

home care



SOMNOvent CR

CS therapy device with autoTriLevel principle

SOMNOvent CR

SOMNOvent CR with SOMNOclick 300

SOMNOvent CR 230 V

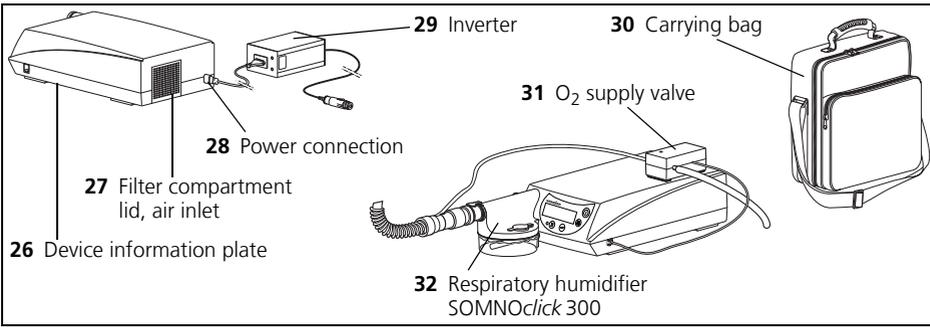
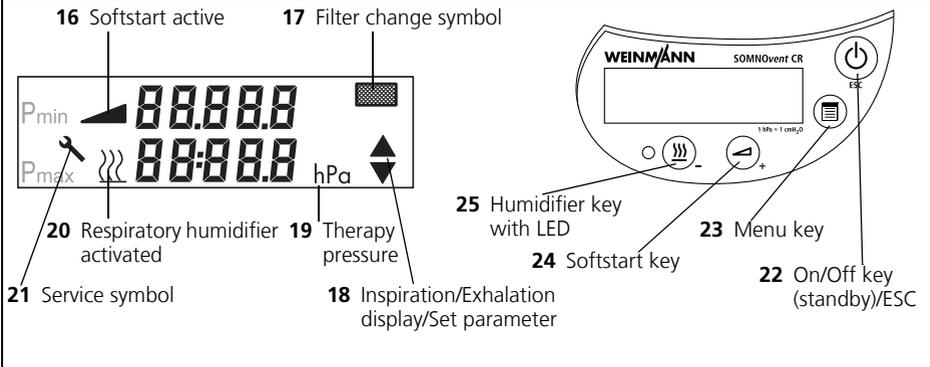
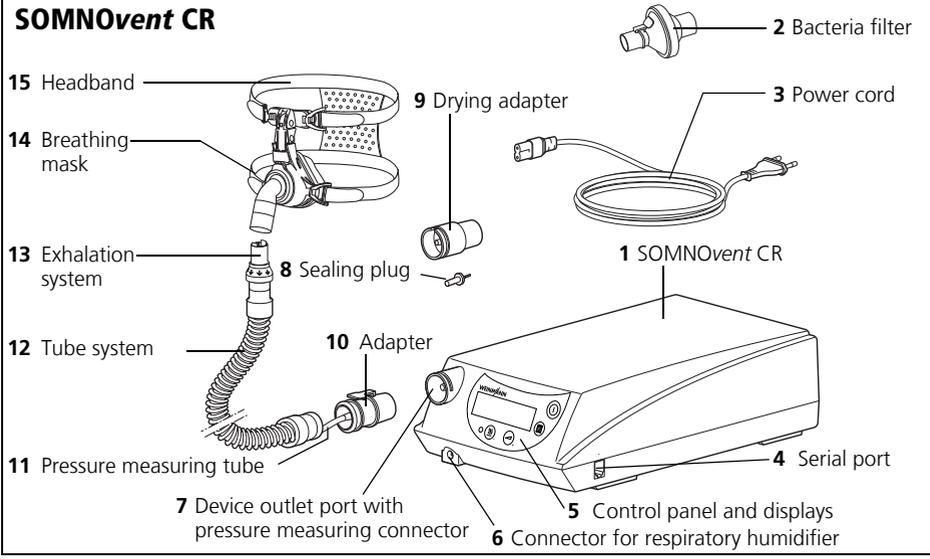
*Device description and instructions for use
with devices as of serial number 10.000
or firmware version 5.0*

WEINMANN
medical technology

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1. Overview



Key

2 Bacteria filter (accessory)

For protecting the patient from bacteria, in particular when the device is used by several patients.

3 Power cord

For connecting the device to the power supply.

4 Serial port

For connecting to devices or computers for setting, displaying and evaluating therapy data and for connecting the O₂ supply valve.

5 Control panel and displays

For controlling and monitoring the SOMNOvent CR and connected accessories.

6 Connector for respiratory humidifier

For connecting the SOMNOclick 300 to the therapy device.

7 Device outlet port with pressure measuring connector

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

8 Sealing plug

For sealing the pressure measuring tube during cleaning.

9 Drying adapter

Required for drying the tube system with the SOMNOvent CR.

10 Adapter

For connecting the breathing tube to the device outlet port.

11 Pressure measuring tube

For measuring prevailing pressure in the breathing mask.

12 Tube system

The air flows through the tube system to the mask. The tube system consists of creased tube, pressure measuring tube and adapter.

13 Exhalation system (accessory)

The carbon dioxide-enriched exhalation air escapes here during therapy.

14 Breathing mask (accessory)

The patient is supplied with respiratory air at the required therapy pressure via the breathing mask.

15 Headband (accessory)

For correct and reliable positioning of the breathing mask.

16 Softstart active

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

17 Filter change symbol

This symbol appears after every 250 operating hours or if the filter is blocked. The fine filter then has to be changed.

18 Inspiration/Exhalation display/Set parameter

The up arrow illuminates during inspiration, the down arrow during exhalation.

Both arrows come on when a value can be amended using the + or - key.

19 Therapy pressure

The therapy pressure is displayed in hPa (hectoPascals). 1 hPa = 1 mbar □ 1 cm H₂O.

20 Respiratory humidifier activated

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

21 Service symbol

This symbol appears after every 5000 operating hours. The device then needs servicing.

22 On/Off key (standby)/ESC

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

23 Menu key

For opening the patient menu and for scrolling to the next value of the patient menu.

24 Softstart key

For activating/deactivating Softstart, for calling up the Softstart setting (press and hold key during therapy) and for reducing a value which can be set.

25 Humidifier key with LED

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

26 Device information plate

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

27 Filter compartment lid, air inlet

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

28 Power connection

This is where the power cord is connected to the optional inverter at the device end.

29 Inverter (accessory)

For operating the therapy device via a direct-current socket (12/24 V).

30 Carrying bag

For transporting the therapy device.

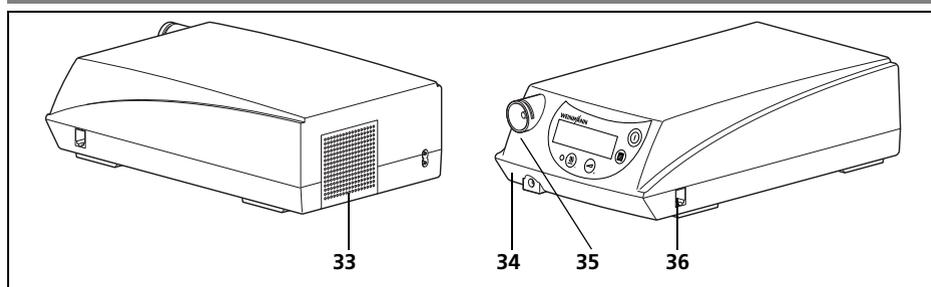
31 O₂ supply valve (accessory)

For introducing oxygen into the breathing mask.

32 Respiratory humidifier SOMNOclick 300

For heating and humidifying the current of air generated by the therapy device.

1.1 Markings on the device

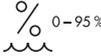


| | Symbol | Significance |
|----|--------|---|
| 33 | | Device inlet: inlet for ambient air at room temperature |
| 34 | | Follow the instructions for use! Connection for respiratory humidifier SOMNOclick 300 WM 24372. |
| 35 | | Device outlet: ambient air outlet at 4 - 20 hPa |
| 36 | | Connection for setting therapy parameters with the SOMNOadjust WM 23930, for reading out the course of therapy with WEINMANNsupport WM 93305 by professional staff or for controlling O ₂ supply valve WM 24042. Max. current consumption 163 mA. Analog output for therapy pressure, flow and leakage (0 V to 1.0 V DC). |

Device information plate

| Symbol | Significance |
|---|---|
|  | Year of manufacture |
|  | Degree of protection against electric shock: device Type B |
|  | Do not dispose of the device with domestic waste! |
|  | Follow the associated instructions for use! |
|  | Serial number of device |
| CE 0197 | CE 0197 symbol: Confirms that the product conforms to the applicable European directives. |
| IPX1 | Protection against ingress of water (drips) |
|  | Type of protection against electric shock: device protection class II Fulfilled standard ISO 17510-1 |

1.2 Markings on the pack

| Symbol | Significance |
|---|---|
|  | Permitted temperature for storage: -20 °C to +70 °C |
|  | Permitted humidity for storage: max. 95 % relative humidity. |
| CE 0197 | CE 0197 symbol: Confirms that the product conforms to the applicable European directives. |
|  | Protect device from wet |
|  | Fragile |

1.3 Safety information in this manual

Safety instructions are marked in this instruction manual as follows:



Warning!

Warns of 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

SOMNOvent CR is an automatically-regulating CS therapy device with autoTriLevel principle suitable for treating patients from the age of 12

- with periodic respiration or Cheyne-Stokes breathing (e.g. in cardiac insufficiency)
- as well as central, mixed and complex sleep apnea.

The therapy device adapts ventilation automatically and continuously to the changing requirements of the patient in question.

The SOMNOvent CR is **not** suitable for life-support use on patients requiring ventilation.

Caution!

To ensure successful therapy with the SOMNOvent CR, the pressure limits prescribed by the doctor and the background ventilation frequency must be determined and adjusted accordingly in a sleep laboratory.

2.2 Description of function

The SOMNOvent CR has an electronically-controlled fan which takes in ambient air through a filter and pumps it to the fan outlet. From here, the air flows through the tube system and the breathing mask to the patient.

The SOMNOvent CR analyzes the pressure in the mask and the air flow to the patient and detects from this sleep-related respiratory disorders such as Cheyne-Stokes breathing or airway obstructions.

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

- If respiratory volume drops, the device supports the patient's breathing by continuously increasing IPAP/EPAP difference. In this way, ventilation in Cheyne-Stokes breathing and in central or mixed sleep apnea syndrome is normalized.

- In the case of apneas, the therapy device ventilates at a fixed respiratory frequency or automatically at an individual frequency
- In the case of increasing respiratory volume, the IPAP/EPAP difference is reduced to calm breathing.
- If obstructions (epochs with apneas, hypopneas, flow limitations or snoring) are detected, EEPAP is increased to keep the airways open.
- In the case of normal breathing, pleasant exhalation relief is administered. Before the transition to exhalation, therapy pressure is reduced to relieve exhalation. This increases patient comfort. Before the start of the next inspiration, pressure is increased back up to therapy pressure. Pressure is slightly increased during inspiration.

The device stores data relating to therapy monitoring and adjustment, thus allowing comprehensive analysis by the doctor.

Automatic Softstart is fitted to facilitate falling asleep. On switching on, pressure is reduced to the Softstart pressure set by the doctor. Therapy pressure then slowly increases to the specified value. The device does not react to respiratory disorders during the Softstart phase.

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.

It is possible to activate automatic on/off on the *SOMNOvent CR*. The device can be switched on by taking a breath into the mask and switches off automatically if not used.

If the power supply is interrupted and then restored, the *SOMNOvent CR* is in the condition in which it was before the interruption. Stored data are retained.

3. Safety information

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

Use the device exclusively for the intended purpose (see "2.1 Intended use" on page 9) described.

For your own safety and the safety of your patients and in accordance with the requirements of Directive 93/42 EEC, follow the safety instructions below.

3.1 Safety instructions

Operating the device

Caution!

- Check whether the power supply of the device matches the power supply in your home. The device can operate with voltages 115 V and 230 V. It automatically adapts to one of these voltages. **Exception:** the SOMNOvent CR 230 V (WM 23470) can only operate with a voltage of 230 V. For operation on 12 V DC or 24 V DC, use an inverter which is available as an accessory.
- The device must be connected to an easily accessible socket so that the plug can be taken out quickly in the event of a fault.
- Do not set up the device close to a radiator and do not expose it to direct sunlight, as this could heat up the respiratory air and also the internal parts. This could cause condensation to form in the respiratory humidifier which would then be deposited in the tube system.
- Do not cover the device with blankets etc.. The air inlet would be blocked and the device could overheat. This may lead to inadequate therapy and damage to the device.
- Maintain a safe distance between the SOMNOvent CR and devices which emit HF radiation (e.g. mobile telephones) (see page 45), otherwise there may be malfunctions.
- Do not operate the therapy device and the respiratory humidifier if the device is not working properly, if parts are damaged and/or the respiratory humidifier is wet at the contact of the heating element.

- The performance of the respiratory humidifier may change if the device is operated outside the permitted ambient temperatures.
- Please also see the instructions for use for your breathing mask.
- Please observe Section "6. Hygiene treatment" on page 28 to prevent infection or bacterial contamination.
- If the SOMNOvent CR is intended for use by several patients, a bacteria filter should be used to protect against infections. It is inserted between the breathing tube with adapter and the device outlet port. If the device is to be used for another patient without a bacteria filter being used, it must be subjected to a hygiene treatment beforehand. This should be performed by the manufacturer, Weinmann, or an authorized dealer.

Transport

Caution!

Do not transport the SOMNOvent CR with the respiratory humidifier fitted. If the device rests at an angle, residual water from the respiratory humidifier may run into the SOMNOvent CR and damage it.

Accessories/replacement parts

Caution!

- If third-party items are used, functional failures may occur and fitness for use may be restricted. Biocompatibility requirements may also not be met. Please note that in such cases, any claim under warranty and liability will be voided if neither the accessories nor genuine replacement parts recommended in the instructions for use are used.
- Masks of third-party manufacture may only be used following authorization by the manufacturer, Weinmann. Using unauthorized masks jeopardizes the success of therapy.
- Ensure that accessories used for therapy are suitable and complete. This applies to the exhalation system in particular. Otherwise the CO₂ content in the exhalation air may impede your breathing and there is a risk of suffocation.

Maintenance

Caution!

- Have servicing and repair work carried out only by the manufacturer, Weinmann, or professionals.

- Modifications to the SOMNOvent CR and the SOMNOclick 300 are not permitted.

Oxygen supply



Warning!

If you use oxygen during treatment, smoking and naked flames are forbidden. **Risk of fire!** The oxygen can accumulate in clothing, bed linen or hair. It can only be removed by thorough ventilation.

Caution!

Oxygen supply is permitted only when using O₂ supply valve WM 24042. On the topic of oxygen, it is essential to follow the safety instructions in the instructions for use of 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 dehydration
- 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 SOMNOvent CR, the following undesired side effects may occur in short-term or long-term use:

- pressure points from the nasal cannula and the forehead cushion on the face
- reddening of facial skin
- blocked nose
- dry nose
- dry mouth in the morning
- feeling of pressure in the sinuses
- irritated mucous membrane in the eyes
- gastrointestinal insufflation of air ("bloating")
- nosebleeds

Note:

These side effects are general side effects of therapy with a CPAP device and not attributable specifically to use of the SOMNOvent CR.

4. Set up device

4.1 Set up and connect the SOMNOvent CR

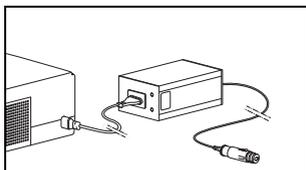
Location

- Set up the device on a flat surface, e.g. on a bedside cabinet or on the floor next to the bed.
- Maintain a distance of at least 5 cm between the wall and the rear of the device, as the air inlet is at the rear of the device.

Caution!

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

Power supply



1. Use the power cord to connect the power connector of the SOMNOvent CR to a socket.

SOMNOvent CR automatically detects whether 115 V or 230 V are connected and switches automatically.

Exception: the SOMNOvent CR 230 V (WM 23470) can only operate with a voltage of 230 V.

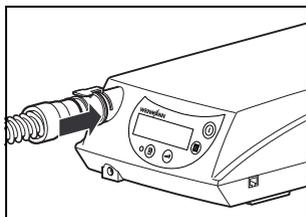
In the display, "0" appears for standby.

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

The options for doing this are either:

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

Use the power cord to connect the power connector of the SOMNOvent CR to the power supply socket of the inverter.

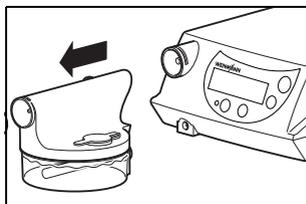


3. Plug the adapter of the tube system into the device outlet port.

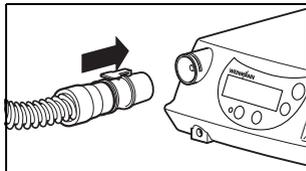
Note:

The appliance automatically compensates for differences in air pressure (e.g. due to high altitude).

4.2 For operation without a respiratory humidifier



1. To disconnect the humidifier if required, pull it forwards off the device outlet port.



2. Push the breathing tube onto the adapter for the device outlet port.
3. Push the adapter of the breathing tube into the device outlet port of the therapy device. Ensure in the process that the locking latch points upwards and engages in the groove of the device outlet port.

4.3 For operation with respiratory humidifier

Note:

Follow instructions relating to filling and adapting the respiratory humidifier SOMNOclick 300 in the associated instructions for use.

4.4 Breathing mask

Put on breathing mask

1. Adjust the forehead support of the breathing mask (if provided).
2. Connect the headgear/headband to the mask.
3. Put on the mask.
4. Adjust the headgear/headband so that the bulge of the mask creates only low pressure so as to prevent pressure points on the face.

Note:

Consult the instructions for use for the breathing mask in question for information on how to proceed.



Warning!

Full-face masks must be equipped with an emergency exhalation valve so that you can breathe through nose or mouth in the event of any device failure. Full-face masks without an emergency exhalation valve may not be used!

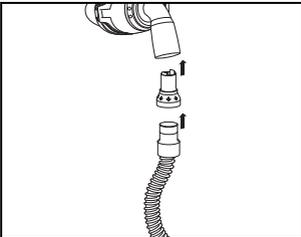
External exhalation system

No exhalation system is integrated in some masks. In order for the used, carbon dioxide (CO₂)-enriched air to be able 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 CO₂ concentration would rise to critical levels in the mask and tube and thus inhibit your breathing. Risk of suffocation!

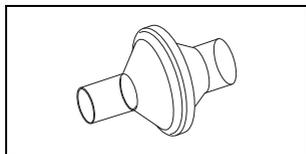


- Fit the external exhalation system between the breathing mask and the breathing tube.

4.5 Connect other accessories

Bacteria filter

If the SOMNOvent CR is intended for use by several patients (e.g. in a hospital), a bacteria filter should be used to prevent infections.



- Fit the bacteria filter between the breathing tube and the adapter.

Caution!

- Pressure consistency and flow rate may be reduced if a bacteria filter is used. If a bacteria filter is connected, check the pressure.
- Follow the manufacturer's instructions, particularly the expiry date of the filter.

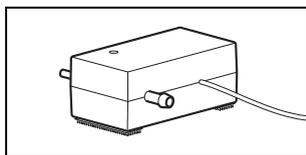
Oxygen supply



Warning!

For safety reasons (risk of fire), it is not permitted to supply oxygen straight into the breathing tube or the breathing mask without a special safety device. It is possible to supply up to 4 l/min oxygen to the breathing mask using oxygen supply valve WM 24042.

An oxygen concentrator (e.g. Oxymat), liquid oxygen or an oxygen cylinder with the appropriate pressure-reducer on it can be used. This use must be prescribed by the doctor in charge.



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.

5. Operation

The SOMNOvent CR is operated with the aid of the four keys on the control panel.

A "Patient Menu" provides various functions and settings in standby mode (device switched off) or during therapy (device switched on). As an alternative to the patient menu, some of these functions can also be called up directly using a key command.

Patient menu in standby mode

- "5.2 Read out therapy time" on page 20
- "5.3 Automatic on/off" on page 21
- "5.4 Softstart setting" on page 22
- "5.5 Set SOMNOclick 300" on page 23
- "Dry breathing tube" on page 30
- "6.4 Clean coarse dust filter, change fine filter" on page 31

Patient menu during therapy

- "Leakage indicator" on page 25
- "5.3 Automatic on/off" on page 21
- "5.4 Softstart setting" on page 22
- "5.5 Set SOMNOclick 300" on page 23

5.1 Patient menu

1. To call up the patient menu, press the Menu key **briefly**. The first thing to be displayed is total therapy time.
2. To scroll through the patient menu and switch to the next parameter, press the Menu key again. If you keep the Menu key depressed, you scroll through the menu items automatically.

| Parameter | Display | Value range | Key command (alternative) | Described in |
|-----------|-----------|----------------------|---|------------------------|
| Leakage | LE | small, medium, large | Press the Menu button briefly while the device is switched on | Chapter 5.6 on page 24 |

| Parameter | Display | Value range | Key command (alternative) | Described in |
|------------------|---|-------------------------|--|------------------------|
| Therapy time | h | | – | Chapter 5.2 on page 20 |
| Autostart | <i>Auto</i> | <i>on</i> <i>OFF</i> | – | Chapter 5.3 on page 21 |
| Softstart time | min  | 5 to 30 | with device switched on:  press and hold | Chapter 5.4 on page 22 |
| Humidifier stage |  | 1 to 6 | with device switched on:  press and hold | Chapter 5.5 on page 23 |
| Drying mode | <i>dr 0:30</i> | |  and press  simultaneously | Chapter 6.2 on page 29 |
| Change filter |  | | – | Chapter 6.4 on page 31 |

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

or:

If you do not press any key for 30 seconds, you exit the patient menu automatically.

5.2 Read out therapy time

The SOMNOvent CR saves therapy data from 366 days.

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

| | |
|--------------|--|
| <i>11 d</i> | mean value for all therapy days (11 days in the example) |
| <i>2302.</i> | for a particular day in the last 7 days, give the date (in the example, 23rd February) |

Total therapy time

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

Daily therapy time

When the device is **switched off**, the therapy time for the current day is displayed.

Operating hours

The operating hours are displayed when you keep the on/off key depressed for a long time when **switching off** the device.

Note:

Each **therapy day** begins and ends at 12 noon. Data recorded from 0 (midnight) to 12 (noon) are assigned to the previous **calendar day** in each case.

5.3 Automatic on/off

If the automatic system is activated, you can switch the SOMNOvent CR on and off using the pressure in the mask.

Note:

When the device is switched on, you can view the current setting via the patient menu, but you cannot change it.

If a full-face mask with integrated emergency exhalation system is used, the device will not switch itself on and off automatically even if setting **Auto on** is selected. The emergency exhalation system of the mask means that the device cannot detect the pressure change required for switching.

Activate/deactivate automatic system

Status: device switched off.

1. Call up the patient menu and scroll to the setting for automatic on/off.

- Press the Softstart key (+) or the humidifier key (-) until the desired setting appears in the display:

| | |
|---------------------|---|
| Auto on | Automatic system activated As soon as a patient breathes into the mask (pressure > 0.5 hPa), the SOMNOvent CR switches on automatically. When the mask is removed, the device switches off automatically after 5 seconds. |
| Auto OFF | Automatic system deactivated The device can only be switched on by pressing the on/off key. If the device is not used for 15 minutes, it switches off automatically. |

- To save the setting and exit the patient menu, press the on/off key/ESC or wait until the menu exits automatically.

5.4 Softstart setting

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

If the Softstart function is activated on your device, the time can be selected in 5-minute increments up to a maximum of 30 minutes.

Set time

- Call up the patient menu and scroll to the setting for time.

or:

with the device switched on: keep the Softstart key depressed until the current setting appears.

- To change the time, press the Softstart key (+) or the humidifier key (-) several times until the desired time is shown.
- To save the setting and exit the menu, press the on/off key/ESC or wait until the menu exits automatically.

Softstart on/off

Status: device switched on.

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

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

5.5 Set SOMNOclick 300

Using a respiratory humidifier prevents the upper airways of the patient drying out during therapy.

Six humidifier stages can be set (1 = low heating output to 6 = maximum heating output). The most favorable setting for you will depend on room temperature and humidity, so the ideal setting will vary with the season and ambient conditions. Preset humidifier stage 3 is adequate under "normal" conditions.

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

Switch on respiratory 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 (Stage 3 in this case) 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.

or:

with the device switched on: keep the humidifier key depressed until the current setting appears.

2. To change the heating stage, press the Softstart key (+) or the humidifier key (-) several times until the desired stage is shown.

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

If condensation forms in the breathing tube during the therapy night, heating output is set **too high**. In this case, select a lower humidifier stage.

3. To save the setting and exit the menu, press the on/off key/ESC or wait until the menu exits automatically.

Switch off respiratory humidifier

You have two options for switching off the respiratory humidifier:

- Press the humidifier key on the therapy device.

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

or:

- press the on/off key of your therapy device.

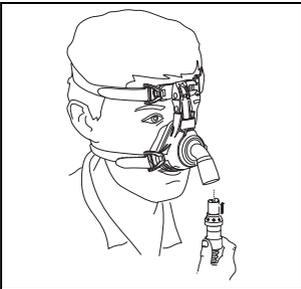
The respiratory humidifier and the therapy device are both switched off. When you switch the therapy device back on, the respiratory humidifier is also switched back on automatically and operated at the heating output of the previous therapy session.

Automatic off

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

5.6 Operating the therapy device

Put on the mask



1. Put on the mask as described in Section “4.4 Breathing mask” on page 17.
2. Connect the breathing tube to the breathing mask (tapered push connector).
3. Route the breathing tube away from your head.



Warning! Risk of injury!

Never put the breathing tube around your neck.

Switch on the device

- To switch on the device, press the on/off key.

or:

If the automatic system is activated, you can switch on the SOMNOvent CR by taking one breath into the mask.

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

SOMNOvent CR is now operational.

Mask test

If the mask test is activated, the preset higher pressure is displayed for 30 seconds (for example 8 hPa).



1. Check the seal on the mask and adjust the head bands if necessary.
2. To cancel the mask test before 30 seconds have elapsed, press the On/Off button.

The therapy device is now ready to use.

Leakage indicator

You can view the current leakage level while the device is operating.



No/small leak. The mask is in the optimal position to ensure effective therapy.

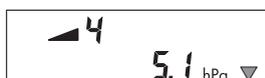


Medium leak. The mask is not in the optimal position, so the quality of the therapy may be limited.



Medium leak. The mask is not in the optimal position, so the quality of the therapy may be limited.

Softstart



If Softstart is preset, the Softstart display and the start time appear in the display.

Current pressure is also shown in the display.

Respiratory phase



The symbol **I** is displayed during inspiration phases.

The symbol **M** is displayed during exhalation phases.

Switch off device

- To switch off the device, press the on/off key. Daily therapy time appears in the display for approx. 3 seconds.

or:

If the automatic system is activated, the device switches off automatically 5 seconds after the mask has been removed.

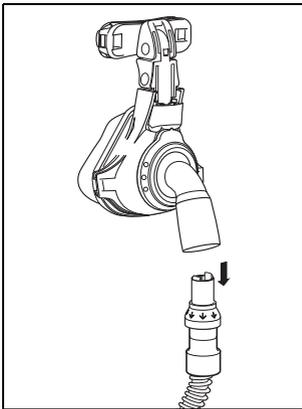
5.7 After use

1. Take off the headgear/headband with the breathing mask.
2. To switch off the device, press the on/off key.

or:

If the automatic system is activated, the device switches off automatically after approx. 5 seconds.

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



3. Pull the tube connection and the exhalation system off the breathing mask.
4. Clean the following parts (see "6. Hygiene treatment" on page 28):
 - breathing mask
 - exhalation system
 - respiratory humidifier (if used)

Save energy

With the mains unit and in standby mode (standby), the SOMNOvent CR uses approx. 4 W. The device does not have a power switch.

To save electricity, you can remove the plug of the power cord from the power socket during the day. To do this, plug the device into an easily accessible socket. The saved values and settings are retained.

Caution!

Always switch off the SOMNOvent CR at the on/off key first before disconnecting the plug or interrupting the power supply at a switchable socket.

5.8 Traveling with therapy devices

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

Pack in the carrying bag:

- device
- power cord
- breathing tube
- breathing mask including exhalation system
- respiratory humidifier if required
- spare filters
- instructions for use
- inverter (if required)

Note:

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

6. Hygiene treatment

Note:

- Follow the information relating to hygiene treatment of the accessories (exhalation system, breathing mask, headgear/headband) in the associated 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 humidifier. | See associated instructions for use |
| | Clean bacteria filter. Change the particle filter of the bacteria filter after no more than 24 h use. | See associated instructions for use |
| Weekly | Clean coarse dust filter. | Section 6.4 |
| | Check fine filter. Change if required. | Section 6.4 |
| | Check breathing tube. Clean if required. | Section 6.2 |
| | Wipe down the housing of the SOMNOvent CR. | Section 6.3 |
| | Wash headgear/headband. | See associated instructions for use |

| | | |
|------------------------------|---|-------------------------------------|
| Monthly | Replace fine filter (depending on contamination, but in any event after no more than 250 hours or one month (filter change indicator)). | Section 6.4 |
| | Clean breathing tube. | Section 6.2 |
| Every 6 months | Replace coarse dust filter | Section 6.4 |
| | Change pressure measuring tube | Section 9.3 |
| Every 12 months | Replace breathing mask and exhalation system. | |
| | Replace breathing tube. | |
| | Replace headgear/headband. | |
| As required | Disinfect the SOMNOvent CR | Section 6.6 |
| | Disinfect the SOMNOclick 300 | See associated instructions for use |
| When changing patient | If necessary, hygiene treatment | Section 6.7 |
| | Change particle filter of the bacteria filter. | See associated instructions for use |

6.2 Breathing tube

Caution!

The breathing tube may only be used again after cleaning if it is completely dry. If moisture gets into the therapy device, this can result in damage to the device and thus a hazard to users and patients.

Clean breathing tube

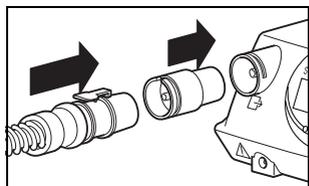
1. Pull the breathing tube off the device and off the exhalation system.
2. Seal both sides of the pressure measuring tube with a sealing plug.
3. Clean the creased tube and the adapter with a little detergent in hot water and make sure no residues are left behind. Flush the inside of tube through thoroughly in the process.
4. Then rinse through thoroughly inside and out using clean hot water.
- 5. Shake 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 SOMNOvent CR. To do so, proceed as follows:

Status: device switched off.

1. Remove the respiratory humidifier if necessary.
2. Remove the plug from the pressure measuring tube.



3. If water gets into the pressure measuring tube by accident, plug the red drying adapter supplied into the device outlet port.
4. Plug the adapter of the tube system into the device outlet port or, if appropriate, 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.

or:

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

The device now switches on and dries the breathing tube (time: 30 minutes). The remaining time is shown in the display. After the end of the drying process, the 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 places after the drying process, start the drying process again.
6. Remove the drying adapter if necessary.

6.3 Clean the housing of the SOMNOvent CR



Warning! Risk of electric shock!

- Before cleaning, it is essential to pull the power cord out of the power connection and the power supply plug out of the socket.
- Ensure that no liquids get into the device. Never immerse the device in disinfectants or other liquids, otherwise this can result in damage to the device and thus a hazard to users and patients.

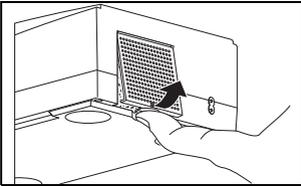
Caution!

Ensure that no liquids get into the device through the pressure measuring connector, otherwise there may be malfunctions.

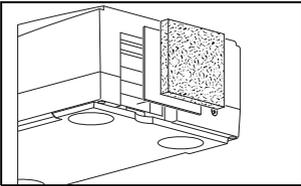
1. Wipe down the device and the power cord with a soft damp cloth.
2. Take off the filter compartment lid.
3. Clean the filter compartment lid under running water until there are no residues. Then dry it carefully.

The SOMNOvent CR must be completely dry before being 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. Change the fine filter if required. It cannot be cleaned.
4. Allow 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 cover back on to the rear of the device.

Following filter change: clear symbol or reset meter

The filter change symbol appears when the filter change meter exceeds 250 operating hours or if the filter is blocked. Whenever you replace the fine filter, the filter change meter should be set to zero and the filter change symbol cleared if required.

To do so, proceed as follows:

1. Call up the patient menu and scroll to the setting for filter change.
2. Keep the humidifier key depressed until the display  appears.

6.5 Accessories

For cleaning the exhalation system, the breathing mask, the headgear/headband, the bacteria filter and the respiratory humidifier SOMNOclick 300, see the chapter entitled "Cleaning" in the relevant instructions for use.

6.6 Disinfect the SOMNOvent CR

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

Device

For disinfecting by wiping, we recommend terralin[®] protect as a disinfectant.



Warning! Risk of electric shock!

- Before cleaning, it is essential to pull the power cord out of the power connection and the power supply plug out of the socket.
- Ensure that no liquids get into the device. Never immerse the device in disinfectants or other liquids, otherwise this can result in damage to the device and thus a hazard to users and patients.

Caution!

Ensure that no liquids get into the device through the pressure measuring connector, otherwise there may be malfunctions.

The housing and the power cord of the SOMNOvent CR are cleaned simply by wiping with disinfectant.

Breathing tube

For disinfecting by immersion, we recommend gigasept[®] FF as a disinfectant.

When disinfecting, proceed in just the same way as when cleaning.

Caution!

The breathing tube may not be heated above 70 °C. It may not be sterilized.

Accessories

To disinfect/sterilize the exhalation system, the breathing mask and the respiratory humidifier *SOMNOclick 300*, see the chapter entitled "Disinfecting and sterilizing" in the relevant instructions for use.

6.7 Change in patients

If the unit is operated with a bacteria filter:

- change the bacteria filter

or:

- sterilize the bacteria filter and change the particulate filter inside it.

If the unit is operated without a bacteria filter:

- have the unit subjected to hygienic preparation by a dealer on change of patient.

7. Function check

7.1 Intervals

Perform a function check on both the SOMNOvent CR and on the SOMNOclick 300 at least every 6 months.



Warning!

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

7.2 Function check SOMNOvent CR

1. Assemble the SOMNOvent CR to make it operational with the breathing tube, exhalation system, breathing mask and power cord.
2. Set the mask test pressure in the Patient menu to 12 hPa (see “ Mask test” on page 25).
3. Switch the therapy device on.

The fan delivers air through the breathing tube to the breathing mask. Current pressure is shown in the display in hPa.

4. Seal the opening of the breathing mask, e.g. with your knee or hand.

While the mask test is active (approx. 30 seconds), a pressure of 12.0 hPa must be shown on the display.

5. Switch off the device at the on/off key.

Caution!

If the values/functions outlined here are not met/performed, send the device to the manufacturer, Weinmann, or to an authorized dealer for repair.

7.3 Function check SOMNOclick 300

Follow the associated instructions for use!

8. Troubleshooting

If faults occur which cannot be eliminated at once, contact the manufacturer, Weinmann, or your dealer immediately to have the device repaired. Do not continue operating the device in order to prevent even greater damage.

8.1 SOMNOvent CR

| Fault | Cause of fault | Remedy |
|--|--|--|
| No running noise, standby/operating indicator not illuminated. | No power supply. | Check power cord is firmly connected. If necessary check function of socket by connecting a different device (e.g. a lamp). |
| Device cannot be switched on by taking a breath. | Automatic on/off not activated. | Activate automatic on/off (5.3, page 21). |
| Softstart cannot be switched on | The Softstart function is deactivated. | Clarify with your doctor whether the Softstart function can be activated for your therapy. |
| Device does not switch off approx. 5 seconds after the mask has been removed. | Automatic on/off not activated. | Activate automatic on/off (5.3, page 21). |
| Device runs, but does not reach therapy pressure. | Filter dirty. | Clean/change filter (6.4, page 31). |
| | Mask leaking. | Adjust headgear/headband so that the mask does not leak. If necessary, replace defective mask. |
| Filter change indicator  illuminates. | Filter dirty. | Clean/change filter (6.4, page 31). |
| Message <i>Err b</i> , <i>Err d</i> , <i>Err n</i> , <i>Err r</i> , <i>Err E</i> or <i>Err E</i> in the display. | Problems in the electronics. | Disconnect the device from the power supply and connect it again. If the fault continues to be displayed, the device needs to be repaired by Weinmann or an authorized dealer as soon as possible. |

| Fault | Cause of fault | Remedy |
|--|-----------------------|---|
| Servicing indicator  illuminates. | Servicing required | The device needs to be checked or serviced by Weinmann or an authorized dealer as soon as possible. |

9. Servicing

Regular servicing must be performed as a preventive measure. To do this, observe the intervals mentioned.

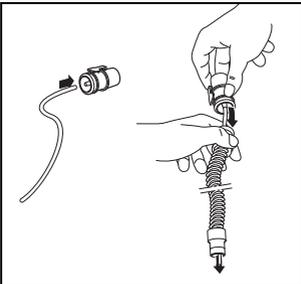
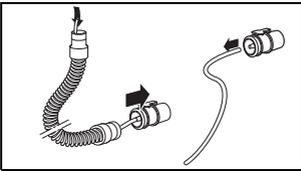
9.1 Intervals

- After every 5000 operating hours (servicing symbol appears in the display)
- After no more than every 2 years (see service sticker on rear of device)

9.2 Scope of service

| | |
|---------------------------------|-------------------------|
| Change filters | see Section 6.4 |
| Complete test of function | see Section 7. |
| Hygiene treatment of the device | Send device to Weinmann |
| Replace any defective parts | Send device to Weinmann |

9.3 Change pressure measuring tube



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

10. Disposal



Do not dispose of the device with domestic waste. To dispose of the device properly, contact a licensed, certified electronic scrap disposal merchant. This address is available from your Environment Officer or from 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

SOMNOvent CR

WM 24720

| Parts | Order number |
|---|--------------|
| SOMNOvent CR basic device | WM 24135 |
| 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 SOMNOvent CR | WM 66321 |
| Short instructions for use SOMNOvent CR | WM 66331 |
| Patient record | WM 16162 |

SOMNOvent CR with SOMNOclick 300

WM 24785

| Parts | Order number |
|-------------------------------------|--------------|
| SOMNOvent CR | WM 24720 |
| SOMNOclick 300 | WM 24372 |
| Instructions for use SOMNOclick 300 | WM 16719 |

SOMNOvent CR 230 V

WM 23470

| Parts | Order number |
|---|--------------|
| SOMNOvent CR 230 V basic device | WM 24775 |
| 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 SOMNOvent CR 230 V | WM 66321 |

| Parts | Order number |
|---|---------------------|
| Short instructions for use SOMNOvent CR | WM 66331 |
| Patient record | WM 16162 |

11.2 Accessories and spare parts

You can order accessories and spare parts separately if required. A current list of accessories and spare parts can be ordered on the Internet at www.weinmann.de or via your dealer.

12. Technical data

12.1 Specifications

| | SOMNOvent CR | SOMNOvent CR with SOMNOclick 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 device is operated at +40 °C, the air given off can heat up to as high as 42 °C. | |
| Permitted humidity in operation and storage | ≤ 95 % rh (no condensation) | |
| Air pressure range | 600 - 1100 hPa (allows operation at altitudes of up to 4000 m) Automatic altitude compensation | |
| Diameter of breathing tube connection (mask side) in mm | 19.5 (fits 22 mm standard tapered connector) | |
| Electrical rating | 115/230 V AC, 50–60 Hz or 12/24 V DC (with inverter WM 24131/WM 24132) (to guarantee constant pressure, the drop in power may not exceed 10 %) | |
| Current consumption during operation standby | 230 V 115 V 24 V 12 V 0.11 A 0.22 A 0.8 A 1.5 A 0.02 A 0.03 A 0.5 A 0.6 A | 230 V 115 V 24 V 12 V 0.22 A 0.44 A 1.6 A 2.8 A 0.02 A 0.03 A 0.5 A 0.6 A |

| | SOMNOvent CR | SOMNOvent CR with SOMNOclick 300 |
|--|--|---|
| Classification as per EN 60601-1 – type of protection from elec. shock – level of protection from elec. shock – protection from damaging ingress of water Operating mode | Protection class II Type B IPX0 Continuous duty | |
| Electromagnetic compatibility (EMC) to EN 60601-1-2: 2007 – Radio interference suppression – Radio interference immunity | Test parameters and limit values can be requested from the manufacturer if required. EN 55011 B EN 61000-4 Parts 2 to 6, Part 11 | |
| Mean sound pressure level to EN ISO 17510 -1: 2002 at a distance of 1 m from the device in the patient position | approx. 31 dB (A) at 18 hPa approx. 29 dB (A) at 15 hPa approx. 27 dB (A) at 12 hPa approx. 26 dB (A) at 10 hPa approx. 23 dB (A) at 7 hPa | |
| Mean sound pressure level to EN ISO 17510 -1: 2009 | approx. 29 dB (A) at 10 hPa (corresponds to a sound level of 37db (A)) | |
| Operating pressure range Pressure accuracy | 4 to 20 hPa ± 0.4 hPa | |
| Max. CPAP pressure in event of a fault to EN ISO 17510 -1: 2009 | < 30 hPa | |

| | SOMNOvent CR | SOMNOvent CR with SOMNOclick 300 |
|--|-----------------------|---|
| Maximum flow rate to EN ISO 17510-1:2002 at : | | |
| 20 hPa | 115 l/min | 100 l/min |
| 13.5 hPa | 150 l/min | 135 l/min |
| 6.5 hPa | 175 l/min | 160 l/min |
| 0 hPa | 195 l/min | 180 l/min |
| Tolerance | ±15 l/min | ±15 l/min |
| Maximum flow rate to EN ISO 17510-1:2009 at: | | |
| 20 hPa | 115 l/min - 110 l/min | |
| 16 hPa | 135 l/min- 130 l/min | |
| 12 hPa | 155 l/min- 150 l/min | |
| 8 hPa | 170 l/min- 165 l/min | |
| 4 hPa | 185 l/min- 180 l/min | |
| Heating of respiratory air | 2.5 °C | depending on heating stage |
| Precision of dynamic pressure (short-term precision) with 10 breaths/min to EN ISO 17510-1:2009 at | | |
| 4 hPa | $\Delta p = 0,1$ hPa | $\Delta p = 0,1$ hPa |
| 8 hPa | $\Delta p = 0,2$ hPa | $\Delta p = 0,2$ hPa |
| 12 hPa | $\Delta p = 0,2$ hPa | $\Delta p = 0,2$ hPa |
| 16 hPa | $\Delta p = 0,2$ hPa | $\Delta p = 0,2$ hPa |
| 20 hPa | $\Delta p = 0,3$ hPa | $\Delta p = 0,3$ hPa |

| | SOMNOvent CR | SOMNOvent CR with SOMNOclick 300 |
|--|--|--|
| Precision of dynamic pressure (short-term precision) with 15 breaths/min to EN ISO 17510-1:2009 at 4 hPa 8 hPa 12 hPa 16 hPa 20 hPa | $\Delta p = 0,2$ hPa $\Delta p = 0,2$ hPa $\Delta p = 0,2$ hPa $\Delta p = 0,2$ hPa $\Delta p = 0,3$ hPa | $\Delta p = 0,2$ hPa $\Delta p = 0,2$ hPa $\Delta p = 0,2$ hPa $\Delta p = 0,3$ hPa $\Delta p = 0,4$ hPa |
| Precision of dynamic pressure (short-term precision) with 20 breaths/min to EN ISO 17510-1:2009 at 4 hPa 8 hPa 12 hPa 16 hPa 20 hPa | $\Delta p = 0,2$ hPa $\Delta p = 0,3$ hPa $\Delta p = 0,4$ hPa $\Delta p = 0,4$ hPa $\Delta p = 0,6$ hPa | $\Delta p = 0,3$ hPa $\Delta p = 0,3$ hPa $\Delta p = 0,4$ hPa $\Delta p = 0,4$ hPa $\Delta p = 0,6$ hPa |
| Precision of static pressure (long-term precision) to EN ISO 17510-1:2009 | $\Delta p = 0.02$ 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 | |

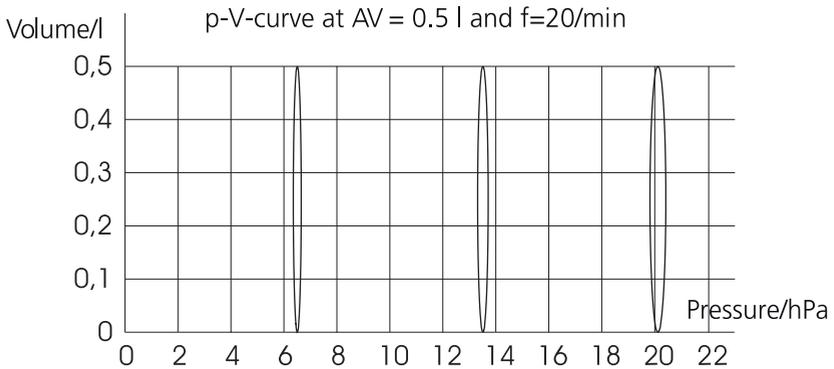
CE 0197

The right to make design modifications is reserved.

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

(1 hPa = 1 mbar \approx 1 cm H₂O).

12.2 Pressure/volume curve



12.3 Safety distances

| Recommended safety distances between portable and mobile HF telecommunications devices (e.g. mobile telephone) and the SOMNOvent CR | | | |
|---|---|------------------|-------------------|
| Nominal output 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

Weinmann gives the customer a limited manufacturer warranty on new original Weinmann products and any replacement part fitted by Weinmann 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 can be downloaded from www.weinmann.de on the Internet. 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 |
|--|------------------------|
| Weinmann devices including accessories (except masks) for sleep diagnosis, sleep therapy, home ventilation, oxygen medicine and emergency medicine | 2 years |
| Masks including accessories, rechargeable batteries, batteries (unless quoted differently in the technical documentation), sensors, tube systems | 6 months |
| Disposable products | None |

14. EC Declaration of conformity

Weinmann Geräte für Medizin GmbH + Co. KG declares herewith that the product complies fully with the respective regulations of the Medical Device Directive 93/42/EEC. The unabridged text of the Declaration of Conformity can be found on our website at www.weinmann.de

15. Glossary

Apnea

A cessation of external respiration lasting at least 10 seconds is called a respiratory cessation or apnea.

The apnea is usually ended by a waking reaction of the body. This interrupts sleep and reduces its recovery function.

A distinction is made between obstructive apneas in which respiration is prevented by an obstruction of the upper airways and central apneas in which the respiratory drive fails.

CPAP

CPAP therapy is for treating obstructive sleep apnea syndrome. CPAP stands for Continuous Positive Airway Pressure, i.e. the patient is continuously supplied with respiratory air at a constant slight pressure whilst asleep. This is generally performed using a nasal cannula or full-face mask. This "pneumatic bracing" is used to keep the airways open and to prevent the occurrence of apneas, hypopneas, flow limitations and snoring.

Cheyne-Stokes breathing

Cheyne-Stokes breathing is a special form of central apnea and is characterized by periodic phases of increasing and decreasing respiratory volumes and consecutive respiratory pauses (apnea).

During phases of decreasing respiratory volume, breathing is supported by increasing the difference between inspiratory and expiratory pressure levels. In the case of increasing volume, respiratory support is suspended.

Hypopnea

A reduction in respiratory flow of at least 50 % is called a hypopnea. There are obstructive and central hypopneas.

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Total therapy time **20, 25**
Transport **12**
Travel **27**
- W**
Warranty **46**

partner for life

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