

# SOMNO*comfort* 2e SOMNO*aqua*

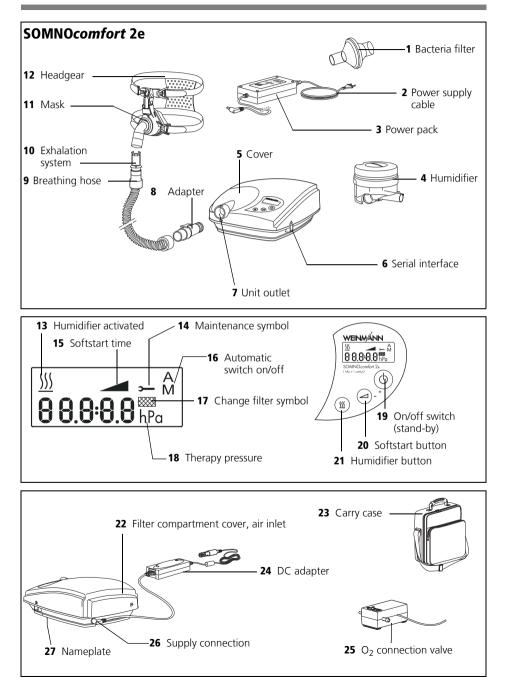
**CPAP** unit

SOMNOcomfort 2e SOMNOcomfort 2e with SOMNOaqua

Description of the equipment and instructions for use



# **Overview**



## Legend

#### 1 Bacteria filter

Used to protect the patient from bacteria, particularly if the unit is being used by a number of patients.

#### 2 Power supply cable

Connects the power pack to the power supply.

#### 3 Power pack

Used to supply power to the unit.

#### 4 Humidifier

Used to heat and humidify the air flow created by the therapy unit.

## 5 Cover

Connects the unit outlet with the humidifier connection. Is required if a humidifier is not being used.

## 6 Serial interface

Connects the therapy device to devices for setting and evaluating therapy data or to the  $O_2$  supply valve.

## 7 Unit outlet

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

## 8 Adapter

Connects the breathing hose to the unit outlet.

#### 9 Breathing hose

The air flows through the breathing hose to the mask.

#### 10 Exhalation system (accessory)

Exhalation air containing carbon dioxide is diverted here during the therapy.

#### 11 Mask (accessory)

The mask is used to provide the patient with air at the required therapy pressure.

## 12 Headgear (accessory)

Helps locate the mask correctly and securely.

## 13 Humidifier activated

This symbol appears when the humidifier is in operation. The current humidity level is displayed.

## 14 Maintenance symbol

This symbol appears every 10,000 operating hours. The unit must then be serviced.

#### 15 Softstart time

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

## 16 Automatic switch on/off

The symbol "A" (automatic) appears when the Automatic switch on/off is active. The symbol "M" (manual) appears when the Automatic switch on/off is inactive.

#### 17 Change filter symbol

Faded in when a filter change is required.

## 18 Therapy pressure

The therapy pressure is shown in hPa (hectoPascal). 1 hPa = 1 mbar = 1 cm  $H_2O$ .

## 19 On/off switch (stand-by)

Switches the therapy unit on and off.

## 20 Softstart button

Activates the softstart or sets the softstart time (5 - 30 minutes in 5 minute steps)

#### 21 Humidifier button

Activates the humidifier or sets the humidifier level (6 levels).

## 22 Filter compartment cover, air inlet

Covers and securely locates the coarse and fine dust filters.

#### **23 Carry case** For carrying the therapy unit.

24 DC adapter (accessory)

For operating the therapy unit via a DC socket (12 - 24 V).

#### **25 O<sub>2</sub> connection valve** (accessory) For introducing oxygen into the mask.

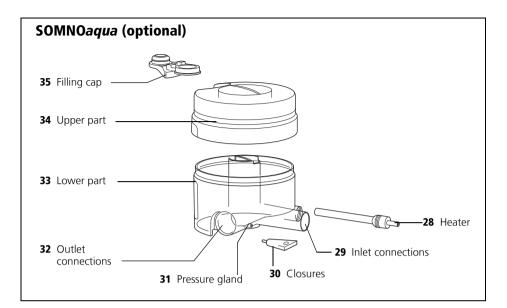
For introducing oxygen into the m

## 26 Supply connection

This is the connection for the external power pack or DC adapter.

## 27 Nameplate

Provides information about the unit, e.g. serial number and year built.



## Legend

#### 28 Heater

Heats the water in the humidifier. This humidifies the air.

#### 29 Inlet connections

The air flows from the therapy unit into the humidifier.

#### 30 Closures

Used to shut off the pressure gland during preparatory hygienic operations.

#### 31 Pressure gland

Measures the present therapy pressure.

#### 32 Outlet connections

The humidified air flows from here through the unit outlet into the breathing hose.

#### 33 Lower part

Holds approx. 300ml water.

## 34 Upper part

Closes the humidifier, contains the filling cap.

## 35 Filling cap

For filling the humidifier.

# Special markings on the unit

Symbol	Meaning			
SOMNOcomfort	SOMNOcomfort 2e:			
ß	Unit inlet: allows air at room temperature to enter			
	Unit outlet: air escapes with 4 - 20 hPa			
Side connection socket: Connection for setting the therapy parameters with SOMN WM 23930 and WEINMANNsupport WM 93305 by special to control the O <sub>2</sub> connection valve, WM 24042. Max. curre consumption 163 mA.				
SOMNO <i>aqua</i> (o	pptional)			
R	Do not use the humidifier on patients whose airways have been bypassed			
555	Unit is heated! Do not touch the heater rod.			
Signs on the ur	iit:			
М	Year built			
Ŕ	Unit type B			
×.	Do not dispose of unit as domestic waste			
SN	Serial number of the unit			
	Type of protection against electric shock: unit of protection class II			

Symbol	Meaning	
CE 0197	CE 0197 symbol: confirms that the product conforms to the applicable European directives.	
IPX1 Protection against ingress of water (drips)		

# Markings on the packaging

Symbol	Meaning		
-40 °C	Permitted storage temperature: -40°C to +70°C		
CE 0197	CE 0197 symbol: confirms that the product conforms to the applicable European directives.		
<b>%</b> 0-95 %	Permitted storage humidity: max. 95% relative humidity.		
Ť	Protect device from wet		
	Fragile		

1.	Desc	ription of Equipment8
	1.1	Intended use SOMNOcomfort 2e8
	1.2	SOMNO <i>aqua</i> intended use8
	1.3	Functional description
		SOMNOcomfort 2e9
	1.4	Functional description SOMNOaqua10
2.	Safe	ty Instructions11
	2.1	Safety instructions11
	2.2	Contraindications
	2.3	Side effects14
3.		p of Equipment15
	3.1	Setting up and connecting the SOMNOcomfort 2e15
	3.2	Fitting the mask16
	3.3	Filling and connecting the SOMNOagua16
	3.4	Accessories
4.	Оре	ration
	4.1	Automatic switch on/off19
	4.2	SOMNOcomfort 2e startup 20
	4.3	SOMNOaqua setting20
	4.4	Softstart setting
	4.5	After usage
	4.6 4.7	Read off therapy duration 23 Travelling with therapy units 24
-		5 15
5.	<b>нуд</b> і 5.1	enic preparation25 Intervals
	5.2	Cleaning SOMNOcomfort 2e25
	5.3	Cleaning the SOMNOaqua28
	5.4	Descaling the SOMNOaqua29

	5.5	Disinfecting the
		SOMNOcomfort 2e 29
	5.6	Disinfecting the SOMNOaqua . 30
	5.7	Multiple patient use SOMNOcomfort 2e 30
	5.8	Multiple patient use SOMNOaqua31
6.	Func	tional checks
	6.1	Intervals
	6.2	Function check of SOMNOcomfort 2e 32
	6.3	Function check of SOMNO <i>aqua</i>
7.	Malf	unctions and Rectification34
	7.1	SOMNOcomfort 2e 34
	7.2	SOMNOaqua 35
8.	Mair	ntenance
	8.1	Intervals
	8.2	Maintenance includes the following:
9.	Disp	osal
10	- Scon	e of supply
10.		Standard scope of supply 38
		Accessories and spare parts 38
11.		nical data
		Specifications
		Pneumatic diagram 43
	11.3	Safety distances
12.	Warı	anty44
13.	Decl	aration of conformity45
13.	Inde	x

7

# **1. Description of Equipment**

# 1.1 Intended use SOMNOcomfort 2e

SOMNO*comfort* 2e is a CPAP unit (CPAP = Continuous Positive Airway Pressure) used to treat sleep-related breathing disorders in patients from the age of 12 years.

No special knowledge or training is required in order to use the unit. All that is required is instruction by a clinic or a medical practitioner.

#### Important!

SOMNO*comfort* 2e can only reliably prevent airway closure when the CPAP pressure prescribed by a doctor for the specific patient has been calculated, e.g. in a sleep laboratory.

SOMNOcomfort 2e is not designed for life support.

Only use the unit for the purposes described below.

# 1.2 SOMNOaqua intended use

The SOMNOaqua humidifier is an optional accessory for the Weinmann SOMNOcomfort 2e therapy unit.

The SOMNOaqua humidifier is used to heat the air flow created by the SOMNOcomfort 2e and to increase its humidity. This will prevent the patient's upper airways drying out during the therapy.

SOMNO*aqua* can only be used with the SOMNO*comfort* 2e therapy unit. Operation with third-party devices is not permitted.

Only use the unit for the purposes described below.

8

# **1.3 Functional description SOMNO***comfort* **2**e

SOMNO*comfort* 2e operates according to the principle of an electrically driven flow generator, with the pressure level being controlled electronically.

- A fan draws in ambient air via a filter and conveys it to the unit outlet. From here the air flows through the breathing hose and the mask to the patient.
- A pressure sensor measures the pressure at the unit outlet and shows this in the display. The microprocessor-controlled flow generator controls the pressure to the set value and reduces fluctuations in pressure caused by breathing.
- A softstart automatic system is installed to help the patient fall asleep more easily. When the unit is switched on, the CPAP pressure starts at the initial pressure selected by the doctor and is then slowly increased to the setpoint pressure selected. The time of the pressure increase can be adjusted between 5 and 30 minutes in 5-minute increments.
- Automatic switch on/off can be activated on SOMNOcomfort 2e. The unit can then be switched on by breathing into the mask. If there is no pressure for approx. 15 seconds (e.g. because the mask has been removed), SOMNOcomfort 2e will switch off automatically.
- The therapy parameters are adjusted using the SOMNOadjust remote control system or the WEINMANNsupport evaluation program.
- SOMNO*comfort* 2e automatically saves all settings in the event of a power failure. This means that the unit does not need to be reset when power is restored.

# 1.4 Functional description SOMNOaqua

The humidifier works on the so-called overflow principle. The air coming from the therapy unit passes over the surface of a heated water tank, increasing the relative humidity and the temperature of the air flow. The amount of humidity released can be adjusted using the buttons on the Weinmann therapy unit. The output of the heater rods and consequently the temperature of the water in the humidifier chamber is controlled electronically by the Weinmann unit.

The water level can be checked whenever required through the window in the humidifier chamber.

# 2. Safety Instructions

Please read these operating instructions through carefully. They form part of the equipment and should be available at all times.

For your own safety, the safety of your patients, and to comply with the requirements of EU Directive 93/42/EEC, please observe the following points.

# 2.1 Safety instructions

## **Operating the unit**

## Caution!

- The power pack supplied allows the unit to be operated at voltages between 115 V and 230 V. Check that your supply voltage falls within this range. With a 12 V DC or 24 V DC supply, use the WM 24469 DC adapter available as an accessory.
- Do not cover the unit or power pack. Do not use in the vicinity of a heater or in direct sunlight. The unit may overheat, resulting in insufficient therapy delivery and damage to the unit.
- Maintain a safe distance between the SOMNOcomfort 2e and equipment that emits HF radiation (e.g. mobile phones). This unit may otherwise malfunction (see page 43). If the SOMNOcomfort 2e interferes with other devices (e.g. a radio), move the SOMNOcomfort 2e further away.

#### Caution!

- Do not use the therapy unit or humidifier if the unit is malfunctioning, parts are damaged and/or the contact between the humidifier and the heater rod is damp.
- The performance of the humidifier can be affected if it is used outside the permitted temperature range.
- Observe the operating instructions for your mask.
- Please observe the section "5. Hygienic preparation" on page 25 to avoid infection or bacterial contamination.

## Transport/Accessories/Spare Parts/Repair

## Caution!

- Do not transport (or tilt) the SOMNOcomfort 2e with the humidifier installed. Tilting might cause water remaining in the humidifier to run into the SOMNOcomfort 2e and damage it.
- Only have checks and repair work carried out by Weinmann or specialist staff.
- 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.

## Caution!

- Modifications to the SOMNOcomfort 2e and SOMNOaqua are not permitted.
- Third-party masks may only be used after being approved by Weinmann. Using unapproved masks may result in unsuccessful therapy.
- Please make sure that the accessories you use are complete and are suitable for the therapy. This particularly applies to the exhalation system. The CO<sub>2</sub> content of the exhaled air may otherwise adversely affect your breathing.

## Oxygen supply

## Warning!



Do not smoke or use open fires if oxygen is being used during therapy. **There is a risk of fire!** The oxygen may be deposited in clothing, bed linen or in your hair. It can only be removed by ventilating the room thoroughly.

## Caution!

- An oxygen supply is only permitted if the WM 24042 O<sub>2</sub> connection valve is used.
- As regards oxygen, please make sure you observe the safety instructions included in the instructions for your oxygen system.

# 2.2 Contraindications

The SOMNOcomfort 2e should not be used with certain diseases or only with particular caution. In each case the decision whether to use SOMNOcomfort 2e for therapy lies with the doctor in charge.

This includes:

- cardiac decompensation
- severe cardiac dysrhythmia
- severe hypotension, particularly in conjunctions with intravascular volume depletion
- Severe epistaxis
- high risk of barotrauma
- ventilatory insufficiency due to a cause other than OSA
- nocturnal hypoxaemia of an origin other than OSA (obesityhypoventilation syndrome)
- pneumothorax or pneumomediastinum
- pneumo-encephalus
- cranial trauma
- status after brain operation and surgical procedure performed on hypophysis or on middle or inner ear
- acute sinusitis, inflammation of the middle ear (otitis media) or eardrum perforation
- dehydration

Threatening situations were not observed with SOMNOcomfort 2e.

When using SOMNOcomfort 2e the following undesirable side effects may occur during short-term and long-term usage:

- pressure points on the face caused by the mask and the forehead padding;
- reddening of the skin on face;
- nasal congestion;
- dry nose;
- dry mouth in morning;
- feeling of pressure in sinuses;
- irritation of conjunctiva of eyes;
- gastrointestinal insufflation of air ("bloated stomach");
- nosebleeds.

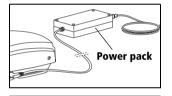
# 3.1 Setting up and connecting the SOMNOcomfort 2e

1. Set up the unit on a flat surface, e.g. on the bedside cabinet or on the floor next to the bed.

## Caution!

Do not cover the unit or power pack. Do not use in the vicinity of a heater or in direct sunlight. The unit may overheat, resulting in insufficient therapy delivery and damage to the unit.

2. Plug the power supply cable into the supply connection of the SOMNO*comfort* 2e. Then plug the power pack into a socket outlet (using the power supply cable).

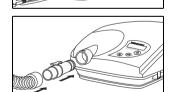


DC adapter

The power pack automatically determines the appropriate mains voltage (115 V - 230 V).

The display shows "0" for standby, together with "**A**" or "**M**" according to the appropriate setting on the automatic on/off switch

3. If SOMNOcomfort 2e is to be operated with a voltage of 12 or 24 V DC, connect the WM 24469 DC adapter (available as an option) instead of the power pack.





- 4. Plug the breathing hose into the socket outlet adapter.
- 5. Lock the cover by pushing the breathing hose adapter into the unit outlet until it latches in place.

#### Note

• The device automatically compensates for differences in air pressure (e.g. as a result of great altitude).

# 3.2 Fitting the mask

- 1. Adjust the forehead support of the mask (if present).
- 2. Connect the headgear to the mask.
- 3. Position the mask.
- 4. Adjust the headgear so that the bulge of the mask only results in low pressure to prevent pressure points on the face.

For further instructions, please refer to the operating instructions for the relevant mask.

# 3.3 Filling and connecting the SOMNOaqua

## Before using for the first time

Before using for the first time, rinse the humidifier with copious amounts of water (see "5. Hygienic preparation" on page 25).

## Filling the humidifier

## Caution!

- Never overfill the humidifier, otherwise water may enter the therapy unit and damage it.
- Do not fill the humidifier when it is connected to the therapy unit, otherwise water may enter the therapy unit and damage it.
- Do not fill the humidifier with hot water as this may damage the housing and heater rod, resulting in incorrect operation and insufficient therapy delivery.

Note

• The use of aromatic additives, such as eucalyptus oil, may damage the plastic parts of the humidifier.

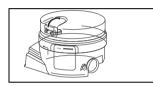


- 1. Open the filling cap of the humidifier.
- 2. Fill the humidifier up to the mark "max \_\_\_\_\_" with distilled water.

If no distilled water is available, low calcium boiled water can be used instead (but not as a rule!). Check that the heater rod does not scale up (see "5.4 Descaling the SOMNOaqua" on page 29).

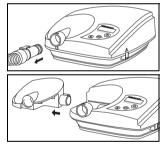
3. Firmly close the humidifier with the filling cap.

4. After filling, check that the humidifier is not leaking.



# Adapting the humidifier

Run your finger over the bottom of the humidifier or place the humidifier on a piece of kitchen paper. Any escaping water will then be easy to spot.



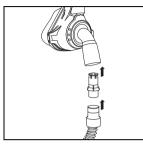
- 1. If necessary, detach the breathing hose from the therapy unit by pushing in the catch on the adapter. Pull the breathing hose and adapter off the unit outlet.
- 2. Push the cover sideways out of the humidifier stub on the therapy unit.





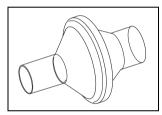
- 3. Push the filled humidifier as far as it will go into the stub on the unit.
- 4. Insert the breathing hose adapter into the outlet of the therapy unit. Check that the locking catch is pointing upwards and has latched into the groove in the unit outlet.

## **External exhalation system**

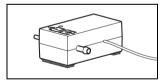


Should the unit fail, the exhalation system enables you to breath through the nose or mouth. Full-face masks must also be fitted with a safety valve. Remove the mask as quickly as possible. First check whether there has been a power failure. Follow the instructions for use of your exhaled air system.

## **Bacteria filter**



## **Oxygen supply**



If SOMNOcomfort 2e is to be used by several patients (e.g. in a hospital), a bacteria filter should be used to protect against infection. It is installed between the breathing hose and the adapter. Using a bacteria filter can reduce the pressure and flow rate.

Follow the manufacturer's instructions carefully, especially with regard to the use-by date of the bacteria filter.

For safety reasons (risk of fire) the direct introduction of oxygen into the breathing hose or the mask without any special protective device is not permitted. However, the supply of up to 4 l/min oxygen to the breathing mask is possible when using the oxygen connection valve WM 24042.

An oxygen concentrator (e.g. Oxymat), liquid oxygen or an oxygen cylinder with a suitable pressure reducer may be used. This application must be prescribed by the doctor in charge. To prevent oxygen entering the therapy unit, the SOMNOcomfort 2e automatically generates a therapy pressure of at least 5 hPa when an oxygen connection valve is attached. You must under all circumstances follow the safety instructions for handling oxygen as well as the operating instructions for the oxygen valve and the oxygen unit used.

# 4. Operation

## 4.1 Automatic switch on/off

## Activate automatic mode

## M = manual

## A = automatic

- 1. With the SOMNO*comfort* 2e switched off, press the softstart button until the current setting "**M**" starts to flash in the display.
- 2. Press the on/off switch to change the setting to "A".

If a button is not pressed for 5 seconds, the current setting is saved.

When the automatic system is activated, you can switch SOMNOcomfort 2e on and off using the on/off switch **or** using the pressure available in the mask.

- SOMNOcomfort 2e is switched on automatically as soon as the patient breathes into the mask (pressure > 0.5 hPa).
- If the mask is removed, the unit will switch off after approx. 15 seconds.

#### Note:

If the JOYCE Full Face mask is used, the device does not switch on/off automatically, even if setting "A" is selected. The emergency exhalation valve of the mask means that the device cannot detect the pressure change required for switching.

## Switch off automatic system

## M = manual

## A = automatic

- 1. With the SOMNO*comfort* 2e switched off, press the softstart button until the current setting "**A**" starts to flash in the display.
- 2. Press the on/off switch to change the setting to " $\mathbf{M}$ ".

If a button is not pressed for 5 seconds, the current setting is saved.

When the automatic system is switched off, you can only switch SOMNO*comfort* 2e on and off using the on/off switch.

If the unit is not used for 15 minutes, it switches off automatically.

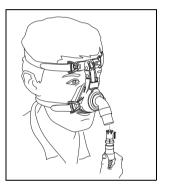
# 4.2 SOMNOcomfort 2e startup

Always use an exhalation system. The exhalation system allows the used air containing carbon dioxide ( $CO_2$ ) to escape from the mask. Without an exhalation system the  $CO_2$  concentration would rise to critical values in the mask and hose, thus hindering your breathing.

The exhalation system must always be installed in the immediate vicinity of the mask.

An exhalation system is already incorporated in some mask systems. In this case no separate exhalation system is required. Please refer to the operating instructions for the relevant mask.

1. If the mask has no integrated exhalation system, place the exhalation system on the end of the breathing hose.



2. Connect the breathing hose including exhalation system to the mask (plug cone). Please follow the relevant operation instructions for the mask and exhalation system.

Feed the breathing hose away from your head. Never place the breathing hose around your neck.

3. Press the on/off switch. If the automatic system is activated, you can also switch on SOMNOcomfort 2e with a breath.

The therapy period will appear for approx. 3 seconds in the display. The flow generator starts to convey air through the breathing hose.

If softstart has been preselected, the softstart display will then light up and the softstart time will appear in the display.

SOMNOcomfort 2e is now ready for operation.

# 4.3 SOMNOaqua setting

## Switching on the humidifier

- 1. Fill up the humidifier and set up as described in "3.3 Filling and connecting the SOMNOaqua" on page 16.
- 2. Switch on the therapy unit.



3. Press the humidifier button <u>∭</u> on your therapy unit. The humidifier symbol <u>∭</u> and the humidification level display (level 4 in this case) are shown in the display of the therapy unit.

## Setting the heating level

1. Make sure your therapy unit is switched on.



- 2. Press the humidifier button <u>SM</u> for approx. 3 seconds until the number and the humidifier symbol <u>SM</u> start to flash.
- 3. Release the humidifier button  $\underline{\$\$}$ .
- 4. Now select the heating level (1-6) using the on/off switch (+) or the softstart button (-).

The displayed value is saved after 4 seconds.

Which is the best setting for you will depend on the room temperature and the air humidity. The optimum setting will therefore vary depending on the time of year. Heating level "3" is fine under "normal" conditions.

If the temperature is  $23^{\circ}$ C and air humidity 70%, a humidity of 100% can be reached with heating level 6 and a flow rate of 20 l/min.

If your airways are dry when you wake up, the heating level is too low. Choose a higher setting in this case.

If condensation forms in the breathing hose during a night therapy session, the heating level is too high. Choose a lower heating level.

## Switching off the humidifier

There are two ways of switching off the humidifier:

- press the humidifier button <u>S</u> of the sleep apnoea unit. The humidifier symbol <u>S</u> in the display of the sleep apnoea unit goes out. The therapy unit remains switched on.
- Press the on/off switch on your therapy unit. The humidifier is switched off at the same time as the therapy unit.
   When you switch the therapy unit on again, the humidifier is also switched on automatically and runs at the heating level of the previous therapy session.

## Automatic switch-off at low levels

If the therapy unit detects that there is not enough liquid in the humidifier, it switches the humidifier off within 15 minutes. The humidifier symbol <u></u>III in the display goes out.

# 4.4 Softstart setting

The softstart time can be selected in 5-minute increments up to a maximum of 30 minutes. Proceed as follows:

- 1. Switch on SOMNO*comfort* 2e and press the softstart button ∠. Hold the button down until the display for the softstart time flashes.
- 2. Now select the softstart time (5-30 minutes in 5-minute increments) using the on/off switch (+) or the softstart button (-).

If a button is not pressed for 4 seconds, the displayed softstart time will be saved and the display stops flashing.

The softstart settings are saved when the unit is switched off. Whenever SOMNOcomfort 2e is started up, it automatically starts in softstart mode if this was switched on.

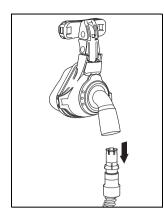
Softstart can be switched on and off at any time by pressing the softstart button  $\square$ .

# 4.5 After usage

- 1. Remove the headgear with the mask.
- 2. Press the on/off switch to switch off the unit. If the automatic system is selected, the unit switches off automatically after approx. 15 seconds.



The daily therapy duration of the last session is shown on the display. Then "0" and "A" or "M" are displayed.



- 3. Remove the tube connection and the exhalation system from the mask.
- 4. Clean the mask and the exhalation system (see "5. Hygienic preparation" on page 25).

#### Note

SOMNOcomfort 2e and the power pack consume approx. 4 watt in standby mode. The unit does not have a mains switch. To save electricity you can remove the power plug from the outlet socket during the day. It is therefore advisable to connect the unit to a readily accessible socket. The stored values and settings will not be lost.

# 4.6 Read off therapy duration

SOMNOcomfort 2e saves the data from 366 days and the associated therapyduration. You can display the following values:

- Total therapy duration in hours
- Average therapy duration per day
- Therapy duration of current day including date

## Note:

A **therapy day** always starts and ends at 12 noon. Data recorded between midnight and 12 noon is allocated to the previous **day**.

The total therapy duration is always shown for a few seconds when the unit is **switched on**. When **switching off** the therapy duration for the current day is displayed.

To read off further data, proceed as follows:

- 1. When switching off the unit hold down the on/off switch for approx. 4 seconds until the average therapy duration per day is displayed.
- 2. Release the on/off switch. The average therapy duration per day and the total therapy duration are each displayed for 5 seconds. The current date and the therapy duration for the day then flash up alternately.
- 3. The daily therapy duration for previous days can now be displayed.

Press the softstart button until the required date appears in the display.

You can also simply press and hold the softstart button, releasing it when the desired date is displayed.

Use the on/off switch in the same way to return to the current date.

If a button is not pressed for 10 seconds, the total operating time will appear for 3 seconds. This display then disappears and "0" reappears in the display.

# 4.7 Travelling with therapy units

To transport the therapy unit over long distances, it should be packed in the carry case (included with the unit).

- 1. Place the unit, the power pack, the power cable, the breathing hose, the mask incl. exhalation system and, if necessary, the humidifier in the carry case.
- 2. Close the zips of the carry case and adjust the shoulder strap to the correct length.

## Important!

Please do not forget to take spare filters and the operating instructions with you, as well as the DC adapter if necessary. If you want to take the therapy unit as hand luggage in an aircraft, you should find out any formalities necessary from the airline before departure.

# 5. Hygienic preparation

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.

## 5.1 Intervals

- Clean the mask and exhalation system every day in accordance with the operating instructions. Replace both parts every 12 months.
- Check the filters regularly:
  - clean the coarse dust filter once a week and replace it at least every 6 months.
  - change the fine filter depending on the level of soiling, however at least every 250 hours or once a month (filter change indicator).
- Regularly wipe clean the housing of the SOMNOcomfort 2e and the power pack.
- The breathing hose should be cleaned according to the level of soiling, however at least once a month. Replace it every 12 months.
- Wash the headgear once a week and replace it every 12 months.
- Clean the humidifier every day.

# 5.2 Cleaning SOMNOcomfort 2e

## **Cleaning the breathing hose**

- 1. Detach the breathing hose from the unit and from the exhalation system.
- 2. Clean the creased hose so no residues remain with a small amount of detergent in warm water. Rinse the inside of the hose thoroughly.
- 3. Then rinse thoroughly both inside and outside using clean, warm water.

## Important!

- 4. Shake the breathing hose thoroughly.
- 5. Hang up the hose and allow to drip to prevent moisture from getting into the SOMNOcomfort 2e.

The breathing hose is dried completely with the help of SOMNOcomfort 2e.

- 6. If necessary, remove the humidifier and fit the cover.
- 7. Insert the breathing hose adapter into the unit outlet.
- 8. To start the drying process, press the softstart button (SOMNOcomfort 2e switched off) and the on/off switch.

The unit will now switch on and dry the breathing hose (this takes 30 minutes). The remaining time is displayed. It switches off automatically at the end of the drying process.

You can interrupt the process at any time by pressing the on/off switch. If the breathing hose is still damp in places after drying, start the drying process again.

## Cleaning the SOMNOcomfort 2e-housing

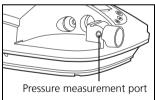
## Warning!



Electric shock! Before cleaning, remove the power supply cable from the supply connection.

Make sure no liquid gets into the housing. Never immerse the unit in disinfectant or any other liquid. This can damage the unit and consequently endanger users and patients.

## Caution!



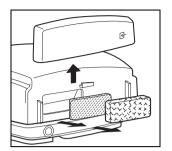
• Make sure no liquid gets into the housing via the pressure measurement port. This may cause the unit to malfunction.

Insert the red closure in the pressure gland in the cover.

Wipe down the unit, the cover, the power pack and the power supply cable with a damp, soft cloth.

The SOMNOcomfort 2e must be completely dry before starting up.

## Cleaning the coarse dust filter/changing the fine filter



- 1. Remove the filter compartment cover on the rear of the unit.
- 2. Remove the coarse dust filter and clean under clear running water until no residues remain.
- 3. Replace the fine filter if necessary, as it cannot be cleaned.
- Let the coarse dust filter dry.
  Before start up, the coarse dust filter must be completely dry.
- 5. Replace the coarse dust filter and close the cover on the rear of the unit.

## Clear the filter change indicator:

When switching on the unit, press the on/off switch until the filter change indicator goes blank.

## **Reset the hours meter**

If the fine filter was changed due to soiling before 250 operating hours, the hours meter must be reset to zero. Proceed as follows:

1. When switching on the unit, press and hold the on/off switch.

The filter change indicator will come on after about three seconds before going off again after another three seconds.

2. Release the on/off switch.

## Accessories

To clean the exhalation system, the mask and the headgear, please see the section "Cleaning" in the relevant operating instructions.

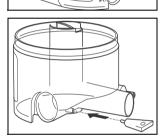
# 5.3 Cleaning the SOMNOaqua

1. Unlock the SOMNO*aqua* by taking the hose adapter out of the unit outlet. Now push the SOMNO*aqua* to the left off the humidifier stub.

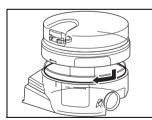


Do **not** touch the heater rod. The metal takes a long time to cool down.

2. Open the humidifier by turning the upper part anticlockwise.



- 3. Place the red closure over the pressure gland.
- Clean the upper and lower parts with lukewarm water to which a little detergent has been added. We recommend that you clean the housing components once a week in the upper basket of a dishwasher at a maximum temperature of 65 °C.
- 5. Then rinse the parts in clean water.
- 6. Vigorously shake the lower part to remove any water that may have entered the heater rod contact. Dry the parts thoroughly with a soft cloth. The heater rod contact must be dry.



- 7. Fit the upper and lower parts together such that the marks are aligned. Turn the upper part clockwise as far as it will go.
- 8. Remove the closure.

The humidifier is now ready for use again.

For hygiene reasons, we recommend that the plastic parts are replaced after a maximum of two years use.

# 5.4 Descaling the SOMNOaqua

If the lower part of the housing and the heater rod are covered in scale:

- 1. Pour about 150 ml of normal vinegar (5% solution without additives) into the lower part of the humidifier and leave to stand for one hour.
- 2. Pour out the vinegar solution.
- 3. Wipe the housing parts with a clean cloth and rinse thoroughly several times with water.
- 4. Finally, dry all parts carefully.

# 5.5 Disinfecting the SOMNOcomfort 2e

If necessary, for example after an infectious illness or if the unit has become unusually contaminated, you can also disinfect the housing, the power supply cable, the breathing hose, and the humidifier. Please observe the operating instructions for the disinfectant used. We recommend that you wear suitable gloves when disinfecting the equipment (e.g. household or disposable gloves).

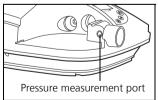
## Unit

## Warning!



- Electric shock! Before cleaning, remove the power supply cable from the supply connection.
- Make sure no liquid gets into the housing. Never immerse the unit in disinfectant or any other liquid. This can damage the unit and consequently endanger users and patients.

## Caution!



• Make sure no liquid gets into the housing via the pressure measurement port. This may cause the unit to malfunction.

The housing, power pack and power supply cable of the SOMNOcomfort 2e are cleaned by being simply wiped over with disinfectant.

## **Breathing hose**

- When disinfecting use the same procedure as for cleaning.
- The breathing hose must not be heated to temperatures in excess of 70 °C. Sterilisation is not permitted.

## Accessories

To disinfect or sterilise the exhalation systems and the mask, please see the section "Disinfection and Sterilisation" in the relevant operating instructions.

# 5.6 Disinfecting the SOMNOaqua

The humidifier can be disinfected. Please observe the operating instructions for the disinfectant used. We recommend that you wear suitable gloves when disinfecting the equipment (e.g. household or disposable gloves).

• The procedure for dismantling and assembling the humidifier is the same as for cleaning.

For hygiene reasons, we recommend that the plastic parts are replaced after a maximum of two years use.

# 5.7 Multiple patient use SOMNOcomfort 2e

If the unit is to be utilised for another patient without using a bacteria filter, it must undergo a hygiene treatment beforehand. This has to be carried out by Weinmann or a dealer.

The procedure used for the hygiene treatment is described in the inspection sheet and the service and repair instructions for SOMNO*comfort* 2e.

# 5.8 Multiple patient use SOMNOaqua

If the SOMNO*aqua* is to be utilised for another patient without using a bacteria filter, it must undergo a hygiene treatment beforehand. This should be carried out by an authorised dealer.

The procedure used for the hygiene treatment when there is a change in patient is described in the service and repair instructions for the SOMNO*comfort* 2e.

# 6. Functional checks

# 6.1 Intervals

Carry out a functional check on the SOMNO*comfort* 2e and the SOMNO*aqua* at least every 6 months.

If you find a defect during the functional check, do not use the unit until the defect has been remedied.

# 6.2 Function check of SOMNOcomfort 2e

- 1. Assemble SOMNOcomfort 2e with the breathing hose, exhalation system, mask and power supply cable ready for operation.
- 2. Press the on/off switch to switch on the unit. If softstart is switched on, switch it off with the softstart button. The fan conveys air through the breathing hose to the mask and the current pressure in hPa is shown in the display.
- 3. Close the opening of the mask, e.g. using your thumb or hand.

Compare the pressure shown on the display with the CPAP pressure prescribed. There should only be a divergence of max.  $\pm 1$  hPa.

4. Press the softstart button to switch on softstart. The softstart display appears and the display shows the softstart time.

The pressure increases slowly and reached the CPAP pressure after the time selected. The CPAP pressure is then shown on the display.

5. Switch off the unit using the on/off switch.

If the valves or functions are not fulfilled, please send in the unit for repair to the dealer or the manufacturer.

# 6.3 Function check of SOMNOaqua

- Perform a visual inspection of the plastic housing.
  If cracks/damage or severe soiling is evident, the plastic parts or seals must be replaced.
- 2. Fill the humidifier up to the mark with water.
- 3. Check whether the humidifier is leaking.
- 4. Empty the water.
- 5. Now pour in about 50 ml of water.
- 6. Connect the humidifier to the therapy unit.
- 7. Lock the humidifier by putting the breathing hose adapter into the unit outlet.
- 8. Switch on the therapy unit.
- 9. Switch the humidifier on by pressing the humidifier button  $\underline{\mathfrak{M}}$  on the therapy unit.
- 10. Set heater level 6 on the therapy unit.
- 11. Check whether the humidifier is getting warmer.

If the water has not heated up after 15 minutes, send the humidifier and the therapy unit for repair to the dealer or the manufacturer.

# 7. Malfunctions and Rectification

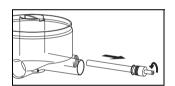
If there are defects which cannot be rectified at once, please contact Weinmann or your dealer immediately to have the unit repaired. To avoid greater damage, do not use the unit.

# 7.1 SOMNOcomfort 2e

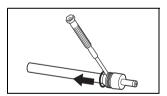
Malfunctions	Cause	Rectification
No running noise, standby/status display not illuminated.	No supply voltage available	Check power supply cable is securely connected. Possibly check function of outlet by connecting another piece of equipment (e.g. a lamp).
Unit cannot be switched on by breathing.	Automatic switch on/ off not activated	Activate automatic switch on/off (4.1, page 19).
Unit does not switch off after approx.15 seconds once mask is removed.		Activate automatic switch on/off (4.1, page 19).
Unit is running but	Filter soiled	Clean/change filter (5.2, page 25).
does not reach CPAP pressure level selected.	Mask not airtight	Adjust headgear so that mask is airtight. Replace mask if defective.
Filter change indicator 🖾 lights up.	Filter soiled	Clean/change filter (5.2, page 25).
Error message "Err E", "Err b", "Err c", "Err A", "Err H" or "Err S" in display.	Problems with electronics or program "crashed"	Disconnect power and reconnect.
Service indicator 🔧 lights up.		Unit must be checked or serviced by Weinmann or a dealer as soon as possible.

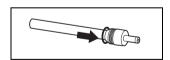
Malfunctions	Cause	Rectification
Humidifier does not	Humidifier is not activated.	Switch on the air humidifier, see 4.3, page 20.
warm up.	Electronics defect.	Send the humidifier and the therapy unit to your dealer for repair.
	The heater rod seal is defective.	Replace the seal, see page 35.
The humidifier is leaking.	The seal on the underside of the housing is leaking.	Replace the seal, see page 36.
	Cracks in lower part.	Replace the lower part.

## **Replacing the heater rod seal**



1. Remove the heater rod from the lower part of the housing by turning anti-clockwise.



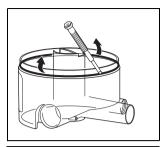


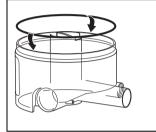
2. Using a small, clean screwdriver, carefully prise out the seal.

## Important!

Take care to ensure that the groove in which the seal fits is not damaged.

- 3. Carefully press the new sealing ring into the groove on the heater rod. Under no circumstances use a tool.
- 4. Fit the new heater rod.





## Replacing the housing lower part seal

- 1. Open the humidifier by twisting the upper and lower parts against each other in an anti-clockwise direction.
- 2. Carefully take the sealing ring out of the groove in the lower part of the unit.

## Important!

Take care to ensure that the groove in which the seal fits is not damaged.

3. Carefully press the new sealing ring into the groove in the lower part of the unit. Under no circumstances use a tool.

4. Join the upper and lower parts together again.

Regular maintenance should be carried out as a preventive measure. Please adhere to the stipulated intervals.

### 8.1 Intervals

- Every 10,000 operating hours (maintenance symbol appears in display)
- Every 4 years at the latest (see maintenance sticker on rear of unit)

### 8.2 Maintenance includes the following:

- Filter change
- Hygienic preparation of the unit
- Replacement of any defective parts
- Complete check of unit functions

# 9. Disposal



To dispose of the unit properly, please contact a licensed and certified electronic waste disposal merchant. Names and addresses can be obtained from your Environmental Officer or municipal authorities. The unit packaging (cardboard box and inserts) can be disposed of as waste paper.

#### 10.1 Standard scope of supply

#### SOMNOcomfort 2e

#### WM 24405

Parts	Order number		
SOMNOcomfort 2e basic unit	WM	24415	
Breathing hose	WM	24445	
Power pack	WM	24480	
Power supply cable	WM	24133	
Operating instructions SOMNOcomfort 2e + SOMNOaqua	WM	16894	
Carry case	WM	24449	
Cleaning plug	WM	24451	
Sleep apnea patient record	WM	16162	
Set of spare filters	WM	15499	

#### SOMNOcomfort 2e with SOMNOaqua

#### WM 24455

Parts	Order number	
SOMNOcomfort 2e	WM	24405
SOMNOaqua	WM	24403

#### **10.2 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.

### **11.1 Specifications**

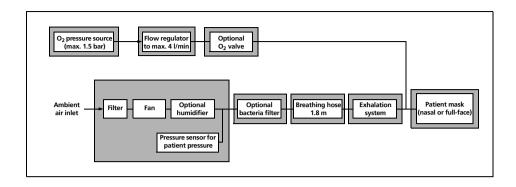
	S	OMNO <i>co</i>	mfort 2	2	SOMNOco	omfort 2e	with SO	MN0aqua
Product class as per 93/42/EEC		lla						
Dimensions WxHxD in cm		21 x 9	x 27		21 x 14 x 27			
Weight		approx.	1.7 kg		appro	x. 1.9 kg (	without	water)
Temperature range – operation – storage	+5 ° C to +35 ° C –40 ° C to +70 ° C If the unit is operated at +40 °C, the air output can heat up to 42 °C.				42 °C.			
Adm. humidity for operation and storage		$\leq$ 95 % rF (no condensation)						
Air pressure range	600 - 11	600 - 1100 hPa (allows for operation in an altitude of up to approximately 4000 meters); automatic height adjustment						
Diameter of breathing hose connection (mask) in mm	19.5 (suitable for 22mm standard cone)							
Electrical connection	100-240 V AC +10/-15 %, 50–60 Hz with WM 24480 power pack or 12-24 V DC +25/-15 % with WM 24469 DC adapter				dapter			
Power consumption during – operation – standby	<b>230 V</b> 0,1 A 0,02 A	<b>115 V</b> 0.2 A 0.03 A	<b>24 V</b> 0.9 A 0.2 A	<b>12 V</b> 1.8 A 0.24 A	<b>230 V</b> 0,23 A 0,02 A	<b>115 V</b> 0.45 A 0.03 A	<b>24 V</b> 2.0 A 0.2 A	<b>12 V</b> 4.0 A 0.24 A
Classification as per prEN 60601-1:2004 – type of protection from electric shock – level of protection from electric shock – protection against damaging ingress of water	Protection class II Type B IPX1							
- operating mode	Constant operation							

	SOMNOcomfort 2e	SOMNOcomfort 2e with SOMNOaqua	
Electromagnetic compatibility (EMC) as per EN 60601-1-2:2001	Test parameters and limit values can required.	be obtained from the manufacturer if	
– radio interference	EN 55011 B		
suppression – immunity to interference	EN 61000-4 parts 2 to 6, part 11		
Mean sound pressure level under EN ISO 17510-1:2009	approx. 25.8 dB (A) at 10 hPa (corresponds to a sound power level of 33.8 dB (A))	approx. 26.2 dB (A) at 10 hPa (corresponds to a sound power level of 34.2 dB (A))	
CPAP operating pressure	4 tc	20 hPa	
range Pressure accuracy	±0,6 hPa (1mbar = 1 hPa ≈ 1cm H <sub>2</sub> O)		
Max. CPAP pressure with malfunction	< 40 hPA		
Maximum flow rate to			
at: 20 hPa	11	5 l/min	
15 hPa		5 l/min	
10 hPa 5 hPa	145 l/min 160 l/min		
0 hPa	175 l/min		
Tolerance	±15 l/min		
Maximum flow rate to EN ISO 17510-1:2009			
at: 4 hPa	171 l/min	166 l/min	
8 hPa	157 l/min	153 l/min	
11 hPa	143 l/min	140 l/min	
15 hPa	128 l/min	127 l/min	
18 hPa	113 l/min	112 l/min	
Heating of respiratory air	2,5 °C	depending on heating level	

	SOMNOcomfort 2e	SOMNOcomfort 2e with SOMNOaqua	
Precision of dynamic pressure (short-term precision) with 10 breaths/min to EN ISO 17510-1:2009 at 4 hPa: 8 hPa: 12 hPa: 16 hPa: 20 hPa:	$\begin{array}{l} \Delta p=0,2 \ hPa\\ \Delta p=0,2 \ hPa \end{array}$	$\Delta p = 0,2 hPa$	
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:	$\Delta p = 0,3 hPa$ $\Delta p = 0,3 hPa$ $\Delta p = 0,3 hPa$ $\Delta p = 0,3 hPa$ $\Delta p = 0,3 hPa$	$\Delta p = 0,3 hPa$	
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:	$\begin{array}{l} \Delta p=0,3 \ hPa\\ \Delta p=0,4 \ hPa \end{array}$	$\Delta p = 0,4 hPa$	
Precision of static pressure (long-term precision) to EN ISO 17510-1:2009	Δp	= 0,07 hPa	
Finefilter separation level to 1 µm to 0.3 µm	≥ 99.5 % ≥ 85 %		
Fine filter service life	$\geq$ 250 hours with normal room air		

**CE0197** Subject to design modifications 1 hPa = 1 mbar

	SOM	NOaqua		
Product class as per 93/42/EEC		ll a		
Dimensions WxHxD in mm	140 x	100 x 121		
Weight (without water)	3	00 g		
Temperature range – operation – storage	-40 ° C	to +35 ° C to +70 ° C		
Humid operation and storage		ative humidity		
Ambient pressure range		1100 hPa		
Electrical connection	24	V DC		
Power consumption	2	0 VA		
Classification as per EN 60601-1 – level of protection from electric shock	Unit	type BF		
Max. permitted capacity	30	00 ml		
Max. permitted operating pressure	20	) hPa		
Max. permitted flow (free-flowing)	190	) l/min		
Max. mask temperature	3	37°C		
Gas leakage at 20 hPa	neg	gligible		
Humidifier output at heating level 6: Flowrate = 20 l/min Flowrate = 30 l/min Flowrate = 40 l/min	7.8	3 mg/l 3 mg/l ) mg/l		
at 23° C and 65% relative humidity	0			
Pressure drop via the humidifier Flow rate = 30 l/min Flow rate = 60 l/min Flow rate = 90 l/min	On inspiration 0.2 hPa 0.7hPa 1.4 hPa	On exhalation 0.2 hPa 0.5 hPa 1.0 hPa		
	This pressure drop has no effect on therapy pressure			



### **11.3 Safety distances**

Recommended safety distances between portable and mobile HF telecommunications equipment (e.g. mobile phones) and SOMNO <i>comfort</i> 2e or SOMNO <i>aqua</i>			
Nominal output of HF equipment	Safety distance dependent on transmission frequency in m		
in W	150 kHz - 80 MHz	80 MHz - 800 MHz	800 MHz – 2.5 GHz
0.01	0.12	0.12	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.33

# 12. Warranty

- Weinmann offers a warranty that the product, when used in accordance with requirements, will remain free from defects for a period of two years from date of purchase. For products whose durability is clearly indicated as less than two years, the warranty expires on the expiration date indicated on the packaging or in the user's manual.
- Claims against the warranty can be made only when accompanied by the sales receipt, which must show salesperson and date of purchase.
- We offer no warranty in the case of:
  - Disregard of usage instructions
  - Operating errors
  - Improper use or handling
  - Third-party intervention by non-authorized persons for the purpose of device repair
  - Acts of God, e.g., lightning strikes, etc.
  - Transport damage as a result of improper packaging of returned items
  - Lack of maintenance
  - Operational and normal wear and tear, which includes, for example, the following components.
    - Filter
    - Batteries and recheargable batteries
    - Articles for one-time usage, etc.
  - failure to use original spare parts.
- Weinmann is not liable for consequential harm caused by a defect if it is not based on intention or gross negligence. Weinmann is also not liable for minor physical injury to life or limb resulting from negligence.
- Weinmann reserves the right to decide whether to eliminate defects, to deliver a defect-free item or to reduce the purchase price by a reasonable amount.
- If Weinmann rejects a claim against the warranty, it assumes no expense for transport between customer and manufacturer.
- Implied warranty claims remain unaffected by these changes.

# 13. 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

# 13. Index

Keyword:	page:
Accessories	38
Automatic switch on/off	9, 19, 20, 34
Automatic switch-on	19
Cleaning	25
Disinfection	<b>25</b> , <b>29</b>
Drying	26
exhalation	32
Exhalation system:	18, 20, 23, 25, 32
Filter	25, 34, 41
Functional Check	32
Humidifier	12, 18, 29, 38, 39
Inspection	12
Malfunctions	34
Mask	<b>16</b> , <b>20</b> , <b>22</b> , <b>23</b>
Safety instructions	11, 12
Side effects	14
Softstart	9, 20, 22, 32
SOMNOaqua	16, 20, 39
Standby mode	23
Travelling	24

#### Weinmann Geräte für Medizin GmbH+Co.KG

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## Center for Production, Logistics, Service



emergency | homecare | diagnostics