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# 1 Intended Use of the iSleep 10



## **WARNING!**

iSleep 10 must only be used:

- For the intended treatment in accordance with this manual and with the instructions given by the responsible clinical personnel.
- In accordance with the operating conditions specified in this manual.
- In original and unmodified shape and only with accessories specified or approved by Breas Medical AB.

Every other use may lead to risk of personal injury!



## **CAUTION!**

Read this manual thoroughly so that you completely understand how the iSleep 10 is operated and maintained before taking it into use, to ensure correct usage, maximum performance and serviceability.



## **WARNING!**

Do not use the iSleep 10 for any kind of life support treatment.



Breas Medical AB reserves the right to make changes to this product without any prior notification.

## 1.1 What is the iSleep 10?

The iSleep 10 is a CPAP system that provides a continuous positive airway pressure. This can prevent the user's upper airways from collapsing and therefore avoid breathing problems associated with airway collapse and obstruction.

## 1.2 Indications for Use

The iSleep 10 is intended for non-invasive use.

The iSleep 10 shall only be used by patients with spontaneous breathing.

The CPAP function is intended to deliver continuous positive airway pressure therapy for the treatment of obstructive sleep apnea in adults (who weigh more than 30 kg).

The iSleep 10 can be used in clinical settings (e.g., hospitals, sleep laboratories, sub-acute care institutions) and home environments. It must always be prescribed by a licensed physician.

The iSleep 10 is intended to be operated by trained users and qualified personnel.



**The iSleep 10 is not intended for life support or life-sustaining applications or for transport of critical care patients.**

### 1.3 Contraindications

Therapy with the iSleep 10 should not be prescribed when the following specific diseases or conditions are present:

- Bullous lung disease
- Pathologically low blood pressure
- Severe cardiac arrhythmias
- Coronary artery disease
- Unstable angina pectoris
- Decompensated cardiac failure or hypotension, particularly if associated with intravascular volume depletion
- Recent thoracic surgery
- Pneumothorax
- Pneumomediastinum
- Massive epistaxis or previous history of massive epistaxis (risk of recurrence)
- Pneumoencephalus, recent trauma or surgery that may have produced cranio-nasopharyngeal fistula
- Cerebral spinal fluid (CSF) leaks
- Acute or unstable respiratory failure or insufficiency

Caution should be used when prescribing CPAP therapy for susceptible patients, such as patients with abnormalities of the cribriform plate, or prior history of head trauma.

The use of CPAP therapy may be temporarily contraindicated if the patient exhibits signs of a sinus or middle ear infection.

## 1.4 About this Manual



Always read this manual before setting up and using the iSleep 10 or performing maintenance on the iSleep 10, to ensure correct usage, maximum performance and serviceability.



Breas Medical AB reserves the right to make changes to the contents of this manual without any prior notification.

### Audience

This manual is intended for patients and other lay users operating the iSleep 10.



*Care providers, clinical personnel, physicians and others who require a working knowledge of the iSleep 10 will find additional information on settings and functions in the Clinician's Manual.*

### Icons

In this manual, icons are used to highlight specific information. The meaning of each icon is explained in the table below.

ICON	EXPLANATION
	<b>Warning!</b> Risk of death and serious personal injury.
	<b>Caution!</b> Risk of minor or moderate injury. Risk of equipment damage, loss of data, extra work, or unexpected results.
	<b>Note</b> Information that may be valuable but is not of critical importance, tips.
	<b>Reference</b> Reference to other manuals with additional information on a specific topic.

## 2 Safety Information

### 2.1 General User Precautions



- The iSleep 10 should not be used for any kind of life support treatment.
- The iSleep 10 shall only be used by patients with spontaneous breathing.
- If you are admitted to a hospital or are prescribed any other form of medical treatment, always inform the medical staff that you are on CPAP treatment.
- The iSleep 10 must only be used:
  - for the intended treatment in accordance with this user manual and with the instructions given by the responsible clinical personnel;
  - in accordance with the operating conditions specified in this manual;
  - in original and unmodified shape and only with accessories specified or approved by Breas Medical AB.
- Do not use the iSleep 10 and contact your responsible care provider for an inspection in the event of suspected damage to the device, unexplainable or sudden pressure, performance or sound changes during operation, or if the delivered air from the iSleep 10 is abnormally hot or emits an odour.
- The iSleep 10 therapy settings must always be based on medical advice and must be carried out by authorized clinical personnel only.
- Always perform the procedure “Checking the iSleep 10 before Use” on page 18 before use.
- Inadequate use of device or accessories may cause loss of treatment or decreased performance.



- Clinical personnel and the patient must read the manual thoroughly and understand the usage of the iSleep 10 before setting up and using the iSleep 10.
- Handle the iSleep 10 with care.
- Do not use the iSleep 10 while in bag.

## 2.2 Electrical Safety



- Do not operate the iSleep 10 if it has a damaged power cord, power supply or casing.
- The iSleep 10 may not work properly if any part has been dropped, damaged or submerged in water.
- To avoid electrical shock, disconnect the electrical supply to the iSleep 10 before cleaning. Do not immerse the iSleep 10 into any fluids.



- If an external battery is used it must be disconnected when the iSleep 10 is switched off. Otherwise the battery will discharge.
- The performance of the iSleep 10 may deteriorate at:
  - AC supply voltage below -15% and above +10% of declared nominal value.
  - DC supply voltage below -15% and above +25% of declared nominal value.

## 2.3 Environmental Conditions



- Do not use the iSleep 10 in any toxic environment.
- Do not use the iSleep 10 in environments where there are explosive gases or other flammable anesthetic agents present.



- The performance of the iSleep 10 may deteriorate at:
  - ambient temperatures below 5°C (41°F) and above 40°C (104°F).
  - ambient relative humidity below 10% RH (relative humidity) and above 95% RH.
  - atmosphere pressure below 700 mbar and above 1060 mbar.
- Do not use the iSleep 10 while positioned in a warm place, such as direct sunlight.
- The device complies with the EMC requirements of standards. Measures should include but not be limited to:
  - normal precautions with regard to relative humidity and conductive characteristics of clothing in order to minimize the build-up of electrostatic charges.
  - avoiding use of radio emitting devices closer than 1 m to the iSleep 10. Radio emitting devices are for example cellular or cordless telephones, microwave ovens and high-frequency surgery apparatus.
- The iSleep 10, any accessories and all replaced parts must be disposed of in accordance with the local environmental regulations regarding the disposal of used equipment and waste.
- The performance of the iSleep 10 and treatment of the patient may deteriorate if the operation conditions in “Technical Specifications” on page 33 are not fulfilled. Do not use the iSleep 10 immediately after storage or transport outside the recommended operating conditions.

## 2.4 Usage of Patient Circuit



- Only use the iSleep 10 with a mask, patient tube and ventilation valve (if applicable) recommended by Breas Medical AB and your health care professional.
- Do not breathe in the connected patient circuit unless the iSleep 10 is turned on and operating properly.
- Do not use patient hoses or tubes made of electrically conductive or static material.
- Patient connected parts and filter must be replaced regularly to ensure correct function of the iSleep 10. All replaced parts must be disposed of according to local environmental regulations regarding the disposal of used equipment and parts.
- If the patient is using a full face mask (covering mouth and nose), the mask must be equipped with a safety entrainment valve.
- Make sure that the ventilation holes in the mask or the adjoining ventilation valve are never blocked or obstructed. These devices are used for ventilating the mask in order to prevent re-breathing of exhaled air. Re-breathing of exhaled gases for longer than a few minutes can, in some circumstances, lead to suffocation.
- At low CPAP pressures, the air flow through the ventilation holes in the mask or the adjoining ventilation valve may be inadequate to clear all exhaled gases from the mask. Some re-breathing may occur.

## 2.5 Usage of Filters



- Always use the iSleep 10 with a patient air inlet filter installed. Only use filters that are specified in this manual.
- Replace or clean the filters regularly to ensure correct function of the iSleep 10, especially when changing patient. Failure to replace or clean a dirty filter may cause the iSleep 10 to operate at higher temperatures than intended.
- When operating the iSleep 10, make sure that the air inlet and the filter is not obstructed or occluded.

## 2.6 Cleaning and Maintenance



- The iSleep 10 shall be cleaned and maintained in accordance with this user manual.
- Do not attempt to autoclave or sterilise the iSleep 10.
- The iSleep 10 shall be subjected to maintenance, service and control and any applicable upgrades, in accordance with Breas service instructions.
- The iSleep 10 should only be repaired or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians authorized by Breas Medical AB.
- Do not under any circumstances attempt to service or repair the iSleep 10 yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the iSleep 10.

## 2.7 Adverse Patient Symptoms



If the patient experiences any of the following symptoms while using the iSleep 10, a physician or responsible clinician shall be contacted immediately:

- Bloating feeling from excessive swallowing of air while awake
- Air continually leaking from the mouth while sleeping
- Dryness of air passages or nose
- Ear pain, runny nose or sinus discomfort
- Day time sleepiness
- Disorientation or memory lapse
- Mood change or irritability
- Skin sensitivity
- Morning headache

## 2.8 Usage of Oxygen

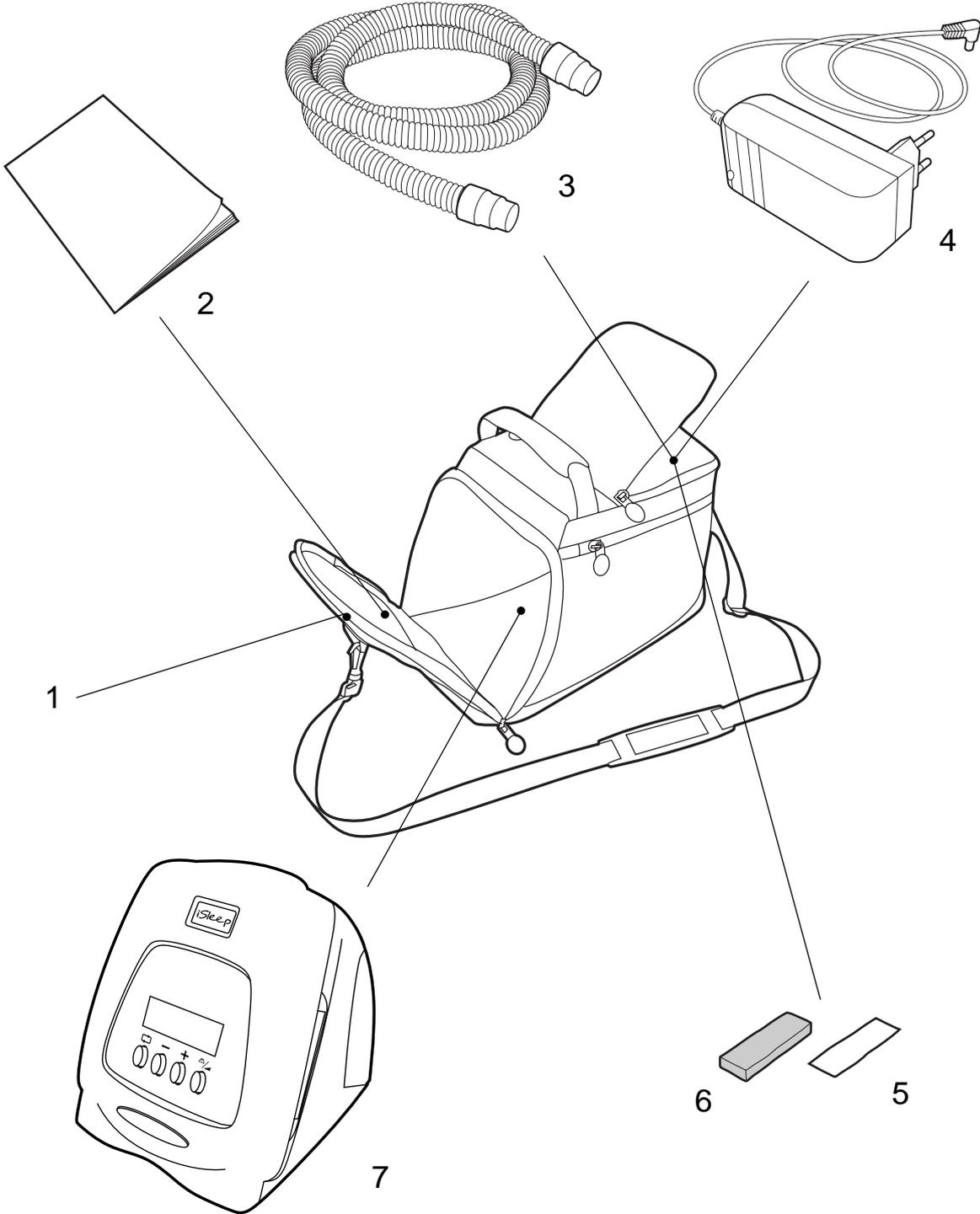


- The presence of oxygen can speed up combustion of inflammable materials.
- If oxygen has been prescribed, connect the oxygen supply tube to the appropriate oxygen port of the nasal mask or breathing system connector.
- At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure delivered, patient's breathing pattern, mask selection, and leak rate.
- When oxygen is used with the iSleep 10, the oxygen flow must be turned off when the iSleep 10 is not operating. If the iSleep 10 is not in operation, and the oxygen flow is left on, oxygen delivered into the patient tubing may accumulate within the iSleep 10 enclosure. Oxygen accumulated in the iSleep 10 enclosure will create a risk of fire.
- Ventilate the room adequately.
- Do not smoke in a room where oxygen is being used.
- Naked light bulbs and other sources of ignition must be kept a minimum of 2 metres away from the oxygen cylinder or any part of the patient circuit.
- Do not use aerosols or solvents close to the oxygen supply, even when the oxygen supply is shut off.

# 3 Product Description

## 3.1 Main Components

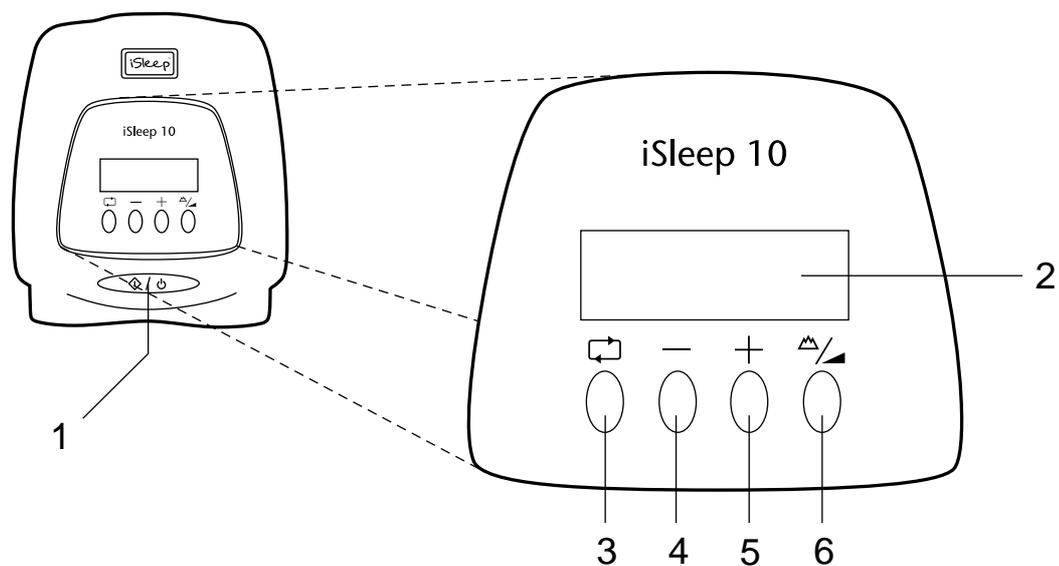
The iSleep 10 system contains the following components:



<b>No.</b>	<b>COMPONENT</b>	<b>FUNCTION</b>	<b>PART NO.</b>
1	Carrying bag	Storage for transportation	003793
2*	Users manual	Product and usage information	004266
3*	Patient tube	Tube for mask and iSleep 10	000245
4*	iSleep power supply		003772
5*	Filter (white, disposable, optional)	Inlet air filtration	003762
6*	Filter (grey, washable)	Inlet air filtration	003693
7*	iSleep 10 main unit		

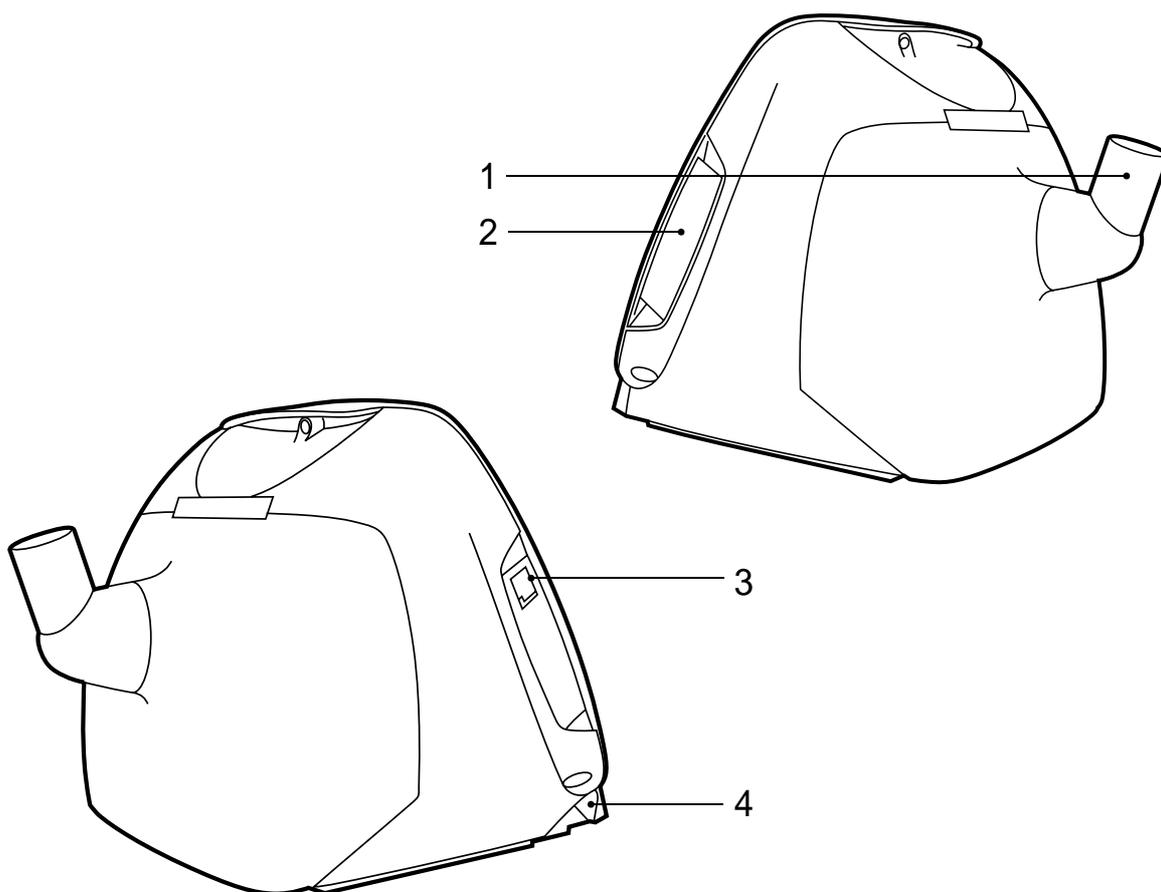
\* Included in the iSleep 10 basic package.

## 3.2 The iSleep 10's Front Panel



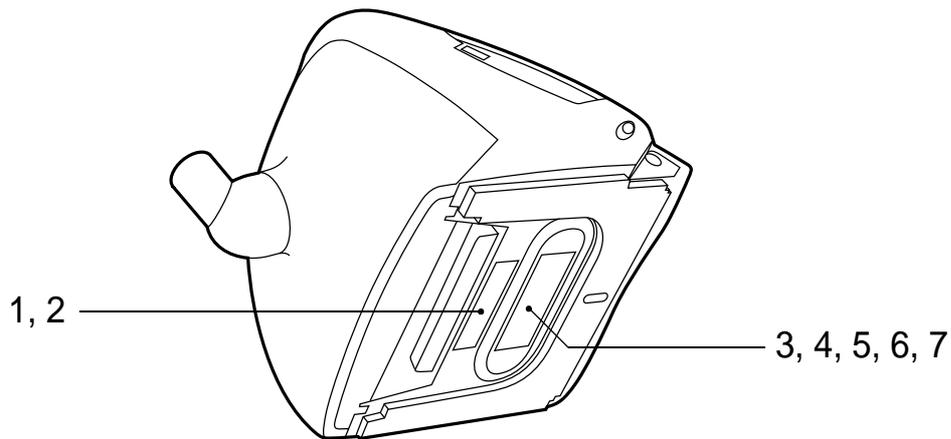
No.	USER BUTTONS AND DISPLAYS	FUNCTION
1	Start/Stop	Main unit: On/Off
2	Display window	Mode and settings display
3	Function	Menu navigation
4	Decrease	Decrease setting
5	Increase	Increase setting
6	Altitude / Ramp start and stop	Altitude setting / Ramp function start and stop

### 3.3 The iSleep 10's Side Panels



No.	ITEM	FUNCTION
1	Air outlet	Air path out to the patient
2	Air inlet	Air path in, replaceable filters
3	Data connection	Data cable connection (only for service purpose)
4	DC inlet	External DC power connection

### 3.4 Equipment Designation and Safety Label



No.	SYMBOL	EXPLANATION
1		Model designation
2		Serial number (the last seven alphanumeric characters)
3		Class II electrical equipment; dual isolation
4		Body floating (IEC 60601-1 Type BF, Isolated Applied Part)
5		Read the User Manual thoroughly before connecting the iSleep 10 to the patient.
6		CE marking applies in accordance with the directive MDD 93/42/EEC.
7		Read “Disposal” on page 32 for information about recycling and disposal.

## 4 Functions and Parameters of the iSleep 10

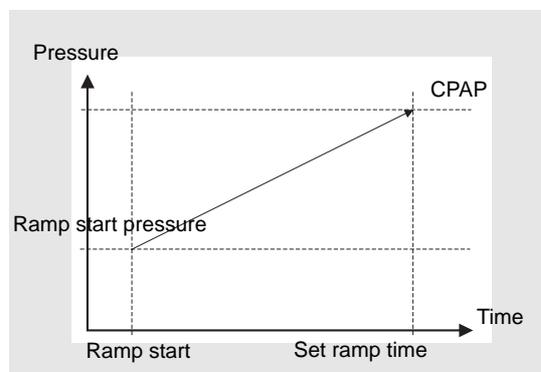
This chapter includes descriptions of the settings used for controlling the functions of the iSleep 10.

### 4.1 Settings

All the parameters that are used for controlling the breathing by the iSleep 10 are listed below.

#### The Ramp function

The ramp function provides a pressure increase from the ramp start pressure to the set CPAP pressure during a set time.



#### Altitude setting

In order to achieve the correct pressure the altitude has to be selected. The altitude settings are divided in three different settings: low, medium and high (Low: 1060 to 900 mbar ambient pressure, equal to approximately <500 m over sea level. Medium: 900 to 800 mbar, 500 m to 1500 m. High: 800 to 700 mbar, 1500 m to 2600 m).

## 5 Using the iSleep 10

### 5.1 Checking the iSleep 10 before Use

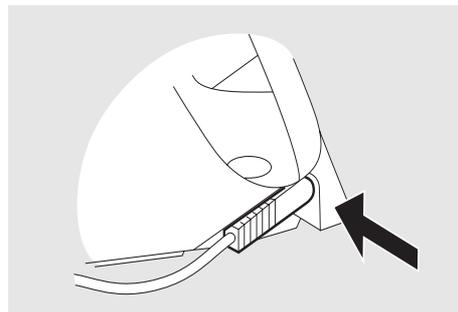
Always make the following checks before using the iSleep 10:

- 1 Connect a cleaned or a new patient circuit to the iSleep 10.
- 2 Connect the iSleep 10 to the mains supply.
- 3 Check patient settings.
- 4 Switch on the iSleep 10 by pressing the Start/Stop button on the front panel. Ensure that the iSleep 10 is running.
- 5 Put on the mask and adjust its fit.
- 6 Ensure that the settings are adjusted as prescribed.

The iSleep 10 is ready for use.

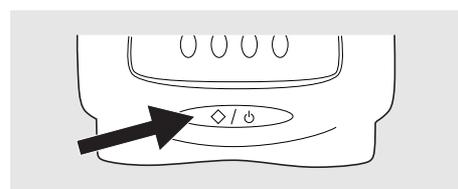
### 5.2 Switching the iSleep 10 On and Off

- 1 Make sure the power supply is connected.



- 2 Turn on the iSleep 10 by pressing the Start/Stop button on the front panel for 2 seconds.

This operation switches the iSleep 10 between standby and operating mode.



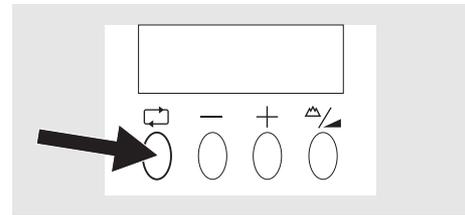
The iSleep 10 is connected to a power supply when the text OFF is shown in the display.

## 5.3 Using the menu

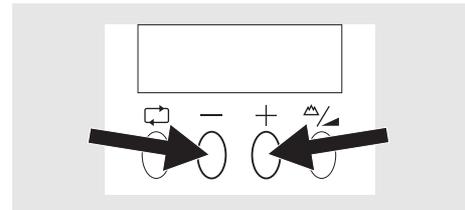


Read chapter “The iSleep 10's Front Panel” on page 14 for exact position of the buttons.

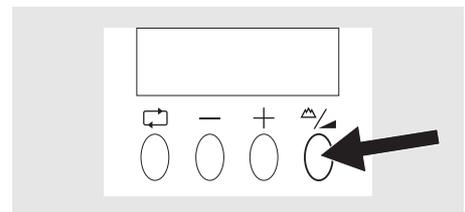
Use the function button to toggle through the different functions of the iSleep 10.



The plus and minus buttons are used to alter a value.

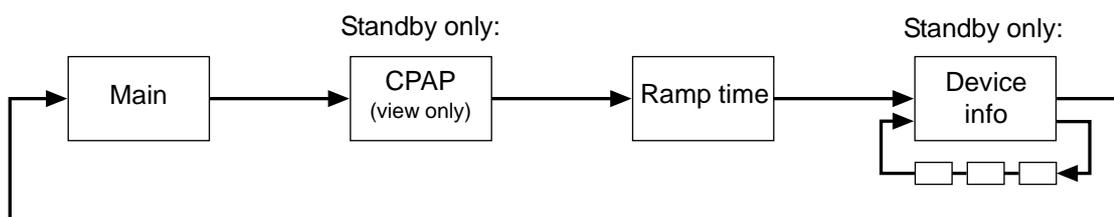


- Standby mode  
The altitude button is used to set the altitude.
- Active mode  
The ramp button is used to activate the ramp function during operation.



### Overview

The iSleep 10 menu has the following layout:



### Icons in the Display Window

ICON	EXPLANATION
	Pressure
	Ramp

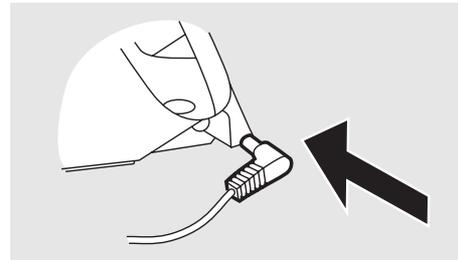
ICON	EXPLANATION
	Information
	Panel lock

## 5.4 Using an External Battery

The iSleep 10 can be powered from:

- The Breas external EB 2 Battery Pack.
- A 12 V external power source. The iSleep DC converter 12-24 V needs to be used.

**1** Connect the external DC cable to the iSleep 10. Make sure it is fitted correctly.



**2** Connect the other end of the cable to the battery source.



- Always make a function check to test the battery condition before operating the iSleep 10 from an external battery source.
- The battery must be disconnected when the iSleep 10 is switched off, otherwise the battery will be discharged.

### Battery Operation Time

The operation time is dependent on the battery condition, its capacity, the ambient air temperature and the iSleep 10 pressure setting.

The operation time is based on the following settings:

SETTING	VALUE
CPAP pressure	10 cmH <sub>2</sub> O
Ambient temperature	20°C (68°F)
Altitude	Sea level

<b>SETTING</b>	<b>VALUE</b>
Battery status	New battery fully charged

<b>BATTERY TYPE</b>	<b>OPERATION TIME</b>
EB 2 (24 V, 7.2 Ah)	13 h
Car battery (12 V, 60 Ah)*	90 h

\* When using a 12 V external power, the iSleep DC converter 12-24 V needs to be used.

## 6 Preparing the iSleep 10 for Use

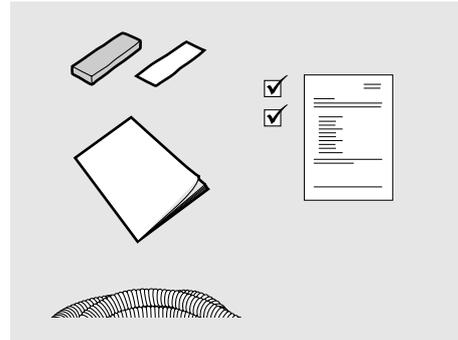


Read the chapter “Safety Information” on page 6 before setting up and using the iSleep 10.

### 6.1 Installing the iSleep 10

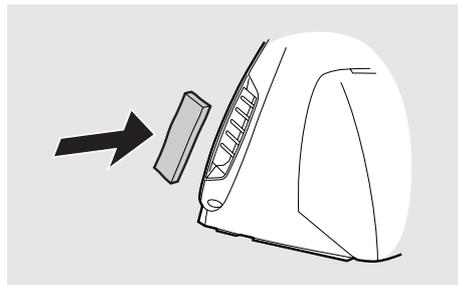
When using the iSleep 10 for the first time, follow the instructions below:

**1** Check that all main components and ordered accessories have been delivered (refer to the packing note or the invoice, if available).



**2** Ensure that the equipment is in good condition.

**3** Check that the mandatory grey patient air filter is installed.

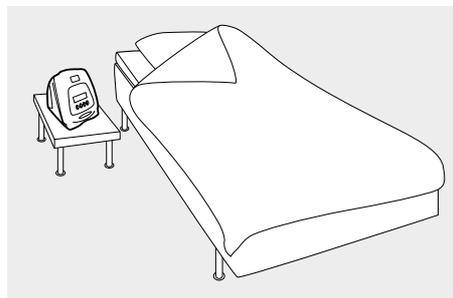


## 6.2 Placing the iSleep 10

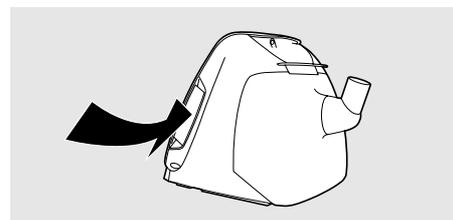


Read the chapter “Environmental Conditions” on page 8 carefully to make sure all conditions are fulfilled and considered.

**1** Place the iSleep 10 on a solid, flat surface. The iSleep 10 should be placed lower than the patient in order to prevent the device from falling on the user.



**2** Make sure that nothing can block the patient air inlet at the side of the iSleep 10.



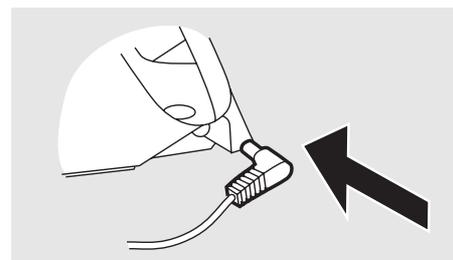
## 6.3 Connecting the iSleep 10 to the Mains Supply



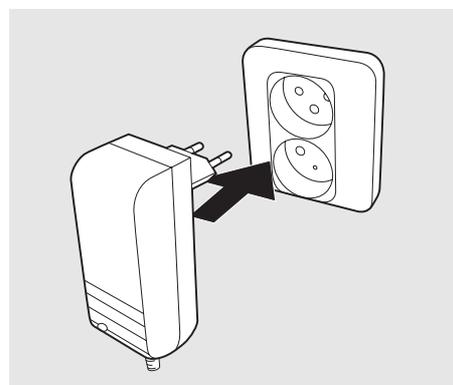
Read the chapter “Electrical Safety” on page 7 carefully to make sure all conditions are fulfilled and considered.

**To Connect the iSleep 10 to the Mains Supply:**

**1** Plug the power supply into the power inlet of the iSleep 10.



**2** Connect the power supply to the mains supply.

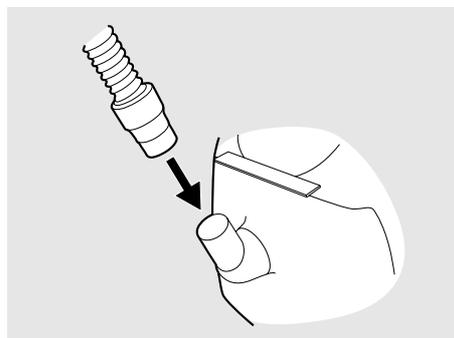


## 6.4 Connecting the Patient Circuit



Read the chapter “Usage of Patient Circuit” on page 9 carefully to make sure all conditions are fulfilled and considered.

1 Connect the patient tube to the air outlet.



2 Connect the other end of the patient tube to the mask and the ventilation valve, if applicable.

### Mask Leakage

The leakage from the mask should be at least 12 l/min at 4 cmH<sub>2</sub>O, to prevent re-breathing of exhaled air. The recommended mask leakage is 20-40 l/min at 10 cmH<sub>2</sub>O pressure.

This leakage may be achieved by:

- small holes in the mask
- an adjoining ventilation valve



In order to receive a suitable leakage the Breas iMask™ Nasal CPAP Mask is recommended.

## 7 Setting up the iSleep 10



The configuration of the iSleep 10 therapy settings must always be prescribed by a licensed physician and carried out by an authorized health care professional.



*For more information about the Breas iSleep 10's settings, please contact your care provider.*

The CPAP setting can be set to 4 to 20 cmH<sub>2</sub>O.

### 7.1 Setting the Parameters



*For more information about how to use the menu, please read the chapter “Using the menu” on page 19.*

*Study the overview picture in “Using the menu” on page 19 if a page or section can not be found.*

#### The Ramp function

Setting range: 5 to 60 min.

Resolution: 5 min.

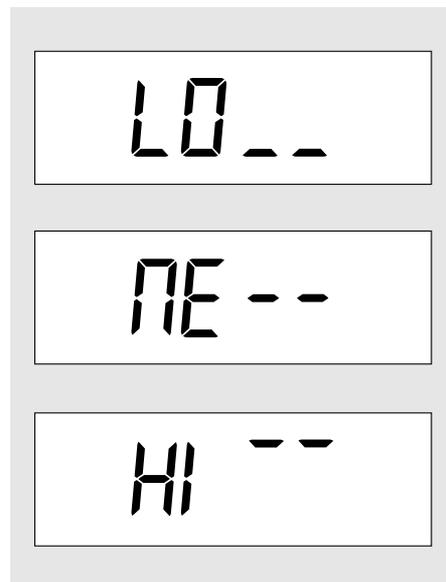
Navigate to the “Ramp” section. The ramp function can only be activated during operation.



#### Altitude

Setting range: low (LO), medium (ME) and high (where HI is used for the highest altitude).

Press the altitude setting button, and adjust setting with the “+” and “-” buttons.



## 7.2 Viewing Device Information



*Check the chapter “Using the menu” on page 19 for information about how to navigate to the device info screen.*

Navigate to the “Device info” section (in standby only). Use the “+” button to cycle through the screens.

The “Device info” section contains three information screens:

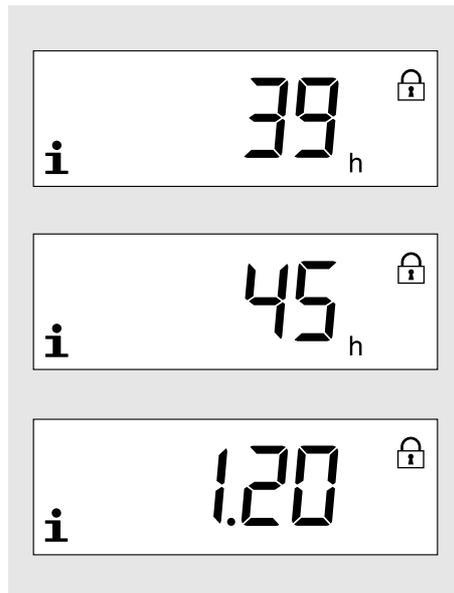
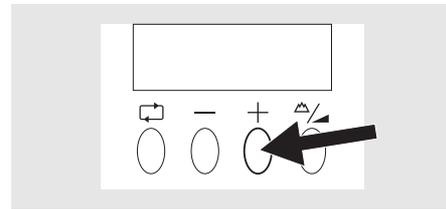
**1 Patient Operating Time:**

Total number of hours a patient has been using the iSleep 10 for CPAP treatment (ramp and mask off not included).

**2 Total Operating Time:**

Total number of hours the iSleep 10 has been operating.

**3 Software version.**



## 8 Internal Function Error

The indication function of the iSleep 10 consists of a message shown in the display window.

ITEM	DESCRIPTION
<b>Definition</b>	<p>An internal function error will be given when the iSleep 10 has an internal function failure. The following error codes exist:</p> <ul style="list-style-type: none"><li>• 20: Function error. Contact your care provider.</li><li>• 21: Low power. Check the power cables and the mains connection.</li><li>• 30: High temperature. Let the iSleep 10 cool down and restart. The ambient temperature might be too high.</li><li>• 61: Check settings. Check that the settings of the iSleep 10 are according to prescription.</li></ul>
<b>Action</b>	<p>The iSleep 10 will continue or stop the treatment depending on the type and priority of the event.</p>
<b>Indication</b>	<p>The indication is asserted visible by a display message.</p>
<b>Reset</b>	<p>If possible, correct the error cause and disconnect and connect the mains power source. If the error remains, contact your care provider.</p>

## 9 Cleaning the iSleep 10 and Replacing the Filters

The patient-connected parts and the filter must be cleaned and replaced regularly to ensure correct function of the iSleep 10. All replaced parts must be disposed of in accordance with local environmental regulations regarding the disposal of used equipment and waste.

### 9.1 Cleaning the iSleep 10



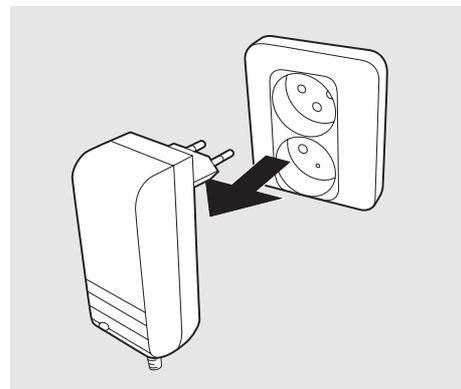
To avoid electrical shock, disconnect the mains supply to the iSleep 10 before cleaning. Do not immerse the iSleep 10 into any fluids.



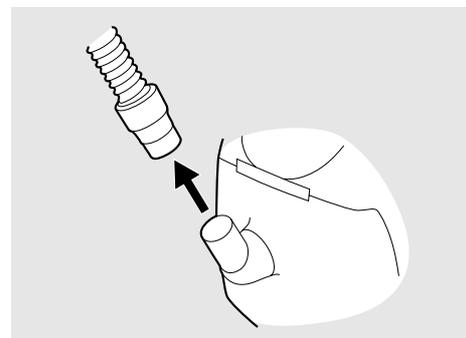
- Always be careful when cleaning to ensure that you do not damage any equipment.
- Fluid must not be allowed to enter into the iSleep 10.

#### Main Unit

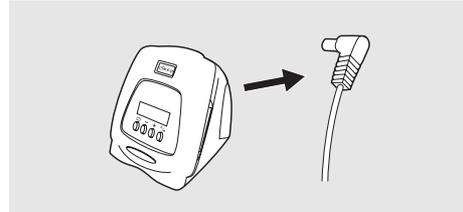
1 Switch off the iSleep 10 and disconnect the mains supply.



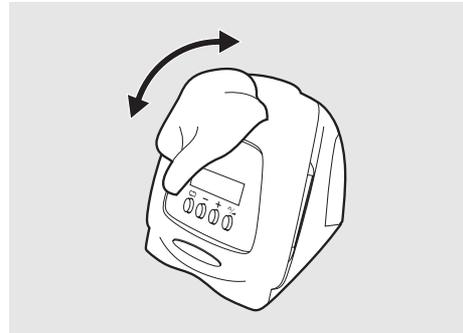
2 Remove the patient circuit.



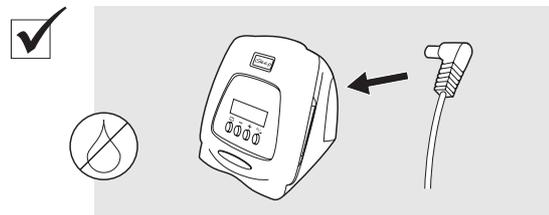
**3** Disconnect all cables.



**4** Clean the outside of the iSleep 10 using a lint-free cloth and a mild detergent solution.



**5** Reconnect cables and the patient circuit. Make sure all parts are dry before the iSleep 10 is put into operation.



### **Patient Circuit**



*The patient circuit should be cleaned in accordance with the care provider's instructions.*

Always clean the parts or use a new set when used by a new patient.

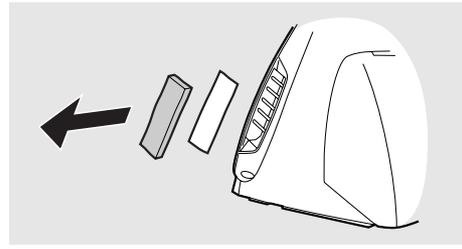
All parts that come into contact with the respiration gas must be cleaned as follows:

- 1** Place the dismantled parts in hot water containing washing-up liquid.
- 2** Remove fouling with a brush.
- 3** Rinse parts thoroughly under running hot water.
- 4** Shake water out of all parts.
- 5** Dry the parts completely.
- 6** Store in dust-free location.

The patient circuit shall be replaced in intervals according to the care provider's instructions. Check the patient circuit for damage regularly. In case of damage, replace the circuit.

## 9.2 Cleaning and Replacing the Patient Air Filter

The patient air filter is located on the side of the iSleep 10. There are two types of filters:



### **Washable Filter (mandatory, grey colour)**

Replace the washable filter at least once a year. Wash the filter at least once a week.

- 1 Wash the filter using warm water and a mild detergent.
- 2 Rinse thoroughly.
- 3 Dry the filter by squeezing it out in a towel. Do not wring the filter.

### **Disposable Filter (white colour, optional)**

Replace the filter at least every 4th week, or more often when used in high pollution or pollen-rich environments.



**Do not wash or reuse the disposable filter.**

## 10 Maintenance



### **WARNING!**

- iSleep 10 should be subjected to maintenance, service and control and any applicable upgrades, in accordance with Breas service instructions.
- iSleep 10 should only be repaired or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians that have been authorized after Breas iSleep 10 service training.
- Do not under any circumstances attempt to service or repair the iSleep 10 yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the iSleep 10.

**DEVIATION FROM THESE SERVICE INSTRUCTIONS MAY LEAD TO RISK OF PERSONAL INJURY!**

### 10.1 Regular Maintenance Control

The iSleep 10 should not require any regular maintenance inspections if it is used and maintained in accordance with the instructions in this manual.



**Do not use the device and contact your responsible care provider for an inspection of the device in the event of:**

- Unexpected patient symptoms during treatment.
- Unexplainable or sudden pressure, performance or sound changes during operation.
- Suspected damage to the device or power supply.

## 10.2 Service and Repair

The service and repair of the iSleep 10 must only be carried out by authorized service personnel in accordance with Breas service instructions. Service inspections must always be carried out after any repair of the device.



*Authorized service workshops can order the iSleep 10 Service Manual that contains all technical documentation required for the maintenance and service of the iSleep 10.*

## 10.3 Disposal

The iSleep 10, any accessories and all replaced parts must be disposed of and recycled in accordance with the local environmental regulations regarding the disposal of used equipment and waste.

# 11 Technical Specifications

## 11.1 Data



The iSleep 10 and its packaging do not contain any natural rubber latex.

SETTING/VALUE	RANGE/SPECIFICATION	RESOLUTION
CPAP	4 to 20 cmH <sub>2</sub> O ±5% of max value and ±10% of set value.	0.5 cmH <sub>2</sub> O
Ramp time	5 to 60 min	5 min
Ramp start pressure	4 cmH <sub>2</sub> O to CPAP	0.5 cmH <sub>2</sub> O
Maximum flow	>125 l/min	
Maximum limited pressure during sin- gle fault condition	30 cmH <sub>2</sub> O	
Max flow in CPAP mode	6.7 cmH <sub>2</sub> O: 77 l/min 13.3 cmH <sub>2</sub> O: 113 l/min 20 cmH <sub>2</sub> O: 138 l/min	
Breathing resist- ance under single- fault	0.7 cmH <sub>2</sub> O at 30 l/min 2.6 cmH <sub>2</sub> O at 60 l/min	
Digital output	0 to 5 V	
Sound level at 10 cmH <sub>2</sub> O	Less than 30 dB(A). Measured at 1 m.	

INDICATIONS	SPECIFICATION	TOLERANCE
Internal function indication	Message shown in the display.	

POWER SUPPLIES	SPECIFICATION
Mains supply	100 to 240 V AC, tolerance: -15%/+10%, 50 to 60 Hz, max 140 VA. DC output: 24 V.

<b>POWER SUPPLIES</b>	<b>SPECIFICATION</b>
External DC supply	24 V DC, tolerance: -15%/+25% (20.4 to 30 V). Max 1 A, 24 W with Breas external battery.
Standby power	3 W

<b>ENVIRONMENTAL CONDITIONS</b>	<b>SPECIFICATION</b>
Operating temperature range	5 to 40°C (41 to 104°F)
Storage and transport temperature	-20 to +60°C (-4 to +140°F)
Ambient pressure range	700 to 1060 mbar
Humidity	10% to 95%, non-condensing
Altitude setting	Low: 1060 to 900 mbar ambient pressure, equal to approximately <500 m over sea level. Medium: 900 to 800 mbar, approx. 500 m to 1500 m. High: 800 to 700 mbar, approx. 1500 m to 2600 m.

<b>OPERATING CONDITIONS</b>	<b>SPECIFICATIONS</b>
Recommended leakage	20 to 40 l/min at 10 cmH <sub>2</sub> O.
Minimum leakage	12 l/min at 4 cmH <sub>2</sub> O.

<b>DIMENSIONS</b>	<b>SPECIFICATIONS</b>
W × H × D	173 × 172 × 209 mm
Weight	1.3 kg
Air outlet	22 mm male conical standard connector

## 12 Accessories

### 12.1 Breas Accessories List



Only use accessories recommended by Breas Medical AB. Breas Medical AB cannot guarantee the performance and safety for the use of other accessories with the iSleep 10.

The following Breas accessories are currently available for the iSleep 10:

DESCRIPTION	PART No.
Carrying bag	003793
Users manual	004266
Patient tube	000245
Filter (grey, washable)	004154 (5 pcs)
Filter (white, disposable, optional)	004153 (5 pcs)
iMask 100	003971
iMask 200	003972
Breas one-size headgear	003434
iSleep power supply	003772
EB 2 external battery pack 24 V DC, including cable, charger and bag	004147
External DC cable (EB 2)	003679
TrafoBox EB 2 external battery	001153
Charger EB 2 external battery	001159
Carrying bag EB 2 external battery	000269
EB 2 power cord	000539
iSleep DC converter 12-24 V	004138

# 13 Patient Settings

## Patient Settings - Breas iSleep 10

Patient .....

Date .....

Clinic .....

Set by .....

iSleep 10 serial number .....

CPAP .....

Ramp Time ..... Ramp Start Pressure .....

Notes .....

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