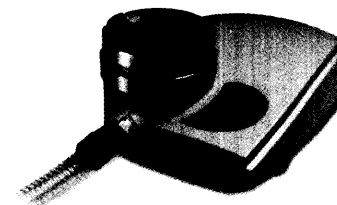
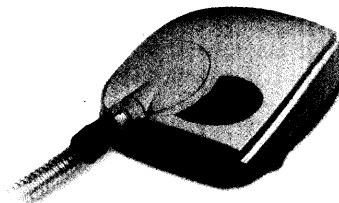


Description of the equipment and
instructions for use

SOMNOcomfort 2e
SOMNOaqua



CPAP unit

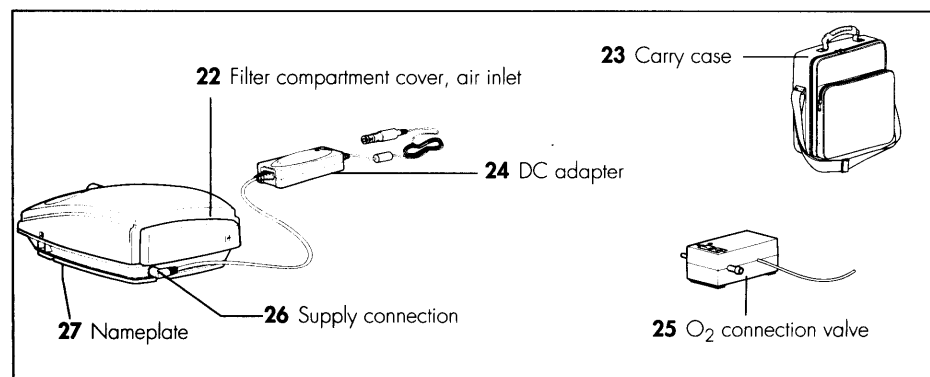
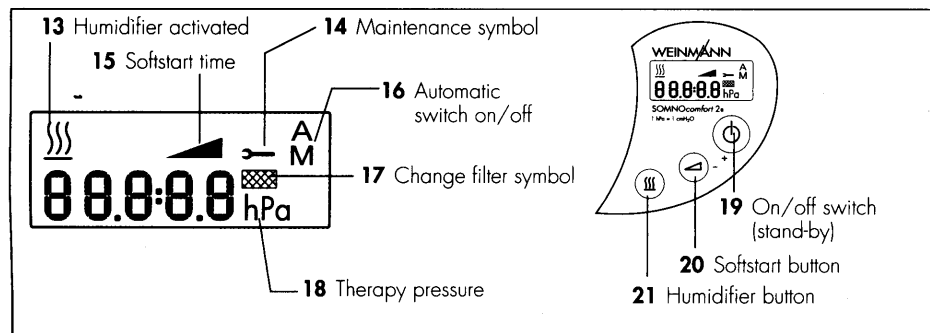
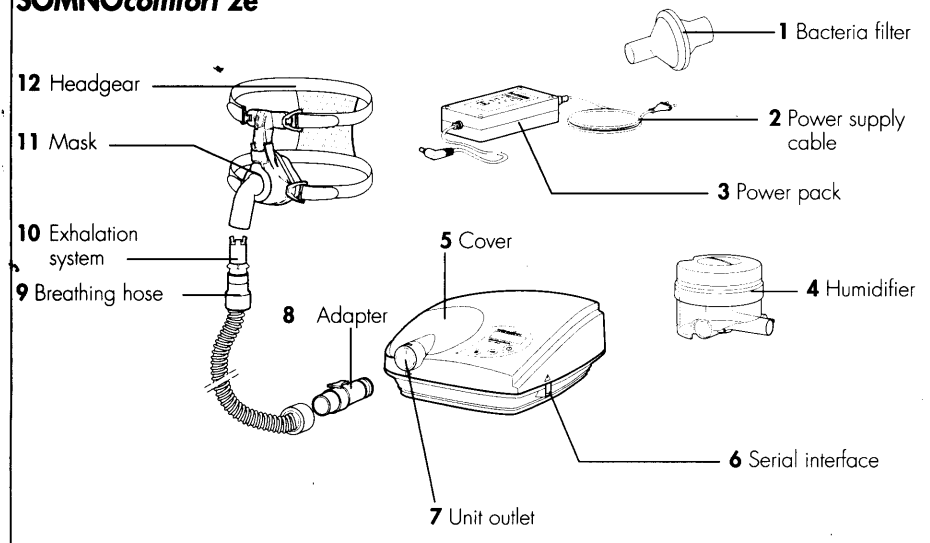
SOMNOcomfort 2e
WM 24405

SOMNOcomfort 2e with SOMNOaqua
WM 24455

WEINMANN

Overview

SOMNOcomfort 2e



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

Used exclusively to connect to devices for visualising and evaluation therapy data.

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

This symbol appears every 250 operating hours. The fine filter must then be changed.

18 Therapy pressure

The therapy pressure is shown in hPa (hectoPascal).
1 hPa = 1 mbar = 1 cm H₂O.

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 O2 connection valve (accessory)

For introducing oxygen into the mask.

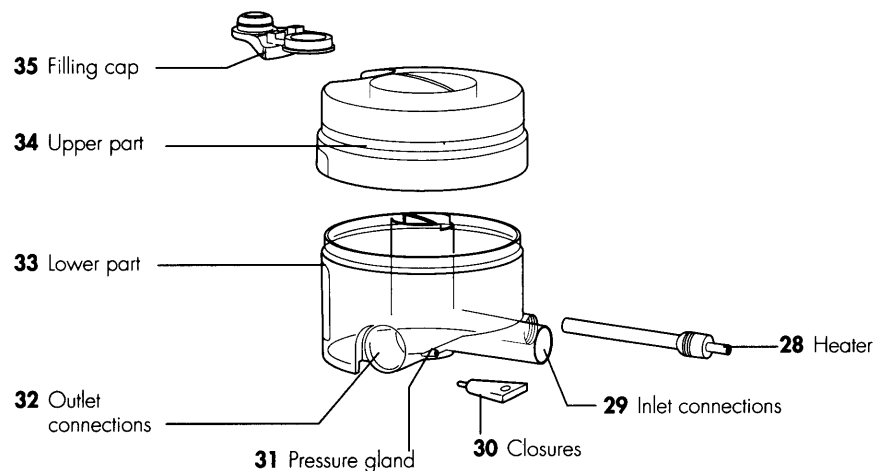
26 Supply connection

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.

SOMNOaqua (optional)



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 2e:	
	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 SOMNOadjust WM 23930 and SOMNOsupport WM 23975 by specialist staff or to control the O ₂ connection valve, WM 24042. Max. current consumption 163 mA.
SOMNOaqua (optional)	
	Do not use the humidifier on patients whose airways have been bypassed
	Unit is heated! Do not touch the heater rod.
Signs on the unit	
	Year built
	Unit type B
	Do not dispose of unit as domestic waste
SN	Serial number of the unit
	Protection class II

Markings on the packaging

Symbol	Meaning
	Permitted storage temperature: -40°C to +70°C
% 0-95	Permitted storage humidity: max. 95% relative humidity.

Contents

1. Description of Equipment	8	5.6 Disinfecting the SOMNOaqua	31
1.1 Intended use		5.7 Multiple patient use	
SOMNOcomfort 2e	8	SOMNOcomfort 2e	31
1.2 SOMNOaqua intended use	8	5.8 Multiple patient use	
1.3 Functional description		SOMNOaqua	32
SOMNOcomfort 2e	9	6. Functional checks	33
1.4 Functional description		6.1 Intervals	33
SOMNOaqua	10	6.2 Function check of	
2. Safety Instructions	11	SOMNOcomfort 2e	33
2.1 Safety instructions.	11	6.3 Function check of	
2.2 Contraindications.	13	SOMNOaqua	34
2.3 Side effects.	14	7. Malfunctions and Rectification	35
3. Setup of Equipment	15	7.1 SOMNOcomfort 2e	35
3.1 Setting up and connecting the		7.2 SOMNOaqua	36
SOMNOcomfort 2e	15	8. Maintenance	38
3.2 Fitting the mask	16	8.1 Intervals	38
3.3 Filling and connecting the		8.2 Maintenance includes the	
SOMNOaqua	16	following:	38
3.4 Accessories.	18	9. Disposal	38
4. Operation	20	10. Scope of supply	39
4.1 Automatic switch on/off	20	10.1 Standard scope of supply	39
4.2 SOMNOcomfort 2e startup	21	10.2 Accessories	40
4.3 SOMNOaqua setting.	22	10.3 Replacement parts	
4.4 Softstart setting	23	SOMNOcomfort 2e	42
4.5 After usage.	24	10.4 Replacement parts	
4.6 Read off therapy duration	24	SOMNOaqua	42
4.7 Travelling with therapy units	25	11. Technical data	43
5. Hygienic preparation	26	11.1 Specifications	43
5.1 Intervals	26	11.2 Pneumatic diagram	46
5.2 Cleaning SOMNOcomfort 2e	26	11.3 Safety distances.	46
5.3 Cleaning the SOMNOaqua	29	12. Warranty	47
5.4 Descaling the SOMNOaqua	30	13. Index	48
5.5 Disinfecting the		14. Declaration of Conformity	49
SOMNOcomfort 2e	30		

1. Description of Equipment

1.1 Intended use SOMNOcomfort 2e

SOMNOcomfort 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!

SOMNOcomfort 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.

SOMNOaqua can only be used with the SOMNOcomfort 2e therapy unit. Operation with third-party devices is not permitted.

Only use the unit for the purposes described below.

1.3 Functional description SOMNOcomfort 2e

SOMNOcomfort 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 SOMNOsupport evaluation program.
- SOMNOcomfort 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 46). 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 26 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.
- Malfunctions and a lack of biocompatibility may result if third-party articles are used. Please bear in mind that in these cases any warranty entitlement and liability shall lapse where the accessories recommended in the instructions for use or original spare parts are not utilised.

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 CO₂ 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 O₂ 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 (obesity-hypoventilation 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*.

2.3 Side effects

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. Setup of Equipment

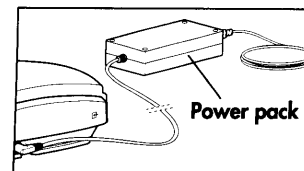
3.1 Setting up and connecting the SOMNOcomfort 2e

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

Caution!

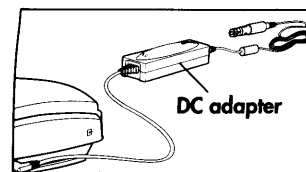
Do not cover the unit or power pack. Do not use in the vicinity of a heater or in direct sunlight. The unit may overheat, resulting in insufficient therapy delivery and damage to the unit.

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

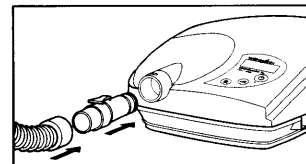


The power pack automatically determines the appropriate mains voltage (115 V - 230 V).

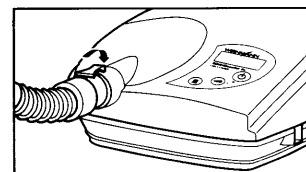
The display shows "0" for standby, together with "A" or "M" according to the appropriate setting on the automatic on/off switch



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.

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 26).

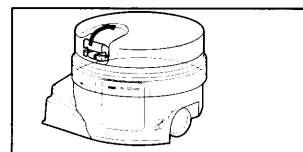
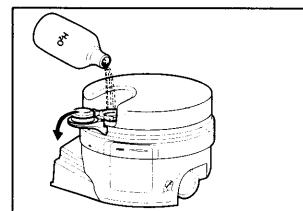
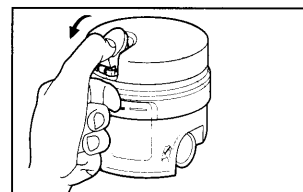
Filling the humidifier

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.

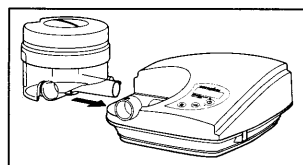
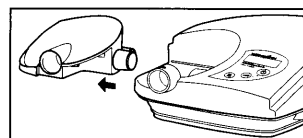
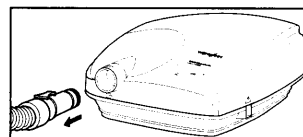
Note

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

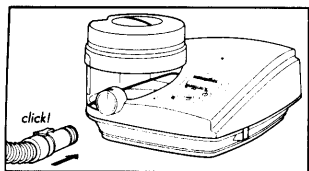


1. Open the filling cap of the humidifier.
2. Fill the humidifier up to the mark "max" with distilled water.
If no distilled water is available, low calcium boiled water can be used instead (but not as a rule!). Check that the heater rod does not scale up (see "5.4 Descaling the SOMNOaqua" on page 30).
3. Firmly close the humidifier with the filling cap.
4. After filling, check that the humidifier is not leaking. 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.

Adapting the humidifier



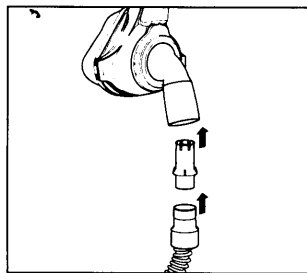
1. If necessary, detach the breathing hose from the therapy unit by pushing in the catch on the adapter. Pull the breathing hose and adapter off the unit outlet.
2. Push the cover sideways out of the humidifier stub on the therapy unit.
3. Push the filled humidifier as far as it will go into the stub 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.

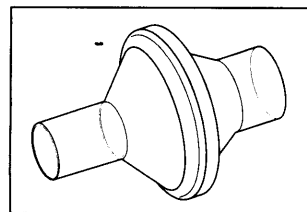
3.4 Accessories

External exhalation system



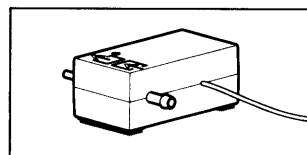
Should the unit fail, the exhalation system enables you to breath through the nose or mouth. Full-face masks must also be fitted with a safety valve. Remove the mask as quickly as possible. First check whether there has been a power failure. Follow the instructions for use of your exhaled air system.

Bacteria filter



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.

Oxygen supply



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 SOMNOcomfort 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.

Switch off automatic system

M = manual

A = automatic

1. With the SOMNOcomfort 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 "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 SOMNOcomfort 2e on and off using the on/off switch.

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

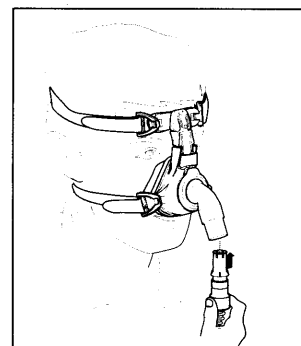
4.2 SOMNOcomfort 2e startup

Always use an exhalation system. The exhalation system allows the used air containing carbon dioxide (CO₂) to escape from the mask. Without an exhalation system the CO₂ 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.

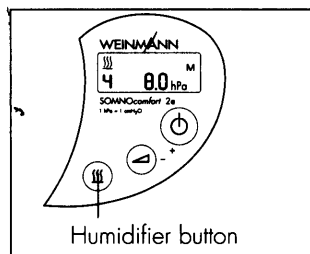
If softstart has been preselected, the softstart display will then light up and the softstart time will appear in the display.



SOMNOcomfort 2e is now ready for operation.

4.3 SOMNOaqua setting

Switching on the humidifier

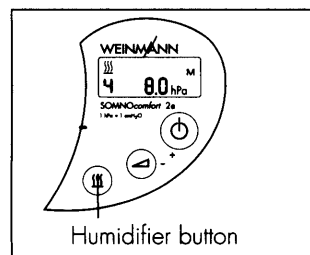
1. Fill up the humidifier and set up as described in "3.3 Filling and connecting the SOMNOaqua" on page 16.
2. Switch on the therapy unit.






3. Press the humidifier button  on your therapy unit. The humidifier symbol  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  for approx. 3 seconds until the number and the humidifier symbol  start to flash.
3. Release the humidifier button .
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°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  of the sleep apnoea unit. The humidifier symbol  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  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 SOMNOcomfort 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 (-).

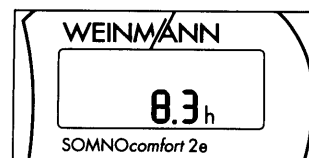
If a button is not pressed for 4 seconds, the displayed softstart time will be saved and the display stops flashing.

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.

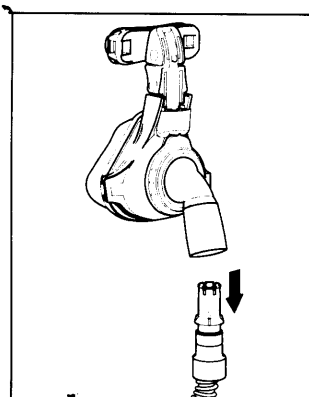
Softstart can be switched on and off at any time by pressing the softstart button .

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 "D" 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 26).

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 therapy duration. 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 "D" 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

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.

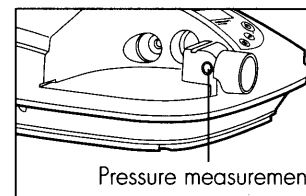
Cleaning the SOMNOcomfort 2e-housing

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!



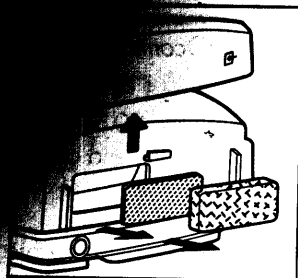
- Make sure no liquid gets into the housing via the pressure measurement port. This may cause the unit to malfunction.

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.

Change 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.

4. 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:

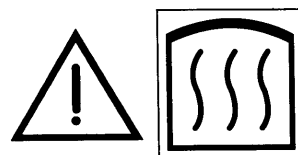
1. When switching on the unit, press and hold the on/off switch.
The filter change indicator will come on after about three seconds before going off again after another three seconds.
2. Release the on/off switch.

Accessories

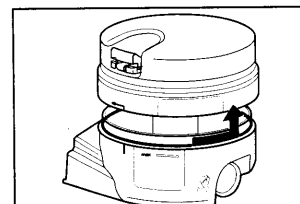
To clean the exhalation system, the mask and the headgear, please see the section "Cleaning" in the relevant operating instructions.

5.3 Cleaning the SOMNOaqua

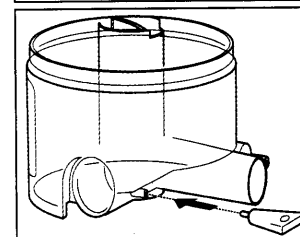
1. Unlock the SOMNOaqua by taking the hose adapter out of the unit outlet. Now push the SOMNOaqua to the left off the humidifier stub.



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



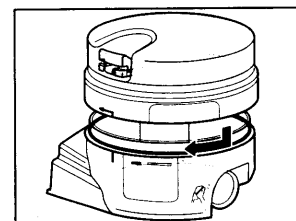
2. Open the humidifier by turning the upper part anti-clockwise.



3. Place the red closure over the pressure gland.
4. 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).

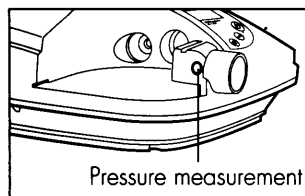
Unit

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 SOMNOcomfort 2e.

5.8 Multiple patient use SOMNOaqua

If the SOMNOaqua 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 SOMNOcomfort 2e.

6. Functional checks

6.1 Intervals

Carry out a functional check on the SOMNOcomfort 2e and the SOMNOaqua 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. ± 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



1. 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  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.

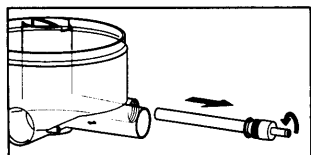
7.1 SOMNOcomfort 2e

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 20).
Unit does not switch off after approx. 15 seconds once mask is removed.	Automatic switch on/off not activated	Activate automatic switch on/off (4.1, page 20).
Unit is running but does not reach CPAP pressure level selected.	Filter soiled	Clean/change filter (5.2, page 26).
	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 26).
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.

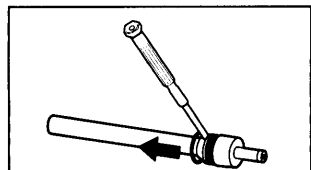
7.2 SOMNOaqua

Malfunctions	Cause	Rectification
Humidifier does not warm up.	Humidifier is not activated.	Switch on the air humidifier, see 4.3, page 22.
	Electronics defect.	Send the humidifier and the therapy unit to your dealer for repair.
The humidifier is leaking.	The heater rod seal is defective.	Replace the seal, see page 36.
	The seal on the underside of the housing is leaking.	Replace the seal, see page 37.
	Cracks in lower part.	Replace the lower part.

Replacing the heater rod seal



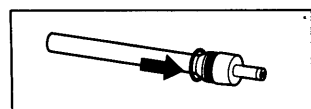
1. Remove the heater rod from the lower part of the housing by turning anti-clockwise.



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

Important!

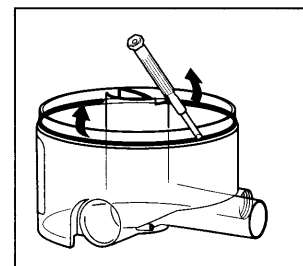
Take care to ensure that the groove in which the seal fits is not damaged.



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.

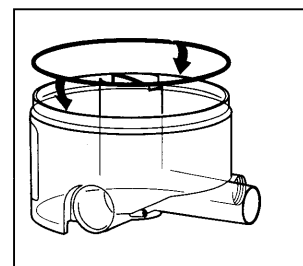
Replacing the housing lower part seal



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.

8. Maintenance

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. Scope of supply

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

SOMNOcomfort 2e with SOMNOaqua

WM 24455

Parts	Order number
SOMNOcomfort 2e	WM 24405
SOMNOaqua	WM 24403

10.2 Accessories

The following accessories can be ordered separately when required.

Parts	Order number
Humidifier SOMNOaqua	WM 24403
SOMNOadjust remote adjustment device (only for specialist medical and technical staff)	WM 23930
SOMNOsupport evaluation software (only for specialist medical and technical staff)	WM 23975
SOMNOmask, size S	WM 25110
SOMNOmask, size M	WM 25120
SOMNOmask, size L	WM 25130
SOMNOmask, size S, blue	WM 25210
SOMNOmask, size M, blue	WM 25220
SOMNOmask, size L, blue	WM 25230
SOMNOplus, size S	WM 25710
SOMNOplus, size M	WM 25720
SOMNOplus, size L	WM 25730
JOYCE, size S	WM 26110
JOYCE, size M	WM 26120
JOYCE, size L	WM 26130
JOYCE 40 hPa, size S	WM 26111
JOYCE 40 hPa, size M	WM 26121
JOYCE 40 hPa, size L	WM 26131
JOYCE NV, size S	WM 26160
JOYCE NV, size M	WM 26170
JOYCE NV, size L	WM 26180
JOYCE NV 40 hPa, size S	WM 26161
JOYCE NV 40 hPa, size M	WM 26171

Parts	Order number
JOYCE NV 40 hPa, size L	WM 26181
Silentflow	WM 23600
Sound absorber, complete (alternative exhalation system)	WM 23685
SOMNOcap, size M, blue	WM 23673
SOMNOcap, size L, blue	WM 23674
SOMNOcap, size M, white	WM 23686
SOMNOcap, size L, white	WM 23687
SOMNOstrap, blue	WM 23695
SOMNOstrap, white	WM 23177
SOMNOstrap extra	WM 25250
JOYCEstrap	WM 26290
JOYCEstrap EXTRA, 3 pcs.	WM 26291
JOYCEstrap EXTRA, 4 pcs.	WM 26292
JOYCEcap	WM 26293
Oxygen valve	WM 24042
DC adapter (12-24 V)	WM 24469
Bacteria filter	WM 24476

When using other mask systems, please observe the relevant operating instructions.

10.3 Replacement parts SOMNOcomfort 2e

Parts	Order number
Coarse dust filter	WM 24481
Fine dust filter, packed	WM 24401
Set of 12 fine filters	WM 15668
Set of 2 coarse dust filters	WM 15321
Carry case	WM 24449
Humidifier SOMNOaqua	WM 24403
Power pack	WM 24480
Power supply cable	WM 24133
Cover, humidifier stub	WM 24424
Cover, rear of unit	WM 24428
Adapter, unit outlet	WM 24452
Closures for pressure glands	WM 24494

10.4 Replacement parts SOMNOaqua

Housing, top part	WM 24411
Housing, bottom part	WM 24412
Heater	WM 24264
Closures	WM 24414
Seal for top of housing	WM 1145/158
Seal, heater	WM 1145/19
Closures for pressure glands	WM 24494

11. Technical data

11.1 Specifications

	SOMNOcomfort 2e	SOMNOcomfort 2e with SOMNOaqua						
Product class as per 93/42/EEC	IIa							
Dimensions WxHxD in cm	21 x 9 x 27	21 x 14 x 27						
Weight	approx. 1.7 kg	approx. 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.							
Adm. humidity for operation and storage	≤ 95 % rF (no condensation)							
Air pressure range	700 - 1060 hPa (automatic height adjustment)							
Diameter of breathing hose connection (mask) in mm	19.5 (suitable for 22mm standard cone)							
Electrical connection	115-230 V AC +10/-15 %, 50–60 Hz with WM 24480 power pack or 12-24 V DC -15/+25 % with WM 24469 DC adapter							
Power consumption during – operation – standby	230 V 0,1 A 0,02 A	115 V 0.2 A 0.03 A	24 V 0.9 A 0.2 A	12 V 1.8 A 0.24 A	230 V 0,23 A 0,02 A	115 V 0.45 A 0.03 A	24 V 2.0 A 0.2 A	12 V 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 – operating mode	Protection class II Type B IPX1 Constant operation							

	SOMNOcomfort 2e	SOMNOcomfort 2e with SOMNOaqua
Electromagnetic compatibility (EMC) as per EN 60601-1-2 – radio interference suppression – immunity to interference	Test parameters and limit values can be obtained from the manufacturer if required. EN 55011 B EN 61000-4 parts 2 to 6, part 11	
Mean sound pressure level/operation at distance of 1 m from unit in patient position	approx. 27 dB (A) at 10 hPa (corresponds to an acoustic power level of 35 dB (A))	
CPAP operating pressure range	4 to 20 hPa	
Pressure accuracy	± 1 hPa (1 mbar = 1 hPa \approx 1 cm H ₂ O)	
max. CPAP pressure with malfunction	< 30 hPa	
Flow at max. speed at:		
20 hPa	85 l/min	85 l/min
15 hPa	100 l/min	100 l/min
10 hPa	120 l/min	115 l/min
5 hPa	140 l/min	135 l/min
0 hPa	155 l/min	150 l/min
Tolerance	± 10 l/min	± 10 l/min
Heating of respiratory air	2,5 °C	depending on heating level
Short-term constant pressure level measured as per prEN ISO 17510:2004 at:		
20 hPa	$\Delta p = 0.5$ hPa	
15 hPa	$\Delta p = 0.5$ hPa	
10 hPa	$\Delta p = 0.4$ hPa	
5 hPa	$\Delta p = 0.4$ hPa	
Long-term constant pressure level prEN 17510-1:2004	$\Delta p = 0.1$ hPa	
Finefilter separation level to 1 μ m	≥ 99.5 %	
to 0.3 μ m	≥ 85 %	
Fine filter service life	≥ 250 hours with normal room air	



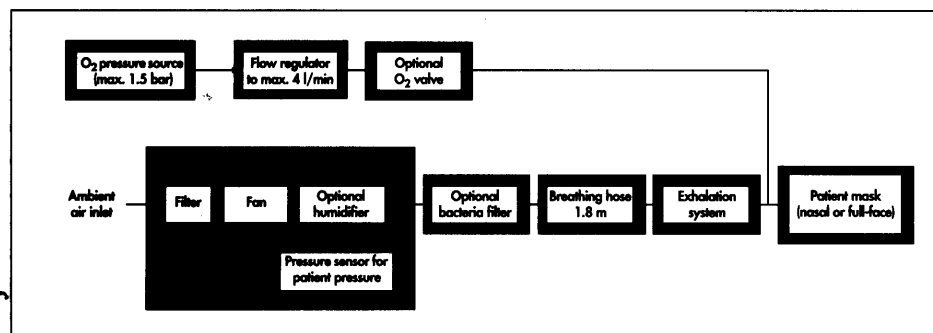
Subject to design modifications

	SOMNOaqua
Product class as per 93/42/EEC	II a
Dimensions WxHxD in mm	140 x 100 x 121
Weight (without water)	300 g
Temperature range – operation – storage	+5 °C to +35 °C –40 °C to +70 °C
Humid operation and storage	≤ 95 % relative humidity
Ambient pressure range	700 to 1060 hPa
Electrical connection	30 V DC
Power consumption	15 VA
Classification as per EN 60601-1 – level of protection from electric shock	Unit type B
Electromagnetic compatibility (EMC) as per EN 60601-1-2 – radio interference suppression – immunity to interference	EN 55011 B EN 1000-4 parts 2 to 6, part 11
Max. permitted capacity	300 ml
Max. permitted operating pressure	30 hPa
Max. permitted flow (free-flowing)	160 l/min
Max. mask temperature	37°C
Gas leakage at 30 hPa	negligible
Humidifier output at heating level 6: Flowrate = 20 l/min Flowrate = 30 l/min Flowrate = 40 l/min	6.3 mg/l 6.8 mg/l 9.0 mg/l
at 23° C and 65% relative humidity	



Subject to design modifications

11.2 Pneumatic diagram



11.3 Safety distances

Recommended safety distances between portable and mobile HF telecommunications equipment (e.g. mobile phones) and SOMNOcomfort 2e or SOMNOaqua			
Nominal output of HF equipment in W	Safety distance dependent 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

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
 - 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. Index

Keyword:	page:
Accessories	40
Automatic switch on/off	9, 20, 21, 35
Automatic switch-on	20
Cleaning	26
Disinfection	26, 30
Drying	26
exhalation	33
Exhalation system:	18, 21, 24, 26, 33, 41
Filter	26, 35, 42, 44
Functional Check	33
Humidifier	12, 18, 30, 39, 40, 42, 43
Inspection	12
Malfunctions	35
Mask	16, 21, 24
Replacement parts	42
Safety instructions	11, 12
Side effects	14
Softstart	9, 21, 23, 33
SOMNOaqua	16, 22, 43
Standby mode	24
Travelling	25

14. Declaration of Conformity

EEC Letter of Conformity on Medical Devices

We, the manufacturer

Weinmann
Geräte für Medizin GmbH+Co.KG
Kronsaaßweg 40 · D – 22525 Hamburg

declare in sole
responsibility the

Product Name: **CPAP Sleep Apnea Set**

Type/Model: **SOMNOcomfort 2 e**
SOMNOcomfort 2 e with SOMNOaqua

being in conformity
with the respective
regulations of the
following guideline:

Medical Device Directive 93/42/EEC

Classification:

II a

Standards used

in particular:
EN 60601-1: 2005,
EN 60601-1-2: 2001,
prEN ISO 17510-1: 2005
prEN ISO 8185-1: 2004
when used in accordance with purpose

The product has the
TÜV Rheinland CE mark.



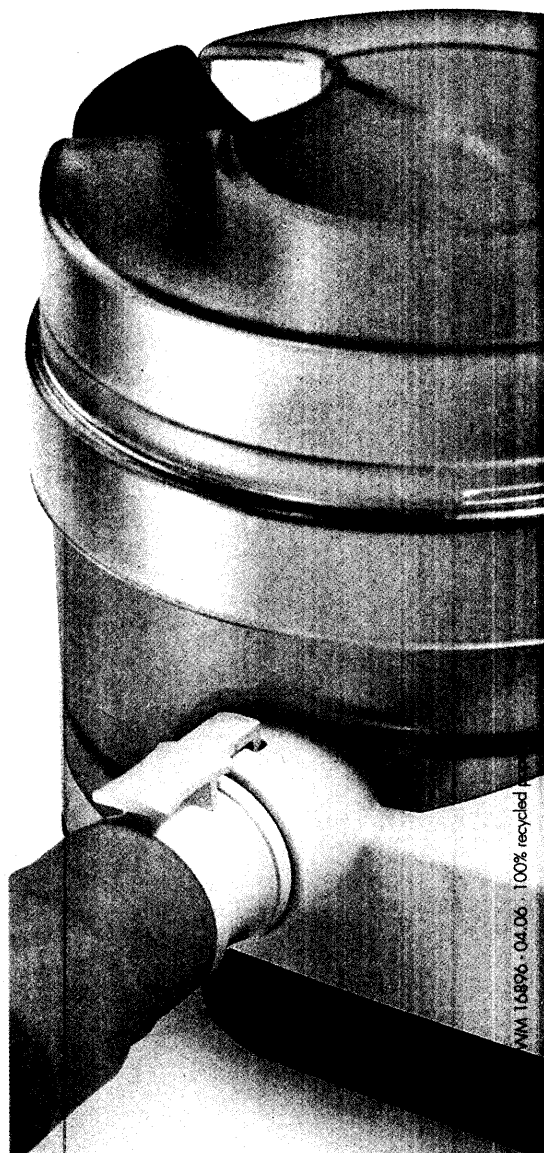
Hamburg, 10.04.2006

K. A. Feldhahn
Dr. K.-A. Feldhahn
President,
Chief Technology Officer

WEINMANN

0206 Ab

For decades Weinmann has been developing, producing and marketing medical devices for markets around the world. In cooperation with our partners we design economic health systems for diagnosis and therapy in Sleep Medicine, Home Mechanical Ventilation, Oxygen Medicine and Emergency Medicine.



WEINMANN

Weinmann

Geräte für Medizin GmbH+Co.

P.O. Box 540268 · D-22502 Hamburg

Phone +49/40/5 47 02-0

Fax +49/40/5 47 02-461

E-mail int.sales@weinmann.de

Internet www.weinmann.de