



SleepCare™ Sleep Screener

# User Manual

CE 0123

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# Device

## Warnings, Cautions, and Contraindications

### Warnings

*A warning indicates the possibility of injury to user or the operator of this device*

This manual serves as a reference.

Read and understand the entire manual before using the device.

Discontinue use if skin reddening or inflammation appears.

Do not smoke while wearing the BMC SleepCare™.

**Do not use USB data cable for communication to PC while the device is recording.**

Only the USB data cable offered by BMC can be used for SleepCare™ communication to PC, otherwise it may cause danger to the operator or the patient.

**Do not use the SleepCare™ device in situation where alarms are required. The SleepCare™ device has no audible alarms.**

### Cautions

*A caution indicates the possibility of damage to the device.*

This device is to be sold by or on the order of a physician.

Avoid exposure to sources of direct airflow such as fans during recording.

Avoid using this device in an MRI environment or in close proximity to a high EMI emission source.

Do not attempt to take the main device apart. No user-serviceable parts are inside.

Do not immerse the main device in water.

If any unexplained changes are noticed in the performance of this device, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact BMC.

### Contraindications

Depending on the skin condition or general state of health, the patient may experience sensitivity to the wrist belt or the self-adhesive finger sensor. Discontinue use if a reaction to the skin-contact materials happens.

## Intended Use

The SleepCare™ device is indicated for the screening of sleep disordered breathing. It records the following data: patient respiratory oral and nasal airflow, snoring, blood oxygen saturation, pulse rate and CPAP pressure. The device uses these recordings to generate a report for screening or for further clinical investigation.

## System Contents

- 1 User manual
- 1 SleepCare™ main device
- 1 USB data cable
- 1 Pulse oximeter sensor
- 1 Oral and nasal airflow unit (optional)
- 1 Cannula (optional)
- 1 CD

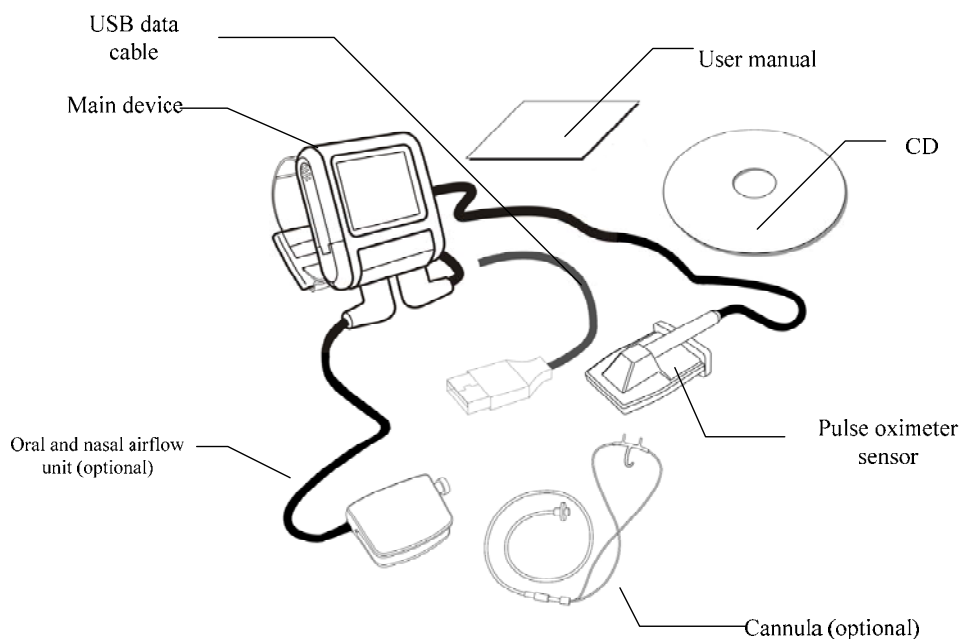







Figure 1-1 System Contents

The belt on the main device is in accordance with the ISO 10993-1, ISO 10993-5, ISO10993-10. The finger sheath and cannula are CE marking approved, indicating compliance to the Medical Device Directive (93/42/EEC).

Several accessories are available for using the SleepCare™. To ensure that the patient experiences a safe and effective use, adopt only BMC accessories.

## Symbols

These symbols are used on the SleepCare™ devices.

	Type B Applied part
	Attention, Consult Accompanying Documents
IPX1	IPX1 –Drip-Proof, Vertical
SN	Serial Number of the product
	Manufacturer
	Authorised Representative in the European Community
	European CE Declaration of Conformity

## SleepCare™ Display

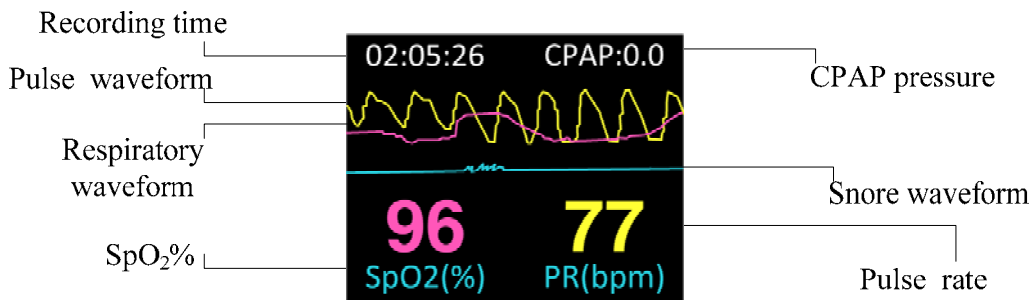


Figure 1-2 SleepCare™ Display

- SpO<sub>2</sub>% Display**  
 Display the value in percent of oxygen saturation.
- Pulse Rate Display**  
 Display the pulse rate in beats per minute.

*Note:*

1. The sampling rate of the SpO<sub>2</sub> signal is about 50Hz, and the update rate of the frame is 1Hz. So even there

are some filtering methods to process the SpO<sub>2</sub> data, it will not delay for a relative long time to the displaying data.

2. The waveform of the pulse is normalized so that the software can adjust the amplitude of the displayed waveform. However, the SleepCare™ does not store the waveform data, just keeps waveform updating to give the implication of the detector in working state.

- **Recording Time**

Show the length of recording time

- **CPAP Pressure**

Display the direct component of airflow pressure.

- **Pulse Waveform**

The yellow line depicting the artery pulse feature

- **Snore Waveform**

The green line indicating the occurrence of a snore

- **Respiratory Waveform**

The red line reflecting user's respiration fluctuation

## Instructions for Use

### Fitting

1. Remove the SleepCare™ main device, oral and nasal airflow unit, pulse oximeter sensor and the two batteries from the package.
2. Open the battery door at the left side of the device. Insert two new AAA batteries following the polarity markings indicated on the battery door. Carefully position the battery door and gently get it into place.
3. Fit the oral and nasal pressure cannula so that the two small open tubes point towards patient's nostrils while the third open tube pointing towards his/her mouth.
4. Fit the loop round the patient's ears and then back around the neck, avoiding pulling it over the head.



Figure 1-3 Illustration of Wearing the Cannula

5. Move the slide towards the user's chin, until the cannula feels secure under the nose.
6. Fit the farther end of the cannula into the tubing end of the oral and nasal airflow unit and insert its data cable into the Flow/COM (left) port at the main device bottom, where the recorded data could be downloaded by a computer.
7. Put the oximeter data cable plug into the SpO<sub>2</sub> (right) socket at the device bottom.
8. Insert the index finger into the pulse oximeter sensor. Take note that the finger must reach the end of the sensor.

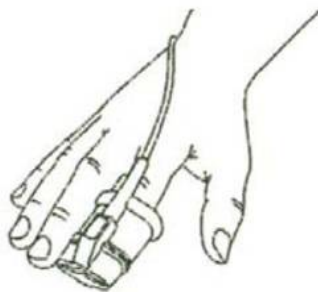


Figure 1-4 Illustration of Wearing the Pulse Oximeter Sensor

9. Wear the SleepCare™ main device around user's wrist just like wearing a watch. Adjust it for a comfortable position and fasten the belt to make it fixed.



Figure 1-5 Illustration of Wearing the Main Device

Note: The SleepCare™ device is watch style, intended for screening sleep-disordered breathing for adult patients only.

## Recording

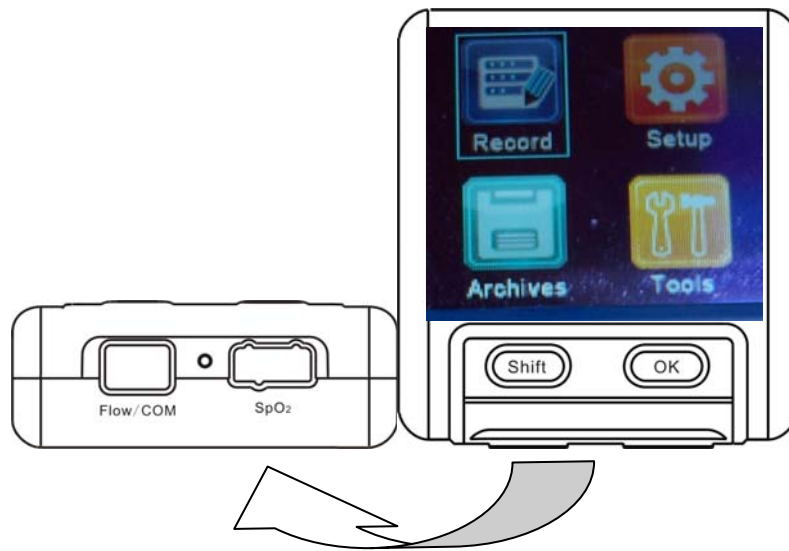


Figure 1-6 Main Device

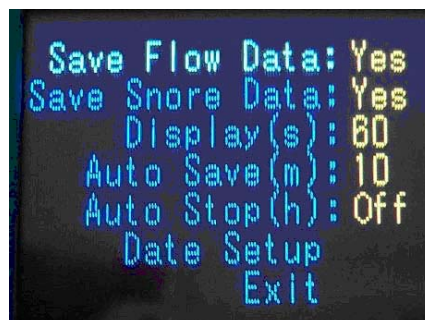


Figure1-7 Setup

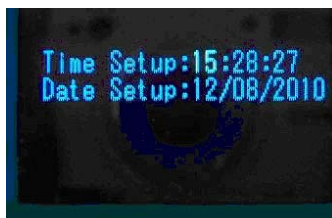


Figure 1-8 Date Setup

1. Start the device by pressing and holding **OK** button, the four icons, **Record**, **Setup**, **Archives**, and **Tools**, are showing in the display screen.
2. Navigating the icons via **Shift** button and select the intended function by pressing **OK** button.
3. **Setup** allows changing some of the recording parameters, see Figure 1-7. For example, user

can choose whether or not to save the flow data, the snore data, and whether or not to need an auto-save or auto-stop. Several different lengths of time are available in the auto-save menu for user's satisfaction. Thus, the patient can preset it when he/she is awake, needing no further operation before falling asleep. This device also has an auto-stop function, with a set of different periods of time after which the device may be triggered turn-off by sensor removal. That is to say, it can stop recording when the sensors are dropped intentionally or by accident after the set time. Users can also set an appropriate time for the Backlight using the "Display(s)" setup. The "Date Setup" allows users to enter the date and time of recording, see figure 1-8. While the cursor is at each settable item, press **Shift** to decrease the value and **OK** to increase it. Press and hold **Shift** to move the cursor to its left position, and when the cursor reaches the left side, it restarts from the right side of the other line. **OK** button has a similar function but with its moving direction towards right.

4. **Record.** When this icon is selected, the device enters the recording page.
5. **Archives.** This icon offers information on the recorded data. The device allows 59 hours of accumulated recording time of full data. But only the latest 8 pieces of data files can be seen through the OLED interface. Enter Archives in the main menu and press **OK**, the on line instant test scores are summarized to the user instantly with acceptable accuracy and much convenience, see figure 1-9. This is just a concise report. Detail data can be reviewed by the PolyLogic™ sleep analysis software on a computer.
6. **Tools.** This icon offers methods of data transfer. In addition to the traditional data transferring with USB communication port, SleepCare™ gives users another choice of transferring data by blue tooth, which is available depending on the customization. The data entries can be viewed when entering the data transferring page, please refer to "PolyLogic™ Sleep Analysis Software for SleepCare™" in this manual for details. Press and hold both "shift" and "OK" buttons to quit this data-entry page. "About" shows device information such as the version, available memory, battery power and the current time, see figure 1-10. Press any key to quit.



Figure 1-9 Online instant test scores



Figure 1-10 About

7. The device automatically turns off in one minute if no action is taken in this page.

*Note: While recording, the OLED colorful display will be off after a set time since the last keystroke and it can be activated again by another hit on the key.*

8. Follow the direction of the 4<sup>th</sup> step to enter the recording page, then press and hold **OK** button to start recording. The timer in the up left corner begins to run. Keep the device on and go to sleep.
9. Press and hold both **Shift** and **OK** buttons at the same time to quit record process.
10. Press and hold **OK** button to turn off the device.

*Note: Please put the batteries out of the device when the SleepCare™ is not in use for a long time.*

## Disassembly

1. Lower the slide from under the patient's chin and take off the cannula. Take off the pulse oximeter sensor. Unplug the data cables from the SleepCare™ main device.
2. Put the cannula off the oral and nasal airflow unit.
3. Remove the batteries and discard according to local regulations.
4. Keep the SleepCare™ main device and the accessories appropriately under the instructions of medical provider.

## Important Steps for Use

It is of essential importance to have the OLED display screen checked to ensure an effective and correct recording before sleeping.

The red line indicating respiratory waveform must be fluctuating with the breathing rhythm, while the yellow line which stands for the pulse fluctuation should also vary thereupon.

Check the SpO<sub>2</sub> and PR (Pulse Rate) to see whether the pulse oximeter sensor is in good position for operation.

## Conditions That May Affect The SleepCare Use

- **Environmental**

Fluctuating or flickering light may affect measurements.

Use of the SleepCare™ outside stated temperature and humidity specifications may affect measurements.

*Contraindications, Warnings, and Cautions.*

- **Motion**

Excessive or rapid movement may affect measurements.

- **Sensor Position**

Sensor position is critical for accurate SpO<sub>2</sub> measurements.

All emitted sensor light must pass through the finger before reaching the detector. **Do not allow positioning such that some or all of the emitted light can by-pass the finger as this will result in inaccurate SpO<sub>2</sub> values.**

While on the finger, do not press the SleepCare™ against any surface and do not squeeze or hold the SleepCare™.

The external spring provides the correct pressure on the finger; additional pressure may affect measurements.

• **Nail Polish**

Fingernail polish may reduce light transmission which may affect SpO2 values.

**In addition, the following factors may degrade performance:**

- an arterial catheter • moisture in the SleepCare™
- a blood pressure cuff • a finger outside the 0.3-1.0” size range
- an electrosurgical procedure • venous pulsations
- an infusion line • anemia or a low hemoglobin count
- cardiovascular dyes • the SleepCare™ not at heart level

## Troubleshooting

Symptoms	Possible Cause	Possible Solution
OLED display blinking	Batteries are low.	Replace batteries immediately.
SleepCare™ will not activate.	Batteries incorrectly inserted.	Check batteries.
	Depleted batteries.	Replace batteries.
The red line keeps straight without fluctuation.	The cannula is not properly positioned or is not connected to the main device, or is pinched.	Adjust the cannula and make sure it is connected firmly to the main device, or contact the medical provider or BMC for a change.
The yellow line does not move.	The pulse oximeter sensor may not be in the correct position.	Adjust the pulse oximeter sensor.

## Specifications

1. Oxygen Saturation Range 0 to 100%
2. Pulse Rate Range 40-240 bpm
3. Oral and Nasal Airflow Rate Range 10/minute~40/minute
4. Wavelengths
  - a) Red: 660 nanometers @ 3mw nominal
  - b) Infrared: 905 nanometers @ 3mw nominal
5. Accuracy
  - a) % SpO<sub>2</sub> Accuracy 70 to 100% ±3%
  - b) Rate Accuracy the larger of ±3% and 1bpm
6. Resolution
  - a) SpO<sub>2</sub> 1%
  - b) Pulse Rate 1bpm
7. Temperature
  - a) operating 5°C ~40°C

b) storage/Transportation	-20°C ~ +55°C
8. Humidity	
a) Operating	30% to 80% non-condensing
b) storage/ transportation	≤93% non-condensing
9. Atmosphere Pressure	
a) Operating	860hPa~1060hPa
b) Storage	500hPa~1060hPa
10. Power Requirements	2 AAA Batteries of 1.5 VDC
11. Batteries Life	approximately 16 hours of continuous operation
12. Dimensions	62mm × 57mm × 21mm
13. Weight	70g (main device without batteries)
14. Max. recording period for one measurement	10hours
15. Classifications per IEC 60601-1	

Type of Protection	Internally Powered (on battery power)
Degree of Protection	Type B-Applied Part
Degree of Protection Against Ingress of Water	IPX1
Mode of Operation	Continuous

## Cleaning

### Caution:

- Never use abrasive agents, alcohol, chlorine-containing substances, acetone, or other solvents to clean the recorder.
- Do not immerse the recorder, the oral and nasal airflow unit, or the pulse oximeter sensor in fluids, and ensure that no fluids penetrate into the products.
- Do not attempt to disinfect or sterilize the recorder, since this could cause unseen damage to the inside of the unit.
- The cannula is nonreusable, dispose of it in accordance with local regulations.

1. Turn off the SleepCare™.
2. Detach the oral and nasal airflow unit and the pressure cannula.
3. Detach the pulse oximeter sensor from the SleepCare™ main device.
4. Clean the following parts with a damp cloth and a mild liquid soap: oral and nasal airflow unit, pulse oximeter housing and pulse oximeter cable.
5. Leave the cleaned parts to dry.

## Disinfection

Between patient uses, the SleepCare™ should be surface disinfected in accordance with established clinical practice.

## Disposal


Dispose of the device in accordance with local regulations.

## EMC Requirements

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
This Device is intended for use in the electromagnetic environment specified below. The user of the Device should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Radiated Emissions CISPR 11	Group 1 Class B	This Device uses RF energy only for its internal function. Therefore, its RF radiated emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Conducted Emissions CISPR 11	This Device is a battery operated device; therefore, these test requirements are not applicable	
Harmonic Emissions IEC 61000-3-2		
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3		

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
This Device is intended for use in the electromagnetic environment specified below. The user of the Device should assure that it is used in such an environment.			
Immunity Test	IEC	Compliance	Electromagnetic Environment - Guidance
	60601 Test Level	Level	
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air	±6 kV Contact ±8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	This Device is a battery operated device and has no patient-coupled cables nor I/O cables which are longer than 3 meters in length; therefore, this test requirement is not applicable.		
Surge IEC 61000-4-5	This Device is a battery operated device; therefore, these test requirements are not applicable.		

Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11			
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
This Device is intended for use in the electromagnetic environment specified below. The user of the Device should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: 

<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>	
<b>a</b>	<p>Field strength 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 Device is used exceeds the applicable RF compliance level above, the Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Device.</p>
<b>b</b>	<p>Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>

<p>Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the Device.</p>			
<p>The Device is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Device as recommended below, according to the maximum output power of the communications equipment.</p>			
Rated Maximum Output Power of Transmitter (Watts)	Separation Distance According to Frequency of Transmitter (meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power of the transmitter manufacturer.</p> <p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

# PolyLogic™ Sleep Analysis Software for SleepCare™

System requirements for running the software

1. hardware requirements: CPU≥P3 1.0G, memory≥512M, display resolution ≥1024×768, hard disk ≥80G
2. software platform: Windows XP/Windows 7/Vista

## Setup

### Setup of the Software

- a) Run the “SETUP.EXE” of SleepCare™ in the installation CD and enter the setup page
- b) Click ‘Next’ to make the software auto-install.
- c) Click ‘Finish’ to quit when the installation is done. Double-click the new shortcut on desktop to launch the software.

### Setup of Driver

- a) Double-click the “USBXpressInstaller.exe” in the USB driver folder.
- b) Click “Next” in the prompt dialogue boxes, the driver will be installed automatically. This may take several minutes to finish.
- c) Click “Finish” when the setup is done.
- d) The dialogue box prompting “found new hardware wizard” comes when the USB data cable connected to a computer for the first time. Click “Next” and wait for the installation finished. Click “Finish” when it is done.

*Note: The “found new hardware wizard” comes only for the first time of a USB data cable connection. The software can be directly used afterwards.*

## Data Reception

Data reception is to transmit the recorded data to computer. Software will analyze the data, and then the operator can edit the results of the analysis to generate analysis reports. Data receiving process is expressed as the following steps:

## Start Software

Firstly double-click shortcut of the software icon on the desktop, the system will enter the SleepCare™ system main window.

## Connection of SleepCare™ and Computer

In the power off status of the SleepCare™, connect one end of the USB data cable to the computer USB port, and the other end to the SleepCare™ Flow/COM socket and then turn on the SleepCare™. Enter **Tools** and choose **Transfer Data (USB)**. Go on with operations of “PolyLogic™ Sleep Analysis Software for SleepCare™” on the computer to make the connection.

## Data Transmission

- a) After recording, the data can be transmitted to a computer for further analysis. Besides, SleepCare™ allows the analyzed data to be manually edited to remove the recording mistakes.
- b) Run the software and choose the “File” from the main menu, select "New" to enter the communication interface. Select USB port and click “Connect”.

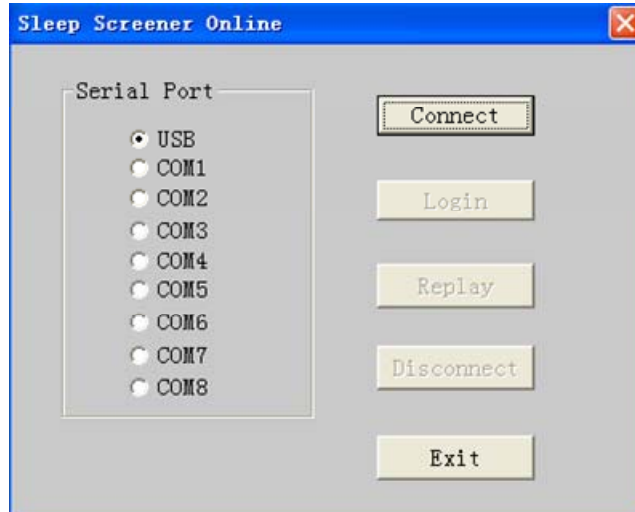


Figure 2-1 Sleep Screener Online

- c) If connection succeeds, the "Connect" button will be grayed. And other originally grayed unavailable buttons will be available now. After online with the computer (see "connection of SleepCare™ and computer"), SleepCare™ will automatically enter the communication status.

After the success of online, click "Replay" button in “Sleep Screener Online” dialog box and the replay dialog box pops up (Figure 2-2).

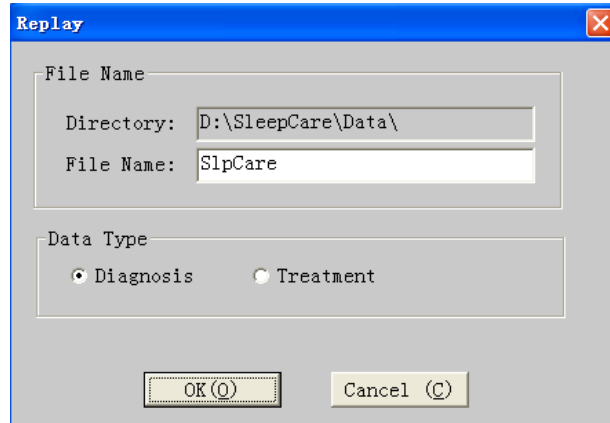


Figure 2-2 SleepCare™ Playback

d) The first content is data filename. The second is data type. Having the above two contents set up, click "OK" and the pop-up dialog box of patient information (Figure 2-3) is then shown on the display screen.

Figure 2-3 Patient Information Input

e) Recording start time is set by system at the beginning of the recording time which is confirmed by the internal clock. If the SleepCare™ clock is not correct, modify it in the above login screen. The recording end time defaults to 12 hours after the record start. In fact, in the process of data transmission, the system can automatically identify the actual end time of record. SleepCare™ will automatically stop after data transmission is finished. So need not to change the recording end time in normal situation.

f) Enter patient information one by one.

g) When the login information input is finished, select "OK". Then computer begin to receive the recorded data. When data transfer is finished, the system returns to communications dialog

box. At this time select "disconnect" or "return" in the dialog box, SleepCare™ will then automatically exit from the communications status.

h) If another device is intended to connect to the computer, repeat the process of data reception. If no data transmit is needed, click "back" button in the communication to return to the main menu.

## Data File Management

a) In the main window of SleepCare™ system, choose "Open" in "File" of menu bar, the system will enter the sleep data management interface. The screen shows the saved data and its related information in the hard disk (Figure 2-4). The desired data can be easily found out by different orders in this page.

b) First of all, find out the route and catalog of the sleep data by using the **Browse** button. Then all the files are listed, with the information such as file name, patient name, serial number, recording date, record length, person on duty and data version etc. Click on the appropriate classification column according to which the files are ranged to alter the files' order.

c) In the lower right of the page are the function keys such as **Open**, **Backup**, **Delete**, and **Cancel**. Click the file name to select the file, and then press the appropriate function key to achieve data playback, data backup and data deletion.

d) Selecting the cancel button in the lower right of the page can return to the main window of the SleepCare™ system.

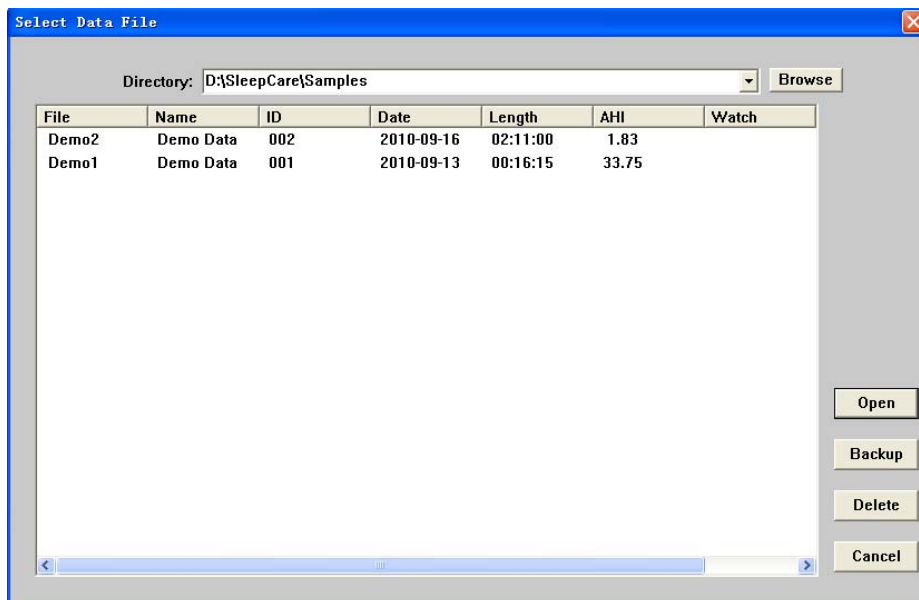


Figure 2-4 Select Data File Dialog Box


## Data Playback

Under the sleep data management page, select the sleep data file, system will enter the data playback interface.

If the data have not been analyzed yet, the prompt of auto analysis will be shown on the screen.






After opening the data file, system will enter the data playback window. There are the trend chart, the waveform, the diagnosis result, the analysis report and other pages.

## Open and Close the Data File

- a) Multiple data files can be opened simultaneously in the main window of the SleepCare™ system. For the method to open the data files please see the data file management part.
- b) Opening a file may be failed if the file is being used.
- c) Select the intended file name in the **Window** menu to open the file.
- d) Clicking  in the toolbar or select “Close” in the “File” option in the menu may close the current window of data file.

## Display of Recorded Data and Analysis Result

The data recording, analysis result and statistical result are shown in 5 pages. The order is: the trend, the raw data, the respiration event, the diagnosis result, and the report. The report includes the concise report, the apnea analysis, the SpO<sub>2</sub> analysis, and if the CPAP pressure is allowed, it is also included.

The first chart displayed in the interface after the file is opened is the trend chart  Trend and other pages  Raw Data ,  Respiration Event ,  Diagnosis ,  Report can be shown via clicking the corresponding tabs above.

## Trend Chart

The trend chart demonstrates all the recorded parameters and analysis results during the entire recording time. By demonstrating multiple parameters, one may observe the different physiology parameters in the same period of time conveniently and may study the relationship between them easily.

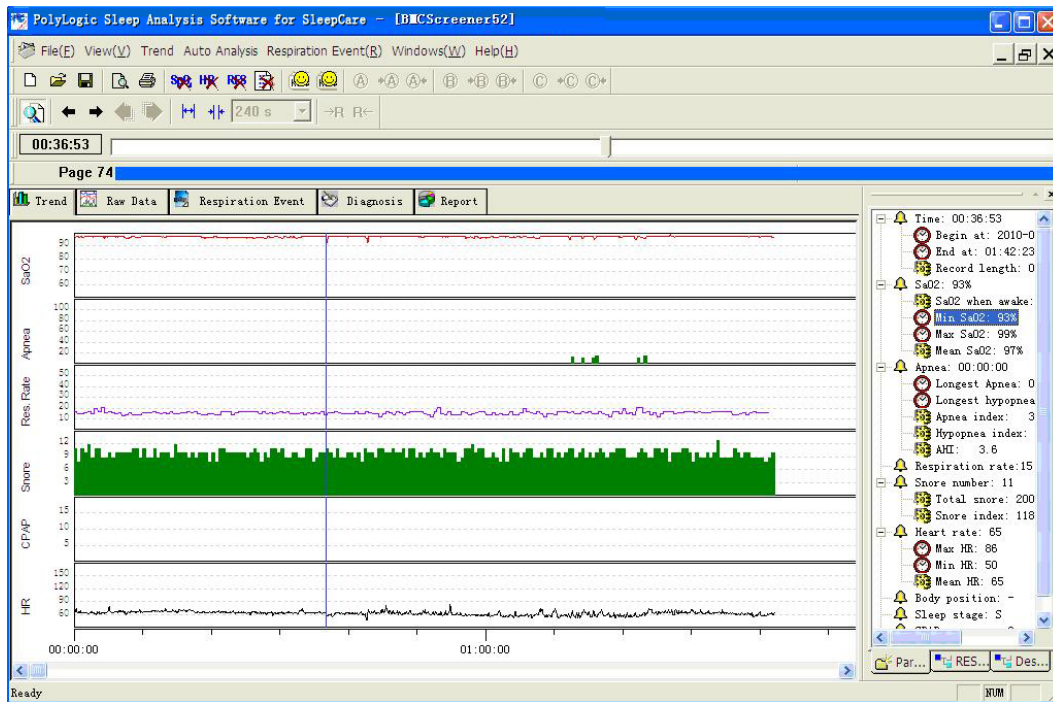





Figure 2-5 Trend chart

The basic functions on the page are:

- ①Parameter browse
- ②Parameter deletion
- ③Event location
- ④Print
- ⑤Analysis

All the operations may complete through the menu choosing. Regarding the commonly used operation, besides the provided menu operation, they may also be done by clicking on the toolbar buttons.

- ①Parameter browse


The two buttons  in the toolbar may enlarge and reduce the time axis for glances over the record parameter according to the different time resolution of the tendency change. Clicking the two buttons  may make the cursor move forward and backward. The button  may open or close the display-assistant window, which is able to show each kind of parameter value at the present time (where the cursor is). Clicks with a mouse throughout the trend chart can drive the cursor to anywhere in it.


At the lower part of the trend chart lays a slide scale which can be dragged left and right to change the cursor position.




The main part of the window shows the data analysis result trend chart. The items in a top-down order by default is, the saturation of blood oxygen trend chart, the apnea event length trend chart, the respiratory rate trend chart, the number of snoring trend chart, and the heart rate trend chart. The horizontal axis stands for the elapsing of time, with the time value marked above the horizontal axis.

### ②Parameter deletion



Parameters that can be deleted in the trend chart include blood oxygen, heart rate and respiratory rate.

Using the  in the toolbar may delete the invalid parameters.


If a certain part of the parameters during a period of time is to be deleted, left-click the mouse and drag it to select the intended part in the chart, click the corresponding item from Trend of the menu bar. It can also be done via the  icons in the toolbar. If only some

points in the chart are to be deleted, stay the cursor at the exact point and click the , ,  button directly to erase them.

### ③Event location



Click on the chart to make the cursor stay anywhere it is wanted to be. Also, clicking on the “” icon in the parameter page of assistant window can bring the viewer to the very moment when this event took place. For example, clicking the  Min SaO2: 93% item is able to point the cursor to the moment of the lowest value of oxygen saturation.

### ④Print

Use  to print or print preview the charts or reports. The printing function also goes well in other pages.

### ⑤Analysis

If the data analysis work has not been done when file is opened or some parameters are not correctly analyzed, a second analysis is necessary after an adjustment to the data. Select the corresponding options to perform the respiratory analysis and/or snoring analysis.

The toolbar has provided three commonly used analysis shortcuts. The buttons “ ” call the respiration event analysis process and the snoring analyzing process respectively.

Also, the analysis function works in other pages.

## Raw Data

This page can show all the recorded signals both in waveform and in numeric value. By different walk speeds of paper, this system can display in the current time scope all the recorded features in this page such as the recorded waveforms, the record parameters as well as the corresponding analysis results and events.

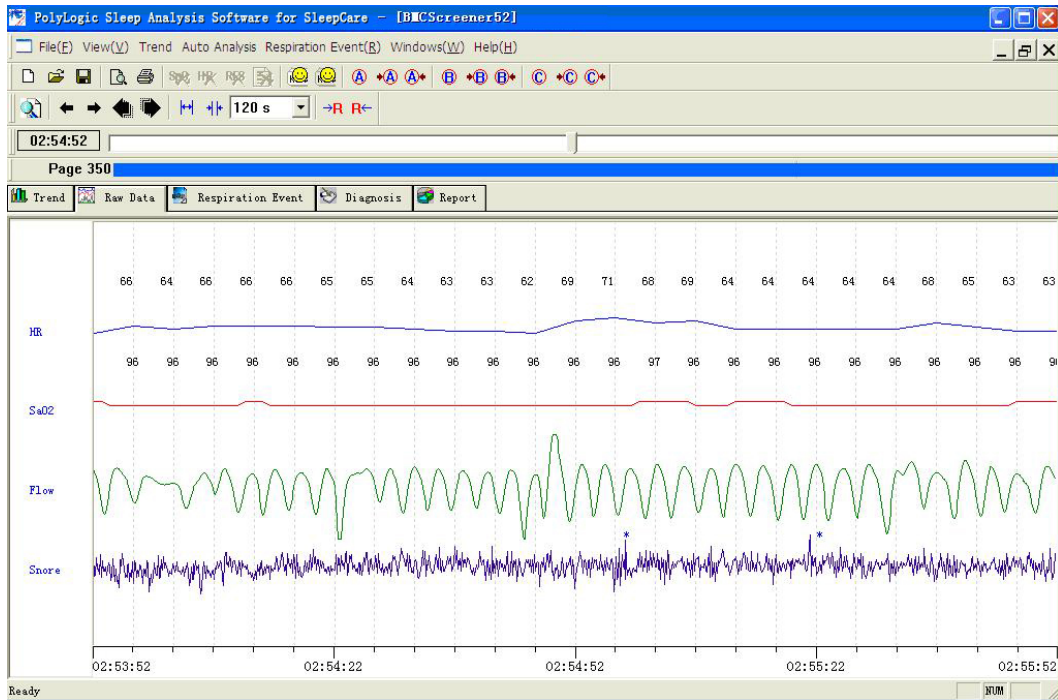


Figure 2-6 Waveform Display

The following operations may be carried out in this page.

Print

Modify display setup

Modify paper speed


Modify time display

Event browse

Event edit

Mark function

### ① Print

Select **File(E)** in the menu or  in the toolbar to print the analysis report.


### ② Modify display setup

Move the cursor to a certain waveform and right-click with mouse to access the pop-up menu, select the correct item to change the gain and color of the waveform.

### ③ Modify paper speed


This function is aimed at conveniently observing the waveforms of different types.

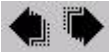



The tool  in the toolbar can zoom in and zoom out the time scale to change the speed at which paper walks. The range is from 8s/page to 480 s/page.

#### ④ Modify time display

This page provides many kinds of methods for the operator to locate any period of time conveniently to observe the waveform and its parameters.

The two buttons  are used to slightly adjust the time back and forth as to when the waveform shall be displayed, with five seconds as a pace.

The two buttons  are used for page turning with each page length depending on the present speed of paper's walking. For example, if the current displaying waveform walks at 1 minute/page, it shows the waveform of either previous or next one minute upon each clicking on the icons.

The bar  is a time vernier, which could be dragged back and forth or clicked on to show a waveform in varying time ranges.


Moving the mouse cursor to the left or right edges of the waveform where the cursor changes to an arrow, can make the waveform walking at the speed of 2 seconds /page automatically.

The display contents can be located in accordance with the markings made by the editor or the various events in the analysis. Refer to the event browse function and marking function in the following parts for details.

#### ⑤ Event browse

##### a) Breathing event

All the breathing events are lined out with a series of colorful blocks in the graph, with the serial number, the type and the length of each one annotated nearby. These breathing events are categorized into HYP and OSA, which means hypopnea and obstructive sleep apnea, respectively.

And a previous event or next event can be easily located by clicking the  buttons.

##### b) Snore

The symbol “★” indicates a snore. In this operation, evaluations can be made to the sensitivity of snoring threshold and it can be adjusted by modifying the threshold of snoring identification and therefore changing the number of snores.

#### ⑥ Event edit

The type and length of breathing events can be revised and every event can be inserted or deleted in this page.

For changing the breathing event type or deleting any event, right-click on the event and select the corresponding item to continue.


For changing the length of a breathing event, firstly point the mouse cursor to the beginning or the end of the block of event, when the mouse arrow changes into a draggable state. Then drag the left or right edges to change the time of beginning and end.

For event insertion, left-click mouse and drag it to form rectangular block on the waveform, when a menu pops up, demonstrating the length of this block. Select a corresponding event type to generate such an event.

### ⑦ Marking function

When the operator feels particularly interested in any recorded part and intends to relocate it on his next opening of the file, he may use this marking function, attaching different marks to different areas of interests.

Three symbols, A, B, and C are provided in this function. And the texts “+A”, “+B” or “+C” are shown at the bottom of waveform.

The  in the toolbar is used to make a mark or search for the previous or next mark. These markings can be kept while file-saving, thus can be relocated quickly upon later reopening.

## Respiration Event

This page has listed all respiration events and their correlations with the statistical data by form.

The respiration event list may sort according to different statistical items, with just clicking on the corresponding statistical tags. And the list will be shown in the intended manner.

Clicking on the list or using the ↑↓ key on keyboard may choose any event in the respiration event list. Click the corresponding button from the “Respiration Event” drop-down menu to change the type of an event. The displaying order of the list of events is not changed at the moment.

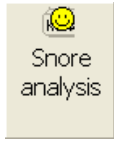
Above the respiration event list is the corresponding waveforms where all the respiration events are characterized by blocks of different color. Right-click on the event block, select the corresponding option to revise or delete an event. When the mouse arrow becomes draggable at the beginning or end of an event block, drag it back and forth to shorten or lengthen the time of the respiration event. Also, a respiration event can be inserted by dragging a rectangular block in the waveform, The list of respiration events below will make a change to be ordered by serial numbers accordingly.

Change the displaying page to a previous or next one, or, magnify and minify the time axis of

waveform by using the toolbar .



If the respiration event or the snore is to be analyzed for a second time, click



in the toolbar.

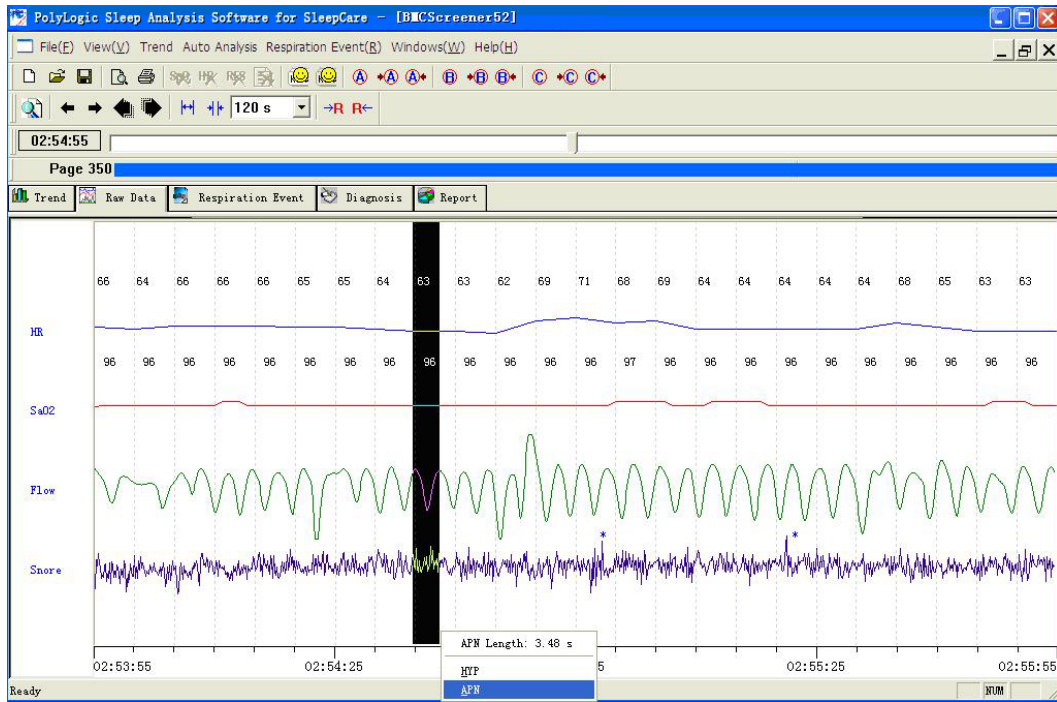


Figure 2-7 Respiration Event Edit

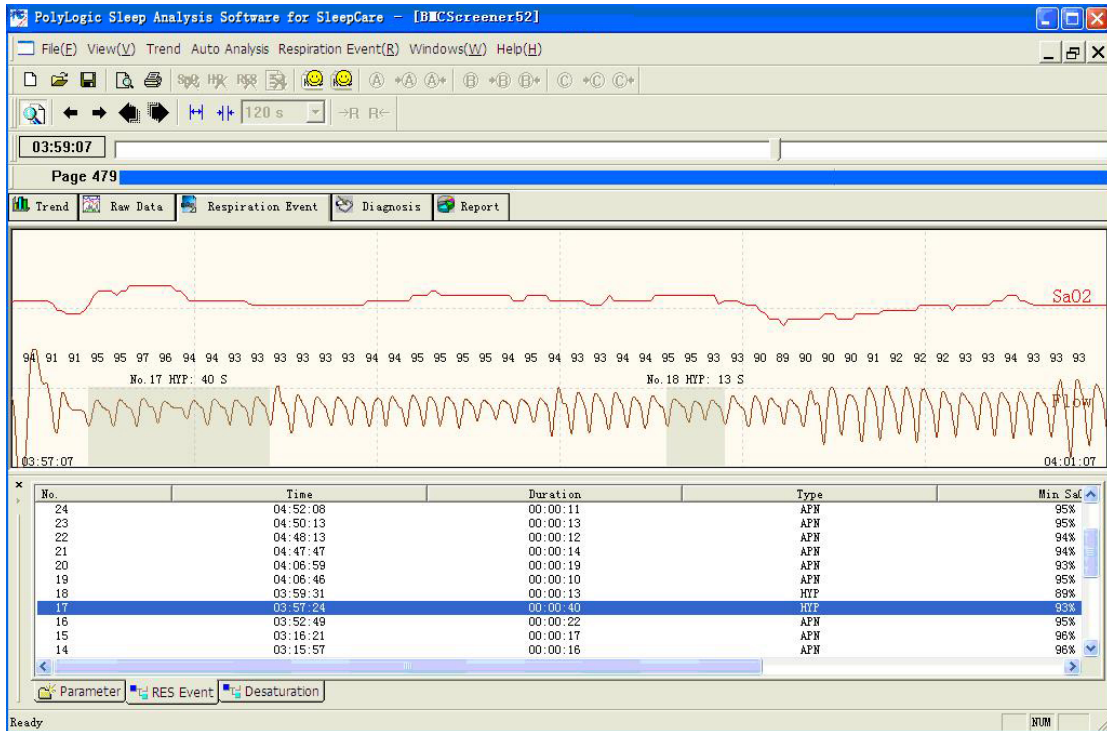


Figure 2-8 Respiration Event

## Analysis Form

All analysis results are produced into concise reports after statistical analysis. If the data recording has contained the CPAP pressure, a CPAP pressure report is also included.

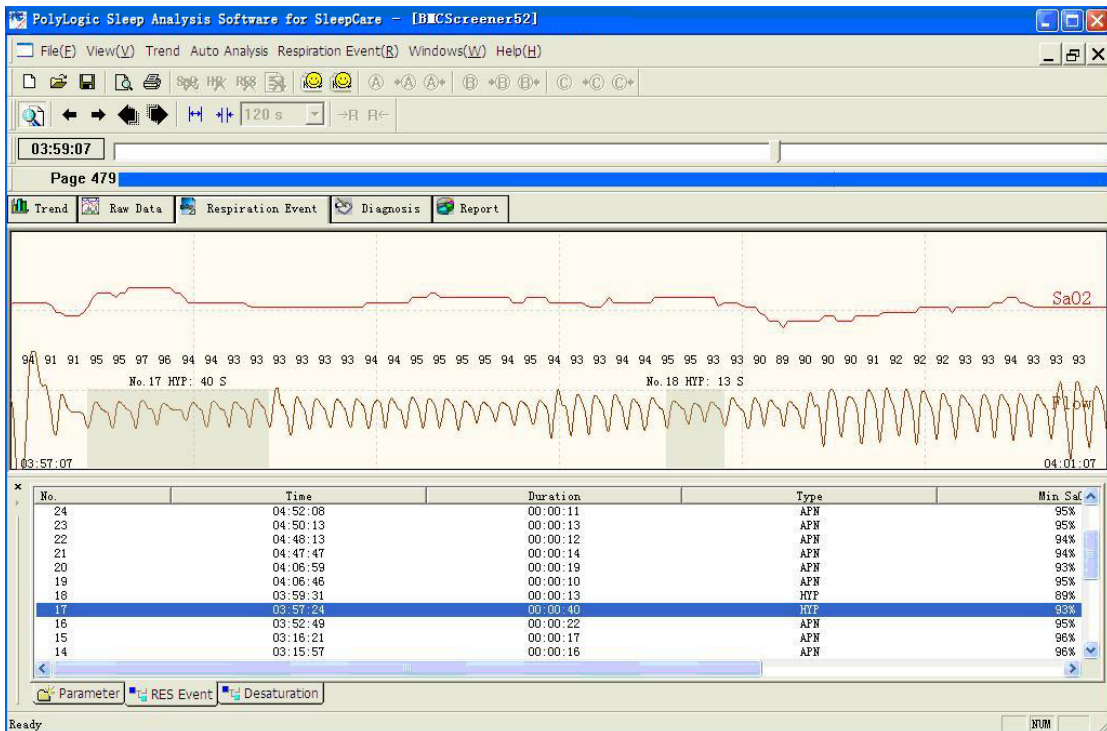


Figure 2-9 Analysis Report

## Diagnosis Result

The conditions and results of examination can be reached by selecting the corresponding items in the drop-down menu. Both English and Chinese can be inputted in the suggestion field. All the above reports can be printed out.

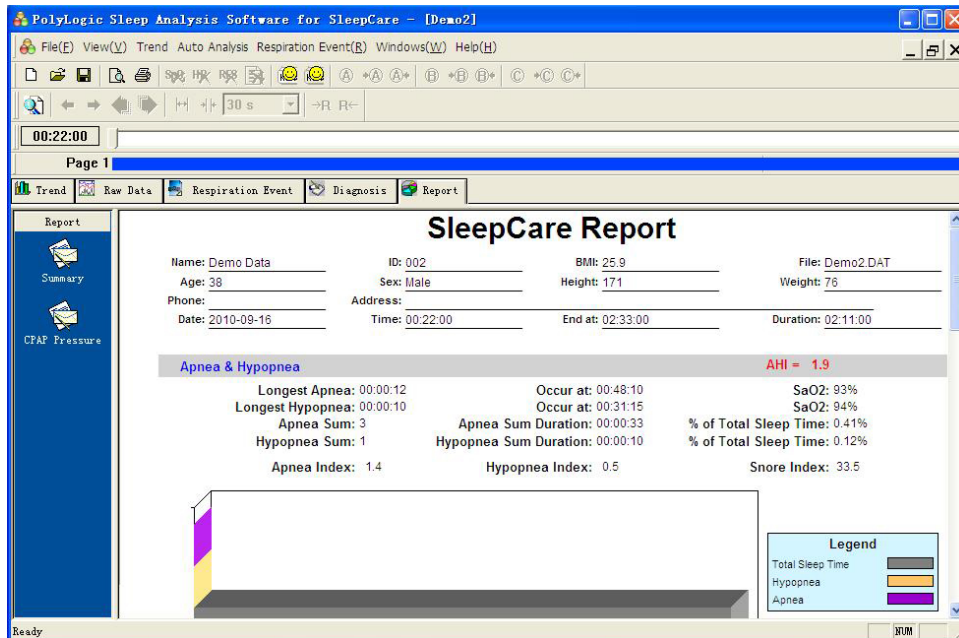



Figure 2-10 Diagnosis Result

## Print Preview and Output

When the waveform is in need of printing, the waveform page should be activated to display.

Press  button or click on preview from the File menu under this page to preview the present waveforms.

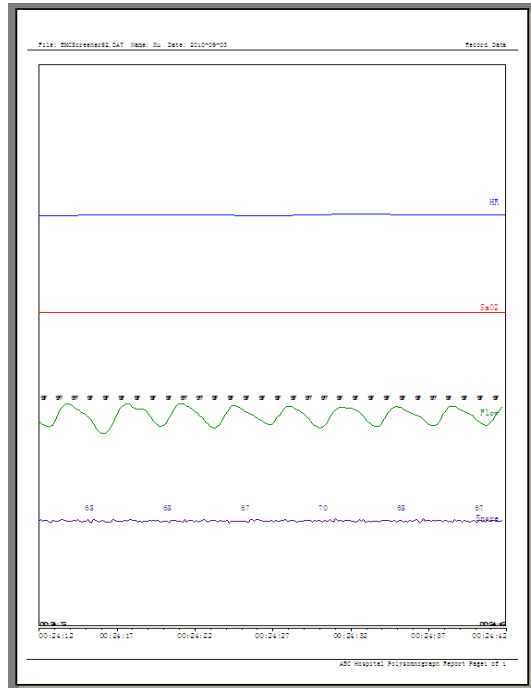

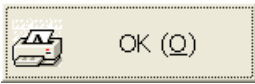


Figure 2-11 Print and Preview of the Raw Data Waveform

In other pages, pressing  button or clicking on preview from the File menu may generate a window for preview options. Select the intended report and press  button, the preview of report will be shown on the screen.

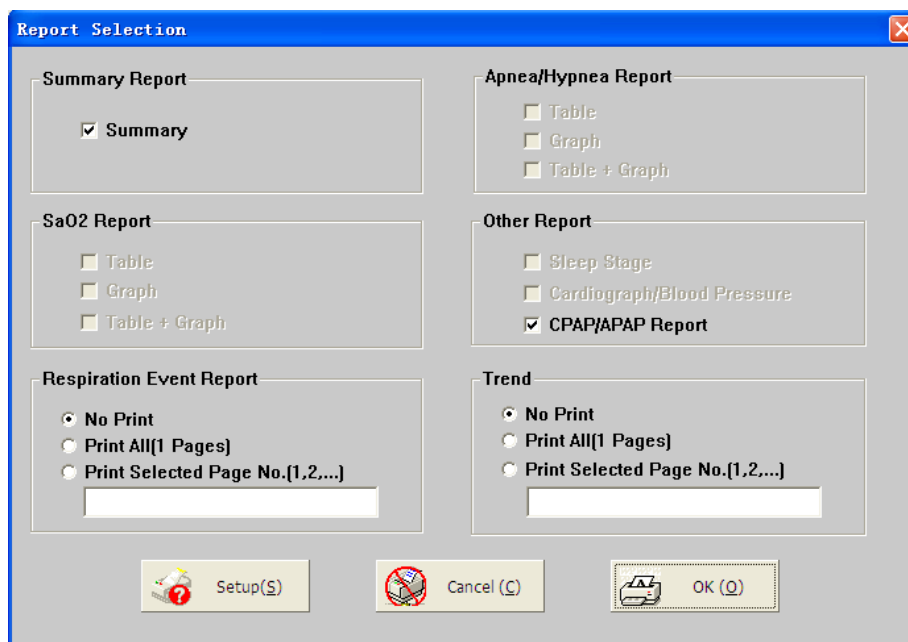




Figure 2-12 Print and Preview of the Report

Similarly, selecting  button in the toolbar, or **Print** from **File** menu will show up the window for preview options. The print work will be done after selecting the intended reports and

pressing the  button. Click  to change the printer settings.

## Exit Program

To back to Windows desktop just click File in the menu and click Exit or  at the top right corner.

## Service

### Technical Support

For technical support and before returning any equipment, call BMC MEDICAL CO., LTD. at 86-10-51663880.

### Limited Warranty

BMC MEDICAL CO., LTD. warrants that the SleepCare™ shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year for main unit and three (3) months for all accessories from the date of sale by BMC MEDICAL CO., LTD. to the dealer. During the warranty period, BMC MEDICAL CO., LTD. will correct any defects in material or workmanship to conform to specifications, free of charge. BMC MEDICAL CO., LTD. reserves the right to replace the SleepCare™ with a comparable unit. Shipping costs are the responsibility of the purchaser. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

BMC MEDICAL CO., LTD. disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this product.

To exercise the rights under this warranty, contact the local, authorized dealers or:

**MANUFACTURER:**

**BMC MEDICAL CO., LTD.**

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