BMC

Portable Diagnostic System

YH-600B Pro

User Manual

CE0123

Table of Contents

CHAPTER 1: DEVICE INTRODUCTION AND OPERATION 1

1. Symbols 1

1.1 Control Buttons 1

1.2 Device Symbols 1

2. Warnings, Cautions and Important Tips 1

3. Contraindications 2

4. Specifications 2

5. Intended Use 4

6. Glossary 5

7. Model 6

8. Package Contents 7

9. System Features 8

9.1 General Introduction 8

9.2 Main Device Structure 8

10. Instructions for Use 9

10.1 Setting up and Wearing the Device 10

10.1.1 Installing the TF Card and Battery 10

10.1.2 Wearing the Main Device 12

10.1.3 Connecting the Respiration Kit 12

10.1.4 Wearing the Airflow Cannula 13

10.1.5 Wearing the Pulse Oximeter Sensor 14

10.1.6 Connecting the Main Device with the Respiration Kit 14

10.2 Operation 14

10.2.1 Accessing the Initial Interface 15

10.2.2 Accessing the Standby Interface 15

10.2.3 Accessing the “Record” Interface 16

10.2.4 Accessing the “Setup” Interface 18

10.2.5 Accessing the “Archives” Interface 19

10.2.6 Accessing the “Tools” Interface 20

10.2.7 Turning Off the Device 22

11. Troubleshooting 23

12. Cleaning and Disinfection 24

12.1 Cleaning 24

12.2 Disinfection 25

13. Disposal 26

14. EMC Requirements 27

CHAPTER 2: POLYLOGIC SLEEP ANALYSIS SOFTWARE 30

1. Installation 30

1.1 Software Installation 30

1.2 Driver Installation 30

2. Patient Information Setup 30

3. Data Reception 32

3.1 Run Software 32

3.2 Connection of YH-600B Pro and Computer 32

3.3 Data Transmission 33

3.3.1 TF Card Data Transmission 35

3.3.2 Bluetooth Data Transmission 35

4. Data File Management 39

5. Data Playback 40

5.1 Opening and Closing the Data File 40

5.2 Display of Recorded Data and Analysis Result 40

6. Print Preview and Output 47

7. Help 48

8. Exit Program 48

CHAPTER 3: SERVICE 49

1. Technical Support 49

2. Limited Warranty 49

CHAPTER 1: DEVICE INTRODUCTION AND OPERATION

The information in this manual has been carefully checked and is believed to be accurate. In the interest of continued product development, BMC Medical Co., Ltd. reserves the right to make changes and improvements to this manual and the products it describes at any time, without notice or obligation. Images shown here are indicative only. If there is inconsistency between the image and actual product, the actual product shall govern.

1. Symbols

1.1 Control Buttons

⏻/✓	**On-Off/OK** Button	⟳	**Shift** Button

1.2 Device Symbols

	Type BF Applied Part
	Follow Instructions for Use
IP22	≥ 12.5 mm Diameter, Dripping (15ºtilted)
SN	Serial Number of the Product
	Manufacturer
	Authorized Representative in the European Community
CE0123	European Union Approval
SpO2	No SpO_2 Alarms
BMC	Logo of BMC Medical Co., Ltd.

2. Warnings, Cautions and Important Tips

WARNING!
Indicate the possibility of injury to the user or operator.

CAUTION!
Indicate the possibility of damage to the device.

IMPORTANT TIP!
Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

3. Contraindications

Depending on the skin condition or general state of health, the patient may experience sensitivity to the wrist belt or the self-adhesive pulse oximeter sensor. Discontinue use if an allergic reaction to the skin-contact materials occurs.

4. Specifications

SpO_2	
Range	0%～100%
Accuracy	≤±3%（70%～85%），≤±2%（85%～100%） ≤±3% (70%～85%), ≤±2% (85%～100%)
Pulse rate	
Range	30～250 bpm
Accuracy	≤2 bpm (30～100 bpm) ≤2% (100 bpm～250 bpm)
Wavelengths	
Red	663 nanometers
Infrared	890 nanometers
Maximal Optical Output Power	Less than 1.5mw maximum average
Airflow waveform	
Frequency	10～40 times per minute
Margin of error	≤±1 time
CPAP pressure	
Range	4～20 hPa
Margin of error	≤±1 hPa
Snore	150～300 Hz
Thorax/Abdomen effort	
Range	10～40 times per minute
Margin of error	≤±3 times per minute
Body position	Supine position, sleep on left or right side, and prone positons can be detected
Wrist movement (sleep/awake)	Automatic sleep-awake identification from wrist movement
Temperature	
Operation	5°C～35°C
Storage/Transportation	-20°C～55°C
Humidity	
Operation	≤80% (non-condensing)
Storage/Transportation	≤93% (non-condensing)

Atmospheric pressure	
Operation	860～1,060 hPa
Storage/Transportation	700～1,060 hPa
Power supply	DC 1.5 V ±0.15 V（1×1.5 V R6 AA）
Minimum record duration	No less than 8 hours
Data storage	64 records can be stored on TF card
Dimensions	78 mm × 60 mm × 21 mm (main device)
Weight	75 g (main device without battery)
Type of protection against electrical shocks	Internal power supply
Classification of protection against electrical shocks	Type BF applied part
Waterproof rating	IP22
Working mode	Continuous operation

5. Intended Use

YH-600B Pro records the following data: patient respiratory nasal airflow, snoring, blood oxygen saturation, pulse, respiratory effort, body position and wrist movement during sleep. It can also be connected to a CPAP system to record and display continuous positive airway pressure. The device uses these recordings to produce a report that may aid in the diagnosis of sleep-disordered breathing or for further clinical investigation. The device is intended for the hospital/institutional environment (supervised) and the home environment (unsupervised) for adults.

WARNING!

- When using consumables and accessories, please read the manufacturer's information supplied with the products.
- This device is intended for adult use only. Do not use the device on infant or neonatal patients.
- Do not use the device in situations where alarms are required. The device has no audible alarms.
- Keep all parts away from children.
- YH-600B Pro and its accessories are for the specified intended use only.
- Do not smoke while wearing YH-600B Pro.
- Risk of explosion. Never use the device in the vicinity of flammable gases (e.g. anesthetics).
- No modification of this equipment is allowed.

CAUTION!

- Heavy smokers with a high level of carbon monoxide (CO) in blood cannot use YH-600B Pro.
- YH-600B Pro cannot be used on a water bed or a bed with an electric blanket, because these electrical equipment will disturb the operation of YH-600B Pro.
- Federal law restricts these devices to sale by or on the order of a physician.
- YH-600B Pro meets requirements of electromagnetic compatibility. If you doubt YH-600B Pro may disturb the operation of other electrical equipments, such as televisions, radios and mobile phones, or if YH-600B Pro does disturb the operation, you should move YH-600B Pro far away from these equipment.
- YH-600B Pro must be able to measure the pulse properly to obtain accurate SpO2 measurement. Make sure that nothing is hindering the pulse measurement before relying on the SpO2 measurement.
- YH-600B Pro measures the percentage of arterial oxygen saturation of functional hemoglobin. Significant levels of dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin may affect the accuracy of the measurement.
- FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this device.

6. Glossary

Snore	Because of the respiratory tract's airway limitation, sound is made when respiratory airflow gets through the narrow respiratory tract, which usually indicates that the patient is likely to have suffered in years from sleep apnea syndrome along with the increase of age.
Apnea	The performance of respiratory intermission during sleep is that the respiratory airflow drops to lower than 10% of the normal range and lasts for at least 10 seconds. The recurrent intermission during sleep is easy to cause severe oxygen-deficit to brain and blood, form hypoxemia and induce hypertension, brain-heart disease, arrhythmia, myocardial infarction and angina, which then can induce multi-system diseases of the human body.
Hypopnea	The reduction range of respiratory airflow is more than 50% of the normal, accompanied with more than 4% of oxyhemoglobin saturation reduction.
SAHS	The SAHS means at least 30 times of apnea in 7 hours of nightly sleep time of adults and each apnea lasts for more than 10 seconds. Or the apnea hypopnea index AHI (the number of apneas and hypopneas per hour) is greater than 5.
OASHS	The OSAHS means the sleep apnea hypopnea syndrome caused by obstruction of the upper respiratory tract (including the collapse of pharyngeal mucosa).
AI	The AI means the number of apneas per hour, which is equal to the number of times apnea has occurred the whole night divided by the sleep time of whole night (awakening and invalid time are not contained). The unit of time is hour.
HI	The HI means the number of hypopneas per hour, which is equal to the number of times hypopnea has occurred the whole night divided by the sleep time of whole night (awakening and invalid time are not contained). The unit of time is hour.
AHI	The AHI means the number of apneas and hypopneas per hour which is equal to the total times of apneas and hypopneas during the whole night divided by the sleep time of whole night (awakening and invalid time are not contained),and the unit of time is hour.
SNI	The SNI means the average number of times the snore has occurred every hour which is equal to the number of times snore has occurred the whole night divided by the sleep time of whole night (awakening and invalid time are not contained). The unit of time is hour.
ODI	The ODI means the number of times when the oxyhemoglobin saturation reduction is more than 3% or 4% every hour.
CPAP	The CPAP means feeding continuous positive airflow into air passage by face mask.

7. Model

Table 1-1 **Monitoring Parameters and Components**

Model	Monitoring Parameters	Components
YH-600B Pro	SpO_2, pulse rate, airflow waveform, thorax/abdomen effort, body position, snore, wrist movement (sleep/wake), CPAP pressure	Main Device, Respiration Kit, Respiration Effort Belt, Effort Lead Cable, USB Data Cable and Bluetooth Data Transmission, TF Card, Pulse Oximeter Sensor, CPAP Pressure Tube, Airflow Cannula, Wrist Belt, Computer Software

8. Package Contents

Table 1-2 shows package contents.

Table 1-2 Package Contents

Main Device		Pulse Oximeter Sensor	
USB Data Cable		Respiration Kit	
Airflow Cannula		Respiration Effort Belt	
CPAP Pressure Tube		Effort Lead Cable	
Quick Operation Manual	Quick Operation Manual	TF Card	
User Manual		Computer Software Disk	
Carrying Case			

All parts and accessories do not contain latex.

WARNING!

- This device should only be used with the tube and accessories manufactured or recommended by BMC or with those recommended by your prescribing physician. The use of inappropriate tubes and accessories may affect the performance of the device and impair monitoring effects.

CAUTION!

- The use of non-BMC-certified accessories may undermine system security, so it is recommended that users only use the pulse oximeter sensor and other accessories provided by BMC.
- It is recommended to use Airflow Cannula with the registration certification for medical device.
- This device and its accessories are for intended use only.

① The belt on the main device is in accordance with the biological evaluation of medical devices.

② The finger sheath and cannula are CE marking approved, indicating compliance to the Medical Device Directive.

③ Several accessories are available for using YH-600B Pro. To ensure a safe and effective therapy, adopt only BMC accessories. All accessories do not contain latex.

9. System Features

9.1 General Introduction

The performance and functional characteristics of YH-600B Pro include all the user-friendly features of the predicate device.
YH-600B Pro is powered by one 1.5 V AA battery. Testing was performed to demonstrate that the performance of YH-600B Pro in its intended environment is as safe and effective as that of the legally marketed predicate devices. The safety and effectiveness of YH-600B Pro have been verified through performance-related testing that consisted of Electrical Safety, Electromagnetic Compatibility, Mechanical and Environment Testing.
The recorded data, such as SpO_2, pulse rate, airflow waveform, snore and CPAP pressure, can be replayed on a computer via the PolyLogic Sleep Analysis Software which is provided with YH-600B Pro. The device can be used as a standalone unit for recording data. It can also interact with a commercially available IEC60950-1 compliant computer, which can be used to review data. The device does not have any audible alarms, and, therefore, should not be used for continuous monitoring.
Patient is an intended operator, who can safely use all functions and can perform all maintenances mentioned in the User Manual.
All parts of the device are applied parts.

9.2 Main Device Structure

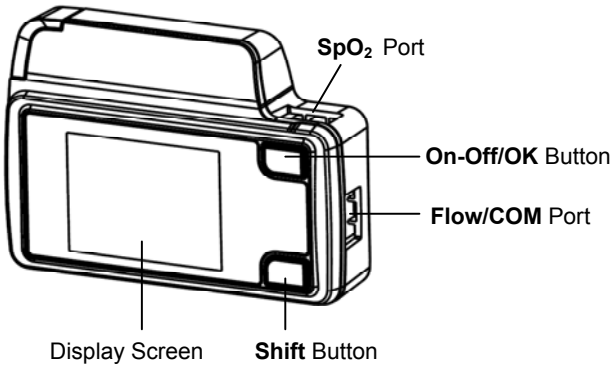


Figure 1-1 Main device structure

Table 1-3 shows Component and Function.

Table 1-3 Component and Function

Component	Function
Display Screen	Display the menu, alerts and data monitored
Shift Button	Switch interfaces and options
On-Off/OK Button	Turn on/off the device, and confirm adjustment
SpO_2 Port	Connect to the pulse oximeter sensor to collect data on SpO_2 and pulse rate
Flow/COM Port	Connect to the respiration kit to collect data on the airflow waveform and snore; connect to the computer with a USB data cable to transfer data.

10. Instructions for Use

CAUTION!

- 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.
- 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.

10.1 Setting up and Wearing the Device

Figure 1-2 shows a user wearing YH-600B Pro. See sections 10.1.1～10.1.6 for detailed wearing instructions.

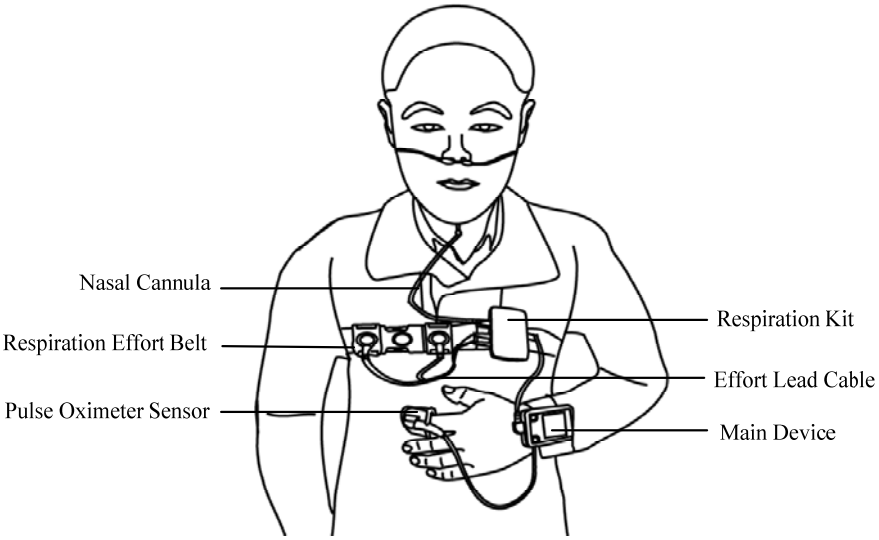
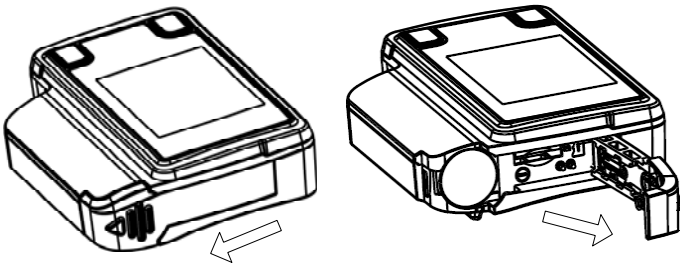


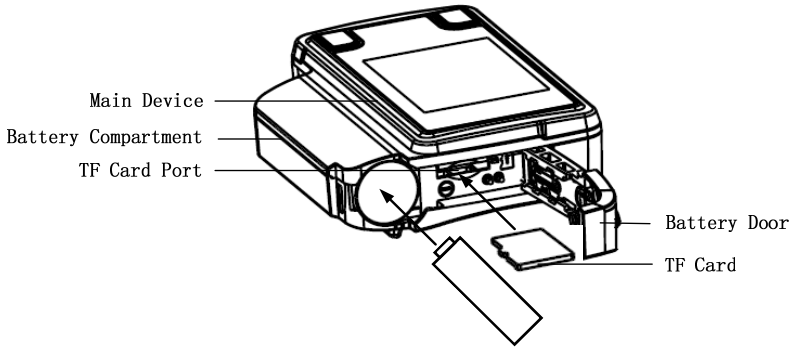
Figure 1-2 Wearing YH-600B Pro

10.1.1 Installing the TF Card and Battery

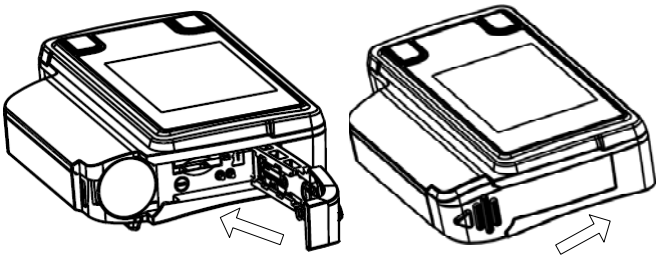
Push and pull the battery door according to Step 1. Insert the TF card into the slot and put a new AA battery with the positive and negative terminals on the correct sides according to Step 2. Close the battery door according to Step 3 (Figure 1-3).



Step 1: Opening battery door



Step 2: Inserting TF card and battery



Step 3: Closing battery door

Figure 1-3 Inserting the TF card and battery

WARNING!

The battery may leak or explode if used or disposed of improperly.

When the TF card and battery are correctly inserted into the device, a symbol indicating correct insertion of the TF card will appear in the standby interface, as shown in Figure 1-4.

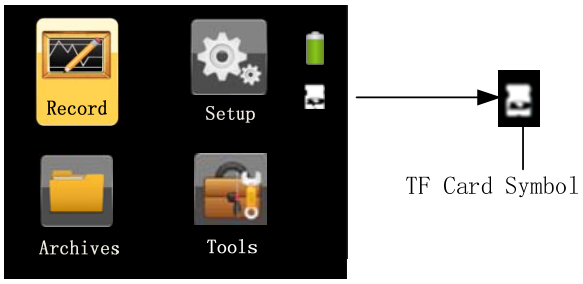


Figure 1-4 Symbol indicating correct insertion of TF card

If the TF card is inserted incorrectly or not inserted, a red “X” symbol will appear on the “TF card” icon in the standby interface, as shown in Figure1-5, indicating “incorrect insertion or absence of TF card”.

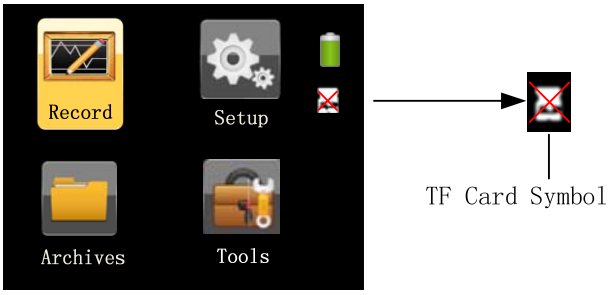


Figure 1-5 Symbol indicating incorrect insertion or absence of TF card

CAUTION!

- When there is a red "X" symbol on the "TF card" icon in the standby interface, the user should check whether the TF card is inserted incorrectly or not inserted. If it is inserted correctly, the TF card may be broken.
- Please place a fully charged or new AA battery every time before recording. Use only the specified types of battery or rechargeable battery.
- Replace the battery when the battery quantity drops below 1.2 V, as the icon shows or when the screen flickers.
- If the device has not been used for a long time, remove and put away the battery to prevent electrolyte leakage from damaging the device.

10.1.2 Wearing the Main Device

Wear the main device on the wrist as a watch, and fasten the wrist belt when the device is properly positioned, as shown in Figure 1-6.

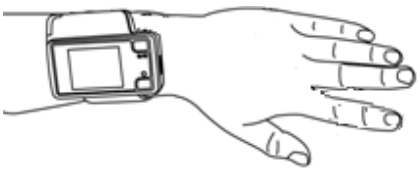


Figure 1-6 Wearing the main device

CAUTION!

Make sure the wrist belt is neither too loose nor too tight; otherwise normal device operation will be affected.

10.1.3 Connecting the Respiration Kit

Connect the respiration kit according to steps 1～3, as shown in Figure 1-7.

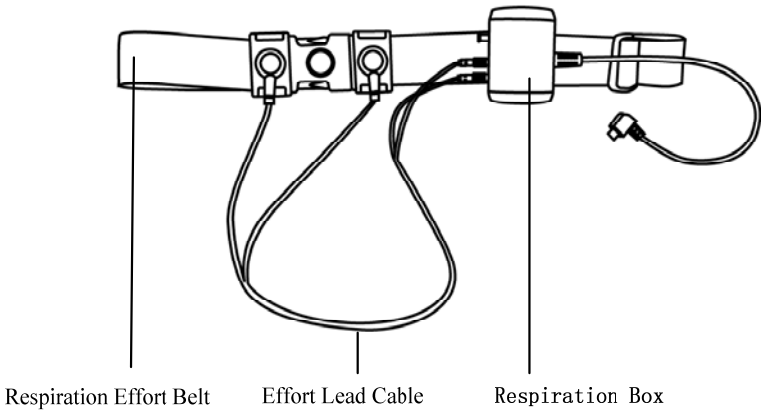


Figure 1-7 Connecting the respiration kit

Step 1 Connect the effort lead cable and respiration effort belt;

Step 2: Fasten the respiration effort belt around the body;

Step 3 Insert the effort lead cable into the holes of the small respiration box, and hang the respiration kit on the respiration effort belt.

10.1.4 Wearing the Airflow Cannula

As Figure 1-8 shows, place the two prongs of the cannula in the nostrils, hook the cannula around the ears, and push the slide fastener upward to fix the cannula on the head. Insert the other end of the cannula into the air pathway interface of the respiration kit.

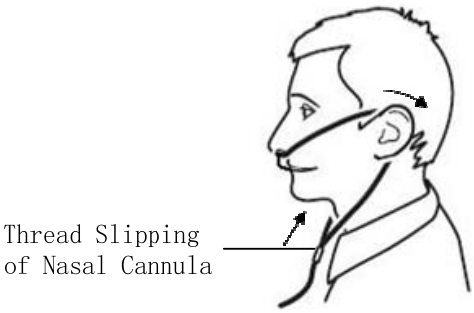


Figure 1-8 Wearing the Airflow Cannula

WARNING!

- Please read the attached product literature carefully before using the device and accessories.
- The Airflow Cannula is for one time use only, and only Airflow Cannula with original and intact packaging should be used.
- Please wear the Airflow Cannula correctly to avoid suffocation.

10.1.5 Wearing the Pulse Oximeter Sensor

As Figure 1-9 shows, insert the index finger until it reaches the bottom of the pulse oximeter sensor, tape the sensor onto the finger, and insert the data connector of the pulse oximeter sensor into the SpO_2 port on the top of the main device.

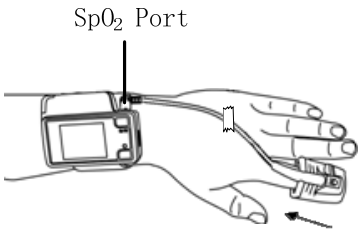


Figure 1-9 Wearing the pulse oximeter sensor

WARNING!

- Change the measured finger regularly according to the patient's conditions after prolonged use. It must be moved every 8 hours or more often and reapplied to another site according to the user's skin integrity and circulatory status.
- Excessive ambient light, excessive motion, use of intravascular dyes, poorly perfused finger, extreme finger sizes or improper placement may affect the accuracy of the measurement.
- Nail polish or false nails may cause erroneous measurement results.
- Overly low blood pressure, overly low systolic blood pressure, severe anemia, or hypothermia may cause erroneous measurement results.
- The pulse oximeter sensor is designed for use with this device only.
- Check the compatibility of the device and pulse oximeter sensor before use; otherwise it may cause injury to the patient.
- A functional tester cannot be used to assess the accuracy of the SpO_2 measurement result.
- Do not use the pulse oximeter sensor during MRI scanning.
- Do not use a broken pulse oximeter sensor.
- Do not immerse the pulse oximeter sensor in liquid, as it causes short circuit.
- The pulse oximeter sensor may not work on cold extremities due to reduced circulation. Warm or rub the finger to increase circulation, or reposition the sensor.
- If the pulse oximeter sensor is shared by multi-users, the users may be exposed to the risk of cross-infection.
- Blood flow must not be impeded during the recording process. The pulse oximeter sensor should be applied snug and comfortable, but not too tight or subject to any excessive pressure.

10.1.6 Connecting the Main Device with the Respiration Kit

Connect the main device with the respiration kit by inserting the data connector of the kit into the **Flow/COM** port on the right side of the device.

10.2 Operation

WARNING!

- Do not smoke when using the device.

- Heavy smokers with high carbon monoxide (CO) blood content cannot use YH-600B Pro.

CAUTION!

- The device has no alarm system, and is thus unsuitable for situations that need an alarm system.
- While working, the device should not be directly exposed to airflow sources (e.g. fan), otherwise the accuracy of airflow monitoring will be affected.
- Do not use the device in nuclear magnetic environments or where there is high electromagnetic interference.
- If the device performance has unexplainable changes, if water has entered the enclosure, if the enclosure is broken, or if the device has been dropped from a high place or hand, discontinue use and contact BMC.

10.2.1 Accessing the Initial Interface

Press and hold the **On-Off/OK** Button ⏻/⊙ for five seconds, and the initial interface will appear, as shown in Figure 1-10.

Figure 1-10 Initial interface

CAUTION!

- If the device is not used for a long time, a time setting window will automatically pop up when you reuse it. Users need to update the date and time according to actual time, then choose “Save and Exit” to enter the standby interface.
- If the present time displayed on the device is later than the preset record starting time, the device will immediately begin to record.

10.2.2 Accessing the Standby Interface

The device automatically enters the standby interface after it is started, as shown in Figure 1-11.

There are six icons in the standby interface: Record , Setup , Archives , Tools , Battery and TF card . The yellow frame can switch among the four icons of Record, Setup, Archives, and Tools, and when it falls on an icon, press the **On-Off/OK** Button⏻/⊙ to enter the corresponding interface. The device can be turned off if the **On-Off/OK** Button⏻/⊙ is pressed and held for five seconds in the standby interface.

Figure 1-11 Standby interface

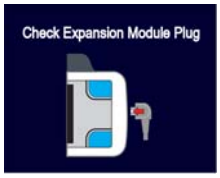
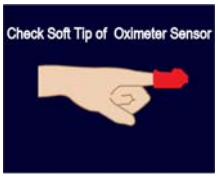
CAUTION!

In all interfaces the screen will dim if there is no operation within the preset screen backlight timeout. Press any key in five minutes to light up the screen. The device will shut off automatically if there is no operation for five minutes.**10.2.3 Accessing the "Record" Interface**

10.2.3.1 Wearing Alert Messages

From the standby interface, press the **Shift** Button to switch the yellow frame to the "Record" icon . Press the **On-Off/OK** Button to enter the "Record" interface. If the device is not worn properly, a corresponding alert message will appear automatically. See the following Table 1-4 for detailed information.

Table 1-4 Wearing alert message

Alert Message	Causes	Alert Removal
	When recording starts, the device cannot detect the SpO_2 probe	Insert the SpO_2 probe or press and hold the **On-Off/OK** Button to start recording compulsorily
	When recording starts, the device cannot detect the expansion module kit (respiration kit)	Insert the expansion module kit or press the **On-Off/OK** Button to start recording compulsorily
	When recording starts, the device can detect the SpO_2 probe, but fails to collect SpO_2 information	Wear the SpO_2 finger cot properly or long-press the **On-Off/OK** Button to start recording compulsorily

	When recording starts, the device can detect the expansion module kit, but fails to collect airflow waveform information	Wear the Airflow Cannula properly or long-press the **On-Off/OK** Button ⏻/⊘ to start recording compulsorily
	When recording starts, the device can detect the airflow kit, but fails to collect thoracoabdominal respiration information	Wear the respiration effort belt properly or long-press the **On-Off/OK** Button ⏻/⊘ to start recording compulsorily
	The battery is low when recording starts	Replace the battery or press and hold the **On-Off/OK** Button ⏻/⊘ for three seconds to enter the "Record" interface

10.2.3.2 "Record" Interface

If there are no wearing alerts, the "Record" interface can be accessed directly. The time notification (0:00:00) in the upper left corner of the "Record" interface flickers. Press and hold the **On-Off/OK** Button ⏻/⊘ for two seconds to start timing and recording monitored data in the device.
If there is no operation within the preset screen backlight timeout (except when the screen is set to stay bright all the time), the screen will turn off automatically. Pressing any key can light up the screen again.
When recording is completed, press the **On-Off/OK** Button ⏻/⊘ and **Shift** Button ⟲ simultaneously to exit the "Record" interface and return to the standby interface.

The "Record" interface of YH-600B Pro, as shown in Figure 1-12.

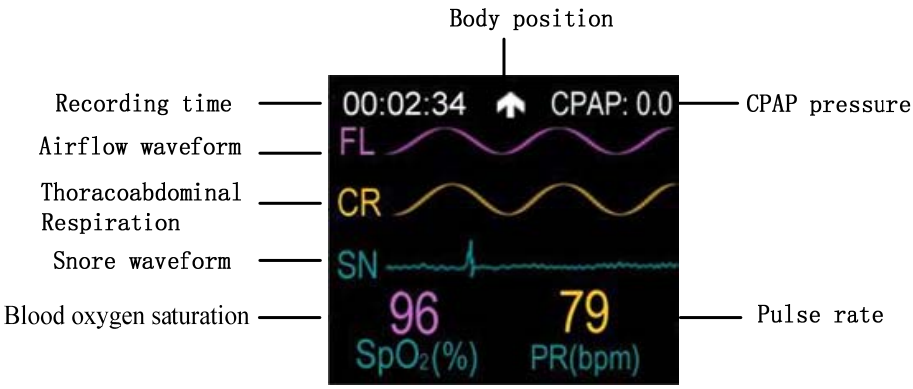


Figure 1-12 "Record" interface of YH-600B Pro

SpO_2(%):	Blood oxygen saturation expressed in percentage
PR(bpm):	Pulse rate expressed as beats per minute (bpm)
Recording time:	The length of a recording
Snore:	Waveform indicates the occurrence of a snore

Airflow waveform:	Respiration fluctuations
Thoracoabdominal Respiration:	Chest or abdominal breathing fluctuations
Body position:	The user's body position when the device is in use

Note:

① The pulse oximeter equipment is calibrated to display functional oxygen saturation.

②The sampling rate of the SpO_2 signal is about 50 Hz, and the update rate of the frame is 1 Hz. So even there are some filtering methods to process the SpO_2 data, it will not delay for a relative long time to the displaying data.

③The waveform of the signal is non-normalized so that the software can provide to the operator that the pulse rate value displayed is potentially incorrect. However, YH-600B Pro which does not store the waveform data just keeps waveform updating to give the implication of the detector in working state.

④If the pulse oximeter sensor is in an abnormal state, the value of SpO_2 will be blank.

⑤The value of SpO_2 and PR is calculated by the average of the former eight pulse waveforms.

10.2.4 Accessing the "Setup" Interface

From the standby interface, press the **Shift** Button to switch the yellow frame to the "Setup" icon

. Press the **On-Off/OK** Button to enter the "Setup" interface. The user can adjust settings, and press the **On-Off/OK** Button to confirm the adjustment, as shown in Figure 1-13.

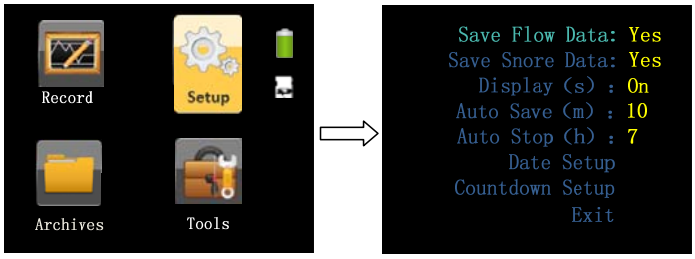


Figure 1-13 "Setup" interface

- **Save Flow Data**, allowing users to save the data of airflow.
- **Save Snore Data**, allowing users to save the data of snore.
- **Display**, allowing users to set the screen backlight timeout.
- **Auto Save**, saving the data automatically.
- **Auto Stop**, stop saving the data automatically.
- **Date Setup**, allowing users to set time and date according to their needs. Select "Save and Exit" to exit the "Date Setup" interface, as shown in Figure 1-14.

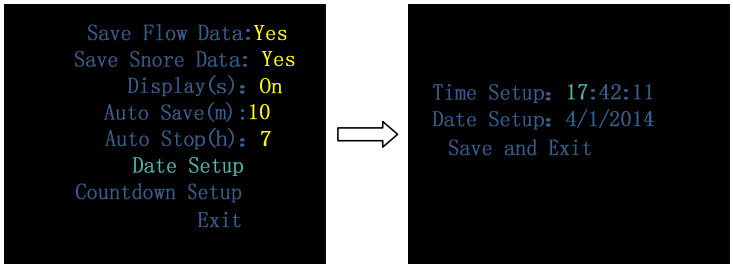


Figure 1-14 “Date Setup” interface

CAUTION!

Do not remove the battery when the device is working in the countdown mode, otherwise the countdown process will be interrupted.

- **Countdown Setup**, allowing users to set the device to start recording at a certain time according to their needs. The maximum countdown time is 14 hours, and the device will start recording automatically when the countdown reaches 0:00:00, as shown in Figure 1-15. Press and hold the **Shift** Button for five seconds to exit the “**Countdown Setup”** interface.

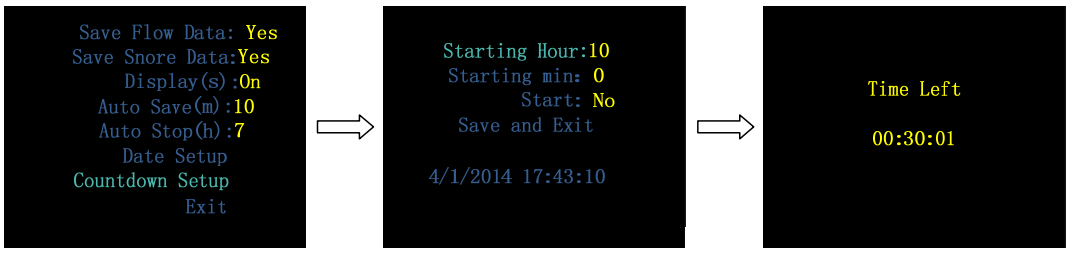


Figure 1-15 “Countdown Setup” interface

- **Exit**, select “Exit” to return to the standby interface.

10.2.5 Accessing the “Archives” Interface

From the standby interface, press the **Shift** Button to switch the yellow frame to the “Archives” icon . Press the **On-Off/OK** Button to enter the “Archives” interface. This interface can display eight records at most, and each record is made up of a serial number and recording time, as shown in Figure 1-16. When there are no records, the screen will display “No Reccords”, as shown in Figure 1-17.

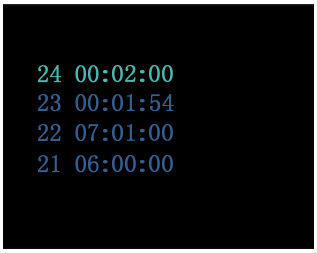


Figure 1-16 “Records” interface-List of records

Figure 1-17 “Records” interface-No Records

Select a record in the list of records, and press the **On-Off/OK** Button ⏻/✓. If the record is valid, a ribbon interface will appear, indicating the severity of SAHS. If not, “Invalid Data” will appear, as shown in Figure 1-18.

Figure 1-18 “SAHS Severity Indication” interface

Select a record in the list of records. If the record is invalid, continue to press the **On-Off/OK** Button ⏻/✓ to trigger the QR code, as shown in Figure 1-19.

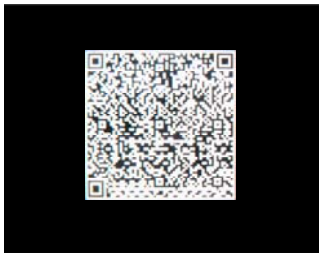


Figure 1-19 QR code interface

Scan the QR code by intelligent terminal app “BMC PolyWatch” to view analysis results.

When operations are done, press the **On-Off/OK** Button ⏻/✓ and **Shift** Button ⟲ to exit the list of records and return to the standby interface.

WARNING!

The analysis results of the app are for reference only. The diagnosis should be given by your physician.

10.2.6 Accessing the “Tools” Interface

From the standby interface, press the **Shift** Button ⟲ to switch the yellow frame to the “Tools” icon

. Press the **On-Off/OK** Button ⏻/✓ to enter the “Tools” interface. There are five options in this interface: Transfer Data(BT), Language, Erase, About, and Exit.

The “Transfer Data(BT)” interface shows all records and allows data transmission. If there are no data records, the screen will display “No Records”, but Bluetooth pairing will not be affected, as shown in figure 1-20.

Figure 1-20“Transfer Data(BT) ” interface

Users can switch among 11 languages in the “Language” interface, as shown in Figure 1-21.

Figure 1-21 “Language” interface

The “Erase” interface shows a question– “Are you sure to erase All records?” To erase all records, select “Yes”, then press and hold the **On-Off/OK** Button ⏻/⊙and **Shift** Button ⟲ simultaneously for two seconds. Then, the interface shows the erasing process which is ended with a message-“Erase Complete!”, as shown in Figure 1-22.

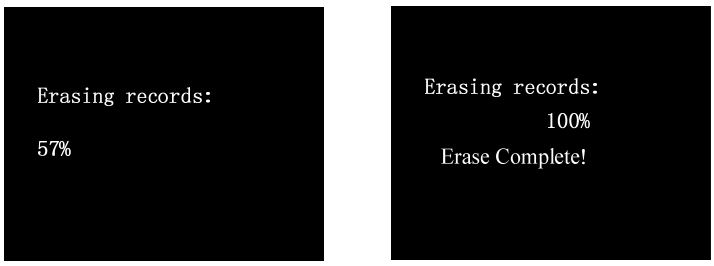


Figure 1-22“Erase” interface

The “About” interface shows the information, software version and battery power are included, as shown in Figure 1-23. Press any key to exit.

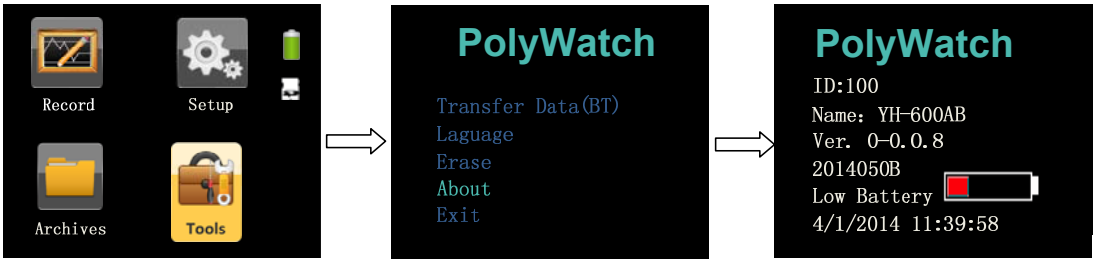


Figure 1-23 “About” interface

CAUTION!

The cyclic recording mode is adopted. Users do not need to delete data manually as new data will overwrite the oldest data automatically.

10.2.7 Turning Off the Device

On the standby interface, press and hold the **On-Off/OK** Button ⏻/✓ for five seconds to turn off the device.

11. Troubleshooting

Table 1-5 shows troubleshooting.

Table 1-5 Troubleshooting

Problem	Possible Cause	Solution(s)
Device won't start	Battery installed incorrectly	Check battery installation
	Battery exhausted	Replace battery
Screen flickers	Low battery voltage	Replace battery
TF card alert	TF card is not inserted, is inserted incorrectly, or is broken	Insert TF card properly or replace it
Flat airflow waveform with no fluctuations	Airflow tube is not inserted into the respiration kit, respiration kit data cable loosely connects to the main device, or the tube is bent or squeezed somewhere	Insert the tube properly, make sure data cable connects to main device properly, or contact equipment supplier for Airflow Cannula replacement
Flat pulse waveform with no fluctuations	Pulse oximeter sensor worn in wrong position	Adjust the sensor's measurement point on finger
Flat thoracoabdominal respiration waveform with no fluctuations	Respiration effort belt worn incorrectly	Wear respiration effort belt properly
Online analysis feature missing	Recording terminated abnormally	Use the automatically stop recording feature or manually stop recording

12. Cleaning and Disinfection

12.1 Cleaning

YH-600B Pro was designed to be simple and easy-to-use. Your YH-600B Pro will operate reliably with good care and regular maintenance.

Cleaning instruction:

Clean YH-600B Pro Main Device

① Turn off YH-600B Pro and take battery out of YH-600B Pro main device.
② Scrub YH-600B Pro main device gently with a damp gauze pad.
③ Dry YH-600B Pro main device with a dry soft gauze pad.

Clean the Respiration Kit

① Detach the Respiration Kit and the CPAP pressure cannula.
② Wipe the Respiration Kit gently with a damp gauze pad.
③ Dry the Respiration Kit with a dry soft gauze pad.

Clean the USB Data Cable

① Disconnect the USB data cable from YH-600B Pro main device.
② Scrub the USB data cable gently with a damp gauze pad.
③ Dry the USB data cable with a dry soft gauze pad.

Clean the Pulse Oximeter Sensor

The pulse oximeter sensor may be surface-cleaned by wiping it with a solution, such as 70% isopropyl alcohol.
① Detach the pulse oximeter sensor from YH-600B Pro main device.
② Saturate a clean, dry gauze pad with the cleaning solution. Wipe all surfaces of the pulse oximeter sensor with this gauze pad.
③ Saturate another clean, dry gauze pad with potable water. Wipe all surfaces of the pulse oximeter sensor with this gauze pad.
④ Dry the pulse oximeter sensor by wiping all surfaces with a clean, dry gauze pad.

Clean the CPAP Pressure Tube

① Detach the CPAP pressure tube from the respiration kit.
② Immerse the CPAP pressure tube completely in a solution ,such as 70% isopropyl alcohol.
③ Rinse the CPAP pressure tube with potable water.
④ Dry the CPAP pressure tube by wiping all surfaces with a clean, dry gauze pad and air dry the lumen of the CPAP pressure tube.

Cleaning the Wrist Belt

① Wash the wrist belt before first time use, as the dye may run.

② Detach the wrist belt from the main device.
③ It is important to always hand-wash the wrist belt.
④ Wash the wrist belt in warm (approx. 40°C) and soapy water. Use pure soap.
⑤ Rinse the wrist belt well with potable water and allow it to air dry out of direct sunlight.

CAUTION!

- Never use abrasive agents, alcohol, chlorine-containing substances, acetone, or other solvents to clean the device.
- Do not immerse the device, the airflow kit, or the pulse oximeter sensor in fluids, and ensure that no fluids penetrate into the product. Do not immerse the main device in water.
- The Airflow Cannula is non-reusable, dispose of it in accordance with local regulations.

12.2 Disinfection

If necessary, i.e. after infectious diseases, uses between patients or if parts have become unusually dirty, you can disinfect certain parts.

Clean YH-600B Pro parts as instructed above. Disinfect YH-600B Pro as follows:

We recommend CaviCide® liquid for disinfection.

We recommend you to wear suitable gloves (e.g. house-hold or disposable gloves) during disinfection procedures.

Disinfect the Pulse Oximeter Sensor

The pulse oximeter sensor may be surface-cleaned by wiping it with CaviCide® solution.

① Detach the pulse oximeter sensor from YH-600B Pro main device.

② Saturate a clean, dry gauze pad with the CaviCide® solution. Wipe all surfaces of the pulse oximeter sensor with this gauze pad.

③ Saturate another clean, dry gauze pad with potable water. Wipe all surfaces of the pulse oximeter sensor with this gauze pad.

④ Discard the used potable water. Always use fresh volumes of water for each wipe. Do not reuse the water for wipe or any other purpose. Repeat rinsing the pulse oximeter sensor for two additional times, for a total of three wipes to remove CaviCide® solution residues.

⑤ Dry the pulse oximeter sensor by wiping all surfaces with a clean, dry gauze pad.

Disinfect the CPAP Pressure Tube

① Detach the CPAP pressure tube from the airflow kit.

② Immerse the CPAP pressure tube completely, filling all lumens and eliminating air pockets, in CaviCide® solution for a minimum of 5 minutes at 20℃(68℉) or higher to destroy all pathogenic microorganisms.

③ Rinse the CPAP pressure tube with potable water. Keep the CPAP pressure tube totally immersed

for a minimum of 1 minute. Manually flush all lumens with large volumes (not less than 100 ml) of rinse water.

④ Remove the CPAP pressure tube and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose. Repeat rinsing the CPAP pressure tube for two additional times, for a total of three wipes to remove CaviCide® solution residues.

⑤ Dry the CPAP pressure tube by wiping all surfaces with a clean, dry gauze pad and air dry the lumen of the CPAP pressure tube.

Disinfect the Wrist Belt

① Detach the wrist belt from the main device.

② Immerse the wrist belt completely in CaviCide® solution for a minimum of 5 minutes at 20℃(68℉) or higher to destroy all pathogenic microorganisms.

③ Rinse the wrist belt with potable water. Keep the wrist belt totally immersed for a minimum of 1 minute in duration.

④ Remove the wrist belt and discard the rinse water. Always use fresh volumes of water for each rinse. Do not reuse the water for rinsing or any other purpose. Repeat rinsing the wrist belt for two additional times, for a total of three wipes to remove CaviCide® solution residues.

⑤ Air dry the wrist belt out of direct sunlight.

Sterilization of the device and its components other than recommended is not permitted.

WARNING!

The device shall not be serviced or maintained while in use with a patient.

13. Disposal

Dispose of the device and its package in accordance with local regulations.
Do not dispose device as household waste. To ensure proper disposal of the device, consult an authorized and certified electronic scrap recovery firm. You can find out their address from your environmental officer or your municipal authorities.

14. 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	The 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	Class B	The device is 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	N/A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	N/A	

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
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	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T)	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power

Input Lines IEC 61000-4-11	for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in UT) for 5 s		supply or from a battery
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
Note: U_T is the AC mains voltage prior to application of the test level.			

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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communication 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** $d=[\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/ m	$d=[\frac{3.5}{E_1}]\sqrt{P}$ 80～800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz～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, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1: At 80～800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a	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.		
b	Over the frequency range 150 kHz～ 80 MHz, field strengths should be less than 3 V/m.		

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the Device.			
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 communication equipment.			
Rated Maximum Output Power of Transmitter /W	Separation Distance According to Frequency of Transmitter/m		
	150 kHz～80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80～800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz～2.5 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
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
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power of the transmitter manufacturer. Note 1: At 80～800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

CHAPTER 2: POLYLOGIC SLEEP ANALYSIS SOFTWARE

System requirements for running the software

Hardware Requirements:	
CPU	≥P3 1.0 GB
Memory	≥512 MB
Display Resolution	≥1024×768 DPI
Hard Disk	≥40 GB
Software Platform:	Operation system X 32 : Windows XP/Windows 7/Vista

1. Installation

1.1 Software Installation

①Run the “SETUP.EXE” of YH-600B Pro in the installation CD and enter the setup page.

②Click “Next” to make the software auto-install.

③Click ‘Finish’ to quit when the installation is done. Double-click the new shortcut on desktop to launch the software.

1.2 Driver Installation

①Double-click the “USBXpressInstaller.exe” in the USB driver folder.

②Click “Next” in the pop-up dialogue boxes, the driver will be installed automatically. This may take several minutes to finish.

③Click “Finish” when the setup is done.

④A dialogue box displaying the message “found new hardware wizard” appears when the USB data cable is 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” dialogue box appears only for the first time of a USB data cable connection. The software can be directly used afterwards.

2. Patient Information Setup

Before recording, YH-600B Pro allows setting the patient information on a computer via the PolyLogic Sleep Analysis Software, and displaying the patient name and ID in “About ”interface (Figure1-12) of YH-600B Pro main device.

1) Start Software

Firstly double-click the shortcut of the analysis software icon on the desktop. The system will enter

YH-600B Pro system main window.

2) Connection of YH-600B Pro and Computer

In the power off state of YH-600B Pro, connect one end of the USB data cable to the computer USB port, and the other end to YH-600B Pro **Flow/COM** port and then turn on YH-600B Pro. Patient information can be set on a computer in all interfaces except About Interface.

3) Run the Software

Run the software and choose the “File” from the main menu, select "New" to enter the communication interface. From the “Select Device” drop-down menu, select “YH-600”, and then select the “USB” serial port. At last, click on “Connect” (Figure 2-1).

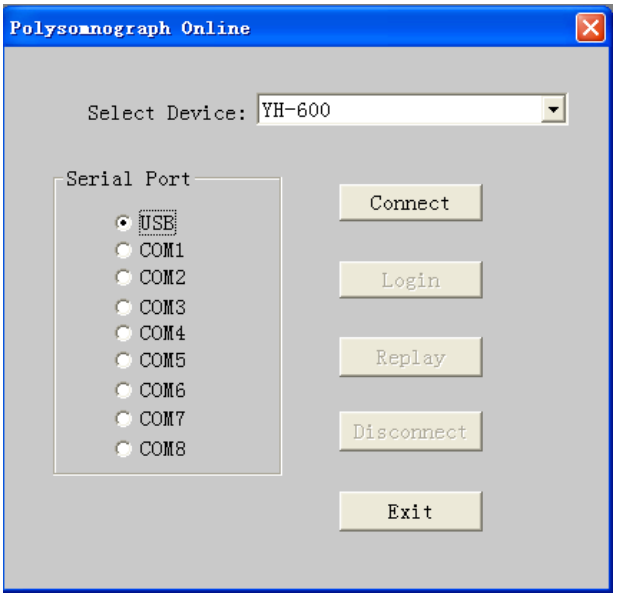


Figure 2-1 “Polysomnograph Online” dialog box

4) Connection

If connection succeeds, the "Connect" button will be grayed. And other originally grayed unavailable buttons will be available now. After connection with the computer (see "Connection of YH-600B Pro and Computer"), YH-600B Pro will automatically enter the communication status.

5) Login

After the success of connection, click "Login" button in the “Polysomnograph Online” dialog box and “Patient Information” dialog box pops up (Figure 2-2).

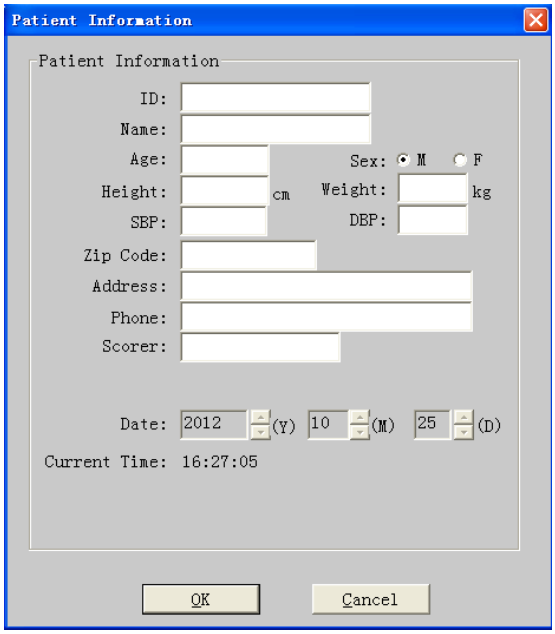


Figure 2-2 “Patient Information” dialog box

6) Enter Patient Information

Enter patient information one by one. When the login information input is finished, select “OK”. There will be a dialog box indicating “Login OK”, press “OK” to confirm the operation. At this time, select "Exit" in the dialog box, then YH-600B Pro will automatically exit from the communication status.

7) Exit Program

To return to windows desktop, just click “File” in the menu and click “Exit” or ☒ at the top right corner.

3. Data Reception

Data reception is to transmit the recorded data to a computer. Software will analyze the data, and then the operator can edit the results of the analysis to generate analysis reports. The data receiving process can be performed through the USB data cable, TF card, or Bluetooth.

Data receiving process is expressed as the following steps.

3.1 Run Software

Firstly double-click the shortcut of the software icon on the desktop, the system will enter analysis software main interface.

3.2 Connection of YH-600B Pro and Computer

In the power off status of YH-600B Pro, connect one end of the USB data cable to the computer USB port, and the other end to YH-600B Pro **Flow/COM** port and then turn on YH-600B Pro. The data can be transmitted to a computer in all interfaces except countdown interface and “Record” Interface. Go on with operations of PolyLogic Sleep Analysis Software on the computer to make the connection.

WARNING!

- Do not use the USB data cable for communication to computer while the device is recording.
- Only the USB data cable offered by BMC can be used for YH-600B Pro communication to computer, otherwise it may cause danger to the operator or the patient.

Note：

① Do not connect YH-600B Pro to a USB hub.

② Only one YH-600B Pro can be connected to the computer at any time.

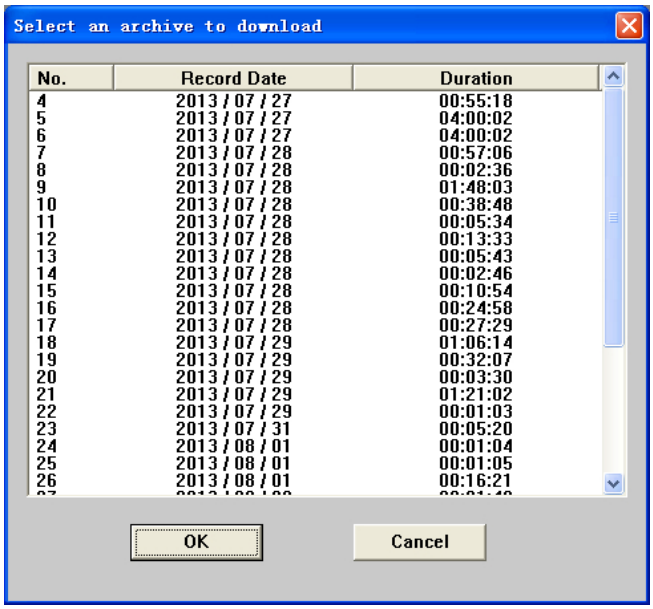
3.3 Data Transmission

①After recording, the data can be transmitted to a computer for further analysis. Besides, YH-600B Pro allows the analyzed data to be manually edited to remove the recording mistakes.

②Run the software and choose the “File” from the main menu, select "New" to enter the communication interface. From the “Select Device” drop-down menu, select “YH-600”, and then select the “USB” serial port. At last, click on “Connect” (Figure 2-1).

③If connection succeeds, the "Connect" button will be grayed. And other originally grayed unavailable buttons will be available now. After connection with the computer, YH-600B Pro will automatically enter the communication status.

④After connection is established, click “Replay”. A window for selection of data to be downloaded will pop up, as shown in Figure 2-3 below.



No.	Record Date	Duration
4	2013 / 07 / 27	00:55:18
5	2013 / 07 / 27	04:00:02
6	2013 / 07 / 27	04:00:02
7	2013 / 07 / 28	00:57:06
8	2013 / 07 / 28	00:02:36
9	2013 / 07 / 28	01:48:03
10	2013 / 07 / 28	00:38:48
11	2013 / 07 / 28	00:05:34
12	2013 / 07 / 28	00:13:33
13	2013 / 07 / 28	00:05:43
14	2013 / 07 / 28	00:02:46
15	2013 / 07 / 28	00:10:54
16	2013 / 07 / 28	00:24:58
17	2013 / 07 / 28	00:27:29
18	2013 / 07 / 29	01:06:14
19	2013 / 07 / 29	00:32:07
20	2013 / 07 / 29	00:03:30
21	2013 / 07 / 29	01:21:02
22	2013 / 07 / 29	00:01:03
23	2013 / 07 / 31	00:05:20
24	2013 / 08 / 01	00:01:04
25	2013 / 08 / 01	00:01:05
26	2013 / 08 / 01	00:16:21

Figure 2-3 “Select an archive to download” dialog box

⑤After selection, click the " OK" button, and “Patient Information” dialog box pops up (Figure 2-4).

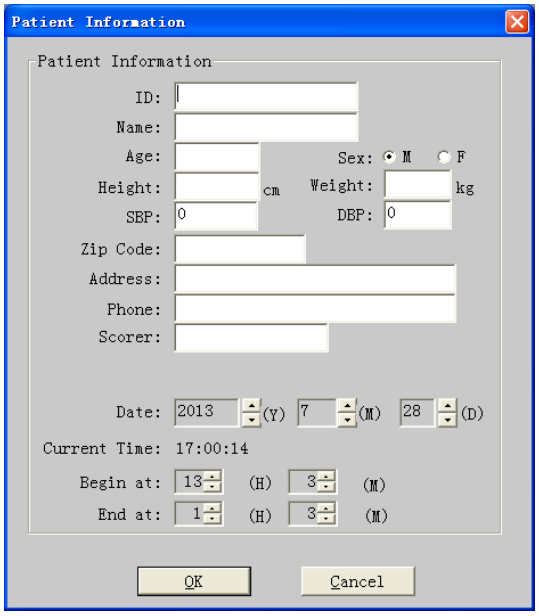


Figure 2-4 “Patient Information” dialog box

⑥Recording start time is set by the system at the beginning of the recording time which is confirmed by the internal clock. If YH-600B Pro clock is not correct, modify it in the above login screen. The recording end time defaults to 12 hours after the recording starts. In fact, in the process of data transmission, the system can automatically identify the actual end time of record. YH-600B Pro will automatically stop after data transmission is finished. So there is no need to change the recording end time in normal situations.

⑦Enter patient information one by one. Click "OK" button and “Replay” dialog box pops up (Figure 2-5).

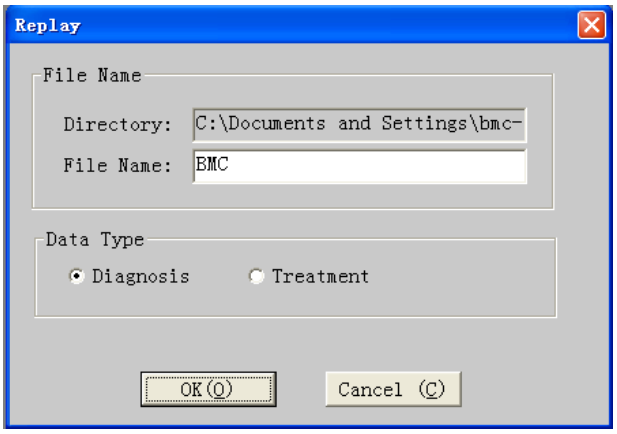


Figure 2-5 “Replay” dialog box

⑧The first content is “File Name”. The second is “Data Type”. If using YH-600B Pro alone, select “Diagnosis”. If using YH-600B Pro with CPAP, select “Treatment”. Having the above two contents set up, click "OK" and then the computer begin to receive the recorded data. When data transmission is finished, the system returns to communication dialog box. At this time, select "Disconnect" or "Exit" in the dialog box, YH-600B Pro will then automatically exit from the communication status.

Note: If YH-600B Pro is used with CPAP, the CPAP noise could affect the accuracy of the snore testing results.

WARNING!

- When the user wears the device, it is prohibited to connect the device to the computer through the USB data cable.
- It is prohibited to connect the device to the computer through the USB data cable other than that provided by BMC.

3.3.1 TF Card Data Transmission

1) Launching the main device software

Click on the windows shortcut for the data analysis software to launch the software.

2) Connecting the TF card to computer

Remove the TF card from the device when it is turned off. Insert the TF card to a card reader, and connect it to a computer for data analysis.

3) Data transmission

Data transmission via a TF card is basically the same as that via the USB data cable, except that when using the TF card, the user should select “YH-600 TF Card” in the “Select Device” drop-down menu (Figure 2-6).

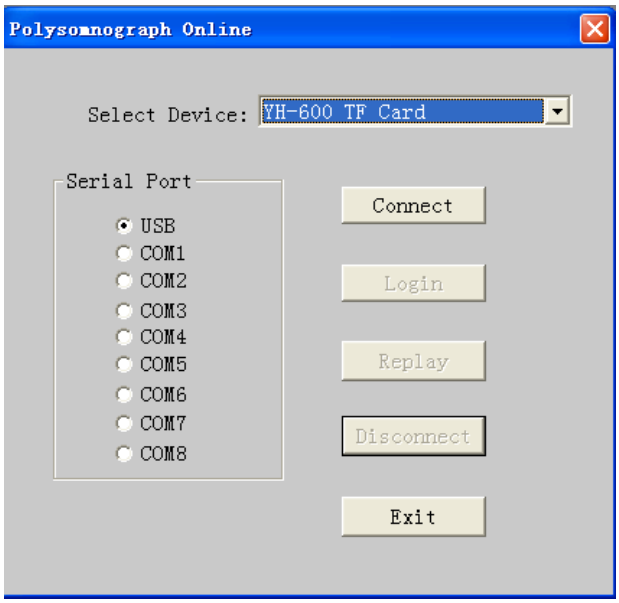


Figure 2-6 Communication window of the data analysis software

3.3.2 Bluetooth Data Transmission

1) Installing the Bluetooth driver

Insert the Bluetooth adapter into the USB port of a Windows computer, and the operating system will

locate the Bluetooth driver automatically. After the driver is installed successfully according to instructions, a Bluetooth shortcut will appear on the desktop.

Note: Bluetooth adapter involved in the Bluetooth data transmission should be bought by the user. The following related image-text information is for reference only.

2) Bluetooth data transmission

(1) Main device setting

①After an AA battery is installed, long-press the **On-Off/OK** Button ⏻/⊙ to turn on the device, and then press the **Shift** Button ⟲ to select the "Tools" icon(Figure 2-7).

Figure 2-7 Main device interface

②Press the **On-Off/OK** Button⏻/⊙ to enter the "Tools" interface(Figure 2-8).

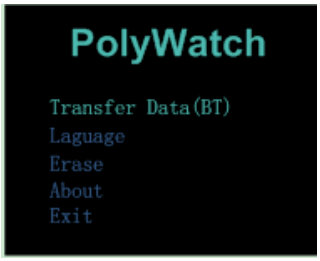


Figure 2-8 "Tools" interface

After the "Tools" interface is accessed, the first option "Transfer Data(BT)" turns green. Press the **On-Off/OK** Button ⏻/⊙ directly to enter the "Transfer Data(BT)" interface. (If there are no records, the screen will display "No Records", and the Bluetooth pairing will not be affected.)

(2) Bluetooth pairing

①Insert the Bluetooth adapter into the USB port of the computer.

② Double-click the Bluetooth shortcut to enter the classic Bluetooth interface (Figure 2-9). (If it is not the classic Bluetooth interface, right-click the Bluetooth icon in the taskbar to choose classic interface)

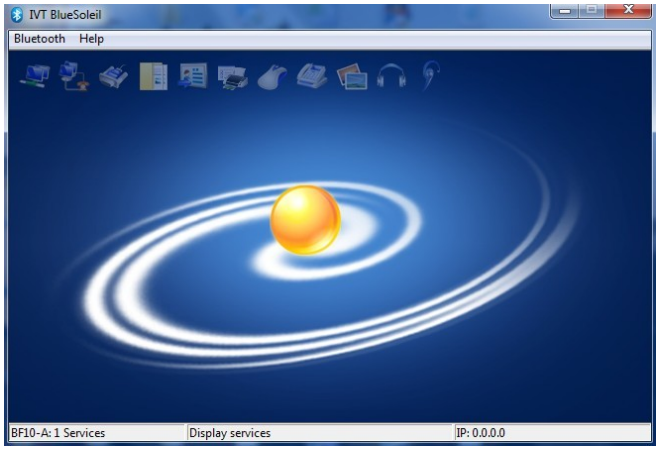


Figure 2-9 Classic Bluetooth interface

③Double-click the sun icon in the classic interface to start searching for BF10 Bluetooth devices (Figure 2-10).

Figure 2-10 Bluetooth searching interface

④Double-click the BF10 icon to highlight the serial port icon on the top of the classic interface, as shown in Figure 2-11 below.

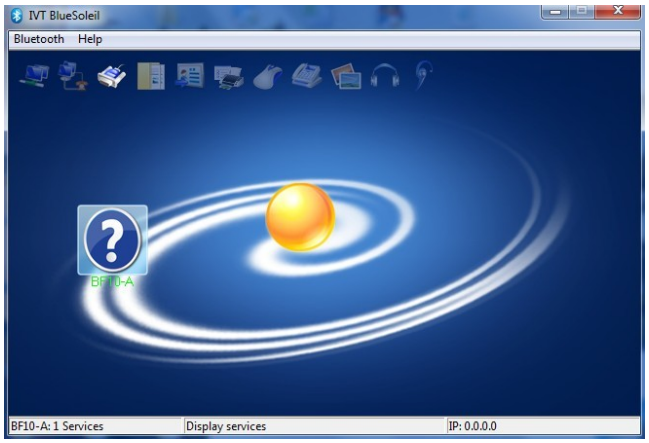


Figure 2-11 Highlighting the serial port icon

⑤Double-click the serial port icon . If connection succeeds, the serial port icon and Bluetooth

device icon will turn green, as shown in Figure 2-12. At the same time, a virtual COM port will be created in the computer.

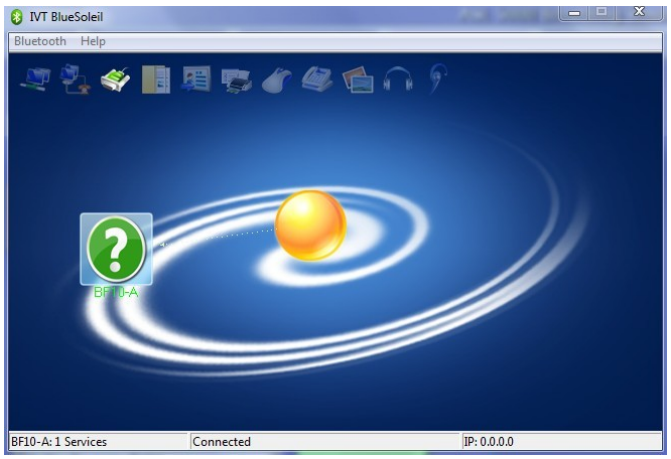


Figure 2-12 and turn green

Note: Please remember the name of the virtual COM port, and make sure the communication port of the data analysis software is consistent with this COM port. If the user fails to remember the name of the virtual COM port, he or she can view the port name by clicking "+" before "Port (COM and LPT)" in "Device Manager" of the computer, as shown in Figure 2-13.

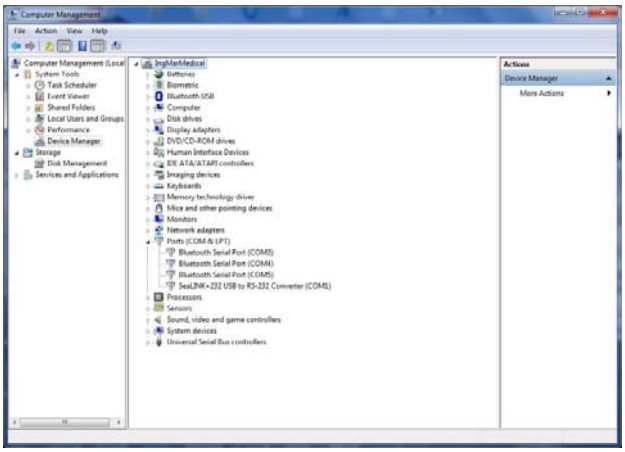


Figure 2-13 Treeview of Device Manager

(3) Data transmission

Data transmission via Bluetooth is basically the same as that via a USB data cable, except that the user must select the virtual COM port for Bluetooth pairing in "Serial Port" (Figure 2-14).

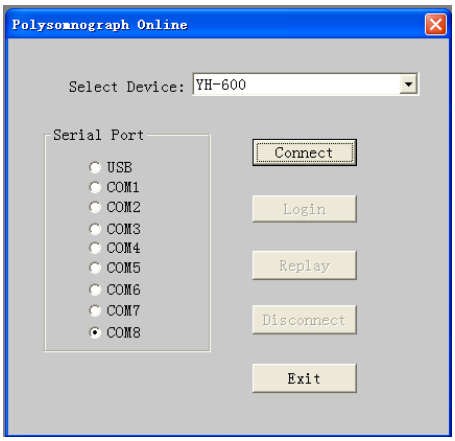


Figure 2-14 Selecting the virtual COM port

If another device is intended to connect to the computer, repeat the process of data reception. If no data transmission is needed, click "back" button in the communication window to return to the main interface.

4. Data File Management

①In the main interface of data analysis software, choose “Open” in “File” of the 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 2-15). The desired data can be easily found by different orders in this interface.

②First 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. The files’ order can be changed by clicking on the corresponding classification column.

③In the lower right of the interface 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.

④Selecting “Cancel” button in the lower right of the interface can return to the main interface of data analysis software.

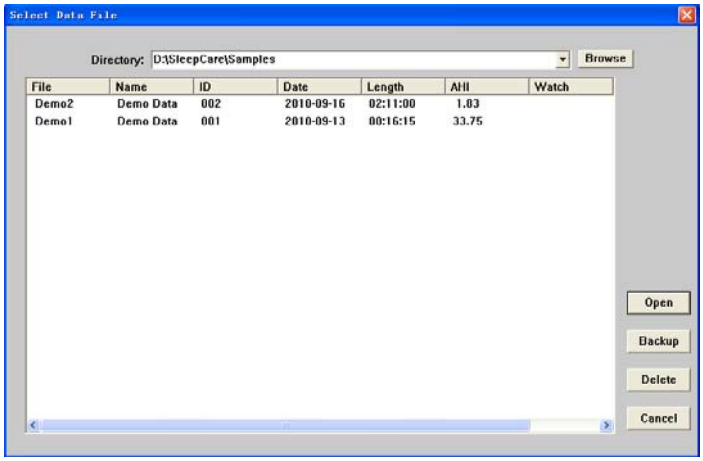


Figure 2-15 “Select Data File” dialog box

5. Data Playback

In the sleep data management interface, select the sleep data file, and the 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, the system will enter the data playback interface. There are the trend chart, the waveform, the diagnosis result, the analysis report and other interfaces.

5.1 Opening and Closing the Data File

①Multiple data files can be opened simultaneously in the main interface of data analysis software. For the method to open the data files, please see “Data File Management” part.

②Opening a file may be failed if the file is being used.

③Select the intended file name in the “**Window”** menu to open the file.

④Clicking in the toolbar or select “**Close**” in the “**File**” option in the menu can close the current window of data file.

5.2 Display of Recorded Data and Analysis Result

The data recording, analysis result and statistical result are shown in 5 interfaces. The order is: Trend, Raw Data, Respiration Event, Diagnosis and Report.

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

1) Trend

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 physiological

parameters in the same period of time conveniently and may study the relationship between them easily (Figure 2-16).

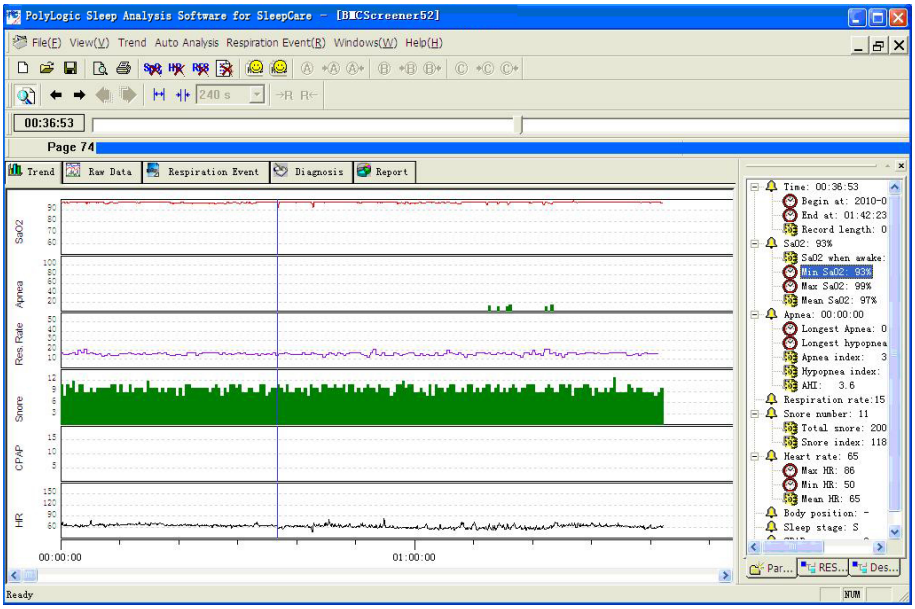


Figure 2-16 “Trend” interface

The basic functions in the interface are:

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

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

(1)Parameter 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). Click with a mouse throughout the trend chart can drive the cursor to anywhere in it.

At the upper 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 interface 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, CPAP pressure trend chart and the heart rate trend chart. The horizontal axis stands for the elapse of time.

(2)Parameter 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, then 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, place the cursor at the exact point and click the 、、、 button directly to erase them.

(3)Event location

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

(4)Print

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

(5)Analysis

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 “” indicate the respiration event analysis process and the snoring analyzing process respectively.

The analysis function also works in other interfaces.

2) Raw Data

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

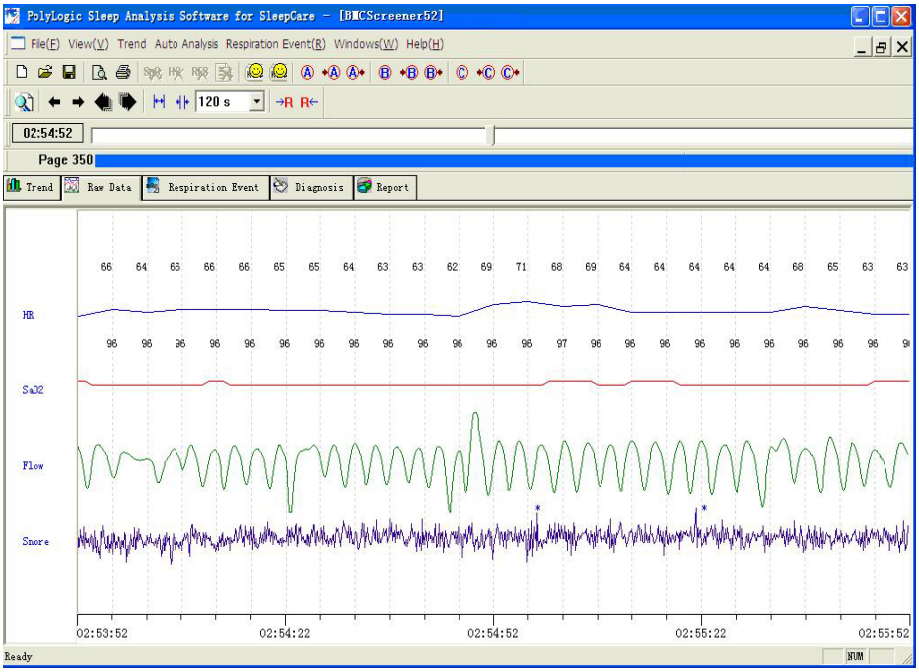


Figure 2-17 “Raw Data”interface

The following operations may be carried out in this interface.

①Print;
②Modify display setup;
③Modify paper speed;
④Modify time display;
⑤Event browse;
⑥Event edit;
⑦Mark function.

⑴Print

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

⑵Modify 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.

⑶Modify paper speed

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

The tool 120 s in the toolbar can zoom in and zoom out the time scale to change the speed at which paper moves. The range is from 8s/page to 480 s/page.

⑷Modify 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 the paper. For example, if the current speed of the paper is 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 various 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 paper moves 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.

⑸Event browse

①Breathing 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.

②Snore.

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

⑹Event edit

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

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 start and end time.

For event insertion, left-click the mouse and drag it to form rectangular block on the waveform, when a menu pops up, demonstrating the length of this block (Figure 2-18). Select a corresponding event type to generate such an event.

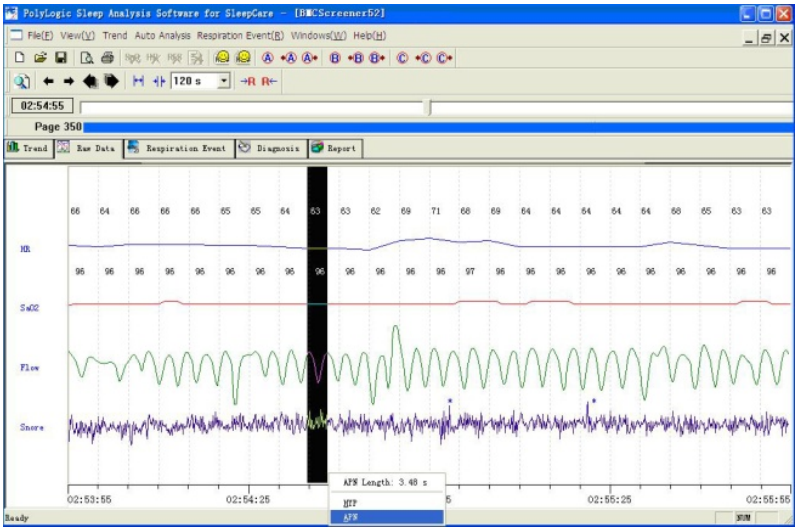


Figure 2-18 Respiration Event Edit

(7)Marking function

When the operator feels particularly interested in any recorded part and intends to relocate it on his/her next opening of the file, he/she 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 “+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 in file-saving, thus can be relocated quickly upon later reopening.

3) Respiration Event

This interface has listed all respiration events and their correlations with the statistical data by form (Figure 2-19).

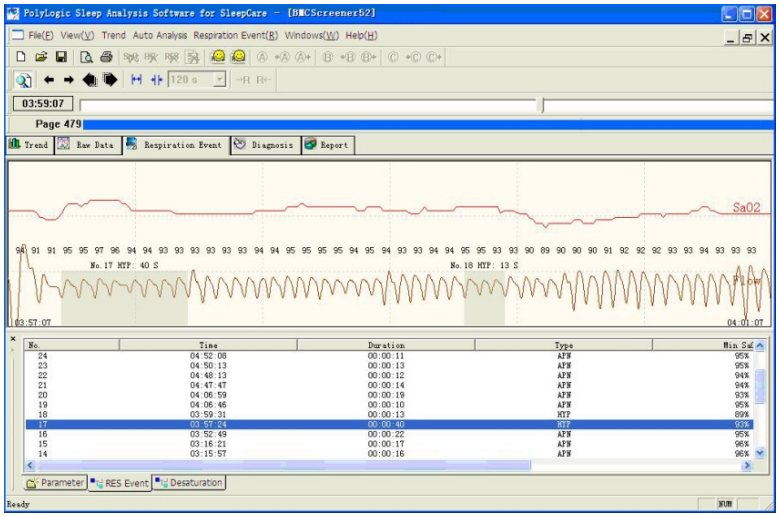


Figure 2-19 “Respiration Event” interface

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 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, and the list of respiration events below will experience changes to the serial number accordingly.

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

4) Diagnosis

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

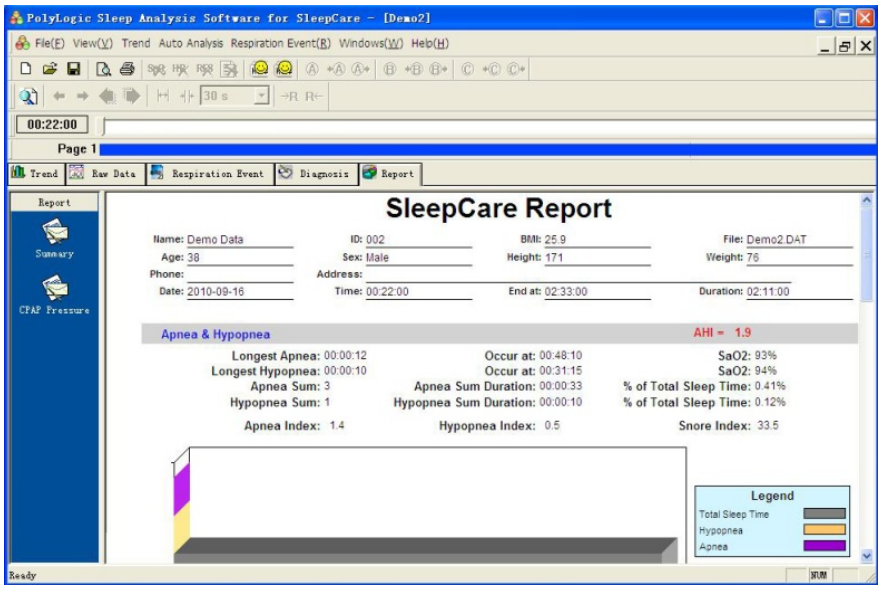


Figure 2-20 Diagnosis Result

5) Report

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

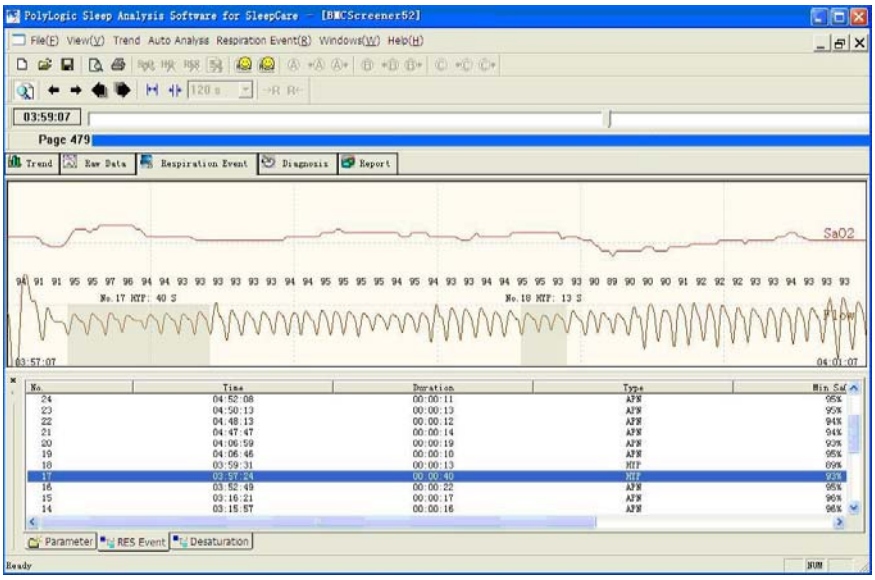


Figure 2-21 “Report” interface

6. 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 2-22).

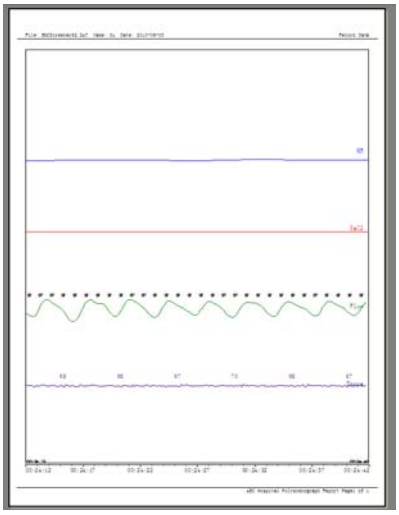
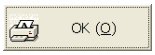


Figure 2-22 Print and Preview of the Raw Data waveform

In other interfaces, 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 2-23).

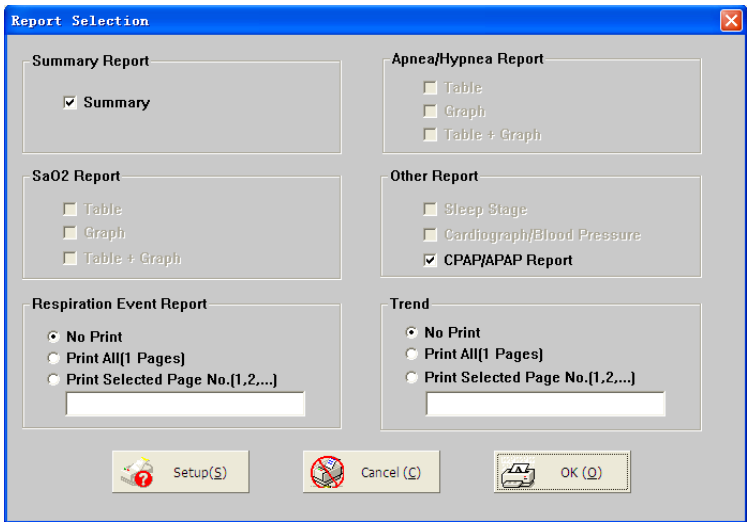


Figure 2-23 Print and Preview of the report

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 OK (O) button. Click Setup(S) to change the printer settings.

7. Help

To show software version and service email, just click “Help” button in the menu bar, then click “About” button.

To alter the report title, just click “Help” button in the menu bar, then select “Report Title”. The “Report Title” dialog box will pop up (Figure 2-24). Enter the report title, then click “OK” button.

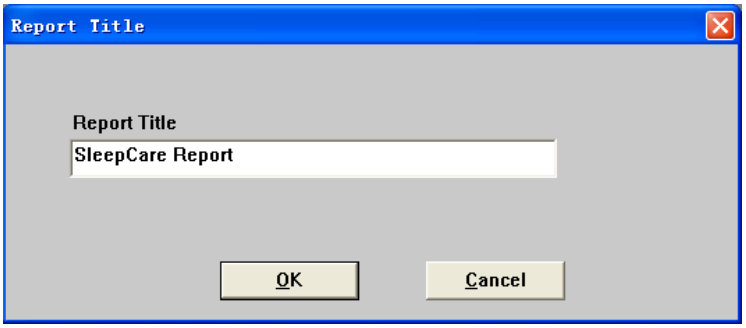


Figure 2-24 “Report Title” dialog box

8. Exit Program

To go back to windows desktop, just click “File” in the menu and click “Exit” or at the top right corner.

CHAPTER 3: SERVICE

1. Technical Support

For technical support or before returning any equipment, call BMC Medical Co., Ltd. at 86-10-51663880.

2. Limited Warranty

BMC Medical Co., Ltd. warrants that YH-600B Pro 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 YH-600B Pro 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.
5/F Main Building, No.19 Gucheng Street West, Shijingshan, Beijing 100043, P.R.China.

Tel: 86-10-51663880
Fax: 86-10-51663880 Ext. 810

EU AUTHORISED REPRESENTATIVE:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraβe 80, 20537 Hamburg，Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

FCC Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user‘s authority to operate the equipment.

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Issue date：April 22, 2014