Table of Contents

1 Introduction

This chapter gives an overview of the iSleep 10/20 CPAP device and this service manual.

WARNING!

This product must be repaired and/or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians that have been authorised after the Breas iSleep 10/20 service training, or have an equivalent technical knowledge on medical respiratory devices.

Deviation from these service instructions may lead to risk of personal injury!

1.1 About the iSleep 10/20 CPAP device

1.1.1 Function

The iSleep 10/20 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.

The iSleep 20 has a pressure sensor that continuously monitors output pressure to the patient and reference ambient pressure, so that the device automatically will compensate for altitude changes.

The internal memory of the iSleep 20 can be downloaded to a PC where you can view the patient compliance data in the "Breas iSleep PC Software".

1.1.2 Intended Use

For a detailed description on intended use, refer to the iSleep 10/20 Clinician's or User Manuals.

1.1.3 Design

The iSleep 10/20 is constructed around a blower assembly.

A microprocessor controls the speed of the blower motor by means of calculations based on the settings and pressure. iSleep 20 also monitors the reference ambient pressure, so that the device automatically will compensate for altitude changes.

1.1.4 Service Personnel's Training Requirements

Service personnel working with the iSleep 10/20 should have medical/technical training and a good knowledge of the construction and function of respiratory devices.

Always contact your Breas representative if you have any questions or if any training is required.

1.2 About this Manual

1.2.1 Scope

This manual describes all the checks and the additional service actions for the iSleep 10/20. The manual contains all the documentation that is required for the service of the CPAP device.

Breas Medical AB reserves the right to make changes to the products and/or the contents of this manual without any prior notice.

1.2.2 Intended Audience

This service manual is intended for service technicians who have medical/technical training and who have a good knowledge of the construction and function of respiratory devices.

Always contact your Breas representative if you have any questions or if any training is required.

The service manual is not intended for clinical personnel or patients, who will find all the information they need in the iSleep 10/20 Clinician's and User Manual.

1.2.3 Icons

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

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

2 Service Instructions

The iSleep 10/20 is designed to give users many years of trouble-free breathing assistance. The iSleep 10/20 requires no periodic maintenance.

This chapter describes all the checks and additional service instructions for the iSleep 10/20.

WARNING!

This product must be repaired and/or modified in accordance with Breas service manuals, technical bulletins, and any special service instructions, by service technicians that have been authorised after the Breas iSleep 10/20 service training, or have an equivalent technical knowledge on medical respiratory devices.

Deviation from these service instructions may lead to risk of personal injury!

The patient and care provider should follow the checks that are described in the iSleep 10/20 User and Clinician's Manual.

2.1 Introduction

Before you start a service, read the safety precautions and make sure you have a new service record and all the necessary equipment, tools, and replacement parts at hand. It is important that any peripheral equipment is checked at the same time as the services are carried out.

2.1.1 Safety Precautions

Follow the safety precautions below when working with the iSleep 10/20:

- Do not work on the CPAP device with the casing removed and the power supply connected, unless the instructions in this manual clearly says so.
- Always use caution when working with the CPAP device connected to the mains and the casing removed.
- Do not use explosive gases and/or fluids near the CPAP device.
- Make sure that all precautions to prevent electrostatic discharge (ESD) have been taken. Follow all regulations regarding ESD.

The iSleep 10/20 User and Clinician's Manuals contains extended lists of safety precautions.

2.1.2 Service Record

The iSleep 10/20 service record is found in "Service Record iSleep 10/20" on page 36.

Copy the service record and use it for noting the service checks while performing the service.

2.1.3 Inspection Equipment and Tools

Before starting the service of the iSleep 10/20, make sure you have the following equipment at hand:

- Pressure manometer (Thommen HM 28 digital manometer, Breas part no 001937, or equivalent).

- Torx key TX 10.
- iSleep to PC communication cable, Breas part no 003588.
- iSleep/Vivo Service Software, available for download from Breas Extranet. Contact Breas technical support for more information.

2.1.4 Replacement Parts

The following replacement parts should be available when servicing the CPAP device:

DESCRIPTION	PART NO.
Patient air filter, grey, washable	004154 (5 pcs)
Patient air filter, white, disposable	004153 (5 pcs)
If required:	
Clock battery, CR 2032 (iSleep 20 only)	002129

2.2 Preparing for Inspection

2.2.1 Initial Recording

1. Copy a new service record (see "Service Record iSleep 10/20" on page 36).
2. Identify the iSleep 10 or iSleep 20.
3. Note the model and serial number and any inventory number on the service record.
4. Check any comments recorded on the previous service records.
5. Document the current patient settings.
6. Note the number of Total operating hours on the service record.

The operating hours are found at the "Device information" screen. Access the "Device information" using the menu as described in the iSleep 10/20 Clinician's Manual.

2.2.2 Inspecting the Markings

Make sure that all markings on the CPAP device's information labels can be read:

- Model description, serial number
- Warning texts
- Any inventory marking
- Any other texts

2.2.3 Information from the Patient/User

Check the following with the patient:

- Has the CPAP device functioned without any problems? If not, what were they?
- How does the patient/care provider check the function of the CPAP device? How often?
- How often is the filter replaced?
- How many filters will be required before the next service?
- Other observations?

2.2.4 Validity of the Documentation

1 Check the validity of the User or Clinician's Manual enclosed with the CPAP device.

2 Check if any modification or upgrading of the CPAP device needs to be done at the same time as the service.

2.3 External Inspection

2.3.1 Visual Inspection for External Damage and Wear

1 Clean the outside of the CPAP device using a mild soap solution.

2 Check for any visible damage to the casing and the other components.

3 Check that nothing has become loose.

4 Check that the rear lid is connected properly to the CPAP device.

2.3.2 Checking the HA01 Humidifier (if used, iSleep 20 only)

1 Remove and open the HA01.

2 Check that there is no visible damage.

3 Check that the water container is clean.

4 Check that the humidifier is connected properly to the CPAP device.

2.3.3 Checking the Power Connection

1 Check the plugs on the power cord, the cord itself, and the CPAP device's power socket.

2 Check the power supply.

3 Inspect the external battery cable, if used.

2.3.4 Inspecting the Patient Circuit

Inspect the patient circuit and replace it if necessary.

2.3.5 Inspecting the CPAP Device Accessories

Check any other accessories that are used with the CPAP device.

2.3.6 Changing/Washing the Patient Filters

1 Change the white air filter (if used).

2 Change or wash the grey filter, if necessary.

2.3.7 Minimum Function Check

1 Connect the power cord.

2 Connect the patient circuit.

3 Start the CPAP device and make sure it operates normally.

2.4 Internal Inspection

Perform an internal inspection if having opened the iSleep 10/20.

Make sure to disconnect the power supply before opening the casing of the CPAP device.

2.4.1 Cleaning the Inside of the CPAP device

1 Open the casing. See "Opening the iSleep 10/20 and Replacing the Main Components" on page 18 for instructions.

2 Remove any dirt or dust that has collected in the CPAP device casing.

3 Open the dark grey air channel top by pulling it straight up and remove any dirt or dust. Press the air channel back in place and make sure it fits properly.

2.4.2 Checking the Cables

Inspect all the cables and their connectors. Check the front and rear panels to make sure that the cables and the wires are not pinched or kinked.

2.4.3 Checking the Fastening of Components

Make sure that all the components, such as the circuit board, the connectors and the tubings (iSleep 20 only) are securely fastened.

2.4.4 Checking the Power Supply

Make sure that the power connector is undamaged and that it is securely in place.

2.4.5 Reassembling the Casing

See "Opening the iSleep 10/20 and Replacing the Main Components" on page 18 for instructions.

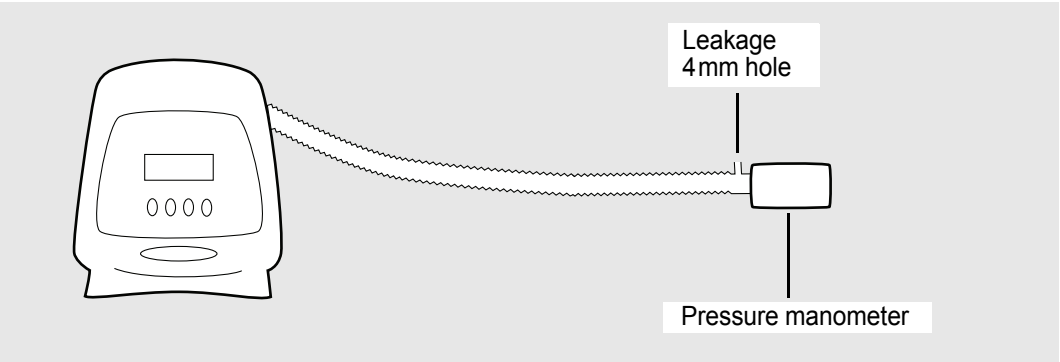
2.5 Complete Function Test.

You can also perform the complete function test using the "iSleep/Vivo Service Software".

To perform a complete function test, all tasks in this section needs to be completed in the written order.

2.5.1 Checking the Pressure

1 Connect a 4mm restrictor and a pressure manometer to the iSleep 10/20.



2 Adjust the settings as follows:

SETTING	VALUE
CPAP	4 cmH_2O

3 Start the iSleep 10/20 and let it run for 30 minutes before the test.

4 Measure and check that the measured value for pressure is correct
iSleep 10 tolerance: ±5% of the maximum value and ±10% of the set value.
iSleep 20 tolerance: ±1 cmH_2O.

5 Change the CPAP pressure to 10 cmH_2O and repeat the measuring.

6 Change the CPAP pressure to 15 cmH_2O and repeat the measuring.

7 Change the CPAP pressure to 20 cmH_2O and repeat the measuring.

If the measured pressure values are not within tolerance, perform a pressure calibration/adjustment of the CPAP device (see "Upgrade and Calibration" on page 23).

2.5.2 Checking the Snooze Function (iSleep 20 only)

1. Start the iSleep 20.
2. Shortly press the on/off button.
3. Check that the iSleep 20 reduces pressure and that the fan symbol starts blinking.
4. Shortly press the on/off button.
5. Check that the iSleep 20 delivers the set pressure.
6. Shortly press the on/off button so that the snooze function activates.
7. Create a spontaneous breath.
8. Check that the iSleep 10/20 delivers the set pressure.

Read more about the Snooze function in the iSleep 20 Clinician's manual.

2.5.3 Adjusting the Settings for the Patient

Adjust the settings as prescribed for the patient.

2.6 Electrical Safety Precautions

Electrical safety measurements must be made in accordance with IEC 601.

Use an automatic electrical safety tester to make the measurements. All tests must be performed in accordance with class II type BF.

Supply Voltage

Note the power voltage reading.

The voltage must be noted at each service check, as the currents measured are directly in relation to the supply voltage. This allows all measurements made on the same CPAP device to be compared with measurements made on different occasions.

Insulation

The insulation resistance is measured using a 500 V DC power supply. The most suitable method is to connect the plus lead to the two CPAP device power socket pins, and the minus lead to the casing or the patient air connector. The measurements made during the delivery inspection can be used as reference values for measurements made during future services. If no reference values are available, the value for the insulation resistance should be >20 MΩ .

Leakage Currents

The leakage currents are measured at different parts of the CPAP device using an RC circuit to earth.

Make the measurements partly at normal case (NC) and at the single fault condition (SFC). Reverse the polarity of the power supply and note the highest value.

Leakage currents to earth must not exceed the stated limit values.

Leakage Currents from the Casing

The leakage current of the casing is measured at an unpainted point, for example, the head of a screw.

Limit values: NC <0.1 mA

SFC <0.5 mA

Break neutral for SFC.

Patient Leakage Currents

The patient leakage current is measured between the patient connector and earth.

Limit values: NC <0.1 mA

SFC <0.5 mA

Break neutral for SFC.

Leakage Currents with Mains Power Supply at the Patient-connected Part

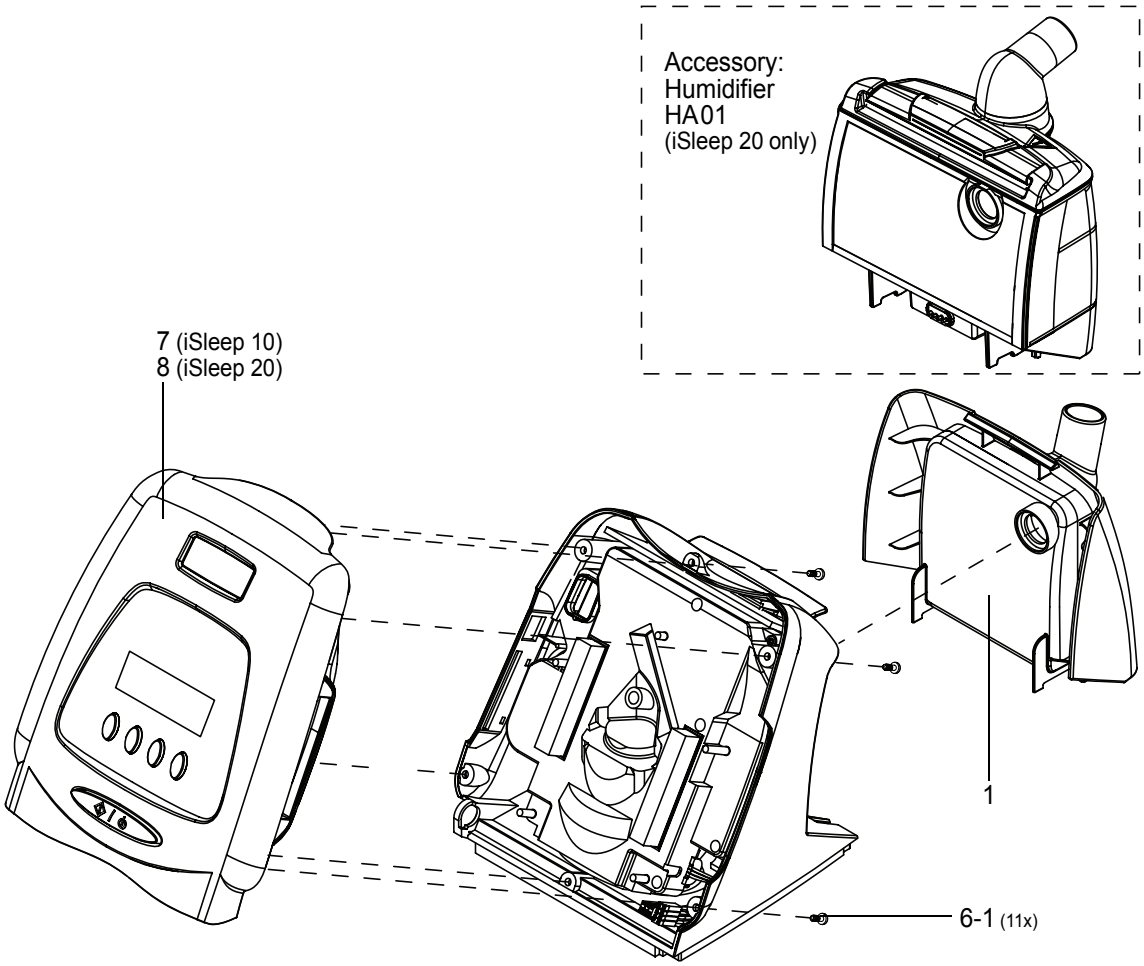
This test must be done using an automatic electrical safety tester with this function. See the safety instructions for the tester.

Limit value: SFC <5 mA

3 Parts Location

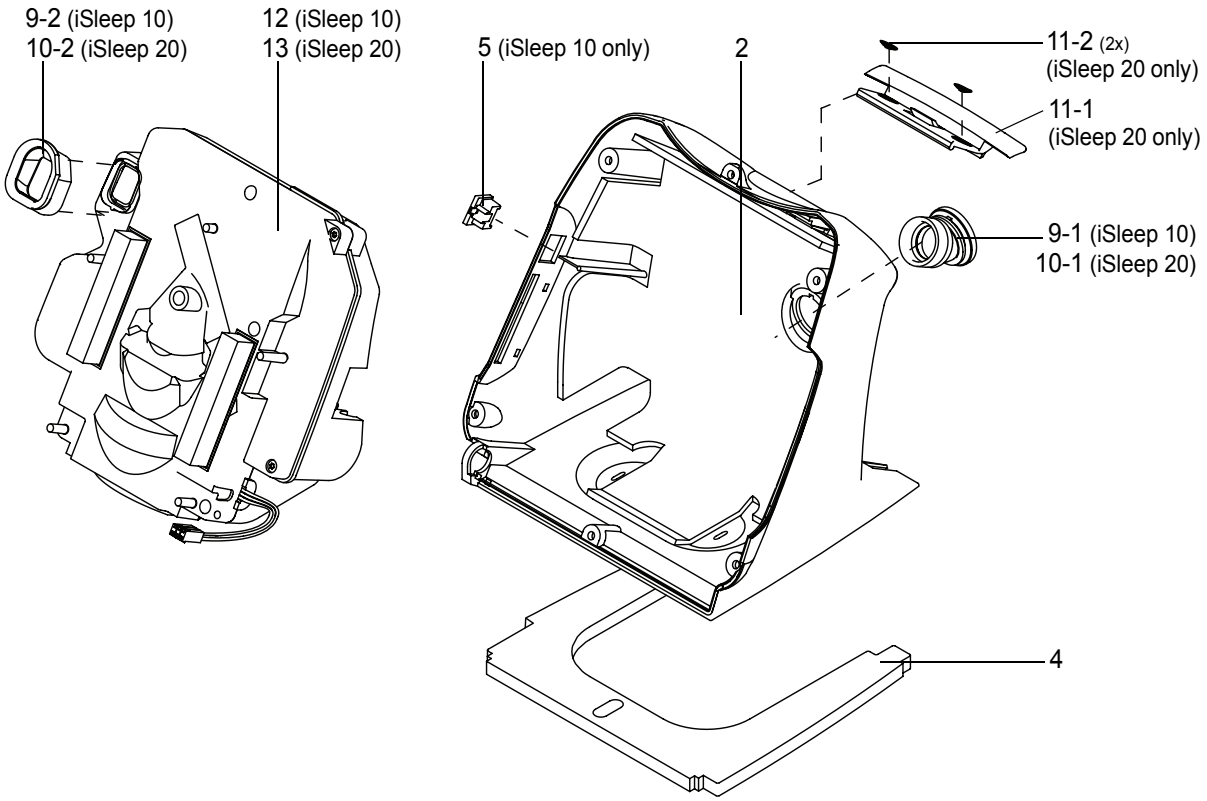
This chapter contains part-number lists and drawings of the parts for the iSleep 10/20.

3.1 Parts Drawing 1 – Main Components



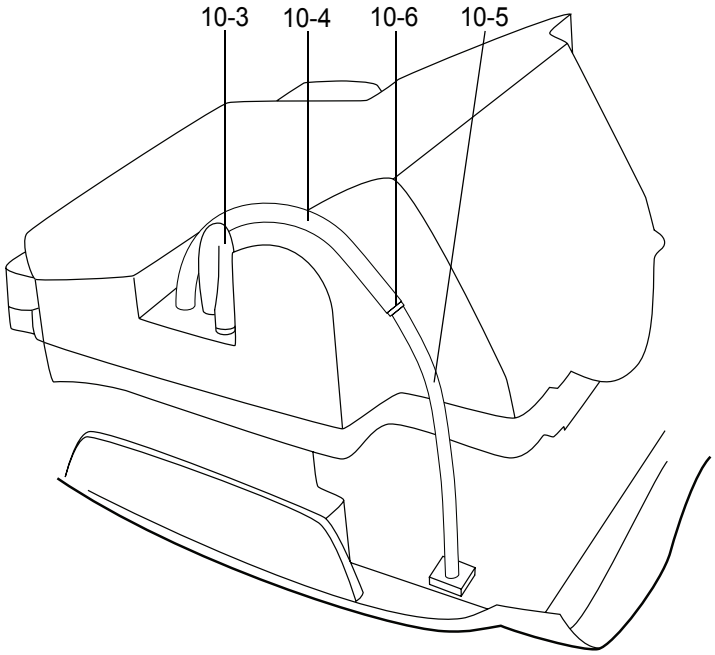
For definitions of the part numbers, refer to the parts list in section 3.5, "Parts List for the iSleep 10 and iSleep 20", on page 14.

3.2 Parts Drawing 2 – Back Casing, Blower Unit



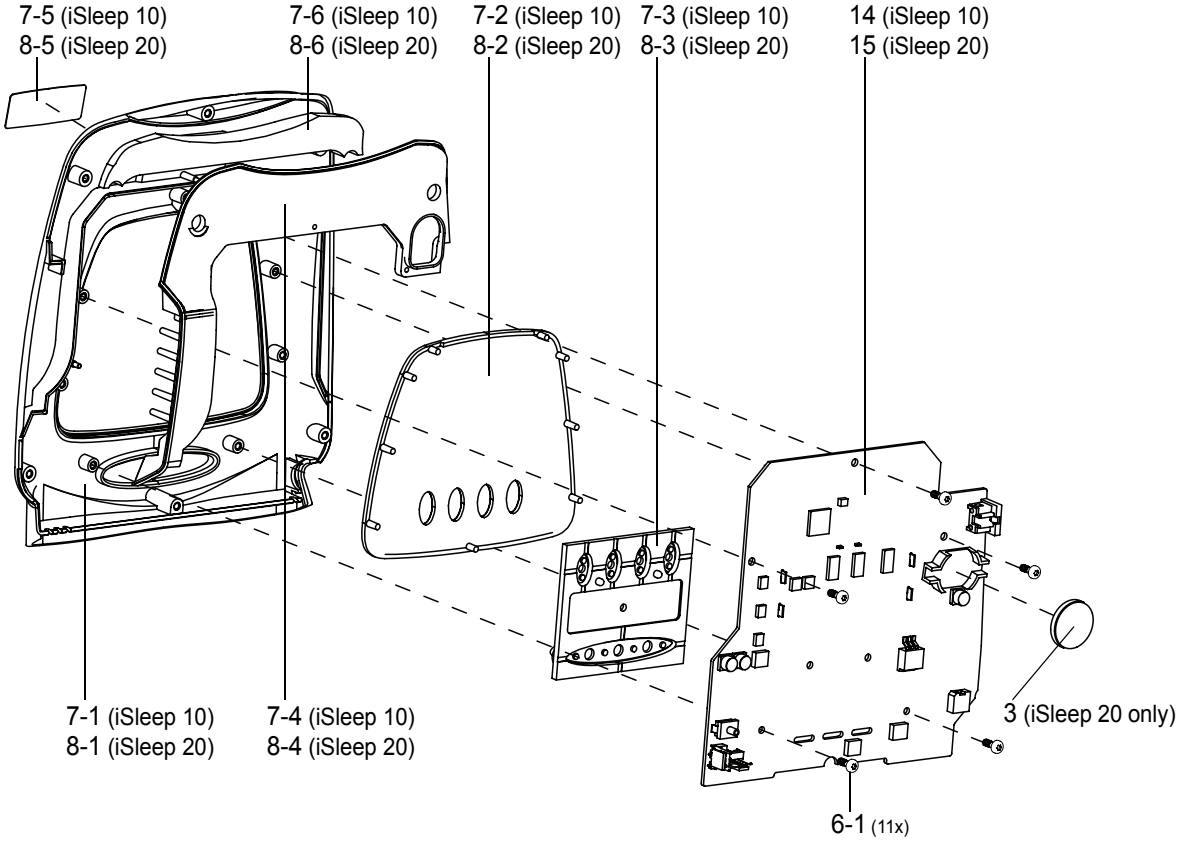
For definitions of the part numbers, refer to the parts list in section 3.5, "Parts List for the iSleep 10 and iSleep 20", on page 14.

3.3 Parts Drawing 3 – Tube connections (iSleep 20 only)



For definitions of the part numbers, refer to the parts list in section 3.5, "Parts List for the iSleep 10 and iSleep 20", on page 14.

3.4 Parts Drawing 4 – Front Casing, Circuit Board



For definitions of the part numbers, refer to the parts list in section 3.5, "Parts List for the iSleep 10 and iSleep 20", on page 14.

3.5 Parts List for the iSleep 10 and iSleep 20

The parts and service kits of the iSleep 10 and iSleep 20 are listed in the table below.

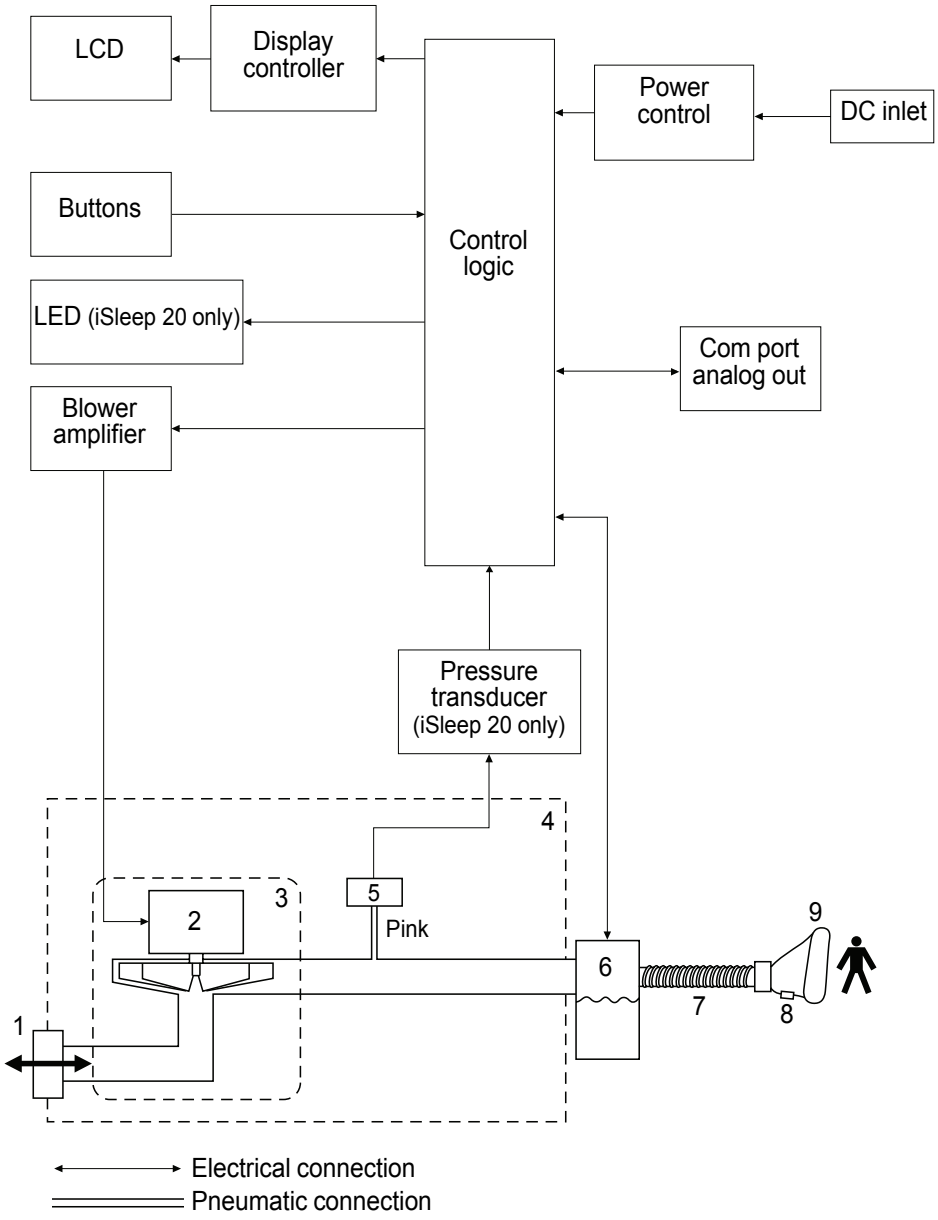
KIT NO.	DESCRIPTION	BREAS PART NO.	*AMOUNT*
1	**Air outlet patient assembly**	**004116**	*1*
2	**Suspension, noise box**	**004202**	*1*
3	**Battery CR2032 3V (iSleep 20 only)**	**002129**	*1*
4	**Friction pad**	**003692**	*1*
5	**Plug RJ45-8 (iSleep 10 only)**	**003733**	*1*
6	**Screw kit – iSleep**	**004296**	
6-1	Screw STS-T30x8 FZB		*11*
7	**Case front kit - iSleep 10**	**004295**	
7-1	Case front		*1*
7-2	Window "iSleep 10"		*1*
7-3	Keypad		*1*

KIT NO.	DESCRIPTION	BREAS PART NO.	*AMOUNT*
7-4	Air channel		*1*
7-5	Logotype “iSleep“		*1*
7-6	Insulation air channel		*1*
8	**Case front kit - iSleep 20**	**004287**	
8-1	Case front		*1*
8-2	Window “iSleep 20“		*1*
8-3	Keypad		*1*
8-4	Air channel		*1*
8-5	Logotype “iSleep“		*1*
8-6	Insulation air channel		*1*
9	**Tube kit - iSleep 10**	**004368**	
9-1	Tube outlet		*1*
9-2	Tube inlet		*1*
10	**Tube kit - iSleep 20**	**004288**	
10-1	Tube outlet		*1*
10-2	Tube inlet		*1*
10-3	Silicone tube - Yellow, short		*1*
10-4	Silicone tube - Yellow, long		*1*
10-5	Silicone tube - Pink		*1*
10-6	Barbed tube connection		*1*
11	**Lock device kit - iSleep 20**	**004289**	
11-1	Lock device		*1*
11-2	Spring conical		*2*
12	**Blower assembly - iSleep 10**	**004225**	***1***
13	**Blower assembly - iSleep 20**	**004226**	***1***
10-3	Silicone tube - Yellow, short		*1*
10-4	Silicone tube - Yellow, long		*1*
10-5	Silicone tube - Pink		*1*
10-6	Barbed tube connection		*1*
14	**CPU board - iSleep 10**	**003771**	***1***
15	**CPU board - iSleep 20**	**003767**	***1***

4 Functional Diagrams

This chapter contains a diagram of the pneumatic system of the CPAP device and a block diagram of the iSleep 10/20's functions.

The functional block diagram below shows how the electronics and pneumatics are designed and how they are connected to the other components.



The table below describes the components of the pneumatic diagram.

NO.	DESCRIPTION
1	Air inlet filter
2	Blower
3	Silencer box
4	iSleep 10/20 casing
5	Pressure sensor (iSleep 20 only)
6	Humidifier (optional, iSleep 20 only)
7	Patient tube
8	Leak holes
9	Mask

4.1 Filtering/Smoothing Techniques

FUNCTION	TECHNIQUE DESCRIPTION
Pressure	Low pass average time constant 16 ms

4.2 iSleep 10/20 Measuring and Display Devices

DEVICE	PURPOSE	TYPE	RANGE	RESOLUTION	ACCURACY	SENSING POSITION
Pressure sensing	Regulate pressure	Differential to ambient	-10 to +60 cmH_2O	0.1 cmH_2O	±0.1% FSS	Air outlet of iSleep
Pressure display	Indicate patient pressure	LCD	0 to 20 cmH_2O	0.1 cmH_2O	±0.5 cmH_2O	Air outlet of iSleep

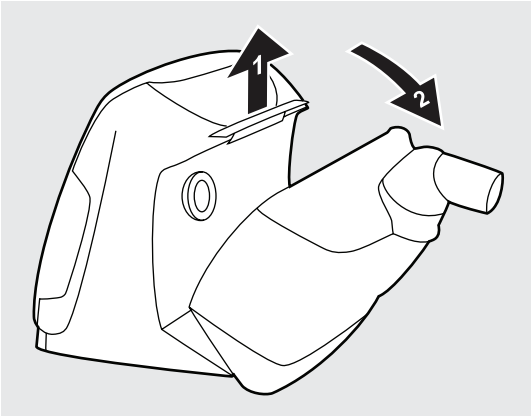
5 Opening the iSleep 10/20 and Replacing the Main Components

Make sure to disconnect the power supply before removing the casing of the CPAP device.

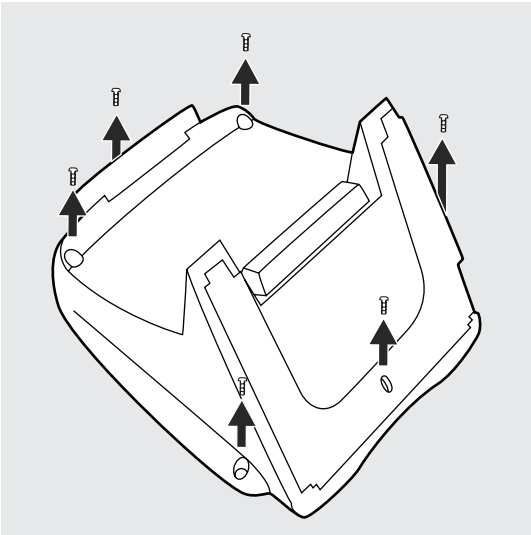
5.1 Opening the iSleep 10/20

- Before closing the iSleep 10/20, perform an internal inspection, see "Internal Inspection" on page 8.
- Always perform a complete function test after reassembling the iSleep 10/20, see "Complete Function Test." on page 9.
- Always perform an electrical safety test after reassembling the iSleep 10/20, see "Electrical Safety Precautions" on page 11.
- Make sure that the iSleep 10/20 is placed on a non-scratching surface.
- Make sure that the tubes are not pinched or kinked when closing the iSleep 20.

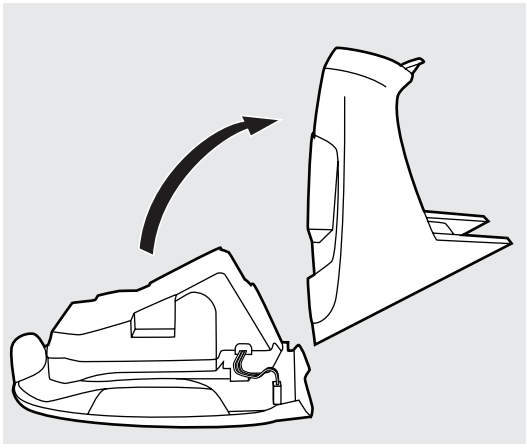
1 Remove the rear lid or the HA01 humidifier (if used, iSleep 20 only).



2 Remove the six screws for the casing.

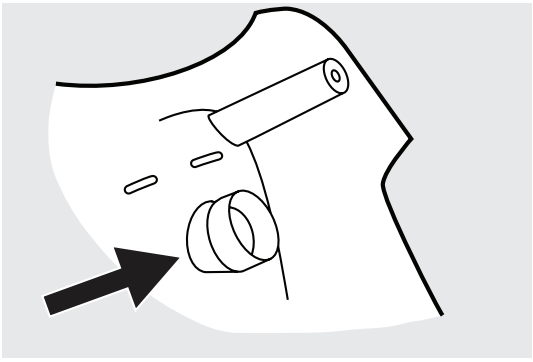


3 Lift the back casing straight up and tilt it backwards onto the table.



4 Reassemble in reverse order.
Make sure that the inlet and outlet tubes are properly fitted.

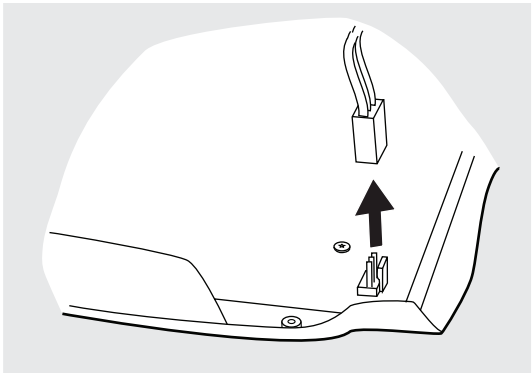
- The outlet tube should be pointing slightly upwards when fitted to the back casing.



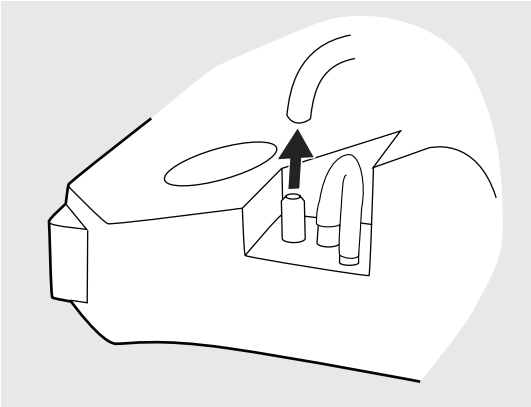
5.2 Replacing the Complete Blower Assembly

1 Open the iSleep 10/20 as in section 5.1.

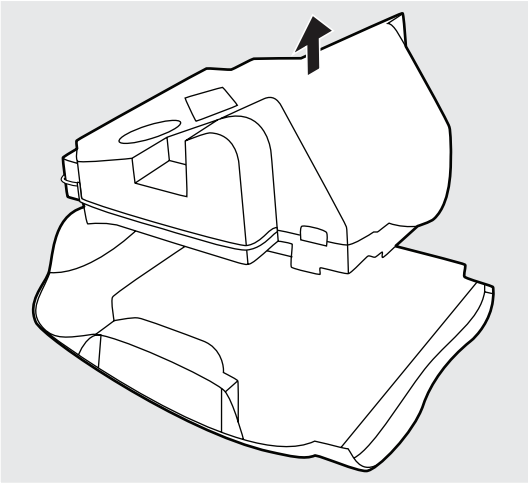
2 Disconnect the cabling for the BLDC motor control.



3 Disconnect the pressure sensing tube (iSleep 20 only).



4 Lift the blower assembly straight up. Remove the old pressure sensing tube from the circuit board and connect the one that is attached to the blower assembly (iSleep 20 only).



5 Reassemble in reverse order.

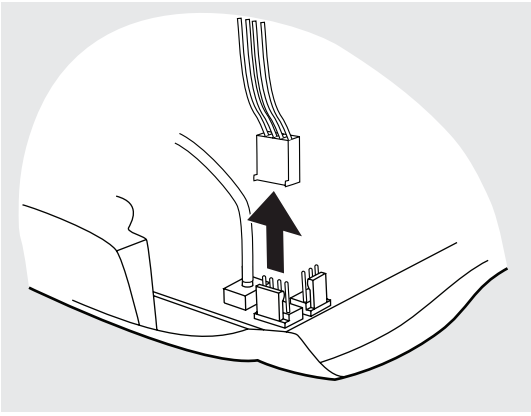
5.3 Replace the Circuit Board

The iSleep 10/20 serial number needs to be programmed into the new circuit board.

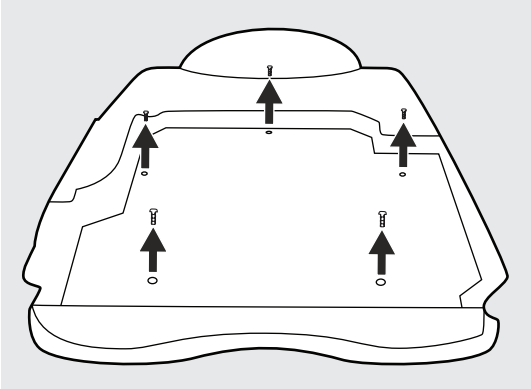
You need the "iSleep/Vivo Service Software" to program the circuit board with the correct serial number after replacement.

1 Open the iSleep 10/20 as in section 5.1.

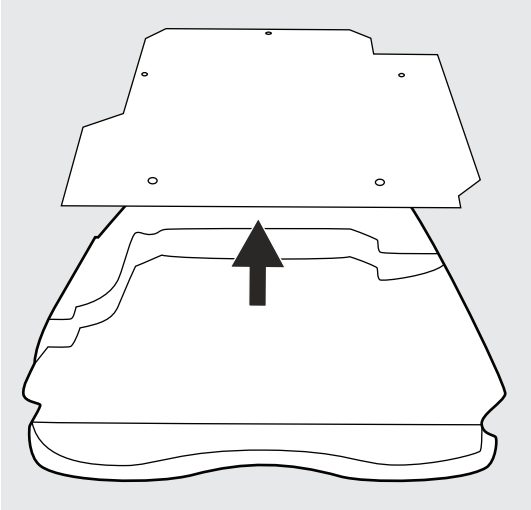
2 Disconnect the cabling for the humidifier (iSleep 20 only).



3 Remove the five screws for the circuit board.



4 Lift the circuit board by it's edges straight up.

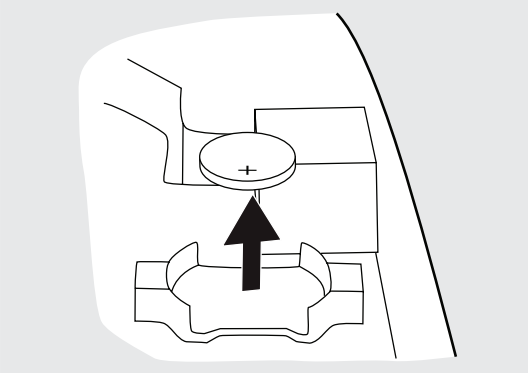


5 Reassemble in reverse order.
Remove the pressure sensing tube from the old circuit board and attach it to the new one (iSleep 20 only).

5.4 Replace the Clock Battery (iSleep 20 only)

1 Open the iSleep 20 as in section 5.1 and move the blower assembly from the circuit board so you can access the clock battery.

2 Remove the clock battery by pulling it straight up. Press a new clock battery into place.



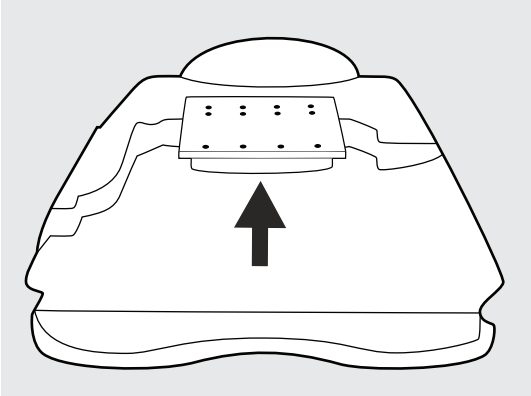
Make sure that the new battery is not handled with bare hands.

3 Reassemble in reverse order.

5.5 Replacing the Keypad

1 Remove the circuit board as in section 5.3.

2 Remove and replace the keypad.



3 Reassemble in reverse order.

6 Upgrade and Calibration

6.1 Firmware Upgrade

To upgrade the iSleep 10/20 firmware you need the "Firmware Upgrade Tool iSleep/Vivo" available for download from Breas Extranet. Contact Breas technical support for more information.

6.2 Pressure Calibration (iSleep 20 only)

To calibrate the iSleep 20 you need the "iSleep/Vivo Service Software" available for download from Breas Extranet. Contact Breas technical support for more information.

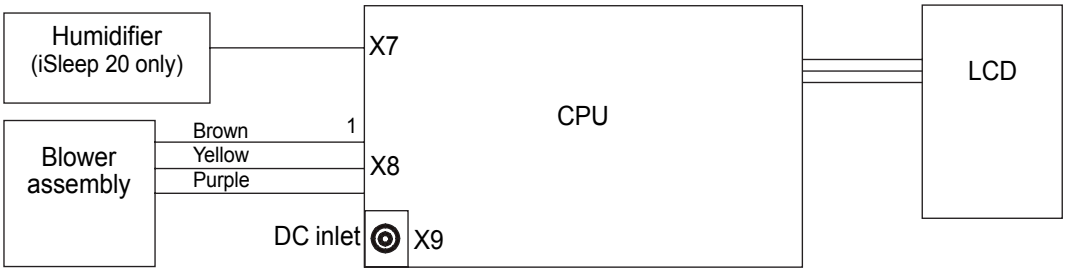
7 Electronics

Always perform a complete function test (see section 2.5 on page 9) if you have opened the iSleep 10/20.

The electronics, optics, mechanics, and pneumatics of the iSleep 10/20 are integrated. To understand fully the electronics of the iSleep 10/20, you must know how to use the CPAP device, study the pneumatic diagram and acquaint yourself with the mechanical construction.

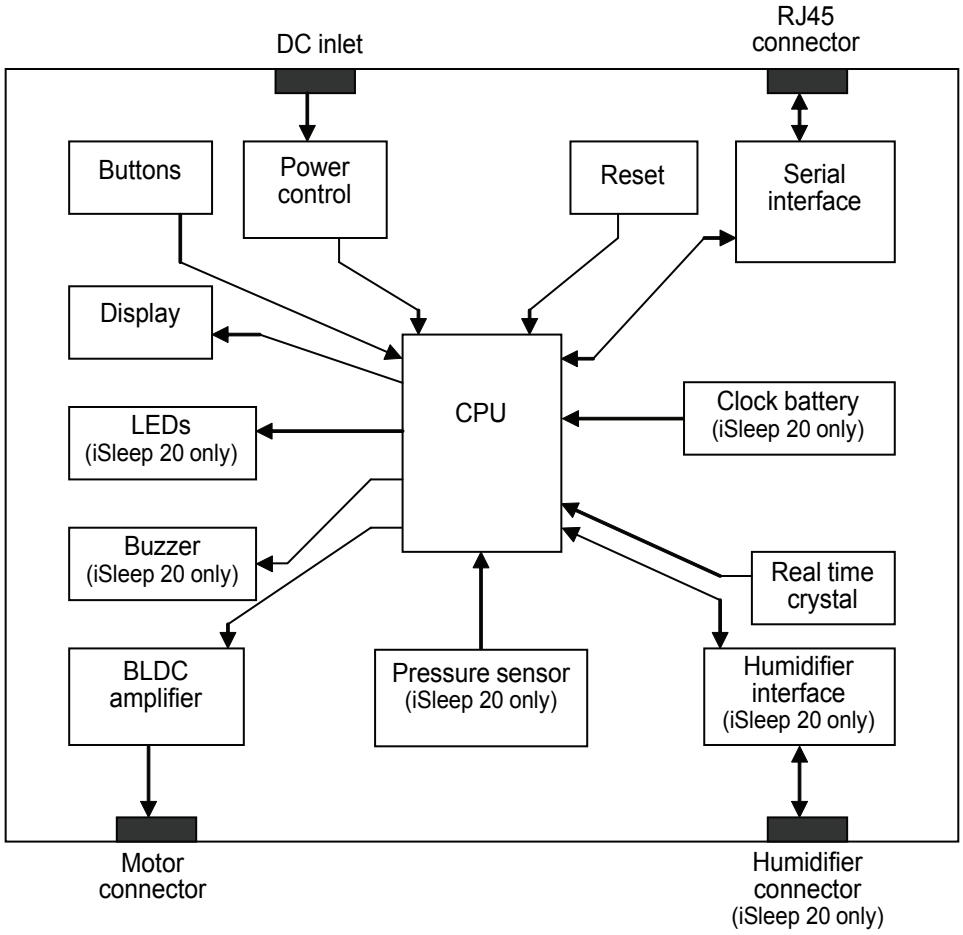
7.1 Main Cabling Diagram

The diagram below illustrates the main cabling of the iSleep 10/20.



7.2 Circuit Board Description

The diagram below is an overview of the circuit board



Power Control

There is one power input (+24V DC). The CPU board contains a voltage regulator for 5V and iSleep 20 also has a 8V regulator.

Battery (iSleep 20 only)

A battery is used to keep the real time clock alive when the iSleep 20 is not powered.

CPU (Central Processing Unit)

The processing core of the main unit is a M30281FAHP microcontroller.

The main processor has a supply voltage of 5V and is not operating when the iSleep 10/20 is not powered (apart from the clock function on iSleep 20 which is powered by the clock battery).

Display

The display used is a segment type and have a visible area of approximately 60x20mm.

Buzzer (iSleep 20 only)

The buzzer is triggered by software or hardware.

Pressure Sensor (iSleep 20 only)

The iSleep 20 is equipped with a pressure sensor. The processor supervise the actual pressure and have the availability to regulate the speed of the motor to attain a correct pressure.

Humidifier Interface (iSleep 20 only)

The iSleep 20 can be equipped with an integrated humidifier, HA01.

The HA01 humidifier consumes 40W when attached to the iSleep 20.

The power to the HA01 humidifier is controlled from the main CPU via a transistor.

The other two signals in the interface beside power and ground are an analogue temperature signal from the HA01 humidifier and a control signal to the HA01 humidifier.

Serial Interface

To communicate with a PC, the iSleep 10/20 uses a RS232 interface.

8 Fault Tracing

Always perform a complete function test (see section 2.5 on page 9) if you have opened the iSleep 10/20.

This chapter contains a fault-tracing table and a table of error codes to use when troubleshooting the iSleep 10/20.

8.1 Fault Tracing Table

If the iSleep 10/20 does not work properly try to identify the problem in the table below. Check the possible causes and carry out the suggested remedial actions.

SYMPTOM	POSSIBLE CAUSE	REMEDIAL ACTION	SEE REF.
The iSleep 10/20 does not start	The power cord is not properly connected.	Connect the power cord.	6.3 in iSleep 10/20 Clinician's manual
	The DC fuse on the circuit board has blown.	Replace the circuit board and check the power supply.	5.3, p.20
	The power supply is not 24V DC.	Check the power transformer.	
	External battery discharged.	Charge external battery.	
	The external battery cable is not connected properly or is faulty.	**1** Connect the cable. **2** Measure the voltage. **3** Replace the cable if faulty.	
	Battery polarity faulty. May be the case if fuse blows immediately after connecting to external battery cable.	Check polarity.	
The iSleep 10/20 does not give the adequate pressure.	External leaks from patient circuit or nasal mask.	Check the tubes, connectors and mask for leaks.	2.3, p.7
	Internal leaks from tubes, humidifier or air channels.	Check the tubes, air channels and the humidifier.	2.4, p.8
	Air inlet is blocked.	Check filter and air channels.	
Pressure indicator shows no pressure reading.	The internal supply tube is blocked or loose.	Check the tubes.	2.4, p.8
	The circuit board is faulty.	Replace the circuit board.	5.3, p.20
The clock resets when having disconnected the power supply. (iSleep 20 only)	The clock battery discharged.	Replace the clock battery.	5.4, p.21

8.2 Function Failure Error Codes

8.2.1 Reading the Error Codes

When an internal function failure occurs a four digit error code will be stored in the iSleep 10/20 error log. The function failure will also generate a message shown on the display.

You need the "iSleep/Vivo Service Software" to access the error log.

8.2.2 Error Code Tables

Error Codes Shown on the Display

The table below lists the error codes and the corresponding text that can be shown on the LCD display. The problem is explained together with the action that is necessary to correct the problem, see also "Internal Error Codes, Not Shown on the Display (iSleep 20 only)" on page 29.

If more than one action is listed, the actions should be performed in the order in which they are listed. For example, if action no. 1 does not solve the problem you should continue with action no. 2, and so on.

See "Opening the iSleep 10/20 and Replacing the Main Components" on page 18 for information about how to replace the circuit board.

Error code	Text on LCD Display	Problem	Action
20	Er20	Internal function failure.	**1** Restart the iSleep 10/20 by disconnecting and reconnecting the power supply. **2** Perform an internal inspection **3** Replace the circuit board or send the iSleep 10/20 for service.
21	Er21	Power supply voltage out of range.	Check the power supply.
28	Er28	Humidifier not heating (iSleep 20 only).	**1** Replace the HA 01 humidifier. **2** Perform an internal inspection. **3** Replace the circuit board or send the iSleep 10/20 for service.
29	Er29	Humidifier temperature too high. (iSleep 20 only).	Replace the HA 01 humidifier.
30	Er30	Internal temperature too high.	**1** Disconnect the iSleep 10/20 from the power supply, let the device cool off and restart. **2** Check the ambient temperature. **3** Replace the circuit board or send the iSleep 10/20 for service.

Error code	Text on LCD Display	Problem	Action
61	Er61	Invalid settings. Settings set to default values.	**1** Restart the iSleep 10/20 by disconnecting and reconnecting the power supply. **2** Replace the circuit board or send the iSleep 10/20 for service.

Internal Error Codes, Not Shown on the Display (iSleep 20 only)

If a function failure listed in the table below occurs the four-digit error code is stored in the iSleep 20 error log and one of the messages listed above is shown on the display.

You need the "iSleep/Vivo Service Software" to access the error log.

Error code	Problem	Error code on display
1000	Flash memory error	Er20
1001	Checksum error when data was read back	Er20
1002	Error when tried to write checksum to flash	Er20
1003	Checksum error when tried to read parameters	Er20
1004	Failed to write data to flash	Er20
1050	Critical flash error	Er20
1051	Flash has failed to be initiated	Er20
1052	Flash has failed to erase memory to write parameters	Er20
1053	Failed to write parameters to flash	Er20
1054	Failed to erase a block in flash	Er20
1055	Failed to erase a block in flash	Er20
1056	Failed to write log data to flash	Er20
1057	Flash memory contains no data	Er20
1058	Flash memory is full	Er20
1059	Flash data is corrupt	Er20
1100-1199	LCD error	Er20
1200-1299	Initiate error	Er20
1300	Selftest error	Er20
1301	Humidifier temperature is not rising	Er28
1350	Critical selftest error	Er20
1351	A/D channel error	Er20
1352	RAM error	Er20

ERROR CODE	PROBLEM	ERROR CODE ON DISPLAY
1353	FLASH error	Er20
1354	Timer error	Er20
1355	Motor voltage out of range at start up	Er20
1356	Motor current out of range at start up	Er20
1357	Motor phase	Er20
1358	Motor phase	Er20
1359	Motor phase	Er20
1360	Pressure to high	Er20
1361	Motor current too high when operating	Er20
1362	VCC too high	Er21
1363	VCC too low	Er21
1364	Motor sense too high in stand by mode	Er20
1365	CPU voltage too high	Er20
1366	CPU voltage too low	Er20
1367	Adapter sense too low	Er20
1368	VCC-Adapter voltage is out of range	Er20
1369	Internal temperature too high	Er30
1370	Internal temperature too low	Er20
1371	Adapter ground potential too low	Er20
1372	Adapter ground potential too high	Er20
1373	Adapter out voltage too high in stand by mode	Er20
1374	Pressure offset compensation out of range	Er20
1376	Humidifier temperature too high	Er29
1377	Inverse copy of parameters is corrupt	Er20
1378	Inverse copy of time is corrupt	Er20
1379	Inverse copy of date is corrupt	Er20
1380	Error buffer has been overrunned	Er20
1400-1499	Log error	Er20
1651	Set pressure out of range	Er61
1652	Tried to set pressure above 20 cmH_2O	Er61
1653	Set pressure out of range	Er61
1654	Start ramp pressure out of range	Er61
1655	Set humidifier out of range	Er61

ERROR CODE	PROBLEM	ERROR CODE ON DISPLAY
1666	An old set of parameters is restored	Er61
1667	Parameters has been set to default	Er61
1700-1799	MMI error	Er20
1850	Motor fault	Er20
1851	High RPM, might generate too high pressure	Er20
2000-2099	Errors codes used for testing only	Er20

9 Appendices

9.1 Emission and Immunity Declaration

According to IEC 60601-1-2(2001) + A1(2004).

9.1.1 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The iSleep 10/20 are intended for use in the electromagnetic environment specified below. The customer or the user of the iSleep 10/20 should assure that it is used in such an environment.

Portable and mobile RF (radio frequency) communications equipment should not be used no closer to any part of the iSleep 10/20, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	RECOMMENDED SEPARATION DISTANCE
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	10 V	d= 0,27*√P m
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	d= 0.27*√P m at 80 MHz to 800 MHz d= 0.54*√P m at 800 MHz to 2.5 GHz **Equation description:** P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].  Interference may occur in the vicinity of equipment marked with this symbol.

9.1.2 Notes

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the iSleep 10/20 is used exceeds the applicable RF compliance level above, the iSleep 10/20 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the iSleep 10/20.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

9.1.3 Guidance and Manufacturer's Declaration – Electromagnetic Emission

The iSleep 10/20 are intended for use in the electromagnetic environment specified below. The customer or the user of the iSleep 10/20 should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The iSleep 10/20 use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The iSleep 10/20 are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Complies	

9.1.4 Recommended separation distances between portable and mobile RF communications equipment and the iSleep 10/20

The iSleep 10/20 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the iSleep 10/20 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the iSleep 10/20 as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO THE FREQUENCY OF TRANSMITTER (M)		
	150 kHz to 80 MHz d= 0.27*√P m	**80 MHz to 800 MHz d= 0.27*√P m**	**800 MHz to 2.5 GHz d= 0.54*√P m**
0.01	0.03	0.03	0.05
0.1	0.08	0.08	0.17
1	0.27	0.27	0.54
10	0.85	0.85	1.7
100	2.7	2.7	5.4

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

9.1.5 Notes

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9.2 CPAP Pressure/Volume Data

The values have been produced during a test where the iSleep 10/20 have been attached to a 0.5 litre test lung simulating a sinusoidal breathing pattern with 20 breaths/minute.

9.2.1 iSleep 10

Average Value and Variation of Air Pressure at the Patient Air Outlet

VOLUME (L)	PRESSURE P (cmH_2O)	BREATHING RATE F (min^{-1})	AVERAGE VALUE (cmH_2O)	VARIATION (cmH_2O)
0.5	$^1/_3 p_{max} = 6.5$	20	7.2	5.2
0.5	$^2/_3 p_{max} = 13$	20	14.2	7.3
0.5	$P_{max} = 20.0$	20	21.8	9.2

9.2.2 iSleep 20

Average Value and Variation of Air Pressure at the Patient Air Outlet

VOLUME (L)	PRESSURE P (cmH_2O)	BREATHING RATE F (min^{-1})	AVERAGE VALUE (cmH_2O)	VARIATION (cmH_2O)
0.5	$^1/_3 p_{max} = 6.5$	20	6.99	2.48
0.5	$^2/_3 p_{max} = 13$	20	13.35	1.14
0.5	$P_{max} = 20.0$	20	20.26	1.42

9.3 Service Record iSleep 10/20

Use a photocopy of this service record for the inspections described in "Service Instructions" on page 5. Use the next page for comments and notes.

Service record no._____

Model:.....	**Serial no. .....**	**Inventory no. .....**
Accessories:		
Delivery date:	Total operating hours:	
Service started:	Signature:	
Service completed:	Signature:	
Product returned:	Signature:	

General	**See instruction ref.**	**Check OK**
Open new service record and identify CPAP device	2.2.1, p.6	.....
Note number of total operating hours	2.2.1	.....
Check all markings	2.2.2	.....
Check information from user	2.2.3	.....
Check validity of documentation	2.2.4	.....
External Checks		
Inspect for external damage and wear	2.3.1, p.7	.....
Check the HA01 humidifier (if used, iSleep 20 only)	2.3.2	.....
Check power connection	2.3.3	.....
Inspect patient circuit	2.3.4	.....
Inspect the CPAP device accessories	2.3.5	.....
Change/wash the patient filters	2.3.6	.....
Perform minimum function check	2.3.7	.....
Internal Checks (when required)		
Clean inside of the CPAP device	2.4.1, p.8	.....
Check cabling	2.4.2	.....
Check fastening of components	2.4.3	.....
Check the power supply	2.4.4	.....
Reassemble the casing	2.4.5	.....
Complete Function Check		
Check the pressure	2.5.1	.....
Check the snooze function (iSleep 20 only)	2.5.2	.....
Adjust settings for patient	2.5.3	.....

Notes

_____

_____

_____

_____

9.4 Returning Products to Breas

You may need to return the CPAP device, components or accessories to Breas Medical AB for service, warranty, upgrade or repair. In this case, follow the instructions below to ensure that the correct action is taken to avoid unnecessary delays.

1 Pack the product in its original packing. If this is not available, pack the product in packaging suitable for the transportation to Breas Medical AB.

2 Take a photocopy of the delivery report on the next page.

3 Fill out the delivery report and pack it together with the product to be returned.

Product damage caused by poor packaging or during transportation is not covered by the factory warranty.

9.5 Product Return Form– Breas iSleep 10/20 CPAP device

Breas ref. no.:.....

Customer information

Customer name:.....

Address: .....

.....

Phone:.....

Reference person: ..... **Customer ref. no.:**.....

Product information

Model: ..... **Serial no.:**..... **Total operating hours:**.....

Error – Complaint – Accessories

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....

.....