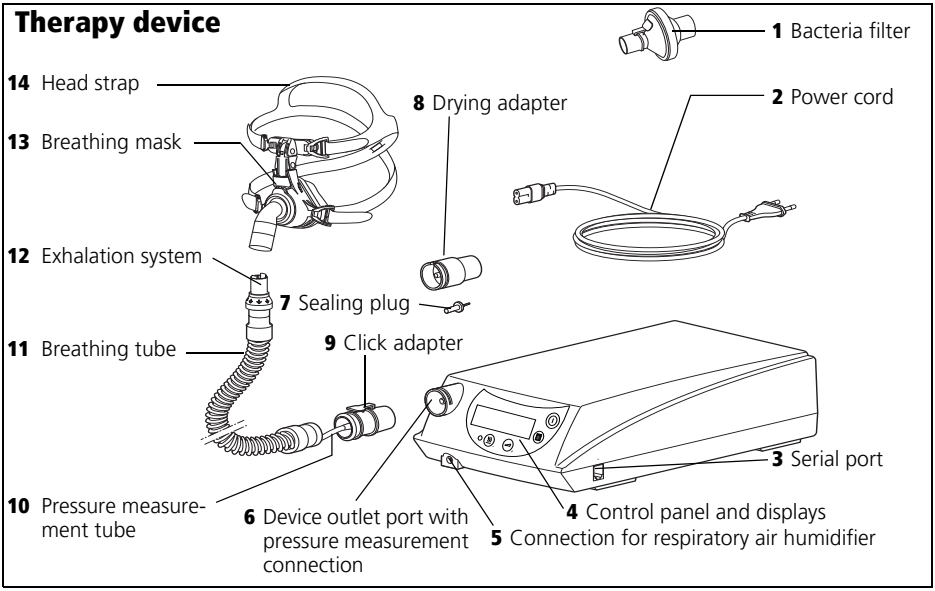
automatic BiLevel S/ST therapy device with autoTriLevel principle
SOMNO*vent* auto-S
SOMNO*vent* auto-S with SOMNO*click* 300
SOMNO*vent* auto-S 230 V
SOMNO*vent* auto-ST
SOMNO*vent* auto-ST with SOMNO*click* 300
SOMNO*vent* auto-ST 230 V

LÖWENSTEIN medical

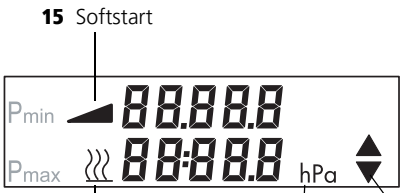
Contents

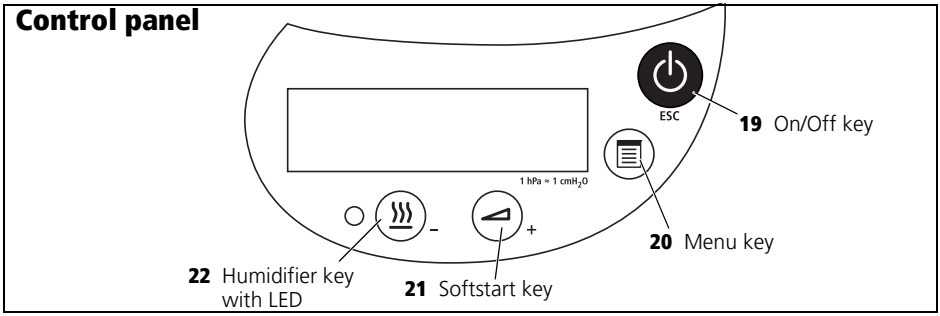
1. Overview

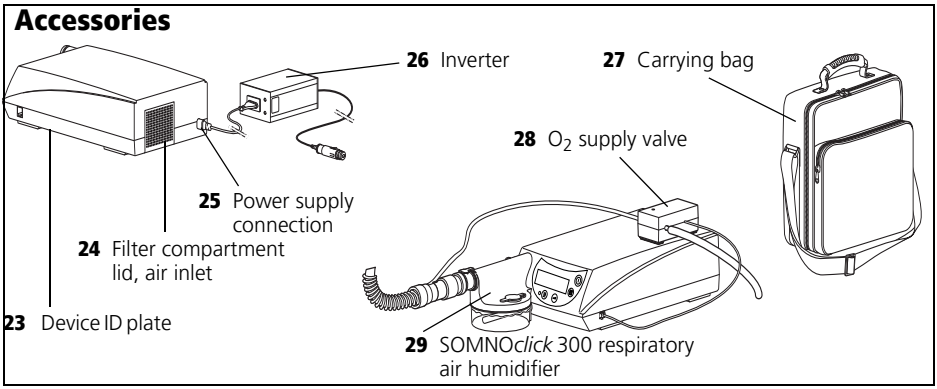
Therapy device



Symbols in the display







Key

1 Bacteria filter (accessory)

For protecting the patient from bacteria, especially when several patients are using the therapy device.

2 Power cord

For connecting the therapy device to the power supply.

3 Serial port

For connecting to devices/computers for setting, displaying and evaluating therapy data and for connecting the O_2 supply valve.

4 Control panel and displays

For controlling and monitoring the therapy device and connected accessories.

5 Connection for respiratory air humidifier

For connecting SOMNO*click* 300 to the therapy device.

6 Device outlet port with pressure measurement connection

The respiratory air flows to the patient from here through the breathing tube and breathing mask.

7 Sealing plug

For sealing the pressure measurement tube during cleaning.

8 Drying adapter

Required to dry the breathing tube using the therapy device.

9 Click adapter

For connecting the breathing tube to the device outlet port.

10 Pressure measurement tube

For measuring the pressure prevailing in the breathing mask.

11 Breathing tube

The air flows to the mask through the breathing tube. The breathing tube consists of creased tube, pressure measurement tube and click adapter.

12 Exhalation system (accessory)

This is where the exhaled air containing carbon dioxide escapes during therapy.

13 Breathing mask (accessory)

Respiratory air at the required therapy pressure is supplied to the patient via the breathing mask.

14 Head strap (accessory)

For correct, secure positioning of the breathing mask.

15 Softstart

This symbol appears when Softstart time is set or when Softstart is activated.

16 Inspiration/exhalation/adjustable value

The up arrow is on during inspiration and the down arrow is on during exhalation.

Both arrows come on if a value can be changed using + (Softstart key) or - (Humidifier key).

17 Unit of measurement for therapy pressure

Therapy pressure is displayed in hPa (hectoPascals) 1 hPa = 1 mbar ≈ 1 cm H_2O.

18 Respiratory air humidifier

This symbol appears when the humidifier is in operation. The set humidifier stage is displayed.

19 On/Off key

For switching the therapy device on and off and for exiting a menu.

20 Menu key

For opening the Patient menu and for scrolling to the next value in the Patient menu.

21 Softstart key

For activating/deactivating Softstart, for calling up Softstart settings and for reducing an adjustable value.

22 Humidifier key with LED

For activating/deactivating the respiratory air humidifier, for setting humidifier stage during therapy and for increasing an adjustable value. The LED comes on when the humidifier is connected and switched on.

23 Device ID plate

Provides information about the therapy device, such as serial number and year of manufacture.

24 Filter compartment lid, air inlet

For covering and securely positioning the coarse dust and fine filters.

25 Power supply connection

This is where the power cord and optional inverter are connected to the device.

26 Inverter (accessory)

For operating the therapy device via a DC socket (12/24 V).

27 Carrying bag

For transporting the therapy device.

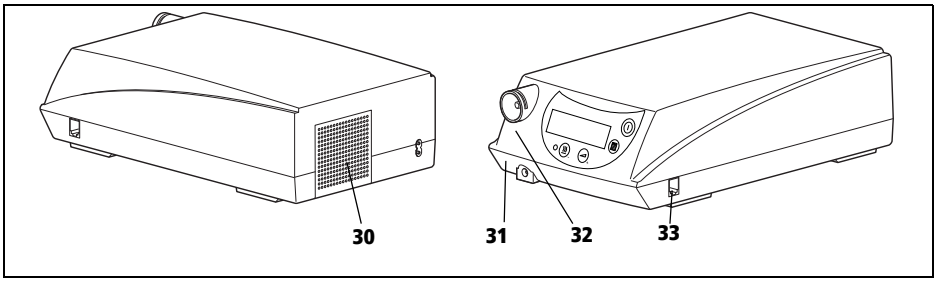
28 O_2 supply valve (accessory)

For supplying oxygen to the breathing mask.

29 SOMNO*click* 300 respiratory air humidifier

For heating and humidifying the air flow generated by the therapy device.

1.1 Markings on the therapy device



	Symbol	Meaning
30		Device inlet: inlet for ambient air at room temperature
31		See instructions for use! Connection for SOMNO*click* 300 respiratory air humidifier.
32		Device outlet port: outlet for ambient air at 4 - 20 hPa
33		Connection for adjusting therapy parameters using WEINMANN*adjust* PC software or SOMNO*adjust* remote setting for professional staff to read out the course of therapy using WEINMANN*support* or for controlling the O_2 supply valve. Max. current consumption 163 mA. Analog output for therapy pressure, respiratory flow rate, relative respiratory minute volume, leakage and respiratory status (0 V to 1.0 V DC).

Device ID plate

Symbol	Meaning
	Year of manufacture
	Degree of protection against electric shock: device type B
	Do not dispose of the device in domestic waste!
	Follow the relevant instructions for use!
SN	Serial number of the device
	Type of protection against electric shock: device of protection class II
CE 0197	CE marking: confirms that the device conforms to the applicable European directives.

1.2 Markings on the packaging

Symbol	Meaning
	Permitted temperature for storage: -20 °C to +70 °C
	Permitted humidity for storage: max. 95 % relative humidity.

1.3 Safety information in these instructions

Safety information is marked as follows in these instructions for use.

Warning!

Warns of a risk of injury and potential material damage.

Caution!

Warns of material damage and potentially false therapy results.

Note

Contains useful tips.

2. Description of device

2.1 Intended use

SOMNO*vent* auto-S

SOMNO*vent* auto-S is an automatically-regulating BiLevel S therapy device with autoTriLevel principle and up to three pressure levels suitable for treating patients from the age of 12 with obstructive, mixed or complex sleep apnea and

- a high pressure requirement,
- poor compliance due to high pressure on exhalation,
- fluctuating pressure requirement or
- nocturnal hypoventilation (OHS).

SOMNO*vent* auto-S is **not** suitable for life-support purposes on patients requiring ventilation.

Note

To ensure successful therapy with SOMNO*vent* auto-S, it is important to determine and set accordingly therapy mode, pressure limits and minimum respiratory frequency.

SOMNO*vent* auto-ST

SOMNO*vent* auto-ST is an automatically-regulating BiLevel ST therapy device with autoTriLevel principle and up to three pressure levels suitable for treating patients from the age of 12 with obstructive, mixed or complex sleep apnea and

- a high pressure requirement,
- poor compliance due to high pressure on exhalation,
- fluctuating pressure requirement,
- central apneas,
- nocturnal hypoventilation (OHS),
- respiratory insufficiency or
- coprevalent COPD (overlap).

SOMNO*vent* auto-ST is **not** suitable for life-support purposes on patients requiring ventilation.

Note

To ensure successful therapy with SOMNO*vent* auto-ST, therapy mode, therapy objective and possibly other therapy parameters have to be determined and set accordingly by specialist medical staff.

2.2 Description of function

The therapy device has an electronically-controlled fan which draws in ambient air through a filter and pumps it to the fan outlet. The air flows to the patient from here through the breathing tube and the breathing mask.

The therapy device analyzes the pressure in the mask and the air flow to the patient and from this, detects sleep-related respiratory disorders such as obstructions of the airways or a central respiratory deficit.

The three pressure levels IPAP (pressure during inspiration), EPAP (pressure at the start of exhalation) and EEPAP (pressure at the end of exhalation) are adapted to suit the patient's current requirements depending on the events detected.

The therapy device has different modes:

- **CPAP**
- **S**: one of three pressure variants can be selected for S mode.
    - **BiLevel**: IPAP and EPAP can be set to a fixed value
    - **TriLevel**: IPAP, EPAP and EEPAP can be set to a fixed value.
    - **auto TriLevel**: IPAP, EPAP and EEPAP are continuously adapted to the patient's current requirements.
      In the event of obstructions, EEPAP is automatically increased within limits which can be set; if there are no obstructions, it is gradually reduced again.
      The difference between IPAP and EPAP (PDIFF) can likewise be adapted automatically up to an upper limit which can be set.
- **ST** (can only be selected on SOMNO*vent* auto-ST): one of three pressure variants can be selected for S mode:
    - **BiLevel**: IPAP and EPAP can be set to a fixed value.
    - **TriLevel**: IPAP, EPAP and EEPAP can be set to a fixed value.
    - **auto TriLevel**: IPAP, EPAP and EEPAP are continuously adapted to the patient's current requirements.
      In the event of obstructions, EEPAP is automatically increased within limits which can be set; if there are no obstructions, it is gradually reduced again.
      The difference between IPAP and EPAP (PDIFF) can likewise be adapted automatically up to an upper limit which can be set.

- **T** (can only be selected on SOMNO*vent* auto-ST).

  A minimum frequency for preventing central apneas can be set in S mode. The minimum respiratory frequency takes effect as a background frequency as soon as the patient breathes more slowly than set.

  One of three therapy objectives can be set in ST mode. Depending on the setting, meaningful default settings are loaded for the remaining parameters and the setting limits for individual parameters are modified.

  ST mode includes two automatic background frequencies, one with the objective of largely spontaneous ventilation and one with the objective of largely controlled ventilation. The appropriate background frequency and the I:E ratio are activated automatically when the therapy objective is selected.

  If no therapy objective is set, background frequency up to 30/min, I:E ratio and a latency time until the first mandatory breath occurs can be specified manually.

  In T mode, frequency and I:E ratio can be set in addition to pressure level on inspiration and exhalation.

  The trigger automatically adapts to the patient. If required, the supervising doctor can increase or reduce trigger sensitivity.

  A different speed can be set for pressure rise on inspiration if required.

  Auto On/Off can be activated on the therapy device. The therapy device can be switched on by a breath being taken into the mask and switches off automatically if not being used.

  The therapy device can be used to check whether the mask is correctly fitted. Leaks due to a poorly-fitted mask often only occur at relatively high pressures. To check that the mask is leaktight, it is possible to output a higher pressure during the first 30 seconds after the therapy device is switched on. This pressure is adjustable.

  A qualitative leakage display is available during therapy.

  Automatic Softstart is integrated to facilitate falling asleep. When you switch on, the pressure is reduced to the Softstart pressure set by the doctor. Therapy pressure then slowly rises to the specified value.

  In CPAP mode, it is also possible to set an initial pressure which is higher than set CPAP pressure. The therapy pressure then remains at the set value during the set initial pressure phase.

  The therapy device saves data for checking and adjusting therapy and thus allows extensive analysis by the doctor.

  If the power supply is interrupted and then restored, the therapy device will be in the state it was in before the interruption. Saved data are retained.

3. Safety instructions

Please read these instructions for use through carefully. They are a constituent part of the therapy device and must be available at all times.

Use the therapy device only for the intended use described (see "2.1 Intended use" on page 8).

For your own safety and that of your patients, and in accordance with the requirements of directive 93/42/EEC, observe the following safety instructions.

3.1 Safety instructions

Operating the therapy device

Caution!

- Check whether the power supply voltage on the therapy device matches that of your local electricity supply. The therapy device can operate with the voltages 115 V and 230 V. It automatically adjusts to one of these voltages. **Exception:** the SOMNO*vent* auto-S/ST 230 V (WM 29210 / WM 29410) can only operate with a voltage of 230 V. Use the inverter available as an accessory for operation with 12 V DC or 24 V DC.
- The therapy device must be connected to an easily accessible socket so that the plug can be disconnected quickly in the event of a fault.
- Do not set up the therapy device close to a radiator and do not expose it to direct sunlight, as this could heat up the respiratory air and internal parts further. This could cause water vapour to form in the respiratory air humidifier which would then condense in the breathing tube.
- Do not cover the therapy device with blankets etc. This would block the air inlet and the therapy device might overheat. This may lead to inadequate therapy and damage to the device.
- Maintain a safe distance between the therapy device and devices which emit HF radiation (e.g. cellphones, DECT base stations or wireless connections) (see page 46), otherwise there may be malfunctions.
- Do not operate the therapy device and the respiratory air humidifier if the therapy device is not working properly, if parts are damaged or if the respiratory air humidifier is wet at the base of the heated rod.
- The performance of the respiratory air humidifier may change if the therapy device is operated outside the permitted ambient temperatures.

- Follow the instructions for use for your breathing mask.
- Follow the section entitled "6. Hygiene treatment" on page 29 to prevent an infection or bacterial contamination.
- If the therapy device is intended for use by several patients, a bacteria filter should be used to protect against infections. This is put in between the breathing tube with click adapter and the device outlet port. If the therapy device is to be used for a different patient without using a bacteria filter, you must subject the device to a hygiene treatment beforehand. This must be performed by the manufacturer or by an authorized specialist dealer.

Transport

Caution!

Do not transport the therapy device with the respiratory air humidifier attached, otherwise residual water from the respiratory air humidifier may run into the therapy device and damage it if it is tilted.

Accessories/replacement parts

Caution!

- If third-party items are used, functional failures and restricted fitness for use may result. Biocompatibility requirements may also not be met. Please note that in these cases, any claim under warranty and liability will be void if neither the accessories nor genuine replacement parts recommended in the instructions for use are used.
- Third-party makes of mask may only be used with the consent of the manufacturer. The success of therapy is jeopardized by the use of non-approved masks.
- Ensure that the accessories used for therapy are suitable and complete. This applies to the exhalation system in particular, otherwise the CO_2 content in the exhaled air may obstruct your breathing and there is a risk of asphyxiation.

Repair

Caution!

- Have servicing and repair work performed only by the manufacturer or professional staff.
- It is not permitted to modify the therapy device and SOMNO*click* 300.

Oxygen supply

Warning!

If oxygen is used during therapy, smoking and naked flames are prohibited. **Risk of fire.** Oxygen may accumulate in clothing, bed-linen or in hair. It can be removed only by thorough ventilation.

Caution!

Oxygen may only be supplied if O_2 supply valve WM 24042 is used. With regard to oxygen, it is essential to follow the safety instructions in the instructions for use for your oxygen supply system.

3.2 Contraindications

The therapy device should be used with particular caution or not at all with some diseases. It is up to the doctor supervising treatment to decide whether use is indicated. In such cases, use needs to be tightly controlled and the risk weighed up against the benefits.

This implies:

- Acute cardiac decompensation
- Severe cardiac arrhythmias, atrial fibrillation with reduced filling of the right ventricle.
- Insufficiency of the right heart or other pulmonary hypertension
- Severe hypotension, especially in combination with intravascular volume depletion
- High risk of barotraumas
- Bullous lung emphysema
- Severe deyhdration
- Severe epistaxis (nosebleeds)
- Acute sinusitis, otitis media or perforated eardrum
- Pneumothorax or pneumomediastinum
- Pneumoencephalus
- Severe skull trauma
- Status following brain surgery and following surgical intervention on the pituitary gland or the middle/ inner ear.

3.3 Side effects

When using the therapy device, the following undesired side effects may occur in short-term or long-term use:

- pressure points on the face from the nasal cannula and forehead cushion
- reddening of facial skin
- blocked nose
- dry nose
- dry mouth in the morning
- sensation of pressure in the sinuses
- irritation of the conjunctiva of the eyes
- gastrointestinal insufflation of air (“bloating”)
- nosebleeds

Note

These side effects are general side effects of therapy with a BiLevel device and are not attributable specifically to use of this therapy device.

4. Device setup

4.1 Set up and connect therapy device

Location

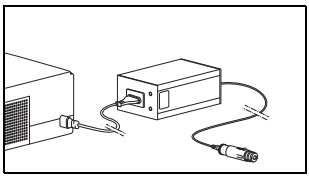
– Place the therapy device on a flat surface, for example a bedside table or on the floor next to the bed.

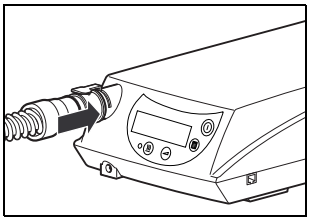
– Keep the rear of the therapy device a distance of at least 5 cm from the wall, as the air inlet is on the rear of the therapy device.

Caution!

Do not cover the therapy device with blankets etc. Do not operate it close to a radiator or in direct sunlight. The therapy device might overheat. This may lead to inadequate therapy and damage to the device.

Power supply





1. Use the power cord to connect the power supply connection of the therapy device to a socket.

   The therapy device automatically detects whether 115 V or 230 V are connected and automatically switches. **Exception:** the SOMNO*vent* auto-S/ST 230 V (WM 29210 /WM 29410) can only operate with a voltage of 230 V.

   "0" for standby appears in the display.

2. If the therapy device is to be operated at a voltage of 12 or 24 V DC, connect the inverter to a cigarette lighter socket.

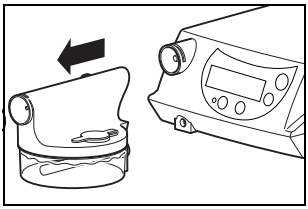
   For this you may use either:

   - inverter, 12 V WM 24131 or
   - inverter, 24 V WM 24132

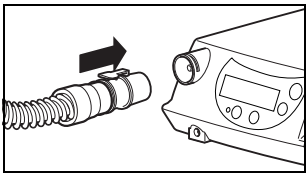
   Use the power cord to connect the power supply connection of the therapy device to the power supply socket of the inverter.

3. Plug the click adapter of the breathing tube into the device outlet port.

4.2 For operation without respiratory air humidifier



1. To remove the humidifier if required, pull this off the device outlet port from the front.



2. Push the breathing tube onto the click adapter for the device outlet port.
3. Plug the click adapter of the breathing tube into the device outlet port of the therapy device. Ensure that the locking tab is on top as you do so, and that it engages in the groove of the device outlet port.

4.3 For operation with respiratory air humidifier

Note

Follow the instructions for filling and adapting the SOMNO*click* 300 respiratory air humidifier in the associated instructions for use.

4.4 Breathing mask

Put on breathing mask

1. Adjust the forehead support of the breathing mask (if there is one).
2. Attach the headgear/head strap to the mask.
3. Put on the mask.
4. Adjust the headgear/head strap so that the mask cushion creates only slight pressure, so as to avoid pressure points on the face.

Note

The rest of the process can be found in the instructions for use for the breathing mask in question. To check that the mask is correctly positioned without leaks, you can use the mask test (see "5.4 Mask test" on page 22).

Warning!

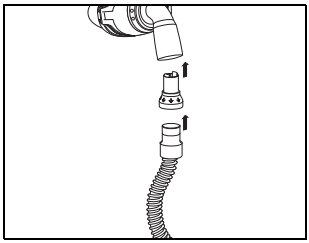
Oronasal masks must be fitted with an emergency exhalation valve so that you can breathe through your nose or mouth even if the device fails. Oronasal masks without an emergency exhalation valve may not be used!

External exhalation system

On some masks, there is no integrated exhalation system. To enable used air containing carbon dioxide (CO_2) to escape, an external exhalation system is required on these masks. Follow the instructions for use for the mask.

Warning!

Without an exhalation system, the CO_2 concentration in the mask and tube may rise to critical values and thus obstruct your breathing. Risk of asphyxiation!

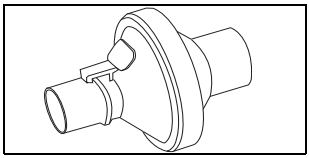


– Fit the external exhalation system between the breathing mask and the breathing tube.

4.5 Connect other accessories

Bacteria filter

If the therapy device is intended for use by several patients (e.g. in hospital), a bacteria filter should be used to protect against infections.



– Fit the bacteria filter between the breathing tube with click adapter and the device.

Caution!

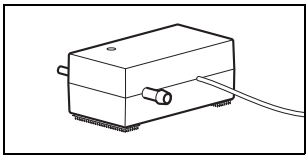
When using a bacteria filter, pressure consistency and flow rate may be reduced. If a bacteria filter is connected, check the pressure. Note the manufacturer's information, especially the expiry date for the filter.

Oxygen supply

Warning!

For safety reasons (risk of fire), it is not permitted to supply oxygen directly to the breathing tube or to the breathing mask without a special safety device. If oxygen supply valve WM 24042 is used, up to 4 l/min oxygen can be supplied to the breathing mask.

It is essential to follow the safety instructions for handling oxygen as well as the instructions for use for the oxygen valve and the oxygen device used.



An oxygen concentrator, liquid oxygen or an oxygen cylinder with the appropriate pressure reducer can also be used. This use must be prescribed by the doctor supervising treatment.

5. Operation

The therapy device is operated with the aid of the four keys on the control panel.

A "Patient menu" allows a variety of functions and settings in standby mode (therapy device switched off) or during therapy (therapy device switched on). Some of these functions can also be called up directly by a key command as an alternative to going through the Patient menu.

Patient menu in standby mode

- "5.2 Read out therapy time" on page 21
- "5.3 Auto On/Off" on page 21
- "5.4 Mask test" on page 22
- "5.5 Softstart setting" on page 23
- "5.6 Respiratory air humidifier" on page 23
- "Dry breathing tube" on Page 30
- "6.4 Clean coarse dust filter/change fine filter" on page 32

Patient menu during therapy

- "Display leakage" on Page 26
- "5.3 Auto On/Off" on page 21
- "5.5 Softstart setting" on page 23
- "5.6 Respiratory air humidifier" on page 23

5.1 Patient menu

1. To call up the Patient menu, press the menu key **briefly**. Total therapy time is displayed.
2. To scroll through the Patient menu and switch to the next parameter, press the Menu key again.

Parameter	Display	Value range	Key command (alternative)	Described in
Leakage	LE	Low, moderate, high	Press menu key briefly with therapy device switched on	Section 5.7, on page 25
Therapy time	**h**		–	Section 5.2, on page 21
Autostart	Auto	On OFF	–	Section 5.3, on page 21
Mask test	P TEST	--, 8, 12, 16, 20 hPa	–	Section 5.4, on page 22
Softstart time	min	5 to 45	With therapy device switched on: press and hold ⊖+	Section 5.5, on page 23
Humidifier stage	)))	1 to 6	With therapy device switched on: press and hold)))	Section 5.6, on page 23
Drying mode	dr 0:30		With therapy device switched off: press ⊖+ and ⏻ esc at the same time	Section 6.2, on page 30

3. To exit the Patient menu, press the On/Off/ESC key.
   Alternatively,
   if you press no key for 30 seconds, the Patient menu closes automatically.

5.2 Read out therapy time

The therapy device stores therapy data from 366 days.

1. Call up the Patient menu with the device switched off. Total therapy time is displayed.
2. To call up the data for a different day or a different period, press the **+** or **–** keys. The following displays appear consecutively (numerical values are examples):

11 d	mean value for all therapy days (11 days in the example)
23.02.	for a particular day of the last 7 days, date quoted (February 23 in the example)

Total therapy time

Total therapy time is displayed for a few seconds when you **switch on** the therapy device.

Daily therapy time

The therapy time for the current day is displayed when you **switch off** the therapy device.

Operating hours

Operating hours are displayed when you keep the On/Off key depressed on **switching off** the therapy device.

Note

A **therapy day** starts and ends every day at 12 noon. Data recorded from 0.00 (midnight) to 12.00 (noon) are always assigned to the previous **calendar day**.

5.3 Auto On/Off

If Auto On/Off is activated, you can switch the therapy device on and off using the pressure in the mask.

Note

If the therapy device is switched on, you can view the current setting via the Patient menu, but you cannot change it.

If an oronasal mask with integrated emergency exhalation system is used, the device does not switch on/off automatically even if setting Auto On is selected. The emergency exhalation system of the mask means that the therapy device is unable to detect the pressure change required for switching.

Activate/deactivate Auto On/Off

Status: therapy device is switched off.

1. Call up the Patient menu and scroll to the setting for Auto On/Off.
2. Press the Softstart key (**+**) or the Humidifier key (**-**) until the desired setting appears in the display.

AUtO On	Auto On/Off activated As soon as you breathe into the mask (pressure > 0.8 hPa), the therapy device switches on automatically. When the mask is removed, the therapy device switches off automatically after 5 seconds.
AUtO OFF	Auto On/Off deactivated The therapy device can only be switched on by pressing the On/Off key. If the therapy device is not used for 15 minutes, it switches off automatically.

3. To save the setting and exit the Patient menu, press the On/Off/ESC key or wait until the menu closes automatically.

5.4 Mask test

If the mask test is activated, a higher pressure is output for 30 seconds after the device is switched on. This gives you the option of checking that the mask is properly located at the start of therapy and correcting it.

Activate/deactivate mask test

Status: therapy device is switched off.

1. Call up the Patient menu and scroll to the setting for Mask test.
2. Press the Softstart key (+) or the Humidifier key (-) until the desired setting appears in the display.

P tESt --	Mask test deactivated
P tESt 8.0	Pressure for mask test: 8 hPa
P tESt 12.0	Pressure for mask test: 12 hPa

P tESt 16.0	Pressure for mask test: 16 hPa
P tESt 20.0	Pressure for mask test: 20 hPa

3. To exit the Patient menu, press the On/Off/ESC key.

   Alternatively,
   if you press no key for 30 seconds, the Patient menu closes automatically.

5.5 Softstart setting

To facilitate falling asleep, specialist staff may set a pressure which deviates from the optimum therapy pressure. This pressure is administered only for a certain period of time.

If the Softstart function on your therapy device is enabled, this time can be selected in 5-minute increments up to a maximum of 45 minutes.

Set time

1. Call up the Patient menu and scroll to the setting for time.
   Alternatively,
   with the therapy device switched on: keep the Softstart key depressed until the current setting appears.
2. To change the time, press the Softstart key (**+**) or the Humidifier key (**-**) several times until the desired time is displayed.
3. To save the setting and exit the menu, press the On/Off/ESC key or wait until the menu closes automatically.

Softstart On/Off

Status: therapy device is switched on.

– To switch Softstart on or off, press the Softstart key.

With Softstart switched on, the remaining Softstart time is shown in the display.

5.6 Respiratory air humidifier

Use of a respiratory air humidifier prevents the patient's upper respiratory tract drying out during therapy.

Humidifier stage can be set in six stages (1 = low heat output to 6 = maximum heat output). The most favorable setting for you depends on room temperature and humidity, so the

ideal setting depends on season and ambient conditions. Under "normal" conditions, pre-set humidifier stage 3 is adequate.

If temperature is 23 °C and humidity is 70 %, humidification of 100 % can be achieved with humidifier stage 6 and a flow rate of 20 l/min.

Switch on respiratory air humidifier

1. Fill and adapt the humidifier as described in the associated instructions for use.
2. Switch on the therapy device.

3. Press the Humidifier key on the therapy device.

   The humidifier symbol and the humidifier stage (in this case Stage 3) are shown in the display of the therapy device.

Set humidifier stage

1. Call up the Patient menu and scroll to the setting for humidifier stage.
   Alternatively,
   with the therapy device switched on: keep the Humidifier key depressed until the current setting appears.
2. To change heating stage, press the Softstart key (**+**) or the Humidifier key (**-**) several times until the desired stage is displayed.

   If you have dry airways in the morning, heat output is set **too low**. In this case, select a higher setting.

   If condensation forms in the breathing tube during a therapy night, heat output is set **too high**. In this case, select a lower heating setting.
3. To save the setting and exit the menu, press the On/Off/ESC key or wait until the menu closes automatically.

Switch off respiratory air humidifier

You have two options for switching off the respiratory air humidifier:

– press the Humidifier key on the therapy device.

  The humidifier symbol in the display goes out. The therapy device remains switched on.

  Alternatively,

– press the On/Off key of your therapy device.

The respiratory air humidifier is switched off together with the therapy device. If you switch the therapy device back on, the respiratory air humidifier is automatically switched back on and operated at the heat output of the previous therapy.

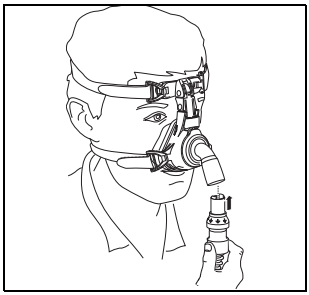
Auto off

If the therapy device detects too low a filling level in the respiratory air humidifier, it switches off the respiratory air humidifier within 15 minutes. The Humidifier symbol in the display goes out.

If you switch the therapy device back on, the respiratory air humidifier also switches back on at the heat output of the previous therapy.

5.7 Operate therapy device

Put on mask



1. Put on the mask, as described in the section entitled "4.4 Breathing mask" on page 16.
2. Connect the breathing tube to the breathing mask (tapered push-connector).
3. Guide the breathing tube away from your head.

Warning! Risk of injury!

Never place the breathing tube around your neck.

Switch on therapy device

– To switch on the therapy device, press the On/Off key.
Alternatively,
if Auto On/Off is activated, you can switch on the therapy device by taking a breath into the mask.

Total therapy time appears in the display for approx. 3 seconds. The fan starts to pump air through the breathing tube, the air flow can be felt at the mask.

Mask test

When the mask test is activated, the higher pressure set is output for 30 seconds (8 hPa in the example).

1. Check that the mask is leaktight and adapt the head strap if necessary.
2. To cancel the mask test before the 30 seconds have expired, press the On/Off key.

The therapy device is now operational.

Display leakage

You can have current leakage displayed during therapy.

No leakage/low leakage: mask is perfectly positioned, ensuring effective therapy.

Moderate leakage: mask is not perfectly positioned, quality of therapy may be restricted.

High leakage: effective therapy is no longer possible. Re-fit the mask.

Softstart

If Softstart is pre-set, the Softstart indicator then lights up and the start time appears in the display.

Current pressure is also shown in the display.

Respiratory phase

The symbol ▲ is displayed during inspiration phases.

The symbol ▼ is displayed during exhalation phases.

Switch off therapy device

– To switch off the therapy device, press the On/Off key. Daily therapy time appears in the display for approx. 3 seconds.
Alternatively,
if Auto On/Off is activated, the therapy device switches off 5 seconds after the mask has been removed.

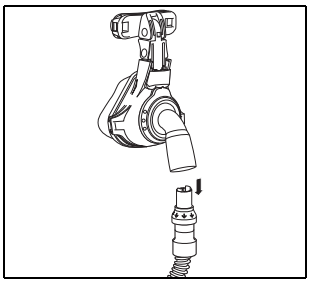
5.8 After use

1. Take off the headgear/head strap with the breathing mask.
2. To switch off the therapy device, press the On/Off key.

   Alternatively,

   if Auto On/Off is activated, the therapy device switches off automatically after approx. 5 seconds.

The date and therapy time for the day for the last use appear briefly in the display. "0" then appears in the display.



3. Take the tube connection and the exhalation system off the breathing mask.
4. Clean the following parts (see"6. Hygiene treatment" on page 29):
   - breathing mask
   - exhalation system
   - respiratory air humidifier (if used)

Save energy

In standby mode with the power supply unit, the therapy device consumes approx. 4.5 W. The therapy device does not have a power supply switch.

To save electricity, you can disconnect the plug of the power cord from the socket during the day. To do so, connect the therapy device to an easily accessible socket. The saved values and settings will be retained.

Caution!

Always switch off the therapy device at the On/Off switch first before disconnecting the plug or interrupting the power supply via a switchable multisocket.

5.9 Travel with the therapy device

To transport the therapy device over a relatively long distance, you should pack it in the carrying bag (included in the scope of the supply for the therapy device).

In the carrying bag you should pack:

- the therapy device
- the power cord
- the breathing tube
- the breathing mask incl. exhalation system
- if appropriate, the respiratory air humidifier
- replacement filters
- the instructions for use
- the inverter (if required)

Note

If you want to take the therapy device onto an aircraft as hand baggage, find out from your airline before departure whether any formalities are involved.

6. Hygiene treatment

Note

- Follow the instructions regarding the hygiene treatment of the accessories (exhalation system, breathing mask, headgear/head strap) in the relevant instructions for use.
- **This product may contain disposable items.** Disposable items are intended to be used only once. So use these items only once and do **not** reprocess them. Reprocessing disposable items may impair the functionality and safety of the product and lead to unforeseeable reactions as a result of ageing, embrittlement, wear, thermal load, the effects of chemical processes, etc.

6.1 Intervals

Daily	Clean breathing mask and exhalation system.	See associated instructions for use
	Clean respiratory air humidifier.	See associated instructions for use
	Clean bacteria filter. Replace particulate filter of bacteria filter after no more than 24 hours' use.	See associated instructions for use
Weekly	Clean coarse dust filter.	Section 6.4
	Check fine filter. Replace if required.	Section 6.4
	Check breathing tube. Clean if required.	Section 6.2
	Wipe down housing.	Section 6.3
	Wash headgear/head strap.	See associated instructions for use
Monthly	Replace fine filter (depending on soiling, but after no more than 250 hours/one month).	Section 6.4
	Clean breathing tube.	Section 6.2
Every 6 months	Replace coarse dust filter	Section 6.4
Every 12 months	Replace breathing mask and exhalation system.	
	Replace breathing tube.	
	Replace headgear/head strap.	

As required	Disinfect therapy device	Section 6.6
	Disinfect SOMNO*click* 300	See associated instructions for use
On change of patient	Hygiene treatment if required	Section 6.7
	Change particulate filter of bacteria filter.	See associated instructions for use

6.2 Breathing tube

Caution!

The breathing tube may only be used again after cleaning once it is completely dry. If moisture gets into the therapy device, this may lead to damage to the device and thus to a risk to users and patients.

Clean breathing tube

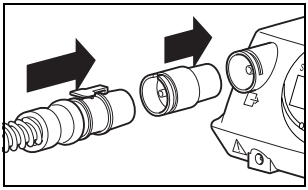
1. Take the breathing tube off the therapy device and off the exhalation system.
2. Seal both sides of the pressure measurement tube with a sealing plug.
3. Clean the creased tube and the click adapter with a little detergent in hot water so that there are no residues. Rinse the inside of the tube thoroughly in the process.
4. Then flush the creased tube thoroughly inside and outside with clean, hot water.
5. **Shake out the breathing tube thoroughly.**
6. Hang up the breathing tube and allow it to drip dry.
7. Dry the breathing tube with the aid of the therapy device.

Dry breathing tube

You can dry the breathing tube completely with the aid of the therapy device. To do so, proceed as follows.

Status: therapy device is switched off.

1. Remove the respiratory air humidifier if required.
2. Remove the plugs from the pressure measurement tube.



3. If water gets into the pressure measurement tube accidentally, plug the red drying adapter supplied into the device outlet port.

4. Push the click adapter of the breathing tube into the device outlet port or if necessary, onto the red drying adapter.

5. To start the drying process, press the Menu key until *dr 0:30* appears in the display. Press the Softstart key to start the drying process.

   Alternatively,

   press the On/Off key and the Softstart key simultaneously.

   The therapy device now switches on and dries the breathing tube (time: 30 minutes). The remaining time is shown in the display. Following the end of the drying process, the therapy device switches off automatically.

   – You can interrupt the process at any time by pressing the On/Off key.

   – If the breathing tube still has damp spots after drying, start the drying process again.

6. Remove the drying adapter if necessary.

6.3 Clean housing

Warning! Risk of electric shock!

- Before cleaning, it is essential to disconnect the power cord from the power supply connection and to remove the plug from the socket.
- Ensure that no liquids penetrate the therapy device. Never immerse the therapy device in disinfectants or other liquids, otherwise this may lead to damage to the therapy device and thus a hazard to users and patients.

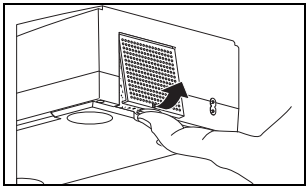
Caution!

Ensure that no liquids penetrate the therapy device via the pressure measurement connection, otherwise there may be malfunctions.

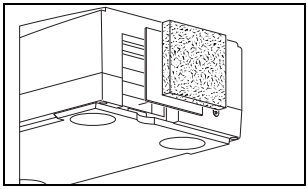
1. Wipe down the therapy device and the power cord with a soft, damp cloth.
2. Take off the filter compartment lid.
3. Clean the filter compartment lid under running water until there are no residues. Then dry it carefully.

The therapy device must be completely dry before it is started up.

6.4 Clean coarse dust filter/change fine filter



1. Remove the filter compartment lid on the rear of the device.



2. Remove the coarse dust filter and clean it under clean running water until there are no residues.
3. Replace the fine filter if necessary. It cannot be cleaned.
4. Leave the coarse dust filter to dry.

   The coarse dust filter must be completely dry before the device is started up.
5. Put the coarse dust filter back in and push the lid back onto the rear of the device.

6.5 Accessories

See the section entitled "Cleaning" in the relevant instructions for use with regard to cleaning the exhalation system, the breathing mask, the headgear/head strap, the bacteria filter and the SOMNO*click* 300 respiratory air humidifier.

6.6 Disinfect therapy device

If required, e.g. following infectious diseases or unusual contamination, you can also disinfect the housing, the power cord and the breathing tube. Follow the instructions for use for the disinfectant used. It is recommended that suitable gloves (e.g. household or disposable gloves) are used for disinfecting.

Therapy device

We recommend terralin® protect as a disinfectant for disinfecting by wiping.

Warning! Risk of electric shock!

Before disinfecting, it is essential to disconnect the power cord from the power supply connection and to remove the plug from the socket.

Ensure that no liquids penetrate the therapy device. Never immerse the therapy device in disinfectants or other liquids, otherwise this may lead to damage to the therapy device and thus to a hazard to users and patients.

Caution!

Ensure that no liquids penetrate the therapy device via the pressure measurement connection, otherwise there may be malfunctions.

The housing and the power cord of the therapy device are cleaned simply by wiping with disinfectant.

Breathing tube

We recommend gigasept® FF for disinfecting by immersion.

For disinfecting, proceed exactly as for cleaning.

Caution!

The breathing tube may not be heated to over 70 °C. Sterilization is not permitted.

Accessories

For disinfecting/sterilizing the exhalation system, the breathing mask and the SOMNO*click* 300 respiratory air humidifier, see the section entitled "Disinfect and sterilize" in the corresponding instructions for use.

6.7 Change of patient

Caution!

- If the therapy device has been used without a bacteria filter, the therapy device must be subjected to a hygiene treatment before it can be used for another patient. This must be performed by the manufacturer or by an authorized specialist dealer.
- The procedure for the hygiene treatment is described on the servicing sheet and in the Servicing and Repair Instructions for the therapy device.

7. Function check

7.1 Intervals

Perform a function check on both the therapy device and on SOMNO*click* 300 at least every 6 months.

Warning!

If you find faults during the function check, you may not use the devices again until the faults have been eliminated.

7.2 Function check of therapy device

1. Assemble the therapy device with breathing tube, exhalation system, breathing mask and power cord so that it is functional.
2. In the Patient menu, set mask test pressure to 12 hPa (see "5.4 Mask test" on page 22).
3. Switch on the therapy device.
   The fan pumps air through the breathing tube to the breathing mask. Current pressure is shown in the display in hPa.
4. Close the opening on the breathing mask, with a knee or hand, for example.

   As long as the mask test is active (approx. 30 seconds), the display must show a pressure of 12.0 hPa.
5. Switch off the therapy device.

Caution!

If the values/functions quoted here are not met, send the therapy device to the manufacturer or to an authorized specialist dealer for repair.

7.3 Function check of respiratory air humidifier

Follow the relevant instructions for use.

8. Troubleshooting

If you are unable to remedy faults with the aid of the table, or in the event of unexpected operation or an incident, contact your authorized specialist dealer to have the device repaired. Do not continue operating the device to prevent greater damage.

Fault	Cause of fault	Remedy
No running noise, standby/operation indicator not illuminated.	No power to device.	Check power cord firmly connected. Possibly check function of the socket by connecting another device (e.g. a lamp) to it.
Therapy device cannot be switched on by a breath being taken into it.	Auto on/off not active.	Activate Auto On/Off (5.3, Page 21).
Softstart cannot be switched on	Sofstart function locked.	Clarify with your doctor whether Softstart can be enabled for your therapy.
Therapy device does not switch off about 5 seconds after mask removed.	Auto On/Off not activated.	Activate Auto On/Off (5.3, Page 21).
Therapy device running, but does not reach therapy pressure.	Filters dirty.	Clean/change filters (6.4, Page 32).
	Mask leaking.	Adjust headgear and head strap so that the mask seals. Replace defective mask.
Message *Err d*, *Err n*, *Err E*, *Err c* in display.	Electronics problems.	Disconnect the therapy device from the electricity supply and reconnect it. Try switching on the device. If the error is still being displayed, the therapy device must be repaired by an authorized specialist dealer.
Err b	Battery voltage is too low.	Therapy can continue without restriction. Inform your dealer.

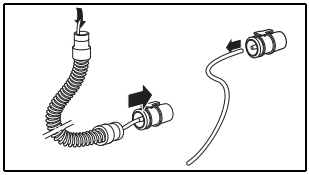
Fault	Cause of fault	Remedy
Err r	Voltage too low. Internal clock (RTC) now longer being supplied with power.	Therapy can continue without restriction. Inform your dealer.
Therapy device not working properly	HF sources	Increase the distance between devices emitting radiation and the therapy device.

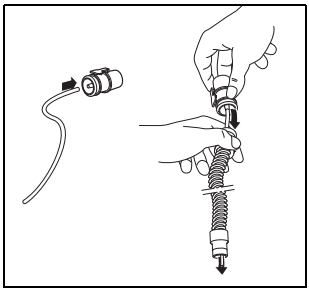
9. Servicing

The device is designed for a service life of 5 years.

When used in accordance with purpose and in accordance with the instructions for use, the device requires no maintenance during this period.

9.1 Change pressure measurement tube





1. Release the sleeve of the creased tube from the click adapter.
2. Pull the pressure measurement tube out of the creased tube.
3. Pull the pressure measurement tube off the click adapter.
4. Push the new pressure measurement tube onto the click adapter.
5. Hold up the creased tube and insert the free end of the new pressure measurement tube.
6. Push the sleeve of the creased tube onto the click adapter.
7. Dispose of the old pressure measurement tube.

10. Disposal

Do not dispose of the therapy device in domestic waste. To dispose of the therapy device properly, contact an approved, certified electronics scrap dealer. You can obtain the address from your Environment Officer or your local authority. The device packaging (cardboard and inserts) can be disposed of in paper recycling facilities.

11. Scope of supply

11.1 Standard scope of supply

SOMNO*vent* auto-S WM 29200

Parts	Order number
SOMNO*vent* auto-S, basic device	WM 29205
Tube system	WM 24130
Drying adapter	WM 24203
Carrying bag	WM 23717
Power cord	WM 24133
Coarse dust filter	WM 24097
Fine filter, packed	WM 23596
Instructions for use	WM 66941

SOMNO*vent* auto-S with SOMNO*click* 300 WM 29250

Parts	Order number
SOMNO*vent* auto-S	WM 29205
SOMNO*click* 300	WM 24375
Instructions for use for SOMNO*click* 300	WM 16719
Tube system	WM 24130
Drying adapter	WM 24203
Carrying bag	WM 23717
Power cord	WM 24133
Coarse dust filter	WM 24097
Fine filter, packed	WM 23596
Instructions for use	WM 66941

SOMNO*vent* auto-ST WM 29400

Parts	Order number
SOMNO*vent* auto-ST, basic device	WM 29405
Tube system	WM 24130
Drying adapter	WM 24203
Carrying bag	WM 23717
Power cord	WM 24133
Coarse dust filter	WM 24097
Fine filter, packed	WM 23596
Instructions for use	WM 66941

SOMNO*vent* auto-ST with SOMNO*click* 300 WM 29450

Parts	Order number
SOMNO*vent* auto-ST	WM 29405
SOMNO*click* 300	WM 24375
Instructions for use for SOMNO*click* 300	WM 16719
Tube system	WM 24130
Drying adapter	WM 24203
Carrying bag	WM 23717
Power cord	WM 24133
Coarse dust filter	WM 24097
Fine filter, packed	WM 23596
Instructions for use	WM 66941

SOMNO*vent* auto-S 230 V WM 29210

Parts	Order number
SOMNO*vent* auto-S 230 V, basic device	WM 29215
Tube system	WM 24130
Drying adapter	WM 24203
Carrying bag	WM 23717
Power cord	WM 24133
Coarse dust filter	WM 24097
Fine filter, packed	WM 23596
Instructions for use	WM 66941

SOMNO*vent* auto-S 230 V with SOMNO*click* 300 WM 29260

Parts	Order number
SOMNO*vent* auto-S 230 V	WM 29210
SOMNO*click* 300	WM 24375
Instructions for use for SOMNO*click* 300	WM 16719
Tube system	WM 24130
Drying adapter	WM 24203
Carrying bag	WM 23717
Power cord	WM 24133
Coarse dust filter	WM 24097
Fine filter, packed	WM 23596
Instructions for use	WM 66941

SOMNO*vent* auto-ST 230 V **WM 29410**

Parts	Order number
SOMNO*vent* auto-ST 230 V, basic device	WM 29415
Tube system	WM 24130
Drying adapter	WM 24203
Carrying bag	WM 23717
Power cord	WM 24133
Coarse dust filter	WM 24097
Fine filter, packed	WM 23596
Instructions for use	WM 66941

SOMNO*vent* auto-ST 230 V with SOMNO*click* 300 **WM 29460**

Parts	Order number
SOMNO*vent* auto-ST 230 V	WM 29410
SOMNO*click* 300	WM 24375
Instructions for use for SOMNO*click* 300	WM 16719
Tube system	WM 24130
Drying adapter	WM 24203
Carrying bag	WM 23717
Power cord	WM 24133
Coarse dust filter	WM 24097
Fine filter, packed	WM 23596
Instructions for use	WM 66941

11.2 Accessories and spare parts

A current list of accessories and replacement parts can be ordered on the internet site of the manufacturer or through your authorized specialist dealer.

Caution!

You must follow the relevant Instructions for Use when using other breathing mask systems.

12. Technical data

12.1 Specifications

	SOMNO*vent* auto-S/ST	**SOMNO*vent* auto-S/ST with SOMNO*click* 300**
Product class to 93/42/EEC	IIa	
Dimensions WxHxD in cm	18 x 9 x 32	18 x 9 x 44
Weight	approx. 3.4 kg	approx. 3.6 kg (excl. water)
Temperature range operation storage	+5 °C to +35 °C –20 °C to +70 °C If the therapy device is operated at +40 °C, the air given off may heat up to as much as 42 °C.	
Permitted humidity for operation and storage	≤ 95 % rh (no condensation)	
Air pressure range	600 - 1100 hPa (allows operation at up to 4000 m altitude) Automatic altitude adaptation	
Connection diameter of breathing tube (mask side) in mm	19.5 (fits standard size 22 mm tapered connector)	
Electrical rating	115/230 V AC, 50–60 Hz or 12/24 V DC (with inverter WM 24131/WM 24132) (to guarantee the pressure consistency demanded by HMV [Heilmittelverordnung – German regulations governing pharmaceutical products], the voltage drop may not exceed 10 %)	
Current consumption:	**230 V 115 V 24 V 12 V**	**230 V 115 V 24 V 12 V**
operation	0,1 A 0.2 A 1.0 A 2.0 A	0,2 A 0.4 A 2.0 A 4.0 A
standby	0,02 A 0.03 A 0.2 A 0.4 A	0,02 A 0.03 A 0.2 A 0.4 A

	SOMNO*vent* auto-S/ST	**SOMNO*vent* auto-S/ST with SOMNO*click* 300**
Classification to EN 60601-1: 1990 +A1:1993 + A2:1995		
Type of protection against electric shock	Protection class II	
Degree of protection against electric shock	Type B	
Protection against damaging ingress of water	IPX0	
Duty cycle	Continuous duty	
Electromagnetic compatibility (EMC) to EN 60601-1-2	Test parameters and limit values can be obtained from the manufacturer on request.	
– Radio interference suppression	EN 55011 B	
– Radio interference immunity	EN 61000-4 Parts 2 to 6, Part 11	
Mean sound pressure level/operation to EN ISO 17510-1:2002 at a distance of 1 m from the therapy device in the patient position	approx. 31.0 dB (A) at 18 hPa approx. 29.0 dB (A) at 15 hPa approx. 27.0 dB (A) at 12 hPa approx. 26.0 dB (A) at 10 hPa approx. 23.0 dB (A) at 7 hPa	
Mean sound pressure level/operation to EN ISO 17510-1:2007 at a distance of 1 m from the therapy device in the patient position	approx. 35.0 dB (A) at 18 hPa approx. 34.5 dB (A) at 15 hPa approx. 32.5 dB (A) at 12 hPa approx. 28.5 dB (A) at 10 hPa approx. 26.5 dB (A) at 7 hPa	
Operating pressure range	4 to 20 hPa	
Pressure precision	±0,4 hPa	

	SOMNO*vent* auto-S/ST	**SOMNO*vent* auto-S/ST with SOMNO*click* 300**
Max. CPAP pressure in the event of a fault to EN ISO 17510 -1	< 36 hPa	
Flow rate at max. speed at:		
20 hPa	125 l/min	115 l/min
16 hPa	145 l/min	135 l/min
12 hPa	165 l/min	150 l/min
8 hPa	180 l/min	165 l/min
4 hPa	195 l/min	180 l/min
0 hPa	210 l/min	190 l/min
Tolerance	±15 l/min	±15 l/min
Heating of respiratory air	2,5 °C (as per HMV - [Heilmittelverordnung – German regulations governing pharmaceutical products])	Depends on heating level
Short-term pressure consistency measured to EN ISO 17510-1 at:		
20 hPa	Δp = 0.6 hPa	Δp = 0.6 hPa
16 hPa	Δp = 0.5 hPa	Δp = 0.5 hPa
13 hPa	Δp = 0.4 hPa	Δp = 0.4 hPa
10 hPa	Δp = 0.4 hPa	Δp = 0.4 hPa
7 hPa	Δp = 0.4 hPa	Δp = 0.4 hPa
4 hPa	Δp = 0.3 hPa	Δp = 0.3 hPa

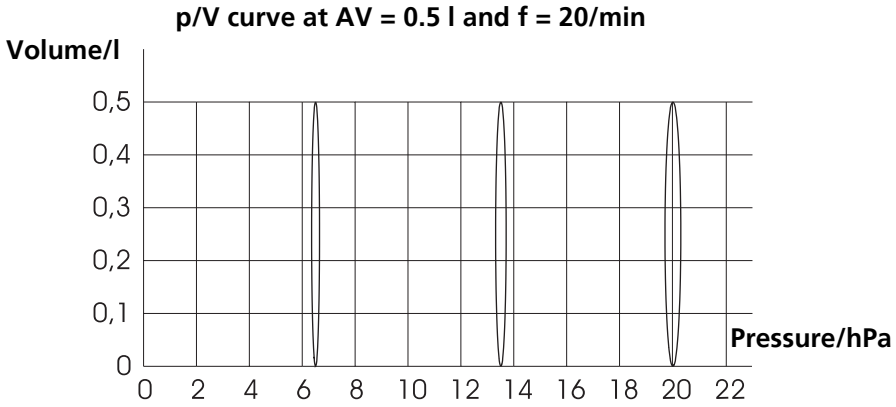
	SOMNO*vent* auto-S/ST	**SOMNO*vent* auto-S/ST with SOMNO*click* 300**
Long-term pressure consistency to EN 17510-1:2002	Δp = 0.2 hPa	Δp = 0.3 hPa
Fine filter, degree of separation up to 1 µm up to 0.3 µm	≥ 99.5 % ≥ 85 %	
Fine filter service life	approx. 250 hours in normal ambient air	

The right to make design modifications is reserved.

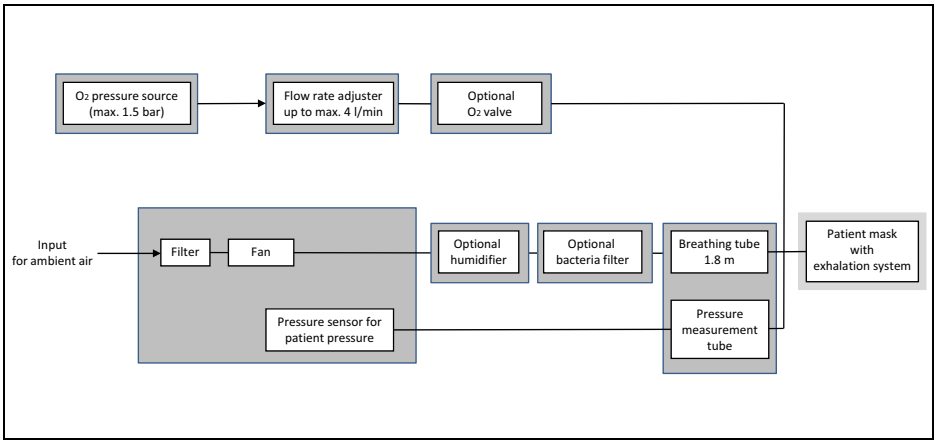
All values determined under ATPD conditions (ambient temperature and pressure, dry).

(1 hPa = 1 mbar ≈ 1 cm H_2O)

12.2 Pressure/volume curve



12.3 Pneumatic diagram



12.4 Safety distances

Recommended safety distances between portable and mobile HF telecommunication devices (e.g. cellphones) and the therapy device			
Nominal power of HF device in W	**Safety distance depending on transmission frequency in m**		
	150 kHz - 80 MHz	**80 MHz - 800 MHz**	**800 MHz – 2.5 GHz**
0.01	0.1	0.04	0.07
0.1	0.37	0.11	0.22
1	1.2	0.35	0.70
10	3.7	1.11	2.21
100	11.7	3.50	7.00

13. Warranty

Löwenstein Medical gives the customer a limited manufacturer warranty on new original Löwenstein Medical products and any replacement part fitted by Löwenstein Medical in accordance with the warranty conditions applicable to the product in question and in accordance with the warranty periods from date of purchase as listed below. The warranty conditions are available on the website of the manufacturer. We can also send you the warranty conditions on request.

In the event of a claim under warranty, contact your specialist dealer.

Product	Warranty period
Löwenstein Medical devices including accessories (except masks)	2 years
Masks including accessories, rechargeable batteries, batteries (unless quoted differently in the technical documentation), sensors, tube systems	6 months
Disposable products	None

14. Declaration of Conformity

Löwenstein Medical Technology GmbH + Co. KG, Kronsaalsweg 40, 22525 Hamburg, Germany, the manufacturer of the devices described in these Instructions for Use, hereby declares that the product complies with the respective regulations of Medical Devices Directive 93/42/EEC. The unabridged text of the Declaration of Conformity can be found on the manufacturer's website.

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